Appendix E: Evidence tables

E.1 Patient information

- What information do people with cataracts and their carers find useful, and what format (for example written or verbal) do they prefer it to be provided in?
- What information on cataract surgery do people and their carers find useful when deciding whether surgery is appropriate for them, and before, during and after any operation(s) they elect to undergo? What format (for example written or verbal) do they prefer it to be provided in?

Study	**Nijkamp M D, Ruiter R A, Roeling M, van den Borne , B , Hiddema F, Hendrikse F, and Nuijts R M. (2002). Factors related to fear in patients undergoing cataract surgery: a qualitative study focusing on factors associated with fear and reassurance among patients who need to undergo cataract surgery. Patient Education & Counseling, 47(3), pp.265-72.**
Study type	Qualitative study – Focus group interviews
Aim/ objective of the study	To identify factors that are related to fear among patients who need to undergo cataract surgery
Source of funding	Not reported
Sample size	Total (n): 27 people in 4 focus groups of 5–8 people each.
Inclusion/ exclusion criteria	Patients who had routine phacoemulsification and intraocular lens implantation in the period from March to May 2000 at the University Hospital Maastricht or the Rotterdam Eye Hospital: • Suffering from senile cataract • Aged 50+ • No ocular co-morbidity • Able to speak and read Dutch
Comparison	N/A
Outcomes	Patient information needs: • Patients reporting being reassured and relieved when the ophthalmologist or nurse told them that worsening of vision is common among patients with a cataract and a cataract surgery is a reliable and successful procedure. • Patients suggested that fears could be reduced by providing more comprehensive information about the procedure, and what to expect from cataract surgery, although the amount and type of information that patients wanted to be exposed to varied among focus group participants. • A live-surgery report on video was also evaluated positively by most patients from Rotterdam Eye hospital.
Risk of bias	CASP qualitative quality checklist:

Study	**Nijkamp M D, Ruiter R A, Roeling M, van den Borne , B , Hiddema F, Hendrikse F, and Nuijts R M. (2002). Factors related to fear in patients undergoing cataract surgery: a qualitative study focusing on factors associated with fear and reassurance among patients who need to undergo cataract surgery. Patient Education & Counseling, 47(3), pp.265-72.**
	1. Was there a clear statement of the aims of the research? Yes 2. Is a quality methodology appropriate? Yes 3. Was the research design appropriate to address the aims of the research? Yes 4. Was the recruitment strategy appropriate to the aims of the research? Yes 5. Was the data collected in a way that addressed the research issue? Yes 6. Has the relationship between the researcher and participants been adequately considered? Unsure 7. Has ethical issues been taken into consideration? Unsure 8. Was the data analysis sufficiently rigorous? Yes 9. Is there a clear statement of findings? Yes 10. Is the research valuable? Yes Overall risk of bias: Low

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Study	**Elder M J, and Suter A. (2004). What patients want to know before they have cataract surgery. British Journal of Ophthalmology, 88(3), pp.331-2.**
Study type	Questionnaire study
Aim/ objective of the study	To investigate what patients want to know before undergoing cataract surgery
Source of funding	Not reported
Sample size	Total (n): 190
Inclusion/ exclusion criteria	• Patients booked to undergo elective routine cataract surgery in the Ophthalmology Department of Christchurch Public Hospital, New Zealand. • No formal information on cataract surgery had been given to the patients prior to administering the questionnaire.
Comparison	N/A
Outcomes	Patient information needs: • The most important information wanted was the chances of the patient's vision improving after surgery, followed by when the vision would improve, the risk of losing vision, the consequences of not having the operation and the types of serious complications. • Awarded the least importance was the technical detail of the cataract operation.

<table>
<tr><th>Study</th><th>Elder M J, and Suter A. (2004). What patients want to know before they have cataract surgery. British Journal of Ophthalmology, 88(3), pp.331-2.</th></tr>
<tr><td>Results</td><td>Proportion of people listing the above as very important information to be given before the operation:
<table>
<tr><th>Factors</th><th>Proportion listing as very important (5 on a 1-5 Likert scale)</th></tr>
<tr><td>The chance of my vision improving after cataract surgery</td><td>85.6% (79.4%, 90.1%)</td></tr>
<tr><td>When my vision will improve</td><td>80.8% (74.3%, 86.1%)</td></tr>
<tr><td>The overall risk of losing vision from the operation</td><td>78.2% (71.5%, 83.9%)</td></tr>
<tr><td>What happens if I don’t have the cataract operation</td><td>73.1% (66.1%, 79.2%)</td></tr>
<tr><td>The types of serious complications</td><td>70.3% (63.0%, 76.7%)</td></tr>
<tr><td>Who will be performing the surgery</td><td>61.5% (54.1%, 68.4%)</td></tr>
<tr><td>All the complications both serious and minor</td><td>61.4% (53.9%, 68.4%)</td></tr>
<tr><td>Details of the anaesthetic</td><td>55.9% (48.5%, 63.1%)</td></tr>
<tr><td>What a cataract is</td><td>55.4% (47.9%, 62.6%)</td></tr>
<tr><td>The general nature of the cataract operation</td><td>50.8% (43.4%, 58.2%)</td></tr>
<tr><td>What the cause of cataracts are</td><td>48.6% (41.3%, 56.0%)</td></tr>
<tr><td>What other treatment options there are besides surgery</td><td>45.1% (38.1%, 52.3%)</td></tr>
<tr><td>The technical details of the cataract operation</td><td>33.7% (27.0%, 41.1%)</td></tr>
</table>
Proportion of people answering yes to the following question:
<table>
<tr><th>Factors</th><th>Proportion listing as very important (5 on a 1-5 Likert scale)</th></tr>
<tr><td>Should you be warned of a serious complication if it has a risk of happening of 1 in 50</td><td>93.5% (88.1%, 96.7%)</td></tr>
<tr><td>Should you be warned of a serious complication if it has a risk of happening of 1 in 100</td><td>84.1% (75.6%, 90.0%)</td></tr>
<tr><td>Should you be warned of a serious complication if it has a risk of happening of 1 in 1,000</td><td>62.4% (52.1%, 71.7%)</td></tr>
<tr><td>Should you be warned of a serious complication if it has a risk of happening of 1 in 10,000</td><td>50.0% (40.0%, 60.0%)</td></tr>
<tr><td>Do you think that your signed consent is a legal requirement for surgery?</td><td>91.5% (86.2%, 95.0%)</td></tr>
</table></td></tr>
</table>

<table>
<tr><th>Study</th><th colspan="2">Elder M J, and Suter A. (2004). What patients want to know before they have cataract surgery. British Journal of Ophthalmology, 88(3), pp.331-2.</th></tr>
<tr><td></td><td colspan="2"><table>
<tr><td>How would you like information about your cataract operation given? Verbal</td><td>99.3% (95.7%, 100.0%)</td></tr>
<tr><td>How would you like information about your cataract operation given? Written</td><td>85.7% (77.2%, 91.5%)</td></tr>
<tr><td>How would you like information about your cataract operation given? Video</td><td>22.9% (12.5%, 37.7%)</td></tr>
<tr><td>How would you like information about your cataract operation given? Internet</td><td>8.9% (2.9%, 22.1%)</td></tr>
</table></td></tr>
<tr><td>Risk of bias</td><td colspan="2">NICE quality checklist:
• Is the source population or source area well described? Yes
• Is the eligible population or area representative of the source population or area? No
• Do the selected participants or areas represent the eligible population or area? Unsure
• Allocation to intervention (or comparison). How was selection bias minimised? Unsure
• Were interventions (and comparisons) well described and appropriate? No
• Was the allocation concealed? N/A
• Were participants or investigators blind to exposure and comparison? N/A
• Was the exposure to the intervention and comparison adequate? N/A
• Was contamination acceptably low? N/A
• Were other interventions similar in both groups? N/A
• Were all participants accounted for at study conclusion? Yes
• Did the setting reflect usual UK practice? Unsure
• Did the intervention or control comparison reflect usual UK practice? Unsure
• Were outcome measures reliable? Unsure
• Were all outcome measurements complete? Unsure
• Were all important outcomes assessed? Unsure
• Were outcomes relevant? Unsure
• Were there similar follow-up times in exposure and comparison groups? N/A
• Was follow-up time meaningful? N/A
• Were exposure and comparison groups similar at baseline? If not, were these adjusted? N/A
• Was intention to treat (ITT) analysis conducted? N/A</td></tr>
</table>

Study	Elder M J, and Suter A. (2004). What patients want to know before they have cataract surgery. British Journal of Ophthalmology, 88(3), pp.331-2.
	• Was the study sufficiently powered to detect an intervention effect (if one exists)? N/A • Were the estimates of effect size given or calculable? N/A • Were the analytical methods appropriate? Unsure • Was the precision of intervention effects given or calculable? Were they meaningful? Unsure • Are the study results internally valid (i.e. unbiased)? Unsure • Are the findings generalisable to the source population (i.e. externally valid)? Unsure Overall risk of bias: High

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Study	Tan L T, Jenkins H, Roberts-Harry J, and Austin M. (2008). Should patients set the agenda for informed consent? A prospective survey of desire for information and discussion prior to routine cataract surgery. Therapeutics & Clinical Risk Management, 4(5), pp.1119-25.
Study type	Survey study
Aim/ objective of the study	To investigate patients' desires for information, in addition to already having received standard information at the time of listing for surgery, pertaining to cataract surgery in general and to its specific complications, prior to surgery.
Source of funding	Not reported
Sample size	Total (n): 100
Inclusion/ exclusion criteria	Consecutive patients from dedicated cataract surgery pre-assessment clinics of 2 hospitals in South West Wales, UK.
Comparison	N/A
Outcomes	Patient information needs: • 32.0% (23.2%, 42.2%) did not wish to know "anything at all" about risks and indeed would prefer to leave decision-making to their ophthalmologist • 22.0% (14.6%, 31.6%) were interested only in knowing their overall chance of visual improvement • 46.0% (36.1%, 56.2%) welcomed a discussion of possible complications • Of the 25 patients who proceeded to watch the audio visual presentation detailing each specific complication, 18 wished to be informed of posterior capsular tearing, 17 of endophthalmitis, 16 each of dropped lens, retinal detachment and corneal clouding, and 15 of bleeding, sympathetic ophthalmia and posterior capsular opacification.
Risk of bias	NICE quality checklist: • Is the source population or source area well described? Yes • Is the eligible population or area representative of the source population or area? No

Study	Tan L T, Jenkins H, Roberts-Harry J, and Austin M. (2008). Should patients set the agenda for informed consent? A prospective survey of desire for information and discussion prior to routine cataract surgery. Therapeutics & Clinical Risk Management, 4(5), pp.1119-25.
	• Do the selected participants or areas represent the eligible population or area? Unsure • Allocation to intervention (or comparison). How was selection bias minimised? N/A • Were interventions (and comparisons) well described and appropriate? Yes • Was the allocation concealed? N/A • Were participants or investigators blind to exposure and comparison? N/A • Was the exposure to the intervention and comparison adequate? N/A • Was contamination acceptably low? N/A • Were other interventions similar in both groups? N/A • Were all participants accounted for at study conclusion? Yes • Did the setting reflect usual UK practice? Yes • Did the intervention or control comparison reflect usual UK practice? Yes • Were outcome measures reliable? Unsure • Were all outcome measurements complete? Yes • Were all important outcomes assessed? Unsure • Were outcomes relevant? Yes • Were there similar follow-up times in exposure and comparison groups? N/A • Was follow-up time meaningful? N/A • Were exposure and comparison groups similar at baseline? If not, were these adjusted? N/A • Was intention to treat (ITT) analysis conducted? N/A • Was the study sufficiently powered to detect an intervention effect (if one exists)? N/A • Were the estimates of effect size given or calculable? N/A • Were the analytical methods appropriate? Unsure • Was the precision of intervention effects given or calculable? Were they meaningful? N/A • Are the study results internally valid (i.e. unbiased)? Unsure • Are the findings generalisable to the source population (i.e. externally valid)? Yes Overall risk of bias: High

9

E.2 Indicators for referral

- What are the indicators for referral for cataract surgery?
- What are the optimal clinical thresholds in terms of severity and impairment for referral for cataract surgery?

E.2.1 Indicators for referral for cataract surgery

Full citation	Bellan L. Why are patients with no visual symptoms on cataract waiting lists? Canadian Journal of Ophthalmology 2005; 40:433-438
Study details	Country/ies where the study was carried out: Canada Study type: Prospective cohort Aim of the study: To determine why patients with minimal complaints are on cataract waiting lists Study dates: January to May 2002 Sources of funding: Not reported
Participants	Sample size 149 people Inclusion criteria On the Manitoba Cataract Waiting List Program (MCWLP) Reported no complaints using the VF-14 questionnaire preoperatively (score of 100) Exclusion criteria Not reported
Methods	Grouping based on patient responses to initial 3 questions of :- Are there any other problems with your vision that you are experiencing that I haven't asked about? Please tell me the reason, as you understand it, why you have been scheduled to have cataract surgery? What activities do you think will be easier for you after surgery? Intervention Cataract surgery followed by follow up telephone questionnaire asking them to:-

<table>
<tr><th>Full citation</th><td>Bellan L. Why are patients with no visual symptoms on cataract waiting lists? Canadian Journal of Ophthalmology 2005; 40:433-438</td></tr>
<tr><td></td><td>
Rate their satisfaction with their vision in the eye that had undergone surgery (not at all, minimally, moderately, very or extremely satisfied)
If they found that the vision had been more impaired that they had thought before surgery (yes/no).
If they felt that their vision had improved after cataract surgery (not at all, minimally, moderately, markedly) and
If they would be willing to repeat this type of surgery again, if needed (yes/no)?

Study outcomes:
Self-assessment after cataract surgery

Group comparisons: Chi-squared tests

Distribution of responses from patients on a waiting list for cataract surgery who scored 100 (no complaints) on VF-14

<table>
<tr><td></td><td colspan="2">First eye patients</td><td colspan="2">Second eye patients</td><td></td></tr>
<tr><td>Group</td><td>No.</td><td>%</td><td>No.</td><td>%</td><td>Total</td></tr>
<tr><td>Symptomatic*</td><td>46</td><td>31</td><td>62</td><td>42</td><td>108</td></tr>
<tr><td>Doctor’s advice*</td><td>14</td><td>9</td><td>14</td><td>9</td><td>28</td></tr>
<tr><td>Asymptomatic*</td><td>4</td><td>3</td><td>9</td><td>6</td><td>13</td></tr>
<tr><td>Total</td><td>64</td><td>43</td><td>85</td><td>57</td><td>149</td></tr>
</table>
First eye indicates patients waiting for first cataract surgery, second eye, second cataract surgery
*Symptomatic group (based on specific complaints mentioned in response to Q1 or 2 or descriptions of specific expected improvements in Q3), Doctor’s advice group (who did not mention any symptoms but indicated they were having surgery because their doctor suggested it) and asymptomatic group (who did not describe any reason for the surgery).
</td></tr>
<tr><td>Results</td><td>
Self-assessment after cataract surgery of patients scoring 100 on VF-14

<table>
<tr><td>Follow-up question</td><td>Yes</td><td>No</td><td>No response</td></tr>
<tr><td>Vision before surgery worse than thought</td><td>74</td><td>28</td><td>3</td></tr>
<tr><td>Willingness to repeat surgery</td><td>99</td><td>6</td><td>0</td></tr>
</table>
</td></tr>
</table>

Full citation	Bellan L. Why are patients with no visual symptoms on cataract waiting lists? Canadian Journal of Ophthalmology 2005; 40:433-438
	At the time of the follow up interview, 105 patients had completed their surgery, 76 from the symptomatic group, 21 from doctor's suggestion group and 8 from the asymptomatic group.
Outcomes	Many patients did have subjective complaints despite responding 'no' to all questions in the VF-14 questionnaire Higher proportion of patients with a VF-14 score of 100 were having second eye surgery High percentage of patients reported they felt vision was worse than thought after surgery and expressed a willingness to repeat surgery in the future if needed.
Comments	Staff reported difficulties in getting a clear answer when conducting the follow-up telephone interview due to patient confusion, difficulties with English as a second language or poor communication skills. Possible reporting bias by patients.

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Full citation	Choi Y, Park E. Analysis of Rating Appropriateness and Patient Outcomes in Cataract Surgery 2009 50 (3):368-374
Study details	Country/ies where the study was carried out: Korea Study type: Retrospective cohort Aim of the study: To create appropriateness criteria using the RAND/UCLA method to assess appropriate ratings in cataract surgery. Study dates: March – June 1997 Sources of funding: Not reported
Participants	Sample size 222 people Inclusion criteria Patients scheduled to undergo cataract surgery in March - June 1997 Exclusion criteria Patients who had undergone cataract surgery Who had a combined procedure involving glaucoma, corneal, or vitreo-retinal surgery Deaf or confused patients
Methods	The Rand Corporation's Health Sciences Program used literature analysis and assessment by expert panels to evaluate the appropriateness or inappropriateness of performing procedures in a wide variety of specified clinical situations. An expert panel, after

Full citation	**Choi Y, Park E. Analysis of Rating Appropriateness and Patient Outcomes in Cataract Surgery 2009 50 (3):368-374**
	performing an extensive review of the literature, rated 2,905 clinical scenarios. The final list of clinical situations or 'indications' was divided into the four appropriateness ratings defined as: 'crucial/necessity', 'appropriate', 'uncertain', and 'inappropriate'. Interventions Cataract operation Measurements Preoperative and postoperative variables Statistical tests : ANOVA, Duncan's test
Results	Comparisons of Preoperative Characteristics by Appropriateness ratings

Variables	Crucial (68)	Appropriate (103)	Uncertain (34)	Inappropriate (17)	F/P value (x2 /ANOVA test)
Age (yrs) mean ± SD	65.45 ± 13.26*	62.67 ± 11.77*	58.50 ± 12.38	56.71 ± 16.33	0.016
Gender Male Female	 30 (44.12) 38 (55.88)	 52 (50.49) 51 (49.51)	 15 (44.12) 19 (55.88)	 8 (47.06) 9 (52.94)	0.841
Operated eye VA Mean ± SD	2.30 ± 0.40*[1]	2.06 ± 0.49*	1.68 ± 0.32	1.74 ± 0.40	< .001
VF-14 Mean ± SD	59.94 ± 19.97*	69.51 ± 22.36*	80.59 ± 21.35	85.32 ± 27.39	< .001
Symptom score Mean ± SD	7.19 ± 5.31*[1]	4.92 ± 4.62	3.88 ± 4.21	4.41 ± 4.51	0.003
Satisfaction with vision. Mean ± SD	26.96 ± 26.55	26.67 ± 23.69	30.21 ± 17.68	19.61 ± 20.61	0.526

SD, Standard Deviation; VA, LogMAR visual acuity; VF-14, visual function-14

*Duncan's test: significant with uncertain and inappropriate ratings.

[1]Duncan's test: significant with appropriate, uncertain, and inappropriate.

Full citation	**Choi Y, Park E. Analysis of Rating Appropriateness and Patient Outcomes in Cataract Surgery 2009 50 (3):368-374**

Changes of Outcome between Preoperative and Postoperative period of 12 months (Mean ± SD)

Variables	Difference of preoperative and postoperative period of 12 months				F value (ANOVA test)
	Crucial	Appropriate	Uncertain	Inappropriate	
Operated eye VA	0.75 ± 0.39*	0.57 ± 0.51*	0.13 ± 0.46	0.23 ± 0.19	< 0.001
VF-14	35.22 ± 22.86*	27.09 ± 22.38*	11.01 ± 17.07	12.79 ± 26.83	< 0.001
Symptom score	6.31 ± 5.29*	4.37 ± 4.98	3.00 ± 5.38	2.82 ± 5.85	0.006
Satisfaction with vision	- 0.41 ± 15.29	0.58 ± 15.72	- 5.62 ± 15.35	- 2.14 ± 18.86	0.308

SD, standard deviation; VA, LogMAR visual acuity; VF-14, visual function-14.
*Duncan's test: significant with uncertain and inappropriate.

Outcomes	The outcome changes of vision acuity ($p < 0.001$), VF-14 ($p < 0.001$), and symptom score ($p = 0.006$) were statistically significant between the four appropriateness ratings. Vision Acuity, VF-14 and symptom score showed the greatest improvement in the crucial group.

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Full citation	**Frost A, Hopper C, Frankel S, Peters T, Durant J, Sparrow J The population requirement for cataract extraction: a cross-sectional study. Eye 2001 15;745-752**
Study details	Country/ies where the study was carried out: UK Study type: Retrospective cohort Aim of the study: To examine the distribution in the population of indications for cataract extraction Study dates: May 1996 – August 1997 Sources of funding: The project was funded by the Department of Health and the South and West NHS Research and Development Directorate. The Department of Social Medicine is the lead centre for the MRC Health Services Research Collaboration
Participants	Sample size 2,647 people (age- and sex-stratified random sample) Inclusion criteria Aged 55 or over Only patients registered in the first 19 general practices

<table>
<tr><td>Full citation</td><td>Frost A, Hopper C, Frankel S, Peters T, Durant J, Sparrow J The population requirement for cataract extraction: a cross-sectional study. Eye 2001 15;745-752</td></tr>
<tr><td></td><td>Exclusion criteria
Not reported</td></tr>
<tr><td>Methods</td><td>Examination to create composite criteria for cataract surgery of those attending clinic

The refracted visual acuity was measured with the ETDRS (logMAR) chart. In the 9 right eyes and 10 left eyes where refraction could not be accomplished (usually for clinical reasons) the habitual acuity, with spectacles if worn, was substituted. Cataract was measured according to the decimalised version of the Oxford Clinical Cataract Classification and Grading System. Vision-related quality of life impairment was measured with the VCM1 questionnaire.

Intervention
Cataract surgery</td></tr>
<tr><td>Results</td><td>Composite criteria for cataract surgery requirements
<table>
<tr><td rowspan="2">Composite criterion</td><td rowspan="2">Visual criteria</td><td colspan="2">Ocular criteria (affected eye)</td></tr>
<tr><td>Ocular co-morbidity absent</td><td>Ocular co-morbidity present</td></tr>
<tr><td>A</td><td>Self-reported poor vision in the affected eye and acuity 6/6 or worse in the affected eye and VCM1 score >1.0</td><td>PSC> 1/3 of the central lens area, or ASC> 1/3 of the central lens area, or CSP> 1/3 of the central lens area, or NC > 2.0 or NO > 3.0</td><td>PSC> 2/3 of the central lens area, or ASC> 2/3 of the central lens area, or CSP> 2/3 of the central lens area, or NC > 2.5 or NO > 4.0</td></tr>
<tr><td>B</td><td>Self-reported poor vision in the affected eye and acuity 6/9 or worse in the affected eye and VCM1 score >1.5</td><td>PSC> 1/3 of the central lens area, or ASC> 1/3 of the central lens area, or CSP> 1/3 of the central lens area, or NC > 2.0 or NO > 3.0</td><td>PSC> 2/3 of the central lens area, or ASC> 2/3 of the central lens area, or CSP> 2/3 of the central lens area, or NC > 2.5 or NO > 4.0</td></tr>
<tr><td>C</td><td>Self-reported poor vision in the affected eye and acuity 6/9 or worse in the affected eye and VCM1 score >2.0</td><td>PSC> 1/2 of the central lens area, or ASC> 1/2 of the central lens area, or CSP> 1/2 of the central</td><td>PSC> 3/4 of the central lens area, or ASC> 3/4 of the central lens area, or CSP> 3/4 of the central lens area, or NC > 3.0 or NO > 4.5</td></tr>
</table></td></tr>
</table>

Full citation	**Frost A, Hopper C, Frankel S, Peters T, Durant J, Sparrow J The population requirement for cataract extraction: a cross-sectional study. Eye 2001 15;745-752**

		lens area, or NC > 2.5 or NO > 3.5	

PSC, posterior sub capsular opacity; NC, nuclear colour, brunescence; NO, nuclear light, scatter, opalescence; CSP, cortical spokes; ASC, anterior sub capsular opacity. Ocular co-morbidity was defined as present in the affected eye if one or more of the following conditions were present in the affected eye: history of retinal detachment or retinal tear, strabismus or lazy eye, central corneal opacity, previous intraocular surgery, advanced age-related macular degeneration, other retinal pathology involving the fovea, optic neuropathy.

Criterion A being the least stringent and criterion C the most stringent for surgery

Prevalence estimates for requirements for cataract extraction according to various criteria

Criterion for cataract surgery	No. of eyes per 1000 requiring CE		No. of people requiring CE per 1000 aged 55+ (95% CIb)	Estimatedc Total no. of CE operations per 1000 persons aged 55+ (95% CIb)
	Right eye (n=949a)	Left eye (n=961a)		
A	14.8	15.6	27 (17,39)	29 (20,41)
B	10.5	8.3	16 (9,26)	17 (10,27)
C	5.3	2.1	(2,13)	7 (3,14)

The prevalence estimates relate to the 55+ age group

CE, cataract extraction

[a]Excludes 56 right and 48 left eyes in which CE was already performed.

[b]95% CI calculated without correcting for clustering.

[c]Assuming 50% of people with bilateral cataract (all of whom were aged over 75 years) have second eye surgery.

Outcomes	Prevalence estimates show a greater number of cataract extractions for patients with the least stringent criterion for surgery (Group A)

16

Full citation	**Gutierrez S, Quintana J, Bilbao A, Escobar A et al. Validation of priority criteria for cataract extraction. Journal of Evaluation in Clinical Practice 2009;15:675-684**
Study details	Country/ies where the study was carried out: Spain Study type: Prospective cohort Aim of the study: To validate and apply a modified RAND/UCLA prioritisation criteria tool to a cohort of patients on a cataract surgery waiting list.

Full citation	**Gutierrez S, Quintana J, Bilbao A, Escobar A et al. Validation of priority criteria for cataract extraction. Journal of Evaluation in Clinical Practice 2009;15:675-684**
	Study dates: Not reported Sources of funding: Fondo de Investigacion Sanitaria (grants nos. PI03/0550, PI03/0724, PI03/0828, PI04/1577); the thematic networks (Red IRYSS) of the Instituto de Salud Carlos III (G03/202), Madrid, Spain and the Department of Health of the Basque Country (2003/11045)
Participants	Sample size 4336 patients Inclusion criteria Aged 18 – 90 prescribed cataract removal surgery Exclusion criteria Patients suffering from corneal dystrophy, receiving additional ocular intervention, malignant pathology, psychiatric conditions. Non Spanish speaking or those who did not understand Spanish or could not respond to the questionnaire due to visual or other types of impairment.
Methods	Data collection Clinical data was collected in the visit prior to cataract surgery and 6 weeks afterwards. The VF-14 questionnaire was mailed to patients at the time of the pre-intervention visit and 3 months after surgery. Up to 3 reminder letters were sent at scheduled points of time to patients not returning the questionnaires. The RAND/UCLA criteria was applied retrospectively to rate them as High, Intermediate or Low
Results	Comparison of means of visual acuity and VF-14 score pre-intervention, post-intervention, and among the priority categories.

	Pre intervention				Post intervention				Change			
	Higha (1408)	Intermediateb (1265)	Lowc (329)	P value	Higha (1408)	Intermediateb (1265)	Lowc (329)	P value	Higha (1408)	Intermediateb (1265)	Lowc (329)	P value
Visual acuity	0.21 (0.13)	0.31 (0.14)	0.51 (0.11)	<0.0001	0.76 (0.23)	0.81 (0.21)	0.88 (0.17)	<0.0001	0.56 (0.24)	0.50 (0.24)	0.34 (0.20)	<0.0001
VF-14	55.48 (22.09)	67.28 (20.51)	67.96 (17.85)	<0.0001	85.76 (17.04)	88.12 (15.01)	88.32 (14.23)	0.0002	29.96 (24.84)	20.77 (22.66)	20.89 (20.59)	<0.0001

Full citation	**Gutierrez S, Quintana J, Bilbao A, Escobar A et al. Validation of priority criteria for cataract extraction. Journal of Evaluation in Clinical Practice 2009;15:675-684**
	 Data given as Means (Standard Deviation) Superindexes are referred to the differences encountered among prioritisation classes by means of Schaffe's test for multiple comparisons: 'a' = high priority interventions, 'b' = intermediate priority interventions and 'c' = low priority interventions.
Outcomes	Pre-intervention VA and VF-14 cores were significantly lower among those judged as high priority groups compared to those judged as low priority. Post-intervention VA and VF-14 scores were significantly higher among those judged as high priority groups compared to those judged as low priority Differences were statistically significant across the 3 priority groups for VA For VF-14 scores there was a significant difference between high priority and the other two priority classes.

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Full citation	**Lash S, Prendiville A, Samson A, Lewis K, Munneke R, Parkin B. Optomrtrist referrals for cataract and 'Action on Cataracts' guidelines: are optometrists following them and are they effective? Ophthal. Physiol. Opt. 2006 26:464-467**
Study details	Country/ies where the study was carried out: UK Study type: Prospective cohort Aim of the study: To assess the information included in optometrist referrals for cataract surgery with reference to the 'Action on Cataracts' recommendations Study dates: October 4th to December 6th 2004 Sources of funding: Not reported
Participants	Sample size 412 referrals Inclusion criteria Referrals seen in the cataract clinic within the study dates Exclusion criteria GP referrals with no optometrist information
Methods	Data collection Collected and analysed the information included in 3 different types of optometrist referrals (Direct, General Ophthalmic Services (GOS), Letter and GP) for cataracts over 8 weeks. The referrals outcomes were assessed in terms of listing rate along with reasons for not listing, for each type of referral.

<table>
<tr><th>Full citation</th><td>Lash S, Prendiville A, Samson A, Lewis K, Munneke R, Parkin B. Optomrtrist referrals for cataract and ‘Action on Cataracts’ guidelines: are optometrists following them and are they effective? Ophthal. Physiol. Opt. 2006 26:464-467</td></tr>
<tr><td></td><td>Intervention
Cataract surgery</td></tr>
<tr><td>Results</td><td>Type of referral form used
<table>
<tr><td></td><td>Total number</td><td>Percentage (%)</td></tr>
<tr><td>Direct referral</td><td>143</td><td>35</td></tr>
<tr><td>GOS 18</td><td>162</td><td>39</td></tr>
<tr><td>Letter</td><td>46</td><td>11</td></tr>
<tr><td>GP</td><td>61</td><td>15</td></tr>
</table>
Information included in referrals
<table>
<tr><td></td><td>Direct [n (%)]</td><td>GOS 18 [n (%)]</td><td>Letter [n (%)]</td></tr>
<tr><td>Full information</td><td>143 (100)</td><td>16 (10)</td><td>8 (17)</td></tr>
<tr><td>Cataract and effect on lifestyle only</td><td></td><td>17 (11)</td><td>1 (2)</td></tr>
<tr><td>Cataract and willingness for surgery only</td><td></td><td>13 (8)</td><td>2 (4)</td></tr>
<tr><td>Cataract only</td><td></td><td>116 (72)</td><td>35 (76)</td></tr>
</table>
Listing rates with information included
<table>
<tr><td></td><td>Direct [n (%)]</td><td>GOS 18 [n (%)]</td><td>Letter [n (%)]</td></tr>
<tr><td>Full information</td><td>119/143 (83)</td><td>13/16 (81)</td><td>7/8 (88)</td></tr>
<tr><td>Cataract and effect on lifestyle</td><td rowspan="3"></td><td>13/17 (77)</td><td>1/1 (100)</td></tr>
<tr><td>Cataract and willingness for surgery</td><td>9/13 (69)</td><td>1/2 (50)</td></tr>
<tr><td>Cataract only</td><td>82/116 (70)</td><td>27/35 (77)</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>10% (n=16) of the GOS 18 referrals and 17% (n=8) of the letter referrals contained the recommended information
The referrals with ‘full information’ resulted in the highest listing rate (83%)
Of the patients not listed for surgery (n=77) the most common reason was ‘no effect on lifestyle’ 42% (n=32), 9% (n=7) declined surgery</td></tr>
</table>

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<table>
<tr><th>Full citation</th><td>Lundstrom M, Albrect S, Hakansson I, Lorefors R, Ohlsson S, Polland W, Schmid A, Svensson G and Wendel E. NIKE: a new clinical tool for establishing levels of indications for cataract surgery. Acta Ophthalmol. Scand. 2006: 84: 495–501</td></tr>
<tr><td>Study details</td><td>Country/ies where the study was carried out: Sweden

Study type: Prospective cohort
Aim of the study: To construct a new clinical tool for establishing levels of indications for cataract surgery, and to validate this tool.

Study dates: Not reported

Sources of funding: Grants from the Swedish Association of Local Authorities and Regions and the Swedish National Board of Health and Welfare.</td></tr>
<tr><td>Participants</td><td>Sample size
307 people

Inclusion criteria
Not reported
Exclusion criteria
Not reported</td></tr>
<tr><td>Methods</td><td>Patients were ranked according to the NIKE indication tool:-
The Canadian Cataract Priority Criteria Tool served as a model for the NIKE tool, which was modified for Swedish conditions. Items included in the tool were visual acuity of both eyes, patients' perceived difficulties in day-to-day life, cataract symptoms, the ability to live independently, and medical /ophthalmic reasons for surgery. The tool was validated and tested in 343 cataract surgery patients.
Indication scores were then measured before and after cataract surgery.

Items included in the NIKE tool
<table>
<tr><th>Item</th><th>Possible score</th></tr>
<tr><td>Visual acuity, surgery eye (< 0.1: score 3; 0.1‑0.3: score 2; 0.4‑0.6: score 1; >0.6: score 0)</td><td>0-3</td></tr>
<tr><td>Visual acuity, fellow eye (< 0.1‑0.1: score 3; 0.2: score 2; 0.3‑0.5: score 1; >0.5: score 0)</td><td>0-3</td></tr>
<tr><td>Patient's perceived difficulty in performing day-to-day activities</td><td>0-4</td></tr>
</table></td></tr>
</table>

<table>
<tr><th>Full citation</th><td>Lundstrom M, Albrect S, Hakansson I, Lorefors R, Ohlsson S, Polland W, Schmid A, Svensson G and Wendel E. NIKE: a new clinical tool for establishing levels of indications for cataract surgery. Acta Ophthalmol. Scand. 2006: 84: 495–501</td></tr>
<tr><td></td><td>
<table>
<tr><td>Cataract symptoms (glare, difference between the eyes)</td><td>0-4</td></tr>
<tr><td>Ability to live independently (work, driving, home help, caring for relatives, etc.)</td><td>0-4</td></tr>
<tr><td>Medical ／ ophthalmic reasons for urgent surgery</td><td>0 or 18</td></tr>
</table>

Indication groups by ranking score
<table>
<tr><td>Indication group</td><td>1</td><td>2</td><td>3</td><td>4</td></tr>
<tr><td>Ranking score sum</td><td>18-15</td><td>14-8</td><td>7-5</td><td>4-0</td></tr>
</table>

Mean and median values of the traditional priority setting in the surgical units and indication groups (IGs) according to the NIKE (n=66). The various traditional priority settings at the participating eye clinics (two, three or four groups of priority) were converted to a scale of 1-4 for comparison.
<table>
<tr><td>NIKE</td><td>1</td><td>2</td><td>3</td><td>4</td></tr>
<tr><td>Traditional priority setting: mean (median)</td><td>-</td><td>2.3 (2.5)</td><td>2.6 (2.8)</td><td>2 (2.6)</td></tr>
</table>

Conversion key for traditional priority setting with two or three priority groups to a four-group scale:
Two groups: ‘Priority’ = 2.6, ‘No priority’ = 3.9; three groups: ‘High priority’ = 1, ‘No priority’ = 3, ‘Very low priority’ = 3.9.</td></tr>
<tr><td>Results</td><td>Impact (percentage reduction) of surgery on the total indication score, separated into different indication groups (IGs). Data are given as both median values and means.
<table>
<tr><td></td><td></td><td colspan="4">Indication group</td></tr>
<tr><td></td><td></td><td>1</td><td>2</td><td>3</td><td>4</td></tr>
<tr><td>First-eye surgery</td><td>Median
Mean</td><td>58.8
60.3</td><td>50
43.5</td><td>33.3
25</td><td>37.5
1.6</td></tr>
<tr><td>Second-eye surgery ／bilateral same-day surgery</td><td>Median
Mean</td><td>72.2
72.3</td><td>55.6
52.6</td><td>50
35.3</td><td>16.7
0</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>The impact of surgery on the indication score in different IGs shows the relative reduction in indication scores was largest in IG 1 and smallest in IG 4.</td></tr>
</table>

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<table>
<tr><th>Full citation</th><th>Quintana J, Escobar A, Bilbao A et al. Validity of newly developed appropriateness criteria for cataract surgery. Ophthalmology 2009;116;409-417</th></tr>
<tr><td>Study details</td><td>Country/ies where the study was carried out: Spain
Study type: Prospective cohort
Aim of the study: To validate newly developed explicit appropriateness criteria
Study dates: October 2004 – July 2005
Sources of funding: Not reported</td></tr>
<tr><td>Participants</td><td>Sample size
4335 patients
Inclusion criteria
Not reported
Exclusion criteria
Not reported

Baseline Characteristics

<table>
<tr><td>Mean age (SD)</td><td>73.36 (8.77)</td></tr>
<tr><td>Mean Previous visual acuity (SD)</td><td>0.28 (0.17)</td></tr>
<tr><td>Mean VF-14 score</td><td>61.02 (22.47)</td></tr>
<tr><td>Mean SF-36 scores (SD)
Physical functioning
Role physical
Bodily pain
General health
Social functioning
Role emotional
Vitality
Mental Health
Physical component
Mental component</td><td>
58.24 (27.31)
61.45 (42.88)
61.72 (30.24)
54.06 (20.81)
77.63 (26.06)
79.37 (37.46)
56.28 (23.02)
65.91 (21.17)
41.11 (10.27)
48.21 (11.19)</td></tr>
</table>
</td></tr>
<tr><td>Methods</td><td>Data collection</td></tr>
</table>

<table>
<tr><th>Full citation</th><td>Quintana J, Escobar A, Bilbao A et al. Validity of newly developed appropriateness criteria for cataract surgery. Ophthalmology 2009;116;409-417</td></tr>
<tr><td></td><td>Clinical data was collected during the visit before the intervention and approximately 6 weeks after surgery. At the time of the pre-intervention visit, 2 quality of life questionnaires were mailed to patients: Short form 36 (SF-36) and the Visual Function Index (VF-14). 2 reminder letters were mailed at scheduled times to patients who had not responded, telephone calls were made when necessary to collect the information.
Approximately 3 months after surgery patients were sent another letter including the same questionnaires.

Intervention
Cataract surgery</td></tr>
<tr><td>Results</td><td>Mean change, percent minimally clinical important difference change by appropriateness categories
<table>
<tr><td></td><td colspan="4">Appropriateness category</td><td></td></tr>
<tr><td></td><td>Necessary</td><td>Appropriate</td><td>Uncertain</td><td>Inappropriate</td><td>P value**</td></tr>
<tr><td>Simple cataract</td><td>n=1481</td><td>n=823</td><td>n=715</td><td>n=107</td><td></td></tr>
<tr><td>VF-14
Change, mean (SD)
%MCID</td><td>
29.08 (24.45)*
984 (68.38)*</td><td>
23.84 (23.24)*
463 (57.95)*</td><td>
18.18 (21.89)*
337 (49.20)*</td><td>
10.52 (17.80)*
22 (21.36)*</td><td>
<0.0001
<0.0001</td></tr>
<tr><td>Visual Acuity
Change, mean (SD)
%MCID</td><td>
0.56 (0.24)*
967 (69.07)*</td><td>
0.50 (0.24)*
479 (60.48)*</td><td>
0.42 (0.23)*
342 (49.57)*</td><td>
0.32 (0.19)*
27 (26.47)*</td><td>
<0.0001
<0.0001</td></tr>
</table>
Note: n=911 patients who had cataract operation with retinopathy or another associated ocular pathology feature – not reported here
298 patients were lost by not having the information necessary to classify the appropriateness of the intervention

Visual acuity data presented in decimal fraction units.
%MCID = minimal clinically important difference
*Differences among the 4 categories by the Scheffe test for multiple comparisons as P<0.05 for continuous variables and by the Chi-squared test considering the Bonferroni correction for multiple comparisons for categorical variables, considering an effect significant at P<0.0083
**Corresponds to the analysis of variance for the comparison of mean change scores or to Chi-square test for the comparison of proportions among the appropriateness categories.</td></tr>
</table>

Full citation	**Quintana J, Escobar A, Bilbao A et al. Validity of newly developed appropriateness criteria for cataract surgery. Ophthalmology 2009;116;409-417**

Visual acuity and Health-Related Quality-of-Life Changes measured by VF-14 and SF-36 scores

	Simple cataract (n=3321)		
	Before intervention – Mean (SD)	After intervention – Mean (SD)	P Value*
VF-14 score	62.27 (22.07)	87.15 (15.91)	<0.0001
Visual acuity	0.29 (0.17)	0.79 (0.22)	<0.0001
SF-36 score			
Physical functioning	59.28 (27.06)	62.66 (26.84)	<0.0001
Role physical	62.44 (42.56)	68.24 (41.13)	<0.0001
Bodily pain	62.07 (29.93)	66.23 (29.88)	<0.0001
General health	54.70 (20.52)	57.32 (21.13)	<0.0001
Social functioning	78.52 (25.79)	81.42 (24.54)	<0.0001
Role emotional	79.89 (37.18)	81.92 (35.60)	0.0023
Vitality	56.87 (23.01)	60.32 (23.14)	<0.0001
Mental Health	66.60 (20.93)	68.95 (21.10)	<0.0001
Physical component	41.40 (10.24)	42.87 (9.92)	<0.0001
Mental component	48.51 (11.06)	49.38 (10.85)	<0.0001

Note: n=1014 patients who had cataract operation with retinopathy or another associated ocular pathology feature – not reported here

Visual acuity data given in decimal fraction units

*P value corresponds to the paired t-test for comparison of pre-intervention and post-intervention main outcome results.

Outcomes	VF-14 data showed greater percentage (68.38%) of necessary procedures had a meaningful benefit, whereas 21.36% of the inappropriate procedures did. Visual acuity data showed 69.07% of necessary patients surpassed the MCID, whereas only 26.47% of the inappropriate patients did. Greater improvement seen in appropriate group than inappropriate. Regarding MCID, %MCID increases as you move from inappropriate to necessary categories for both visual acuity and VF-14. There were no significant differences across the appropriate categories in SF-36 scores. Significant differences were found in the changes in VF-14 and visual acuity among all appropriate categories except between necessary and appropriate

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Full citation	**Tobacman J, Zimmerman B, Lee P, Hilborne L, Kolder H, Brook R. Visual Acuity following cataract surgeries in relation to preoperative appropriateness ratings. Med Decis Making 2003;23:122–130**
Study details	Country/ies where the study was carried out: USA Study type: Retrospective cohort Aim of the study: To consider if the formal preoperative assessment of appropriate or inappropriate utilisation of cataract surgery by an expert panel could predict postoperative improvement or decline in visual acuity Study dates: 1990 Sources of funding: Not reported
Participants	Sample size 768 patients Inclusion criteria Patients who had cataract surgery performed in 1990 Exclusion criteria Patients who underwent additional intraocular procedures
Methods	Data collection Patient reports, such as the ophthalmology examinations for at least 1 year prior and several months after the cataract operation along with the Operative records were copied and sent to RAND to be classified for appropriateness. Outcomes measures of visual acuity were compared to the appropriateness category given. Characteristics of patients who had postoperative visual acuity data

Characteristic	n	%
Preoperative appropriateness classification		
Appropriate and crucial	309	39
Appropriate	414	52
Uncertain	56	7
Inappropriate	14	2
Postoperative visual acuity		
Better than or equal to 20/40	51	7
20/50 – 20/100	418	54
Worse than 20/100	301	39

Full citation	**Tobacman J, Zimmerman B, Lee P, Hilborne L, Kolder H, Brook R. Visual Acuity following cataract surgeries in relation to preoperative appropriateness ratings. Med Decis Making 2003;23:122–130**

Postoperative visual acuity (2-4 months)		
Better than or equal to 20/40	603	78
20/50 – 20/100	109	14
Worse than 20/100	58	8

Intervention
Cataract surgery

Analysis
Associations between appropriateness ratings and outcomes were assessed by 2-tailed Fisher's exact tests for tables greater than 2 × 2 (also called Freeman-Halton test), using the SAS procedure FREQ.22, 23 P-values less than 0.05 were considered significant.

Results

Associations between distribution of appropriateness ratings and postoperatively visual acuity

		Improvement		No Change		Decline		
Measurement of visual acuity	Total number	n	%	n	%	n	%	P-Value
2-4 months post-op	768							<0.001
Appropriate or appropriate and crucial	701	627	89	56	8	18	3	
Uncertain	53	36	68	14	26	3	6	
Inappropriate	14	5	36	8	57	1	7	
>4 months post-op	558							0.001
	513	460	90	42	8	11	2	

Full citation	**Tobacman J, Zimmerman B, Lee P, Hilborne L, Kolder H, Brook R. Visual Acuity following cataract surgeries in relation to preoperative appropriateness ratings. Med Decis Making 2003;23:122–130**
	Appropriate or appropriate and crucial: 38 / 29 / 76 / 7 / 18 / 2 / 5 Uncertain: 7 / 2 / 29 / 4 / 57 / 1 / 14 Inappropriate Note: Visual acuity improvement is defined as an increase of 2 or more lines by Snellen visual acuity. All P-values were determined by Fisher's exact test for tables greater than 2 × 2.
Outcomes	Better visual acuity outcomes occurred in the patients for whom preoperatively the operation was considered to be appropriate or appropriate and crucial ($P < 0.0001$, Fisher's exact test). Improvement in visual acuity occurred in 89% of the surgeries rated as appropriate or appropriate and crucial, 68% of the surgeries rated as uncertain, and 36% of the surgeries rated as inappropriate. No change occurred in 56 (8%) of the appropriate or appropriate and crucial operations, 14 (26%) of the uncertain surgeries, and 8 (57%) of the inappropriate surgeries. Decline in visual acuity at 2 to 4 months occurred in 18 of 701 (3%) operated on for appropriate or appropriate and crucial reasons, 3 of 53 (6%) operated on for indications rated as uncertain, and 1 of 14 (7%) operated on for an indication that was rated as inappropriate.
Comments	Applicability to the UK due to differences in healthcare systems

2E.2.2 Thresholds for referral for cataract surgery

Full citation	**Bilbao A, Quintana J, Escobar A, Garcia S, Andradas E, Bare M, Elizalde B. Responsiveness and Clinical Important Differences for the VF-14 Index, SF-36, and Visual acuity in patients undergoing cataract surgery. Ophthalmology 2009;116:418-424**
Study details	Country/ies where the study was carried out: Spain Study type: Prospective cohort Aim of the study: To assess visual acuity, VF-14 and SF-36 as instruments for capturing clinically important changes after cataract surgery Study dates: October 2004 to July 2005 Sources of funding: Fondo de Investigacion Sanitaria (grants nos. PI03/0550, PI03/0724, PI03/0471, PI104/1577); the thematic networks (Red IRYSS) of the Instituto de Salud Carlos III (G03/202), Madrid, Spain and the Department of Health of the Basque Country (2003/11045), Victoria, Alava, Spain.
Participants	Sample size 4356 patients Inclusion criteria Not reported Exclusion criteria Not reported
Methods	Data collection Visual acuity was determined in patients before surgery and 6 weeks after surgery. Completion of the VF-14 and SF-36 forms by the patients before surgery and 3 months after surgery. Intervention Cataract surgery Analysis Paired t-test
Results	Mean changes in Visual Acuity 6 weeks after intervention and in Health-Related Quality of Life 3 months after intervention

	Before Intervention	After Intervention	Change	P value
VA by VA at baseline				
≤0.1	0.07 (0.04)	0.64 (0.30)	0.57 (0.30)*	<0.0001
0.2-0.4	0.29 (0.09)	0.77 (0.22)	0.48 (0.23)*	<0.0001
≥0.5	0.55 (0.09)	0.85 (0.18)	0.30 (0.20)*	<0.0001
VF-14 by VA at baseline				
≤0.1	53.27 (24.85)	82.06 (21.98)	28.61 (26.90)*	<0.0001
0.2-0.4	62.30 (21.28)	85.57 (16.97)	23.14 (23.66)*	<0.0001

Full citation	**Bilbao A, Quintana J, Escobar A, Garcia S, Andradas E, Bare M, Elizalde B. Responsiveness and Clinical Important Differences for the VF-14 Index, SF-36, and Visual acuity in patients undergoing cataract surgery. Ophthalmology 2009;116:418-424**
	≥0.5 | 67.37 (20.09) | 87.85 (15.21) | 20.57 (21.83)* | <0.0001 *p<0.0001 for the analysis of variance for the comparison of mean change of VF-14 and VA between subgroups defined by the categories of pre-intervention VA
Outcomes	Mean changes in visual acuity were higher for patients in the lowest visual acuity category at baseline (≤0.1) compared to those in the two higher categories. Mean changes in VF-14 scores were higher for patients in the lowest visual acuity category at baseline (≤0.1) compared to those in the two higher categories.

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Full citation	**Black N, Browne J, et al. Is there overutilisation of cataract surgery in England. Br J Ophthalmol 2009;93:13–17**
Study details	Country/ies where the study was carried out: UK Study type: Prospective cohort Aim of the study: To measure the impact of surgery on a representative sample of patients Study dates: 2006 Sources of funding: Department of Health Policy Research Programme and Commercial Directorate
Participants	Sample size 745 people Inclusion criteria Not reported Exclusion criteria Patients with cognitive impairment, poor sight, literacy or language comprehension problems.
Methods	Data collection Patients completed a preoperative VF-14 questionnaire and the index section of the EQ-5D. Postoperative questionnaires were sent to patients 3 months after surgery with non-responders sent a remainder letter and replacement questionnaire 5 weeks after the original mailing. Intervention Cataract surgery
Results	Association between ‘‘appropriateness’’ (determined by preop VF-14 score) and ‘‘How would you describe the results of your operation?’’ Numbers and percentages.

Full citation	**Black N, Browne J, et al. Is there overutilisation of cataract surgery in England. Br J Ophthalmol 2009;93:13–17**

Result of operation	‘‘Appropriate’’ preop VF-14 ,94.5	‘‘Inappropriate’’ preop VF-14 94.5+	‘‘Appropriate’’ preop VF-14 ,87.8	‘‘Inappropriate’’ preop VF-14 87.8+
Excellent	236 (45.7)	106 (46.1)	152 (41.3)	190 (50.3)
Very good	144 (27.9)	77 (33.5)	112 (30.4)	109 (28.8)
Good	96 (18.6)	34 (14.8)	74 (20.1)	56 (14.8)
Fair	25 (4.8)	8 (3.5)	18 (4.9)	15 (4.0)
Poor	15 (2.9)	5 (2.2)	12 (3.3)	8 (2.1)
Overall	516 (100)	230 (100)	368 (100)	378 (100)

Outcomes	A high proportion of patients, 30–50%, can achieve little or no improvement according to patients’ reports of the impact on their visual function using the VF-14 tool. Most patients were satisfied with the result of their operation: 93.1% viewed the outcome as good to excellent; 93.5% reported that their problem was better.
Comments	The decision to excluded patients due to difficulties in completing the questionnaires probably excluded some of those with the worst visual function and general health

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Full citation	**Kessel L, Andresen J, Erngaard D, Flesner P, Tendal B, Hjortdal J. Indication for cataract surgery. Do we have evidence of who will benefit from surgery? A systematic review and meta-analysis. Acta Ophthalmol. 2016;94:10-20**
Study details	Country/ies where the study was carried out: Denmark Study type: Systematic review Aim of the study: To determine indications for cataract surgery Study dates: August 2014 Sources of funding: None reported
Participants	Sample size 8 studies Inclusion criteria Not reported Exclusion criteria Not reported
Methods	Data collection

Full citation	**Kessel L, Andresen J, Erngaard D, Flesner P, Tendal B, Hjortdal J. Indication for cataract surgery. Do we have evidence of who will benefit from surgery? A systematic review and meta-analysis. Acta Ophthalmol. 2016;94:10-20**
	A systematic literature search was performed in the MEDLINE, CINAHL, EMBASE and COCHRANE LIBRARY databases to answer 2 questions: (1) Will the patient with age-related cataract and poor preoperative visual acuity (20/40 or lower) benefit more from cataract surgery than the patient with fair preoperative visual acuity (better than 20/40)? (2) Will the patient with fair preoperative visual acuity (≥20/40) and subjective cataract-related complaints benefit more from cataract surgery than the patient with poor preoperative visual acuity (<20/40) but few or no subjective cataract-related complaints. For both questions, benefit was defined as an improvement in objective visual acuity (2 Snellen lines or greater or a doubling of the visual angle or improvement as defined by the included studies) or subjective visual function assessed by validated questionnaires. Intervention Cataract surgery Analysis Meta-analysis and GRADE
Results	Postoperative visual acuity (logMAR) in patients with fair or poor postoperative visual acuity (VA). CI, confidence interval; SD, standard deviation; IV, inverse variance.

	Fair pre op VA			Poor pre op VA				
Study or subgroup	Mean	SD	Total	Mean	SD	Total	Weight	Mean difference IV, Random, 95% CI
Douthwaite 2007 Subtotal (95% CI)	-0.02	0.07	25 25	-0.03	0.08	21 21	100.0 % 100.0 %	0.01 (-0.03, 0.05) 0.01 (-0.03, 0.05)

Heterogeneity: Not applicable

Test for overall effect Z =0.45 (P = 0.65)

Number of patients who had an improved visual acuity (VA) after cataract surgery. CI, confidence interval; M-H, Mantel–Haenszel

	Fair pre op VA		Poor pre op VA			
Study or subgroup	Events	Total	Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Kanthan 2011	26	93	23	28	23.6%	0.34 (0.24, 0.49)
Lundstrom 2013	249572	254359	112384	113709	38.8%	0.99 (0.99, 0.99)
Saw 2002	212	221	175	234	37.6%	1.28 (1.19, 1.39)
Total (95% CI)		254673		113971	100.0%	0.85 (0.64, 1.13)

Full citation	**Kessel L, Andresen J, Erngaard D, Flesner P, Tendal B, Hjortdal J. Indication for cataract surgery. Do we have evidence of who will benefit from surgery? A systematic review and meta-analysis. Acta Ophthalmol. 2016;94:10-20**

Total events	249810		112582			

Heterogeneity: Tau² = 0.06; Chi² = 72.63, df = 2 (P < 0.00001); I² = 97%
Test for overall effect: Z = 1.12 (P = 0.26)

Number of patients who reported an improvement in subjective visual function after cataract surgery. CI, confidence interval; M-H, Mantel–Haenszel; VA, visual acuity.

	Fair pre op VA		Poor pre op VA			
Study or subgroup	Events	Total	Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Garcia-Gutierrez 2012	3180	3501	632	674	51.8%	0.97 (0.95, 0.99)
Lundstrom 1999	1219	1329	538	604	48.2	1.03 (1.00, 1.06)
Total (95% CI)		4830		1278	100.0%	1.00 (0.94, 1.06)
Total events	4399		1170			

Heterogeneity: Tau² = 0.00; Chi² = 9.80, df = 1 (P < 0.002); I² = 90%
Test for overall effect: Z = 0.08 (P = 0.94)

Subjective visual function measured using the visual function questionnaire (VF-14). CI: confidence interval. IV, inverse variance; SD, standard deviation; VA, visual acuity.

VF-14 Score	Fair pre op VA			Poor pre op VA				
Study or subgroup	Mean	SD	Total	Mean	SD	Total	Weight	Mean difference IV, Random, 95% CI
Rosen 2005	94.82	5.36	18	94.59	8.81	180	57.0%	0.23 (-2.56, 3.02)
Subtotal (95% CI)			18			180	57.0%	0.23 (-2.56, 3.02)

Heterogeneity: Not applicable
Test for overall effect Z =0.16 (P = 0.87)

<table>
<tr><th>Full citation</th><th>Kessel L, Andresen J, Erngaard D, Flesner P, Tendal B, Hjortdal J. Indication for cataract surgery. Do we have evidence of who will benefit from surgery? A systematic review and meta-analysis. Acta Ophthalmol. 2016;94:10-20</th></tr>
<tr><td></td><td>
<table>
<tr><td>Change in VF-14 score</td><td colspan="3">Fair pre op VA</td><td colspan="3">Poor pre op VA</td><td></td><td></td></tr>
<tr><td>Study or subgroup</td><td>Mean</td><td>SD</td><td>Total</td><td>Mean</td><td>SD</td><td>Total</td><td>Weight</td><td>Mean difference IV, Random, 95% CI</td></tr>
<tr><td>Davis 2012
Subtotal (95% CI)</td><td>4.2</td><td>10.3</td><td>27
27</td><td>11.5</td><td>12</td><td>24
24</td><td>43.0%
43.0%</td><td>-7.30 (-13.48, -1.12)
-7.30 (-13.48, -1.12)</td></tr>
</table>
Heterogeneity: Not applicable
Test for overall effect Z = 2.23 (P = 0.02)

Studies combined
<table>
<tr><td></td><td>Fair pre op VA: Total</td><td>Poor pre op VA: Total</td><td>Weight: Total</td><td>Mean difference IV, Random, 95% CI</td></tr>
<tr><td>Total (95% CI)</td><td>45</td><td>204</td><td>100.0%</td><td>-3.01 (-10.32, 4.30)</td></tr>
</table>
Heterogeneity: Tau² = 22.37; Chi² = 4.74, df = 1 (P < 0.03); I² = 79%
Test for overall effect: Z = 0.81 (P = 0.42)
Test for subgroup differences: Chi² = 4.74, df = 1 (P < 0.03); I² = 78.9%
</td></tr>
<tr><td>Outcomes</td><td>There was no difference in visual acuity after surgery in the patients with poor or fair preoperative visual acuity
No studies reported the gain in visual acuity of the pre-specified outcome of a doubling of the visual acuity
98% of patients with fair preoperative visual acuity had an improvement in visual acuity versus 98.8% of patients with poor preoperative visual acuity – difference was not statistically significant
No overall difference in the postoperative VF-14 score between patients with fair or poor preoperative visual acuity.</td></tr>
</table>

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Full citation	**Kuoppala J, Falck A, Winblad and Tuulonen A. The Pyhajarvi cataract study II. Criteria for cataract surgery. Acta Ophthalmol. 2012;90:327-333**
Study details	Country/ies where the study was carried out: Finland Study type: Prospective cohort Aim of the study: To develop tools for patient selection to target cataract surgery to patients with the best expected outcomes Study dates: January to June 2003 Sources of funding: Finnish Office for Health Technology Assessment (FinOHTA)

<table>
<tr><th>Full citation</th><th>Kuoppala J, Falck A, Winblad and Tuulonen A. The Pyhajarvi cataract study II. Criteria for cataract surgery. Acta Ophthalmol. 2012;90:327-333</th></tr>
<tr><td>Participants</td><td>Sample size
93
Inclusion criteria
Patients on the waiting list for cataract surgery at the Department of Ophthalmology, Oulu University Hospital, from five municipalities (Pyhajarvi, Haapajarvi, Nivala, Haapavesi, Karsamaki) in January 2003
Exclusion criteria
None reported

Baseline characteristics of patients
<table>
<tr><th>Characteristic</th><th>n</th><th>%*</th></tr>
<tr><td>Visual acuity in the operated eye (LogMAR)**
<0.3
0.3-0.51
≥0.52</td><td>
41
27
25</td><td>
44
29
27</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td>Visual function (median, range) VF-14</td><td>Median = 79.5</td><td>Range = 27.3-100</td></tr>
</table>
*% may not add up to 100 due to rounding
**categories are not mutually exclusive</td></tr>
<tr><td>Methods</td><td>Data collection
Visual acuity was determined in patients before surgery and 6 weeks after surgery
Completion of the VF-14 forms by the patients during a nurse led interview before surgery and 9 months after surgery by the same nurse via a telephone interview.
The following requirements were developed to justify cataract surgery:
The visual acuity had to be at least 0.30 logMAR (at most Snellen) in the better eye and at least 0.52 logMAR (at most 0.3 Snellen) in the worse eye (these are the national criteria). The VF-14 total score had to be less than 80.

To define the criteria for successful cataract operations the following definitions were used:
The difference between pre and post-operative visual acuity of the operated eye had to be at least 0.2 logMAR, which corresponds to improvement by 2 lines in the logarithmic visual acuity chart. The VF-14 score was arbitrary required to improve at least 14 points, or if above 86 before surgery, it had to be 100 after surgery.</td></tr>
</table>

<table>
<tr><th>Full citation</th><td>Kuoppala J, Falck A, Winblad and Tuulonen A. The Pyhajarvi cataract study II. Criteria for cataract surgery. Acta Ophthalmol. 2012;90:327-333</td></tr>
<tr><td></td><td>Intervention
Cataract surgery

Analysis
Chi squared test and Logistical regression</td></tr>
<tr><td>Results</td><td>Results on treatment success by criteria for surgery
<table>
<tr><td></td><td colspan="3">Visual acuity</td><td colspan="3">VF-14</td></tr>
<tr><td>Criteria for surgery</td><td>a/n</td><td>%</td><td>OR (95% CI)*</td><td>a/n</td><td>%</td><td>OR (95% CI)</td></tr>
<tr><td>Visual acuity**</td><td>28/34</td><td>82</td><td>3.68 (1.12-12.1)</td><td>22/37</td><td>59</td><td>3.02 (1.07-8.51)</td></tr>
<tr><td>VF-14</td><td>24/35</td><td>69</td><td>0.91 (0.32-2.62)</td><td>34/39</td><td>87</td><td>1.53 (18.1-1297)</td></tr>
<tr><td>Visual acuity and VF-14</td><td>19/24</td><td>79</td><td>2.09 (0.62-7.01)</td><td>-</td><td>-</td><td>-</td></tr>
</table>
a = number of patients treated successfully among those who met the criteria for surgery; n = number of patients who met the criteria for surgery
*Adjusted for age, sex, macular degeneration and other eye disease
**The study eye was selected randomly if the patient was operated bilaterally</td></tr>
<tr><td>Outcomes</td><td>Postoperative Visual acuity has an odds of surgery success of 3.68 more for patients who met the criteria for surgery than those who did not.</td></tr>
<tr><td>Comments</td><td>Possible bias due to patients self-reporting on VF-14 questionnaire</td></tr>
</table>

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Full citation	**Monestam E, Wachtmeister L. Impact of cataract surgery on visual acuity and subjective functional outcomes: a population-based study in Sweden. Eye 1999;13:711-719**
Study details	Country/ies where the study was carried out: Sweden Study type: Prospective cohort Study dates: 1st April 1992 to 31st March 1993 Sources of funding: None reported

<table>
<tr><th>Full citation</th><th>Monestam E, Wachtmeister L. Impact of cataract surgery on visual acuity and subjective functional outcomes: a population-based study in Sweden. Eye 1999;13:711-719</th></tr>
<tr><td>Participants</td><td>Sample size
459 surgical events in 453 patients (6 patients had bilateral surgery)
Inclusion criteria
None reported
Exclusion criteria
None reported</td></tr>
<tr><td>Methods</td><td>Data collection
Before surgery the patients were categorised into one of three levels of visual impairment according to the distance acuity with best correction of the better eye. The
following grading system was used:
VA level I: 'Good acuity'. Decimal acuity better than 0.5 (>20/40).
VA level II: 'Moderate acuity'. Decimal acuity between 0.2 and 0.5 (20/100-20/40).
VA level III: 'Low acuity'. Decimal acuity less than 0.1 (20/200 or worse).
Two to three months after surgery the patients VA was re-examined

Intervention
Cataract surgery

Analysis
To evaluate changes in VAs the decimal acuity values were converted into a log scale using the method outlined by Holladay and Prager. The range of VA’s includes acuities such as counting fingers (CF) and hand movements (HM). The following arbitrary logMAR (minimum angle of resolution) values have been used by other authors: CF in front of the eye = logMAR 2.2, HM = logMAR 2.3, and light perception (P) = logMAR
2.5
Mann-Whitney U test to compare VA before and after surgery</td></tr>
<tr><td>Results</td><td>Visual acuity before and after surgery in each VA level group
<table>
<tr><td></td><td>VA-level I (>20/40)</td><td>VA-level II (20/120 – 20/40)</td><td>VA-level III (20/200 or less)</td></tr>
<tr><td>Number</td><td>211</td><td>206</td><td>42</td></tr>
<tr><td>Median decimal acuity (range)</td><td></td><td></td><td></td></tr>
</table></td></tr>
</table>

Full citation	**Monestam E, Wachtmeister L. Impact of cataract surgery on visual acuity and subjective functional outcomes: a population-based study in Sweden. Eye 1999;13:711-719**

Before surgery Eye to be operated	0.06 (P - 0.5)	(P – 0.5)*	0.015 (P – 0.1)
After surgery Operated eye	0.8 (0.02 – 1.0)**	0.6 (HM – 1.0)**	0.4 (HM – 1.0)**

Ranges of VA are within parenthesis.
P refers to perception of light and HM to hand movements
*significantly better VA of the eye to be operated in patients of group II compared with groups I and III ($p<0.00001$, respectively)
**significantly improved media decimal acuity of the operated aye after surgery ($p<0.00001$)

Outcomes	Before surgery the median decimal acuity of the eyes to be operated on was significantly better in the moderate acuity group (0.1) compared with those of the low (0.015; $p < 0.00001$) and good acuity groups (0.06; $p < 0.00001$) After surgery the visual acuity of the operated eye improved significantly in all groups ($p < 0.00001$) A post-operative decimal acuity of the operated eye of less than 0.5 (< 20/40) was found in a significantly larger proportion of the patients at level III (52%; 22/42) compared with level II (27%; 55/206) and level I (11%; 24/211) ($p < 0.0001$).
Comments	6 patients had bilateral surgery - no correction for bias was made

E.3 Pre-operative assessment and biometry

- What is the effectiveness of different techniques for undertaking biometry?
- What are the most appropriate formulae to optimise intraocular lens biometry calculation?
- What is the effectiveness of strategies used to select intraocular lens constants in order to optimise biometry calculation?
- What other factors should be considered such as, who should undertake biometry and when should preoperative biometry be assessed?
- What is the effectiveness of risk stratification techniques to reduce surgical complications?
- What are the risk factors associated with increased surgical complications in cataract surgery?

E.3.1 Biometry techniques

E.3.1.1 Ultrasound (immersion and contact) and optical biometry to measure axial length

Full citation	**Fontes BM, Fontes BM, Castro E. Intraocular lens power calculation by measuring axial length with partial optical coherence and ultrasonic biometry. Arq Bras Oftalmol 2011 74(3):166-70**
Study details	**Country/ies where the study was carried out:** Brazil **Study type:** Randomised controlled trial **Aim of the study:** To compare the achieved refractive outcomes in people undergoing phacoemulsification cataract surgery following intraocular lens (IOL) calculation using conventional immersion ultrasonic biometry (US) or partial coherence interferometry (PCI) **Study dates:** Not reported **Source of funding:** None
Participants	**Sample size** 79 people (120 eyes) **Diagnostic criteria** Not reported **Inclusion criteria** • People undergoing phacoemulsification cataract surgery **Exclusion criteria** • Corneal astigmatism of more than 2.5 dioptres (D) • Eyes with axial length (AL) <20mm and >25.8mm • Complications during surgery

<table>
<tr><td>Full citation</td><td>Fontes BM, Fontes BM, Castro E. Intraocular lens power calculation by measuring axial length with partial optical coherence and ultrasonic biometry. Arq Bras Oftalmol 2011 74(3):166-70</td></tr>
<tr><td></td><td>• People with poor visual prognosis e.g. macular scar, amblyopia

Baseline characteristics
<table>
<tr><th></th><th>Ultrasound biometry (immersion), n=46 (70 eyes)</th><th>Optical biometry (PCI), n=33 (50 eyes)</th></tr>
<tr><td>Age (years)*</td><td>70.0 ± 9.3 (45-86)</td><td>69.8 ± 13.1 (11-85)</td></tr>
<tr><td>Male/ female</td><td>16 (35%) / 30 (65%)</td><td>15 (45%) / 18 (55%)</td></tr>
<tr><td>Axial length (mm)*</td><td>23.22 ± 1.06 (20.05-25.78)</td><td>23.22 ± 1.00 (21.01-25.45)</td></tr>
<tr><td colspan="3">*Data in means ± standard deviations (range)</td></tr>
</table>
No significant between group differences were reported for age (p=0.7165) and AL (p=0.9110). No details of analyses provided for sex.</td></tr>
<tr><td>Methods</td><td>Interventions
Ultrasound biometry: Immersion ultrasound, n=46 (70 eyes)
• Ultrascan, Alcon.

Optical biometry: Partial coherence interferometry, n=33 (50 eyes)
• IOLMaster, Carl Zeiss Meditec.

Measurements and formula
• Keratometry measurements: not reported.
• IOL formula: Holladay 1 was used to calculate the IOL power for all patients.
• IOL constant optimisation: not reported.
• Experience of assessor: assessments were undertaken by an experienced ophthalmologist.

Cataract surgery and IOL implantation: 1 surgeon performed small-incision phacoemulsification with standard phaco-chop technique and in-the-bag implantation using an AcrySof IQ IOL in all cases.

Randomisation, allocation, blinding
Randomisation/allocation: no details provided – “randomly separated into 2 groups”.
Blinding: no details were provided of the procedures involved in the post-operative assessments.

Details
Sample size calculation: not reported
Pre-operative assessment: desired final refraction was determined for all cases.
Post-operative assessment: the final manifest refraction was assessed at least 4 weeks after the surgery by the same examiner. The preferred target post-operative refraction was not reported.</td></tr>
</table>

<table>
<tr><td>Full citation</td><td>Fontes BM, Fontes BM, Castro E. Intraocular lens power calculation by measuring axial length with partial optical coherence and ultrasonic biometry. Arq Bras Oftalmol 2011 74(3):166-70</td></tr>
<tr><td></td><td>Study outcomes:
• Mean absolute error (difference between the desired refraction pre-operatively and achieved post-operative refraction); spherical equivalent in dioptres used for all measures
• Number of eyes within various ranges of the difference between final spherical equivalent and pre-operative prediction
Group comparisons: Wilcoxon rank-sum test

Missing data handling/loss to follow up
No details provided.</td></tr>
<tr><td>Results</td><td>Mean absolute errors
<table>
<tr><th></th><th>Ultrasound biometry (immersion)*, n=46 (70 eyes)</th><th>Optical biometry (PCI)*, n=33 (50 eyes)</th><th>Between group difference p value</th></tr>
<tr><td>Pre-operative desired refraction</td><td>-0.76 ± 0.26 (-1.59 to -0.33)</td><td>-0.47 ± 0.43 (-2.15 to 0.75)</td><td>p<0.0001</td></tr>
<tr><td>Post-operative achieved refraction</td><td>-0.50 ± 0.50 (-1.75 to 1.00)</td><td>-0.32 ± 0.54 (-2.00 to 1.00)</td><td>p=0.0313</td></tr>
<tr><td>Mean absolute errors</td><td>0.26 ± 0.48 (-1.05 to 1.76)</td><td>0.15 ± 0.33 (-0.65 to 0.9)</td><td>p=0.0836</td></tr>
<tr><td colspan="4">*All data in means ± standard deviations (ranges) dioptres</td></tr>
</table>
Number (proportion) of eyes within various ranges of difference between final spherical equivalent and pre-operative prediction
<table>
<tr><th>Difference between final spherical equivalent and pre-operative prediction (dioptres, D)</th><th>Ultrasound biometry (immersion, 70 eyes)</th><th>Optical biometry (PCI, 50 eyes)</th></tr>
<tr><td>≤0.25</td><td>32 (45.7%)</td><td>34 (68%)</td></tr>
<tr><td>0.25 to ≤0.5</td><td>21 (30%)</td><td>7 (14%)</td></tr>
<tr><td>0.5 to ≤0.75</td><td>7 (10%)</td><td>6 (12%)</td></tr>
<tr><td>0.75 to ≤1.0</td><td>6 (8.6%)</td><td>3 (6%)</td></tr>
<tr><td>>1.0</td><td>4 (5.7%)</td><td>0</td></tr>
</table></td></tr>
<tr><td>Comments</td><td>Overall risk of bias: This study has a high risk of bias due to the lack of or limited reporting of all aspects of the methods including randomisation, blinding, measurement procedures (particularly keratometry), outcome definitions, missing data and statistical analyses. Due to the ambiguous methods and uneven sized groups, it is unclear whether there was biased allocation. In addition, it is unclear whether keratometry was standardised for both groups. Moreover, the mean absolute errors were taken as the positive values of the overall differences of the mean post-operative achieved refraction and pre-operative desired refraction, rather than the means of the absolute individual differences.

Other information: Not relevant

Was the allocation sequence adequately generated? Unclear
Was allocation adequately concealed? Unclear
Was knowledge of the allocated intervention adequately prevented during the study? Unclear</td></tr>
</table>

Full citation	**Fontes BM, Fontes BM, Castro E. Intraocular lens power calculation by measuring axial length with partial optical coherence and ultrasonic biometry. Arq Bras Oftalmol 2011 74(3):166-70**
	Were incomplete outcome data adequately addressed? Unclear **Are reports of the study free of suggestion of selective outcome reporting?** Unclear **Was the study apparently free of other problems that could put it at a high risk of bias?** No

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Full citation	**Kolega MS, Kovacevic S, Canovic S, et al. Comparison of IOL Master and ultrasound biometry in pre-operative intraocular lens (IOL) power calculation. Coll Antropol 2015 1:233-5**
Study details	**Country/ies where the study was carried out:** Croatia **Study type:** Randomised controlled trial **Aim of the study:** To compare the accuracy of intraocular lens (IOL) power calculations using conventional applanation ultrasound biometry and partial coherence laser interferometry (PCI) in people undergoing phacoemulsification cataract surgery **Study dates:** Not reported **Source of funding:** Not reported
Participants	**Sample size** 40 people (1 eye per person) **Diagnostic criteria** Not reported **Inclusion criteria** • People with age-related cataracts and post-operative natural visual acuity >0.7 **Exclusion criteria** • Eyes with other ocular pathology or intraoperative complication **Baseline characteristics** • Age range: 60 to 84 years • Male/female: 17 (42.5%) / 23 (57.5%) • Pre-operative visual acuity: 0.2 to 0.4
Methods	**Interventions** Ultrasound biometry: Contact ultrasound, n=20 • Alcon Ultra Scan Biometry.

<table>
<tr><td>Full citation</td><td>Kolega MS, Kovacevic S, Canovic S, et al. Comparison of IOL Master and ultrasound biometry in pre-operative intraocular lens (IOL) power calculation. Coll Antropol 2015 1:233-5</td></tr>
<tr><td></td><td>Optical biometry: Partial coherence interferometry, n=20
• IOLMaster v5, Carl Zeiss.

Measurements and formula
• Keratometry measurements: keratometry for ultrasound biometry was performed using automated keratometry, Righton Speedy-K type. The IOLMaster was used for keratometry measurements in the optical biometry group.
• IOL formula: Holladay II formula was used to calculate the IOL power.
• IOL constant optimisation: not reported.
• Details of assessment/assessor: not reported.

Cataract surgery and IOL implantation: 2 surgeons performed the same clear corneal phacoemulsification surgery technique on all patients. A foldable IOL was implanted in the capsular bag for all patients.

Randomisation, allocation, blinding
Randomisation/allocation: details not reported. The term “prospective randomized trial” was used only in the abstract to indicate study design.
Blinding: no details were reported.

Details
Sample size calculation: not reported
Post-operative assessment: post-operative refractive error was carried out 6 weeks after surgery.
Study outcomes:
• Post-operative mean absolute refractive error
• Number of eyes within various ranges of (assumed) absolute refractive errors
Group comparisons: t-test

Missing data handling/loss to follow up
Not reported.</td></tr>
<tr><td>Results</td><td>Mean absolute refractive errors
<table><tr><th></th><th>Ultrasound biometry (contact), n=20</th><th>Optical biometry (PCI), n=20</th></tr><tr><td>Mean absolute refractive error in dioptres*</td><td>0.75 ±0.5</td><td>0.5 ± 0.5</td></tr><tr><td colspan="3">*Data in means ± assumed standard deviations</td></tr></table>
Number (proportion) of eyes within various ranges of (assumed) absolute refractive errors
<table><tr><th>Refractive errors (dioptres, D)</th><th>Ultrasound biometry (contact, 20 eyes)</th><th>Optical biometry (PCI, 20 eyes)</th></tr></table></td></tr>
</table>

Full citation	**Kolega MS, Kovacevic S, Canovic S, et al. Comparison of IOL Master and ultrasound biometry in pre-operative intraocular lens (IOL) power calculation. Coll Antropol 2015 1:233-5**

0-0.25	6 (30%)	14 (70%)
0.25-0.5	4 (20%)	4 (20%)
0.5-1.0	7 (35%)	2 (10%)
>1.0	3 (15%)	0 (0%)

Comments	**Overall risk of bias:** This study has a high risk of bias, due to the lack of reporting of specific methods such as randomisation, blinding, missing data and limited description of outcome definitions and the potential confounding of unstandardised keratometry between the groups. **Other information:** Not relevant **Was the allocation sequence adequately generated?** Unclear **Was allocation adequately concealed?** Unclear **Was knowledge of the allocated intervention adequately prevented during the study?** Unclear **Were incomplete outcome data adequately addressed?** Unclear **Are reports of the study free of suggestion of selective outcome reporting?** Unclear **Was the study apparently free of other problems that could put it at a high risk of bias?** No

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Full citation	**Naicker P, Sundralingam S, Peyman M, et al. Refractive outcomes comparison between the Lenstar LS 900 optical biometry and immersion A-scan ultrasound. Int Ophthalmol 2015 35:459-66**
Study details	**Country/ies where the study was carried out:** Malaysia **Study type:** Randomised controlled trial **Aim of the study:** To determine the accuracy of intraocular lens (IOL) calculations using immersion ultrasound biometry (US) or optical low-coherence reflectometry (OLCR) in people undergoing elective phacoemulsification cataract surgery with posterior chamber IOL implantation **Study dates:** Not reported **Source of funding:** University of Malaya research grant
Participants	**Sample size** 200 people (1 eye per person) **Diagnostic criteria** Lens opacities classification system III (LOCS III): all cataracts were of nuclear sclerosis of 1-2+ **Inclusion criteria** • People undergoing elective phacoemulsification cataract surgery

Full citation	**Naicker P, Sundralingam S, Peyman M, et al. Refractive outcomes comparison between the Lenstar LS 900 optical biometry and immersion A-scan ultrasound. Int Ophthalmol 2015 35:459-66**
	Exclusion criteria • Diabetes mellitus • Corneal astigmatism of more than 1.5 dioptres (D) • Eyes with axial length (AL) <20mm and >25mm • Complicated surgeries • Other ocular pathology including retinal, choroidal, vitreous, corneal or neurologic abnormalities with poor vision potential **Baseline characteristics** • Mean (SD, range) age: 66.9 (7.0, 50 to 80) years • Male/female: 87 (43.5%) / 113 (56.5%) • Ethnicity: not specified but reports similar proportions were observed as indicated by Pearson's Chi square test
Methods	**Interventions** Ultrasound biometry: Immersion A-scan ultrasound, n=100 • Quantel Medical Axis II Ultrasonic Biometer was used with a Prager shell. Optical biometry: Optical low-coherence reflectometry, n=100 • Lenstar LS 900 version 4.1. **Measurements and formula** • Examination undertaken in sitting with head reclined gently against headrest. • Five readings within an acceptable standard deviation were required and the average total length was used. • Keratometry measurements: readings were standardised using the automated Nidek keratometer and measurements were entered into the different biometry technique and IOL calculation. • IOL formula: the Hoffer Q IOL power calculation formula was used. • IOL constant optimisation: not reported. • Experience of assessor: assessments were undertaken by a clinical technician with 4 years of experience in biometry measurement. **Cataract surgery and IOL implantation:** 1 surgeon performed uneventful, sutureless phacoemulsification on all eyes through a 2.4mm limbal incision. A hydrophilic AcrySof IQ aspheric IOL was implanted into the capsular bag. **Randomisation, allocation, blinding** Randomisation/allocation: no details provided – "randomly separated into 2 groups". Blinding: no details were provided of the procedures or individuals involved in the post-operative assessments.

Full citation	**Naicker P, Sundralingam S, Peyman M, et al. Refractive outcomes comparison between the Lenstar LS 900 optical biometry and immersion A-scan ultrasound. Int Ophthalmol 2015 35:459-66**

Details

Sample size calculation: 200 people required to achieve 85% power (calculated using G*Power software v3.0.10).

Pre-operative assessment: refraction was undertaken on all patients.

Post-operative assessment: refraction was performed 2 months after surgery. The preferred target post-operative refraction was -0.5D.

Study outcomes:

- Prediction error (difference between target predicted value of refractive error pre-operatively and post-operative spherical equivalent values)
- Absolute prediction error (magnitude of prediction error without considering the positive or negative sign)
- Number of eyes within various ranges of prediction errors and absolute prediction errors
- Means and/or medians for AL, K1, K2, IOL power, target and achieved spherical equivalent measurements

Group comparisons: independent *t* test for differences in prediction errors

Other analyses: correlational analysis between prediction error and AL using Pearson's correlation coefficient

Missing data handling/loss to follow up

People were recruited until the required sample size of 200 was achieved. There was no reported missing data or loss to follow up.

Results

Prediction errors and absolute prediction errors

	Ultrasound biometry (immersion), n=100	**Optical biometry (OLCR), n=100**
Pre-operative target*	-0.421 ± 0.182	-0.397 ± 0.207
Post-operative spherical equivalent (SE)*	-0.380 ± 0.529	-0.369 ± 0.557
Prediction error (SE – target)*	-0.0409 ± 0.5247	-0.0279 ± 0.5812
Within group difference (*p* value)	0.438	0.632
Absolute prediction error*	0.4259 ±0.3062	0.4415 ± 0.3764
Difference in prediction errors between groups*	0.0130 ± 0.0789	
Between group difference (*p* value)	0.868	
*Data in means ± standard deviations (assumed units are in dioptres)		

Number of eyes within various ranges of prediction errors

Range of prediction error (dioptres, D)	**Ultrasound biometry (immersion, 100 eyes)**	**Optical biometry (OLCR, 100 eyes)**
[-2.0, -1.5]	0	1
[-1.5, -1.0]	2	4
[-1.0, -0.5]	15	10
[-0.5, -0.0]	40	40
[0.0, 0.5]	29	28
[0.5, 1.0]	10	14
[1.0, 1.5]	4	1

Full citation	**Naicker P, Sundralingam S, Peyman M, et al. Refractive outcomes comparison between the Lenstar LS 900 optical biometry and immersion A-scan ultrasound. Int Ophthalmol 2015 35:459-66**

[1.5, 2.0]	0	2

Number of eyes within various ranges of absolute prediction errors

Range of prediction error (dioptres, D)	Ultrasound biometry (immersion, 100 eyes)	Optical biometry (OLCR, 100 eyes)
[0.0, 0.25]	35	34
[0.25, 0.5]	34	37
[0.5, 0.75]	14	12
[0.75, 1.0]	11	9
[1.0, 1.25]	5	2
[1.25, 1.50]	1	3
[1.50, 1.75]	0	2
[1.75, 2.0]	0	1

Correlation between prediction errors and axial lengths

	Ultrasound biometry (immersion), n=100	Optical biometry (OLCR), n=100
Pearson's correlation coefficient	-0.24	0.14
p value	0.014	0.14

There was a small negative but significant correlation observed between prediction error and axial lengths for the ultrasound group only.

Comments

Overall risk of bias: This study has a moderate risk of bias due to the lack of reporting of specific methods such as randomisation, blinding and missing data, and specific group details of a comprehensive set of baseline characteristics.

Other information: Not relevant

Was the allocation sequence adequately generated? Unclear
Was allocation adequately concealed? Unclear
Was knowledge of the allocated intervention adequately prevented during the study? Unclear
Were incomplete outcome data adequately addressed? Unclear
Are reports of the study free of suggestion of selective outcome reporting? Unclear
Was the study apparently free of other problems that could put it at a high risk of bias? Yes

41

Full citation	**Rajan MS, Keilhorn I, Bell JA. Partial coherence laser interferometry vs conventional ultrasound biometry in intraocular lens power calculations. Eye 2002 16:552-6**
Study details	**Country/ies where the study was carried out:** England **Study type:** Randomised controlled trial

<table>
<tr><td>Full citation</td><td>Rajan MS, Keilhorn I, Bell JA. Partial coherence laser interferometry vs conventional ultrasound biometry in intraocular lens power calculations. Eye 2002 16:552-6</td></tr>
<tr><td></td><td>Aim of the study: To evaluate the predictability of refractive outcome using partial coherence laser interferometry (PCI) and applanation ultrasound biometry (US) in people undergoing phacoemulsification cataract surgery
Study dates: Not reported
Source of funding: Not reported</td></tr>
<tr><td>Participants</td><td>Sample size
100 people (1 eye per person)

Diagnostic criteria
Not reported

Inclusion criteria
• People attending phacoemulsification cataract surgery providing informed consent

Exclusion criteria
• Complicated cataracts related to chronic uveitis, trauma or silicone oil

Baseline characteristics
<table>
<tr><th></th><th>Ultrasound biometry (contact), n=50</th><th>Optical biometry (PCI), n=50</th></tr>
<tr><td>Age (years)*</td><td>71 ± 8 (40-86)</td><td>67 ± 6 (38-80)</td></tr>
<tr><td>Axial length (mm)*</td><td>23.43 ± 1.2 (20.1-27)</td><td>23.47 ± 1.1 (20-27.6)</td></tr>
<tr><td colspan="3">*Data in means ± standard deviations (ranges)</td></tr>
</table></td></tr>
<tr><td>Methods</td><td>Interventions
Ultrasound biometry: Contact A-scan ultrasound, n=50
• Nidek Echoscan-2000.

Optical biometry: Partial coherence interferometry, n=50
• IOLMaster, Carl Zeiss Meditec.

Measurements and formula
• US intraocular distance measurements were checked for reliability using retinal spikes.
• PCI intraocular distance measurements were checked for reliability using the signal-to-noise ratio > 2.0.
• Keratometry measurements: corneal curvature measurements for US group were performed using Javal Schiotz keratometer.
• Intraocular lens (IOL) formula: SRK-T formula was used to calculate the IOL power for all patients.
• IOL constant optimisation: not reported, states that the A constant was the same for all eyes.</td></tr>
</table>

Full citation	**Rajan MS, Keilhorn I, Bell JA. Partial coherence laser interferometry vs conventional ultrasound biometry in intraocular lens power calculations. Eye 2002 16:552-6**

- Experience of assessor: pre-operative biometry was performed by an experienced biometrist on all patients.

Cataract surgery and IOL implantation: 1 surgeon performed phacoemulsification through a 4.1 mm superior corneal tunnel and a folding IOL (Acrysof MA60BM, Alcon) was implanted in the capsular bag for all patients.

Randomisation, allocation, blinding

Randomisation/allocation: details not reported.

Blinding: no details were reported.

Details

Sample size calculation: not reported

Pre-operative assessment: the desired post-operative refraction based on pre-existing refractive error was decided prior to surgery.

Post-operative assessment: all patients were followed up on the first post-operative day, 1 week and 2 months later by experienced observers. Post-operative refraction was carried out at 2 months with an autorefractor and confirmed by subjective refraction. All patients underwent pseudophakic axial length measurements by IOLMaster at 2 months and were carried out by the same biometrist.

Study outcomes:

- Mean error and mean absolute error (differences between predicted and attained post-operative refraction); post-operative mean spherical equivalent was calculated for each patient

Group comparisons: not reported for between group analyses

Other analyses: paired t tests were used to compare pre-operative axial length measurements and pseudophakic axial length measurements post-operatively.

Missing data handling/loss to follow up

4/50 people failed PCI biometry due to dense cataracts (4%) and fixation instability due to macular degeneration (4%) and had to undergo US biometry for axial length measurements. No details were provided regarding the inclusion of these individuals in the analyses.

Results

Mean absolute errors

	Ultrasound biometry (contact), n=unclear	**Optical biometry (PCI), n=unclear**
Mean absolute error in dioptres*	0.6 ±0.4	0.52 ± 0.35
*Data in means ± standard deviations Between group difference, *p*=0.24		

Eyes that underwent PCI had increased tendency for hyperopic shift (65%) than eyes in ultrasound (50%).

Number (proportion) of eyes achieving post-operative refraction within various ranges of the predicted value

Mean absolute errors (dioptres, D)	**Ultrasound biometry (contact, 50 eyes)***	**Optical biometry (PCI, 45 eyes)***
<0.5	30 (60%)	28 (62.2%)

Full citation	**Rajan MS, Keilhorn I, Bell JA. Partial coherence laser interferometry vs conventional ultrasound biometry in intraocular lens power calculations. Eye 2002 16:552-6**

0.5-1.0	11 (22%)	11 (24.4%)
1.0-1.5	9 (18%)	5 (11.1%)
1.5-2.0	0 (0%)	1 (2.2%)
*Data estimated from graphs		

Comments

Overall risk of bias: This study has a moderate to high risk of bias, due to the lack of reporting of specific methods such as randomisation, blinding and missing data and potential confounding of unstandardised keratometry between the groups.

Other information: Not relevant

Was the allocation sequence adequately generated? Unclear
Was allocation adequately concealed? Unclear
Was knowledge of the allocated intervention adequately prevented during the study? Unclear
Were incomplete outcome data adequately addressed? No
Are reports of the study free of suggestion of selective outcome reporting? Unclear
Was the study apparently free of other problems that could put it at a high risk of bias? No

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Full citation	**Raymond S, Favilla I, Santamaria L. Comparing ultrasound biometry with partial coherence interferometry for intraocular lens power calculations: a randomized study. Invest Ophthalmol Vis Sci 2009 50:2457-52**
Study details	**Country/ies where the study was carried out:** Australia **Study type:** Randomised controlled trial **Aim of the study:** To determine whether intraocular lens (IOL) power calculations using partial coherence interferometry (PCI) are more accurate in improving post-operative outcomes than applanation (contact) ultrasound biometry (US) in people undergoing phacoemulsification cataract surgery **Study dates:** April 6 2006 to August 24 2006 (preadmission clinic) **Source of funding:** Not reported
Participants	**Sample size** 169 people (1 eye per person) **Diagnostic criteria** Not reported

Cataract type	Ultrasound biometry (contact), n=85	Optical biometry (PCI), n=84
Nuclear	35 (41.2%)	43 (51.2%)
Cortical	6 (7.1%)	7 (8.3%)
Posterior subcapsular cataract	2 (2.4%)	1 (1.2%)
Mixed	42 (49.4%)	33 (39.3%)

Full citation	Raymond S, Favilla I, Santamaria L. Comparing ultrasound biometry with partial coherence interferometry for intraocular lens power calculations: a randomized study. Invest Ophthalmol Vis Sci 2009 50:2457-52

Mature	0	0

Inclusion criteria

- People attending preadmission phacoemulsification cataract surgery clinic during the specified period, providing informed consent who were randomly sampled using a lottery system

Exclusion criteria

- Not specified (eligibility criteria kept simple to increase generalisability to target population)

Baseline characteristics

	Ultrasound biometry (contact), n=85	Optical biometry (PCI), n=84
Age (years)*	73.55 ± 9.78 [95% CI: 71.47 to 75.63]	73.71 ± 9.45 [95% CI: 71.83 to 75.87]
Female	59%	58%
Best corrected visual acuity*	0.34 ± 0.14 [95% CI: 0.31 to 0.37]	0.33 ± 0.12 [95% CI: 0.31 to 0.36]
Axial length (mm)*	23.22 ± 1.08 [95% CI: 22.99 to 23.45]	23.39 ± 1.00 [95% CI: 23.17 to 23.60]
Keratometry (dioptres) = (K1 + K2)/2*	44.09 ± 2.80 [95% CI: 43.50 to 44.69]	43.53 ± 2.69 [95% CI: 42.95 to 44.10]
VF-14 score*	72.95 ± 19.38 [95% CI: 68.83 to 77.07]	71.29 ± 20.48 [95% CI: 66.91 to 75.67]
Age-related macular degeneration	14 (16.5%)	10 (11.9%)
Glaucoma	4 (4.7%)	6 (7.1%)
Diabetic retinopathy	5 (5.9%)	3 (3.6%)
Asteroid hyalosis	1 (1.2%)	2 (2.4%)
Pseudoexfoliation	1 (1.2%)	2 (2.4%)
Corneal disease	1 (1.2%)	1 (1.2%)
*Data in means ± standard deviations. Standard deviations calculated from reported 95% CI in parentheses		

Methods

Interventions

Ultrasound biometry: Contact ultrasound calculated IOL, n=85

- Microscan Model 100A+, Sonomed.

Optical biometry: Partial coherence interferometry calculated IOL, n=84

- IOLMaster, Carl Zeiss Meditec.

Measurements and formula

- At preadmission clinic, the axial length (AL) and IOL power calculation for all patients were measured using PCI, followed by US. IOL power was kept blind with respect to group allocation.

Full citation	**Raymond S, Favilla I, Santamaria L. Comparing ultrasound biometry with partial coherence interferometry for intraocular lens power calculations: a randomized study. Invest Ophthalmol Vis Sci 2009 50:2457-52**

- PCI AL measurements were conducted with the IOLMaster AL scan protocol, with readings repeated until 4 scans were consistent within ±0.02mm of ideal waveform and acceptable signal-to-noise ratio > 2.0; average reading was used. The PCI IOL implant power was calculated by the IOLMaster using the SRK/T formula with the manufacturer-recommended A constant set at 118.9.
- US measurements were repeated until 4 high-quality scans were consistent within ±0.10mm. The highest quality scan was used. The SRK-II formula was used applying the IOLMaster auto-keratometry and US AL measurements and the IOL manufacturer-recommended A constant of 118.7.
- To eliminate confounding introduced by keratometry performed by different techniques, auto-keratometry with the IOLMaster protocol was performed on all patients before US biometry to avoid corneal contact that may affect the readings (median of 3 measurements within 0.3D in each meridian).
- Experience of assessor: PCI AL measurements were performed by the primary researcher and all US AL measurements were performed by a senior orthoptist, blind to the PCI results.

Cataract surgery and IOL implantation: 8 consultant and 4 senior ophthalmology registrars performed phacoemulsification through a superior corneoscleral incision (3.2 mm). An aspheric acrylic posterior chamber IOL (SN60WF, Alcon) was implanted in the capsular bag in 201 people. In 4 people, posterior capsule rupture prevented placement of the IOL within the capsular bag and each person received a ciliary sulcus fixation IOL (MA60AC, Alcon).

Randomisation, allocation, blinding

Randomisation/allocation: opaque envelope containing a card that stated PCI or US.

Double blinding: patient and outcome assessors were blind to biometric group allocation. Selection and randomisation of trial participants, data collection and analysis were all centrally controlled and concealed by the primary researcher.

Details

Sample size calculation: 158 people required to detect a 0.24D difference (power 90%, α=0.05) in the mean absolute error between patients with PCI and US calculated IOLs. Including attrition and reported failure rate of PCI to obtain AL measurements, sample size was increased to 205.

Data collection: demographic and baseline ocular information for all patients were obtained by the primary researcher from the standard hospital surgical admission forms and preadmission ophthalmic history and examination notes.

Post-operative assessment: all patients were examined by an ophthalomologist 7 to 12 days after surgery. In the 5th post-operative week, patients returned for refraction to their community ophthalmologists or optometrists who were blind to trial assignment and group allocation. The community ophthalmologists and optometrists used their own standard methods for measuring refraction i.e. subjective (59%) or autorefractor (41%). The final refraction for each patient was forwarded to the primary researcher, converted to its spherical equivalent, and compared with the pre-operative prediction.

Study outcomes:

- Mean absolute error (mean of the absolute difference between the measured and predicted post-operative spherical equivalent)
- Number of eyes achieving post-operative refraction within various ranges of the predicted spherical equivalent

Group comparisons: Student's *t* test (two-tailed) for differences in mean absolute errors and χ^2 statistic was used to assess the proportional variation of patients achieving a mean absolute error within various dioptric ranges

Other analyses: to test the validity of the post-operative refraction, Student's *t* test (two-tailed) was used to compare the post-operative spherical equivalent refraction in eyes refracted by subjective refraction vs. autorefractor.

Full citation	**Raymond S, Favilla I, Santamaria L. Comparing ultrasound biometry with partial coherence interferometry for intraocular lens power calculations: a randomized study. Invest Ophthalmol Vis Sci 2009 50:2457-52**
	Missing data handling/loss to follow up 205 people were randomly selected to participate from the initial pool of 410 people attending the preadmission clinic. PCI AL measurements were not obtained from 36/205 people and were not randomised to PCI or US-IOL groups. No loss to follow up was reported.
Results	**Mean absolute errors**

	Ultrasound biometry (contact), n=85	**Optical biometry (PCI), n=84**
Mean numerical error*	0.12 ±0.61 [95% CI: -0.01 to 0.25]	-0.10 ±0.63 [95% CI: -0.24 to 0.03]
Mean absolute error*	0.45 ±0.42 [95% CI: 0.36 to 0.54]	0.40 ± 0.37 [95% CI: 0.32 to 0.48]
*Data in means ± standard deviations. Standard deviations calculated from reported 95% CI in parentheses (assumed units are in dioptres)		

Number (proportion) of eyes achieving post-operative refraction within various ranges of the predicted spherical equivalent

Mean absolute errors (dioptres, D)	**Ultrasound biometry (contact, 85 eyes)***	**Optical biometry (PCI, 84 eyes)***
<0.5	59 (69.4%)	58 (69%)
<1.0	76 (89.4%)	77 (91.7%)
<1.5	81 (95.3%)	82 (97.6%)
<2.0	85 (100%)	84 (100%)
Numbers calculated from reported percentages in parentheses		

Comments	**Overall risk of bias:** This study has a low risk of bias, despite limited information on allocation sequence generation. **Other information:** Not relevant **Was the allocation sequence adequately generated?** Unclear although centrally controlled **Was allocation adequately concealed?** Yes, centrally controlled and use of opaque envelopes **Was knowledge of the allocated intervention adequately prevented during the study?** Yes **Were incomplete outcome data adequately addressed?** Yes **Are reports of the study free of suggestion of selective outcome reporting?** Unclear **Was the study apparently free of other problems that could put it at a high risk of bias?** Yes

4E33.1.2 Keratometry (manual and automated) and topography to measure corneal curvature

44 Randomised controlled trials

Full citation	**Antcliff RJ, Bell J, Flanagan DW. Comparison of the accuracy of computerized videokeratography and keratometry for use in the SRK II formula for lens calculations. Eur J Implant Ref Surg 1995 7:288-90**
Study details	**Country/ies where the study was carried out:** UK **Study type:** Randomised controlled trial

<table>
<tr><td>Full citation</td><td>Antcliff RJ, Bell J, Flanagan DW. Comparison of the accuracy of computerized videokeratography and keratometry for use in the SRK II formula for lens calculations. Eur J Implant Ref Surg 1995 7:288-90</td></tr>
<tr><td></td><td>Aim of the study: To compare the accuracy of intraocular lens (IOL) power calculations using standard keratometry and computerised videokeratography in people undergoing uncomplicated routine phacoemulsification cataract surgery
Study dates: Not reported
Source of funding: Not reported</td></tr>
<tr><td>Participants</td><td>Sample size
46 people (1 eye per person)

Diagnostic criteria
Not reported

Inclusion criteria
• People undergoing routine phacoemulsification cataract surgery

Exclusion criteria
• Unable to undergo standard keratometry or computerised videokeratography
• Fundal lesions sufficient to reduce post-operative acuity and reduce the accuracy of refraction

Baseline characteristics
<table>
<tr><th></th><th>Keratometry, n=23</th><th>Corneal topography (ECAS), n=23</th><th>Overall, n=46</th></tr>
<tr><td>Mean age (range) in years*</td><td>74</td><td>73.6</td><td>74 (32 to 92)</td></tr>
<tr><td>Male/Female*</td><td>5/18</td><td>7/16</td><td>12/34</td></tr>
<tr><td colspan="4">*Between group differences, p>0.05</td></tr>
</table></td></tr>
<tr><td>Methods</td><td>Interventions
Keratometry: Standard keratometry, n=23
• Not reported.

Corneal topography: Computerised videokeratography, n=23
• Eyesys Corneal Analysis System (ECAS).
• 3mm zone keratometric equivalent readings obtained from ECAS.

Measurements and formula
• Biometry measurements: A-scan biometry was carried out.
• IOL formula: SRK II formula was used to calculate the IOL power.
• IOL constant optimisation: not reported.</td></tr>
</table>

<table>
<tr><td>Full citation</td><td>Antcliff RJ, Bell J, Flanagan DW. Comparison of the accuracy of computerized videokeratography and keratometry for use in the SRK II formula for lens calculations. Eur J Implant Ref Surg 1995 7:288-90</td></tr>
<tr><td></td><td>
• Details of assessment/assessor: not reported.

Cataract surgery and IOL implantation: 2 surgeons performed uncomplicated phacoemulsification cataract operations through a 5mm sutureless frown incision and 3-step scleral tunnel, with implantation of the same type of 5mm posterior chamber lens (Pharmacia 809P) in the capsular bag.

Randomisation, allocation, blinding
Randomisation/allocation: details not reported. Stated “patients were randomized” only.
Blinding: stated that patients were refracted 3 months post-operatively “on a masked basis by the first author”.

Details
Sample size calculation: not reported
Post-operative assessment: post-operative refraction carried out 3 months after surgery.
Study outcomes:
• Mean prediction error or deviation from predicted refraction i.e. difference between planned refraction and actual refraction was determined using the calculated spherical equivalent
• Absolute mean prediction error
• Number of eyes within a deviation from predicted (assumed) absolute refraction of 0.5 dioptres
Group comparisons: t-test (mean errors), Wilcoxon 2-sample test (mean absolute errors)

Missing data handling/loss to follow up
Not reported.
</td></tr>
<tr><td>Results</td><td>
Prediction errors and absolute prediction errors
<table>
<tr><th></th><th>Keratometry, n=23</th><th>Corneal topography (ECAS), n=23</th></tr>
<tr><td>Prediction error*</td><td>0.13 ± 1.03</td><td>-0.19 ± 0.81</td></tr>
<tr><td>Absolute prediction error*</td><td>0.80 ± 0.65</td><td>0.55 ± 0.62</td></tr>
<tr><td colspan="3">*Data in means ± standard deviations dioptres
Between group differences: p>0.1 (mean prediction error) and p>0.05 (absolute mean prediction error)</td></tr>
</table>
Number (proportion) of eyes within a deviation from predicted (assumed) absolute refraction of 0.5 dioptres
<table>
<tr><th>Range of prediction error (dioptres, D)</th><th>Keratometry, n=23</th><th>Corneal topography (ECAS), n=23</th></tr>
<tr><td><0.5*</td><td>8 (34.8%)</td><td>16 (69.6%)</td></tr>
<tr><td>>0.5</td><td>15 (65.2%)</td><td>7 (30.4%)</td></tr>
<tr><td colspan="3">*Between group differences: p<0.05</td></tr>
</table>
</td></tr>
<tr><td>Comments</td><td>Overall risk of bias: This study has a high risk of bias, due to the lack of reporting of specific methods such as randomisation, blinding, missing data and measurement procedures for biometry and keratometry.</td></tr>
</table>

Full citation	**Antcliff RJ, Bell J, Flanagan DW. Comparison of the accuracy of computerized videokeratography and keratometry for use in the SRK II formula for lens calculations. Eur J Implant Ref Surg 1995 7:288-90**
	Other information: Not relevant **Was the allocation sequence adequately generated?** Unclear **Was allocation adequately concealed?** Unclear **Was knowledge of the allocated intervention adequately prevented during the study?** Unclear **Were incomplete outcome data adequately addressed?** Unclear **Are reports of the study free of suggestion of selective outcome reporting?** Unclear **Was the study apparently free of other problems that could put it at a high risk of bias?** No

45 **Observational studies in people undergoing phacoemulsification cataract surgery with a history of corneal refractive surgery**

Full citation	**Canto AP, Chhadva P, Cabot F, et al. Comparison of IOL power calculation methods and intraoperative wavefront aberrometer in eyes after refractive surgery. J Refract Surg 2013 7:484-9**
Study details	**Country/ies where the study was carried out:** USA **Study type:** Retrospective case series **Aim of the study:** To compare different methods of intraocular lens (IOL) power determination using keratometry and topography in eyes with a history of corneal refractive surgery undergoing phacoemulsification and to compare the results with those of the intraoperative wavefront aberrometer (Orange) method **Study dates:** June 2011 to March 2012 **Source of funding:** unrestricted grant from the Research to Prevent Blindness
Participants	**Sample size** 33 people (46 eyes) **Diagnostic criteria** Not reported **Inclusion criteria** • People with a history of laser-assisted in situ keratomileusis (LASIK), photorefractive keratectomy (PRK) and radial keratotomy (RK) who had phacoemulsification cataract surgery with posterior chamber lens implantation **Exclusion criteria** • No post-operative data • Unreliable post-operative refractions because of macular pathology

Full citation	**Canto AP, Chhadva P, Cabot F, et al. Comparison of IOL power calculation methods and intraoperative wavefront aberrometer in eyes after refractive surgery. J Refract Surg 2013 7:484-9**
	• Keratometry value below 30 dioptres that could not be entered in the intraoperative aberrometer **Baseline characteristics** • Mean age (SD, range): 60 (7.9, 34 to 72) years • Male/female: 22 (66.7%) / 11 (33.3%) • Right/left eye: 21 (45.6%) / 25 (54.4%) • Myopic PRK / myopic LASIK / hyperopic LASIK / RK: 7 / 26 / 6 / 10 [3 people had RK and another refractive procedure]
Methods	**Interventions** Keratometry: IOLMaster, n=33 (46 eyes, assumed) • IOLMaster (Carl Zeiss Meditec, Dublin CA). Corneal topography: TMS or Pentacam, n=33 (46 eyes, assumed) • Topography Modelling System (Tomey Inc, Phoenix Inc) or Pentacam (Oculus Optikgerate GmbH, Germany). • Average 3mm central keratometry values used in IOL formula. **Measurements and formula** • Biometry measurements (axial length and anterior chamber depth): IOLMaster. • IOL formula: SRK-T formula was used to calculate the IOL power for keratometry and corneal topography groups. Additionally, the American Society of Cataract and Refractive Surgery (ASCRS) online calculations (www.iolcalc.org) were used to calculate the IOL power for the keratometry group, taking the average IOL power value. For myopic treatments, the calculator used information from two formulas (Shammas method and Haigis-L). For hyperopic treatments, only the Haigis-L formula was used. For RK treatments, the Double K-Holladay 1 formula was used. Information on measurements before and after refractive surgery was not entered. • IOL constant optimisation: not reported. **Cataract surgery and IOL implantation:** 8 surgeons performed phacoemulsification cataract surgery with posterior chamber lens implantation. Four lens models were used: 29 Alcon SN60WF, 11 Advanced Medical Optics ZA9003, 4 Alcon SN6AT and 2 Bausch and Lomb Crystalens AT52AO. No intraoperative complications were recorded. **Details** Post-operative assessment: Post-operative cataract surgery spherical equivalent refraction and type and power of the implanted IOL were obtained from clinical records. Desired post-operative spherical equivalent target of emmetropia. Study outcomes: • Mean prediction error (difference between predicted and actual power for emmetropia) • Absolute mean prediction error (absolute difference between predicted and actual power for emmetropia)

Full citation	**Canto AP, Chhadva P, Cabot F, et al. Comparison of IOL power calculation methods and intraoperative wavefront aberrometer in eyes after refractive surgery. J Refract Surg 2013 7:484-9**
	Group comparisons: repeated measures analysis of variance (ANOVA) and post-hoc pairwise least significant difference tests
Results	**Prediction errors and absolute prediction errors**

	Keratometry (ASCRS estimation using variable formulas), n=33 (46 eyes, assumed)	**Keratometry (SRK-T formula), n=33 (46 eyes, assumed)**	**Corneal topography (SRK-T formula), n=33 (46 eyes, assumed)**
Prediction error*	-0.33 ± 1.65	1.27 ± 1.55	0.84 ± 2.14
Absolute prediction error*	1.23 ± 1.13	1.52 ± 1.29	1.69 ± 1.56
*Data in means ± standard deviations dioptres			

Comments	**Overall risk of bias:** This small retrospective case series has a high risk of bias, due to the lack of reporting of specific methods such as details of measurement procedures including experience of assessors, methods of assessing post-operative refraction and how IOL power was selected at surgery. Biometry measurements were standardised using the IOLMaster. **Other information:** Not relevant

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Full citation	**Kim EC, Cho K, Hwang HS, et al. Intraocular lens prediction accuracy after corneal refractive surgery using K values from 3 devices. J Cataract Refract Surg 2013 39:1640-6**
Study details	**Country/ies where the study was carried out:** South Korea **Study type:** Retrospective case series **Aim of the study:** To compare methods of intraocular lens (IOL) power calculation using different values of keratometry and topography in people with a history of myopic refractive surgery undergoing phacoemulsification **Study dates:** 2008 to 2010 **Source of funding:** not reported
Participants	**Sample size** 47 people (47 eyes) **Diagnostic criteria** Not reported **Inclusion criteria** • People with a history of laser-assisted in situ keratomileusis (LASIK) or photorefractive keratectomy (PRK) for myopia and subsequent phacoemulsification cataract surgery • People that were examined with all methods (Orbscan II, Pentacam and IOLMaster) **Exclusion criteria**

Full citation	**Kim EC, Cho K, Hwang HS, et al. Intraocular lens prediction accuracy after corneal refractive surgery using K values from 3 devices. J Cataract Refract Surg 2013 39:1640-6**
	• No manifest refraction after cataract surgery • Missing biometry data such as axial length or keratometry **Baseline characteristics** • Mean age (SD, range): 52.4 (9.5, 41 to 65) years • Male/female: 22 (46.8%) / 25 (53.2%) • Mean duration from refractive surgery to cataract surgery (SD, range): 8.67 (5.45, 1 to 16) years • Mean spherical equivalent before cataract surgery (SD, range): -5.37 (2.58, -9.25 to -1.75) dioptres • Mean corrected distance visual acuity: 20/100 • Mean axial length (SD): 27.75 (2.19) mm
Methods	**Interventions, measurement and formula** Keratometry: Partial coherence interferometry (PCI), n=47 (assumed) • IOLMaster version 5.0. • Keratometry (K; corneal radii) measurements using IOLMaster. • Biometry measurements (axial length and anterior chamber depth): immersion ultrasound. • IOL formula: SRK/T formula using the PCI system's K value was used to calculate IOL power. In addition, the Haigis-L formula was calculated online using study access provided by Haigis. The data for the Haigis-L formula were not extracted because confounding from the different formulas used in the keratometry and topography groups would obscure the findings. • IOL constant optimisation: not reported. Corneal topography A: Pentacam Scheimpflug, n=47 (assumed) • Pentacam version 1.17r24. • Keratometric measurements for cataract surgery were performed 3 times and a central value on the Scheimpflug system's true net corneal power (TNP) map was selected after the centration and alignment of the cornea were confirmed. The exact central value in the TNP map and equivalent K of the Scheimpflug system were selected as the K value and used in the IOL power calculations. The TNP data were preferentially compared with the keratometry data. • Biometry measurements (axial length): partial coherence interferometry. • IOL formula: SRK/T formula. • IOL constant optimisation: not reported. Corneal topography B: Orbscan II, n=47 (assumed) • Orbscan II version 3.12.

Full citation	**Kim EC, Cho K, Hwang HS, et al. Intraocular lens prediction accuracy after corneal refractive surgery using K values from 3 devices. J Cataract Refract Surg 2013 39:1640-6**

- This study reports the analysis of the achieved refraction and its deviation from the calculated value using the corneal power measured with the Orbscan II after previous corneal refractive surgery. Corneal power was assessed using: simulated K, 2.0mm diameter central zone of the total mean power (TMP 2.0mm) map and 4.0mm diameter central zone of total optical power (TOP 4.0) maps centred on the pupil.
- Biometry measurements (axial length): partial coherence interferometry.
- IOL formula: SRK/T formula.
- IOL constant optimisation: not reported.

Cataract surgery and IOL implantation: 1 experienced surgeon performed uneventful standard phacoemulsification cataract surgery with IOL implantation (Acrysoft SN60AT, Alcon Laboratories Inc) in the capsular bag in all patients.

Details

Post-operative assessment: The target refraction was plano in 37 eyes and -3.00 dioptres in 10 eyes. The manifest refraction was measured 2 months after surgery. Data were collected from primary sources in patient charts.

Study outcomes:

- Mean prediction error (difference between post-operative refraction and expected refraction)
- Absolute median prediction error
- Number of eyes achieving absolute prediction errors within various ranges

Group comparisons: one-way analysis of variance (ANOVA) between prediction errors according to each K value and corneal radius and paired t-tests between estimated refraction and post-operative refraction

Results

Prediction errors and absolute prediction errors

	Keratometry (Haigis-L formula), n=47	Keratometry (SRK-T formula), n=47	Corneal topography A (Scheimpflug and SRK-T formula)), n=47		Corneal topography A (Orbscan II and SRK-T formula), n=47		
			True net corneal power	Equivalent K	Simulated K	2.0mm diameter central zone of the total mean power	4.0mm diameter central zone of total optical power
Prediction error*	0.03 ± 1.06 (-1.8 to 1.315)	1.68 ± 1.34 (-0.665 to 4.265)	0.34 ± 1.75 (-1.735 to 3.905)	1.69 ± 1.41 (-1.075 to 5.055)	-0.95 ± 1.61 (-4.01 to 3.28)	0.16 ± 1.90 (-5.065 to 4.515)	0.37 ± 2.18 (-5.135 to 4.715)
Median absolute prediction error^	0.81 ± 0.52 (0.085 to 1.815)	1.73 ± 1.20 (0.02 to 4.265)	1.13 ± 0.95 (0.26 to 3.815)	1.81 ± 1.34 (0.07 to 5.055)	1.25 ± 1.07 (0.005 to 4.01)	0.94 ± 1.09 (0.38 to 4.515)	1.23 ± 1.22 (0.25 to 5.29)
*Data in means ± standard deviations (range) dioptres							

Full citation	**Kim EC, Cho K, Hwang HS, et al. Intraocular lens prediction accuracy after corneal refractive surgery using K values from 3 devices. J Cataract Refract Surg 2013 39:1640-6**

^Data in median absolute error ± SD of mean error (range) dioptres

Mean IOL power implanted (SD, range): 17.63 (4.20, 4.0 to 23.5) dioptres

Number (proportion) of eyes achieving absolute prediction errors within various ranges

	Keratometry (Haigis-L formula), n=47	Keratometry (SRK-T formula), n=47	Corneal topography A (Scheimpflug and SRK-T formula), n=47		Corneal topography A (Orbscan II and(SRK-T formula), n=47		
			True net corneal power	Equivalent K	Simulated K	2.0mm diameter central zone of the total mean power	4.0mm diameter central zone of total optical power
Within ±0.5 dioptres	30 (64.5%)	5 (11.1%)	15 (31.3%)	10 (22.2%)	6 (13.6%)	17 (36.1%)	9 (19.5%)
Within ±1.0 dioptres	38 (80.6%)	16 (33.3%)	24 (51.7%)	18 (37.5%)	17 (36.4%)	27 (58.3%)	21 (45.2%)
Within ±1.5 dioptres	43 (92.3%)	30 (63%)	32 (68.8%)	23 (48.1%)	21 (45.5%)	33 (69.4%)	27 (58.1%)
Within ±2.0 dioptres	47 (100%)	31 (66.7%)	41 (87.5%)	31 (66.7%)	36 (77.3%)	39 (83.3%)	38 (80.6%)

Numbers calculated from reported percentages in parentheses, assumed n=47 in each group

Comments	**Overall risk of bias:** This small retrospective case series has a high risk of bias, due to the use of unstandardized biometry measurements between keratometry and Pentacam topography groups, unclear IOL constant optimisation, lack of details on how the IOL power was selected at surgery and methods for assessing post-operative refraction. **Other information:** Not relevant

4E.3.2 Intraocular lens formulas

4E3.2.1 Virgin eyes without a history of corneal refractive surgery

Full citation	**Aristodemou P, Cartwright NEK, Sparrow JM, et al. Formula choice: Hoffer Q, Holladay 1, or SRK/T and refractive outcomes in 8108 eyes after cataract surgery with biometry by partial coherence interferometry. J Cataract Refract Surg 2011; 37:63-71**
Study details	**Country/ies where the study was carried out:** England **Study type:** Retrospective database study **Aim of the study:** To assess how intraocular lens (IOL) formula choice affects refractive outcomes after cataract surgery using IOLMaster biometry **Study dates:** November 2005 to September 2009 **Source of funding:** None reported, but co-author RL Johnston declared as medical director of Medisoft Ltd which supplies the hospital trust included in this study with the Electronic Patient Record for Ophthalmology that was used to collect the data

Full citation	**Aristodemou P, Cartwright NEK, Sparrow JM, et al. Formula choice: Hoffer Q, Holladay 1, or SRK/T and refractive outcomes in 8108 eyes after cataract surgery with biometry by partial coherence interferometry. J Cataract Refract Surg 2011; 37:63-71**
Participants	**Sample size** 8108 eyes **Diagnostic criteria** Not reported **Inclusion criteria** • People undergoing uneventful phacoemulsification cataract surgery with in-the-bag IOL placement at 1 hospital trust • Pre-operative biometry and keratometry undertaken using the IOLMaster • Post-operative subjective refraction • Post-operative corrected distance visual acuity (CDVA) of 6/12 or better **Exclusion criteria** • Corneal astigmatism of more than 3.0 dioptres (D) • Concurrent additional surgical procedures e.g. trabeculectomy, vitrectomy, limbal relaxing incisions **Baseline characteristics** (not reported in this paper. Data below extracted from accompanying publication included in review question 7 on IOL constant optimisation "Aristodemou P, Cartwright NEK, Sparrow JM, et al. Intraocular lens formula constant optimization and partial coherence interferometry biometry: refractive outcomes in 8108 eyes after cataract surgery. J Cataract Refract Surg 2011; 37:50-62")
Methods	**<u>Interventions and comparators</u>: IOL formulas** • Hoffer Q • SRK/T • Holladay 1 NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee **Biometry and keratometry measurements** • <u>Biometry (axial length, AL) and keratometry</u>: IOLMaster • <u>Formula</u>: Using the K values, AL and selected IOL model and power, the predicted post-operative refractive outcome for each eye and every formula was calculated using the appropriate optimised formula constant • <u>IOL constants</u>: optimised using method similar to that of Jabbour 2006 (J Cataract Refract Surg 32:2091-7). Bausch & Lomb L161AO Sofport Advanced Optics and Bausch & Lomb Akreos Fit have a manufacturer's A constant of 118.0. **Cataract surgery and IOL implantation:** 66 surgeons performed phacoemulsification cataract surgery with in-the-bag implantation using Bausch & Lomb L161AO Sofport Advanced Optics (3-piece IOL with an aspheric silicone optic, 2 polymethylmethacrylate haptics) or Bausch & Lomb Akreos Fit (1-piece hydrophilic IOL).

IOL model	L161AO Sofport Advanced Optics IOL (6159 eyes)	Akreos Fit IOL (1949 eyes)
Age (years)*	76.15 ± 9.29	76.30 ± 8.90
Axial length (mm)*	23.51 ± 1.26	23.41 ± 1.17
Keratometry (dioptres)*	43.83 ± 1.52	43.87 ± 1.48
*Data in means ± standard deviations		

Full citation	**Aristodemou P, Cartwright NEK, Sparrow JM, et al. Formula choice: Hoffer Q, Holladay 1, or SRK/T and refractive outcomes in 8108 eyes after cataract surgery with biometry by partial coherence interferometry. J Cataract Refract Surg 2011; 37:63-71**

Details

Post-operative assessment: subjective post-operative refraction assessed at least 4 weeks after surgery in hospital or via a proforma letter from the community optometrist at the individual's post-operative clinic visit 6 weeks after surgery.

Study outcomes:

- Prediction error and mean absolute error in deviation from the predicted post-operative refraction (difference between actual post-operative spherical equivalent of the subjective refraction and the predicted post-operative refractive outcome)
- Proportion of eyes within various ranges of the predicted post-operative refractive outcome

Group comparisons: two-way analysis of variance (ANOVA)

Axial length subgroups: refractive outcomes were compared between eyes grouped in 0.5mm and 1.0mm intervals of AL, depending on the number of eyes available for analysis

Missing data handling/loss to follow up

No missing data reported.

Results

Mean errors and mean absolute errors

Study did not report measures of dispersion to accompany mean errors and mean absolute errors, and therefore these data have not been extracted. Commentary of the statistical analysis provided in the results section relevant to the statistically significant findings is extracted below. NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

IOL	Axial length subgroup	Number of eyes	Statistically significant findings
L161AO Sofport Advanced Optics	20.00 and 21.49	134	Hoffer Q performed best with AL<21.49mm
	22.00 to 22.49mm	663	SRK/T had the lowest mean absolute error
	27.00 to 28.99mm	29	SRK/T performed best
	30.00+mm	9	SRK/T performed best

Number of eyes (proportion) within various ranges of the target refraction

Axial length group (mm)	Number of eyes (proportion) within ±0.25D of the target refraction*					
	L161AO Sofport Advanced Optics IOL (6159 eyes)			Akreos Fit IOL (1949 eyes)		
	Number of eyes	Hoffer Q	SRK/T	Number of eyes	Hoffer Q	SRK/T
20.00-20.99	42	22	8	18	1	1
21.00-21.49	92	36	24	27	9	9
21.50-21.99	323	110	113	106	34	40
22.00-22.49	663	245	265	223	80	87
22.50-22.99	1091	447	458	361	134	141
23.00-23.49	1232	505	542	381	160	145
23.50-23.99	1046	429	439	329	145	135
24.00-24.49	667	273	280	214	90	92
24.50-24.99	364	149	149	123	57	58
25.00-25.49	208	77	73	65	30	28
25.50-25.99	140	49	50	46	18	19
26.00-26.49	99	42	37	26	9	10

Full citation	Aristodemou P, Cartwright NEK, Sparrow JM, et al. Formula choice: Hoffer Q, Holladay 1, or SRK/T and refractive outcomes in 8108 eyes after cataract surgery with biometry by partial coherence interferometry. J Cataract Refract Surg 2011; 37:63-71						
	26.50-26.99	72	23	27	9	7	5
	27.00-27.99	71	25	36	10	2	6
	28.00-28.99	29	7	11	2	Not reported	Not reported
	29.00-29.99	8	2	3	3	Not reported	Not reported
	30.00+	9	0	2	2	Not reported	Not reported
	Axial length group (mm)	**Number of eyes (proportion) within ±0.50D of the target refraction***					
		L161AO Sofport Advanced Optics IOL (6159 eyes)			**Akreos Fit IOL (1949 eyes)**		
		Number of eyes	**Hoffer Q**	**SRK/T**	**Number of eyes**	**Hoffer Q**	**SRK/T**
	20.00-20.99	42	30	15	18	6	4
	21.00-21.49	92	60	54	27	15	15
	21.50-21.99	323	203	207	106	64	72
	22.00-22.49	663	431	464	223	134	149
	22.50-22.99	1091	742	753	361	238	249
	23.00-23.49	1232	862	899	381	263	267
	23.50-23.99	1046	764	764	329	240	240
	24.00-24.49	667	467	474	214	158	156
	24.50-24.99	364	240	248	123	96	91
	25.00-25.49	208	144	141	65	51	49
	25.50-25.99	140	90	92	46	26	30
	26.00-26.49	99	65	70	26	19	20
	26.50-26.99	72	47	51	9	8	8
	27.00-27.99	71	40	53	10	6	9
	28.00-28.99	29	15	22	2	Not reported	Not reported
	29.00-29.99	8	2	5	3	Not reported	Not reported
	30.00+	9	1	5	2	Not reported	Not reported
	Axial length group (mm)	**Number of eyes (proportion) within ±1.00D of the target refraction***					
		L161AO Sofport Advanced Optics IOL (6159 eyes)			**Akreos Fit IOL (1949 eyes)**		
		Number of eyes	**Hoffer Q**	**SRK/T**	**Number of eyes**	**Hoffer Q**	**SRK/T**
	20.00-20.99	42	36	30	18	13	12
	21.00-21.49	92	81	78	27	23	22
	21.50-21.99	323	291	291	106	95	96
	22.00-22.49	663	630	636	223	203	203
	22.50-22.99	1091	1015	1015	361	329	336
	23.00-23.49	1232	1170	1158	381	354	347
	23.50-23.99	1046	983	994	329	309	309
	24.00-24.49	667	634	627	214	205	203
	24.50-24.99	364	342	346	123	121	118

Full citation	Aristodemou P, Cartwright NEK, Sparrow JM, et al. Formula choice: Hoffer Q, Holladay 1, or SRK/T and refractive outcomes in 8108 eyes after cataract surgery with biometry by partial coherence interferometry. J Cataract Refract Surg 2011; 37:63-71

25.00-25.49	208	196	196	65	63	59
25.50-25.99	140	134	132	46	40	38
26.00-26.49	99	89	92	26	25	25
26.50-26.99	72	63	67	9	9	9
27.00-27.99	71	62	66	10	9	10
28.00-28.99	29	25	28	2	Not reported	Not reported
29.00-29.99	8	7	7	3	Not reported	Not reported
30.00+	9	5	7	2	Not reported	Not reported

*Number of eyes (proportion); calculated from reported percentages
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

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Full citation	Bang S, Edell E, Yu Q, et al. Accuracy of intraocular lens calculation using the IOLMaster in eyes with long axial length and a comparison of various formulas. Ophthalmology 2011; 118:503-6
Study details	**Country/ies where the study was carried out:** USA **Study type:** Retrospective case series **Aim of the study:** To evaluate the relationship between eyes with long axial length and post-operative refractive errors as predicted by various commonly used intraocular lens (IOL) formulas using the Zeiss IOLMaster **Study dates:** January 2004 to March 2009 **Source of funding:** None reported
Participants	**Sample size** 53 eyes in 36 people **Diagnostic criteria** Not reported **Inclusion criteria** • People with axial length greater than 27.0mm measured by the IOLMaster with a sound noise ratio of more than 2.1 undergoing uneventful phacoemulsification cataract surgery with IOL implantation • Post-operative best corrected visual acuity more than 20/40 **Exclusion criteria** • Incomplete pre-operative or post-operative data • History of amblyopia • Severe macular damage **Baseline characteristics**

IOL models	Alcon MA60MA (22 eyes), MA50BM (28 eyes), SA60AT (3 eyes) in 36 people
Age (years)*	69.76 (34 to 84)
Axial length (mm)*	30.3

Full citation	**Bang S, Edell E, Yu Q, et al. Accuracy of intraocular lens calculation using the IOLMaster in eyes with long axial length and a comparison of various formulas. Ophthalmology 2011; 118:503-6**

Right:left eyes	24:29
Posterior staphyloma^	10 (19%)
Previous retinal detachment^	7 (13%)
*Data in means ± standard deviations (ranges) as appropriate ^Number of eyes (proportion); calculated from reported percentages	

Methods

Interventions and comparators: IOL formulas

- Haigis
- Hoffer Q
- Holladay 2
- SRK/T
- Holladay 1 NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Biometry and keratometry measurements

- Biometry and keratometry: IOLMaster with a sound noise ratio of more than 2.1
- Formula: not reported.
- IOL constant: not reported.

Cataract surgery and IOL implantation: 6 surgeons performed uneventful phacoemulsification cataract surgery with IOL implantation of the Alcon MA60MA, MA50BM or SA60AT.

Details

Post-operative assessment: post-operative refraction assessed at a mean of 44 days after surgery

Study outcomes:

- Mean absolute errors (actual post-operative spherical equivalent minus predicted post-operative spherical equivalent)
- Proportion of eyes within various ranges of the predicted post-operative spherical equivalent

Group comparisons: (repeated) analysis of variance (ANOVA)

Axial length subgroups: refractive outcomes were reported in 3 categories: 27 to <29.07mm, 29.07 to 30.62mm, >30.62mm

Missing data handling/loss to follow up

No missing data reported.

Results

Mean absolute errors

		Alcon MA60MA (22 eyes), MA50BM (28 eyes), SA60AT (3 eyes) in 36 people			
		Mean absolute errors in dioptres*			
Axial length group (mm)	**Number of eyes**	**Haigis**	**Hoffer Q**	**Holladay 2**	**SRK/T**
27 to <29.07	18	0.26 ± 0.55	0.58 ± 0.66	0.41 ± 0.66	0.16 ± 0.48
29.07-30.62	18	0.36 ± 0.57	0.76 ± 0.82	0.58 ± 0.77	0.42 ± 0.64
>30.62	17	0.95 ± 0.56	1.72 ± 0.73	1.44 ± 0.63	1.28 ± 0.69
All eyes	53	0.52 ± 0.63	1.02 ± 0.88	0.81 ± 0.81	0.62 ± 0.77
*Data in mean ± standard deviation					

Full citation	**Bang S, Edell E, Yu Q, et al. Accuracy of intraocular lens calculation using the IOLMaster in eyes with long axial length and a comparison of various formulas. Ophthalmology 2011; 118:503-6**
	NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Number of eyes within various ranges of the predicted post-operative spherical equivalent

	Alcon MA60MA (22 eyes), MA50BM (28 eyes), SA60AT (3 eyes) in 36 people			
	Number of eyes within various ranges of the predicted post-operative spherical equivalent*			
Within	**Haigis**	**Hoffer Q**	**Holladay 2**	**SRK/T**
<0.5D	30	18	22	27
<1.0D	39	32	33	35
<2.0D	52	42	50	51
<3.0D	53	53	53	53

*Number of eyes (proportion); calculated from reported percentages
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

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Full citation	**Carifi G, Aiello F, Zygoura V, et al. Accuracy of the refractive prediction determined by multiple current available intraocular lens power calculation formulas in small eyes. Am J Ophthalmol 2015; 159:577-83**
Study details	**Country/ies where the study was carried out:** England **Study type:** Retrospective case series **Aim of the study:** To observe the refractive outcomes of cataract surgery in small adult eyes and to investigate the accuracy of different intraocular lens (IOL) power prediction formulas **Study dates:** Not reported **Source of funding:** None reported
Participants	**Sample size** 28 eyes in 28 people **Diagnostic criteria** Not reported **Inclusion criteria** • People with axial length less than 20.9mm undergoing uneventful phacoemulsification cataract surgery with in-the-bag IOL implantation of Acrysof SA60AT at 1 institution **Exclusion criteria** • Combined surgical procedures • Previous intraocular surgery (including corneal refractive surgery) • Intraoperative complications • Any corneal pathology • IOL power lower than 35 dioptres • Lack of accurate optical biometric data • Marked lens opacities

<table>
<tr><td>Full citation</td><td>Carifi G, Aiello F, Zygoura V, et al. Accuracy of the refractive prediction determined by multiple current available intraocular lens power calculation formulas in small eyes. Am J Ophthalmol 2015; 159:577-83</td></tr>
<tr><td></td><td>• Poor fixation requiring ultrasound biometry
• Post-operative corrected distance visual acuity worse than 20/40 (logMAR 0.3)
• Subjective refraction taken less than 4 weeks after surgery
• Incomplete datasets

Baseline characteristics
<table>
<tr><th>IOL model</th><th>Acrysof SA60AT (28 eyes)</th></tr>
<tr><td>Age (years)</td><td>72 ± 10 (71, 55 to 92)</td></tr>
<tr><td>Male:female^</td><td>11:17</td></tr>
<tr><td>Axial length (mm)*</td><td>19.86 ± 0.55 (19.94, 18.41 to 20.64)</td></tr>
<tr><td>Mean corneal power (dioptres)*</td><td>43.76 ± 2.07 (43.84, 38.70 to 48.22)</td></tr>
<tr><td>Anterior chamber depth (mm)*</td><td>2.56 ± 0.42 (2.51, 1.93 to 3.25)</td></tr>
<tr><td colspan="2">*Data in means ± standard deviations (medians, ranges)
^Number of eyes</td></tr>
</table></td></tr>
<tr><td>Methods</td><td><u>Interventions and comparators</u>: IOL formulas
• Haigis
• Hoffer Q
• Holladay 2
• SRK/T
• Holladay 1
• SRK II NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Biometry and keratometry measurements
• <u>Biometry (axial length, AL) and keratometry</u>: performed using the IOLMaster (Carl Zeiss, Germany). Only the signal-to-noise ratio values above 2.0 were accepted as accurate
• <u>Formula</u>: The IOLMaster was used to calculate the required IOL power with the Hoffer Q formula (specifically recommended for short eyes). The IOLMaster software and the Holladay IOL Consultant software were used to back-calculate the mean numerical errors, median and mean absolute errors for each of the tested formulas. Biometry data were obtained from IOLMaster; lens thickness measurement was obtained using the A-scan ultrasonography with the Accutome A-scan Plus (values accepted if at least 3 readings were available with a deviation inferior to 0.10mm)
• <u>IOL constant</u>: The recommended lens constant for optical biometry was used as suggested by the ULIB website.

Cataract surgery and IOL implantation: various surgeons (consultant or fellow grade undertook 27 of the 28 procedures) performed uneventful sutureless phacoemulsification cataract surgery with either a 3.2mm or 2.75mm clear corneal incision and endocapsular-fixated IOL implantation of Acrysof SA60AT. Standard pseudophakic endophthalmitis prophylaxis was employed in all cases.

Details
<u>Post-operative assessment</u>: Post-operative refraction was assessed at least 4 weeks after surgery
<u>Study outcomes</u>:
• Mean prediction errors</td></tr>
</table>

Full citation	**Carifi G, Aiello F, Zygoura V, et al. Accuracy of the refractive prediction determined by multiple current available intraocular lens power calculation formulas in small eyes. Am J Ophthalmol 2015; 159:577-83**
	• Median and mean absolute errors (absolute values of the difference between the actual and predicted post-operative spherical equivalent) • Proportion of eyes achieving absolute errors within various ranges of target refraction Group comparisons: one-way analysis of variance (ANOVA) **Missing data handling/loss to follow up** No missing data reported.
Results	**Mean prediction errors**

Mean errors in dioptres*			
Acrysof SA60AT (28 eyes)			
Haigis	**Hoffer Q**	**Holladay 2**	**SRK/T**
0.28 ± 1.33	-0.22 ± 1.22	0.05 ± 1.13	1.19 ± 1.21
Mean ± standard deviation NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee			

Median and mean absolute errors

Median and mean absolute errors in dioptres*			
Acrysof SA60AT (28 eyes)			
Haigis	**Hoffer Q**	**Holladay 2**	**SRK/T**
1.03 ± 0.87 (1.01)	0.95 ± 0.78 (0.76)	0.82 ± 0.77 (0.80)	1.34 ± 1.04 (1.20)
Mean ± standard deviation (median) NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee			

Proportion of eyes achieving absolute errors within various ranges of target refraction

	Acrysof SA60AT (28 eyes)			
Proportion of eyes within*	**Haigis**	**Hoffer Q**	**Holladay 2**	**SRK/T**
±0.50D	12	11	12	6
±1.00D	13	17	18	12
±2.00D	24	25	26	22
Number of eyes (proportion) NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee				

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Full citation	**Cooke DL, Cooke TL. Comparison of 9 intraocular lens power calculation formulas. J Cataract Refract Surg 2016; 42:1157-64**
Study details	**Country/ies where the study was carried out:** USA **Study type:** Retrospective case series **Aim of the study:** To evaluate the accuracy of 9 intraocular lens (IOL) formulas using 2 optical biometers **Study dates:** 15th March 2010 to 27th December 2012 **Source of funding:** None reported
Participants	**Sample size** 1079 eyes in 1079 people

Full citation	Cooke DL, Cooke TL. Comparison of 9 intraocular lens power calculation formulas. J Cataract Refract Surg 2016; 42:1157-64

Diagnostic criteria
Not reported

Inclusion criteria
- People who had small-incision (≤3.0mm wide surgical wound) phacoemulsification cataract surgery with in-the-bag IOL implantation of Acrysof SN60WF at 1 private practice
- Complete pre-operative data
- Post-operative corrected distance visual acuity (CDVA) of at least 20/25
- No additional ocular surgery, no history of contact lens wear, no intraoperative complications, no ocular or systemic disease that might have prevented obtaining good pre-operative measurements

Exclusion criteria
- Unexpected refractions
- Second eye surgery from the same person

Baseline characteristics

	Axial length ≤22.0mm (41 eyes)	Axial length ≥26.0mm (54 eyes)	Any axial length (1079 eyes)
Axial length (mm)*	21.71; 20.87 to 22.01	26.84; 25.97 to 29.44	23.81; 20.87 to 29.44
*Data in means; range			

Methods

Interventions and comparators: IOL formulas
- Haigis
- Hoffer Q
- SRK/T
- Ladas Super Formula
- Olsen standalone formula (via PhacoOptics software version 1.10.100.2020, IOL Innovations ApS)
- Olsen OLCR formula (via Lenstar biometer, EyeSuite i8.0.0.0 Haag-Streit AG)
- Holladay 2 (via Holladay IOL Consultant, version 2014.06.07, Holladay Consulting)
- Barrett Universal II formula (online)
- T2 formula (online)
- Holladay 1 NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Biometry and keratometry measurements
- Biometry and keratometry: IOLMaster version 3.02 and Lenstar LS 900 version 5.4
- IOL constants: Group-optimised constants were derived using computer software developed by the author. The software automatically entered patient measurements into PhacoOptics, Holladay IOL Consultant and EyeSuite software. Data from 10 eyes were manually entered into these software to verify the accuracy of the method. Patients' eyes measurements were entered multiple times into the programs with different lens constants. This trial-and-error approach was used until the mean prediction error for the entire dataset was as close to zero as possible. The value was considered to be the optimised lens constant for that particular formula. The Haigis lens constants were obtained using linear regression

Full citation	Cooke DL, Cooke TL. Comparison of 9 intraocular lens power calculation formulas. J Cataract Refract Surg 2016; 42:1157-64

	Lens constants				
	Anterior chamber depth			Lens Factor	A Constant
	Holladay 2 – PreSurgRef	Holladay2 – NoPreSurgRef	Olsen	Barrett Universal II	T2
PCI (1079 eyes)	5.498	5.554	4.66	1.904	119.02
OLCR (1079 eyes)	5.469	5.52	4.65	1.890	119.00

Cataract surgery and IOL implantation: 7 surgeons performed uneventful phacoemulsification cataract surgery with in-the-bag implantation of Acrysof SN60WF.

Details
Post-operative assessment: Subjective manifest refraction between 3 weeks and 3 months conducted by qualified technicians who had passed standardised in-office accuracy training.
Study outcomes:
- Prediction error and mean absolute error in deviation from the predicted post-operative refraction (difference between actual post-operative SE of the subjective refraction and the predicted post-operative SE)
- Proportion of eyes within various ranges of the predicted post-operative refractive outcome

Group comparisons: F tests
Axial length subgroups: ≤22.0mm and ≥26.0mm

Missing data handling/loss to follow up
No missing data reported.

Results

Mean absolute errors

	Mean absolute errors in dioptres*			
	Axial length ≤22.0mm (41 eyes)		Axial length ≥26.0mm (54 eyes)	
IOL formulas	PCI - IOLMaster	OLCR - Lenstar	PCI - IOLMaster	OLCR - Lenstar
Olsen_standalone	0.46±0.57	0.32±0.40	0.29±0.35	0.25±0.33
Haigis	0.41±0.51	0.39±0.46	0.28±0.37	0.26±0.35
T2	0.39±0.49	0.41±0.47	0.32±0.40	0.29±0.39
Barrett Universal II	0.39±0.48	0.34±0.42	0.30±0.38	0.27±0.36
Holladay 2 – PreSurgRef	0.43±0.47	0.43±0.45	0.41±0.43	0.39±0.40
Holladay 2 – NoPreSurgRef	0.44±0.47	0.44±0.43	0.39±0.41	0.38±0.38
SRK/T	0.40±0.51	0.41±0.49	0.40±0.45	0.39±0.44
Ladas Super Formula	0.40±0.48	0.43±0.47	0.35±0.40	0.34±0.39
Hoffer Q	0.48±0.49	0.50±0.46	0.43±0.45	0.44±0.44

*Data in means ± standard deviations
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee
NB: Mean prediction errors not data extracted as no measures of dispersion have been reported

Full citation	Cooke DL, Cooke TL. Comparison of 9 intraocular lens power calculation formulas. J Cataract Refract Surg 2016; 42:1157-64

Number of eyes (proportion) within various ranges of the target refraction

IOL formulas	Number of eyes (proportion) within ±0.50D of the target refraction*			
	Axial length ≤22.0mm (41 eyes)		Axial length ≥26.0mm (54 eyes)	
	PCI - IOLMaster	OLCR - Lenstar	PCI - IOLMaster	OLCR - Lenstar
Olsen_standalone	(61.0%)	(75.6%)	(83.3%)	(85.2%)
Haigis	(68.3%)	(65.9%)	(81.5%)	(83.3%)
T2	(73.2%)	(70.7%)	(81.5%)	(83.3%)
Barrett Universal II	(78.0%)	(78.0%)	(75.9%)	(83.3%)
Holladay 2 – PreSurgRef	(65.9%)	(70.7%)	(68.5%)	(72.2%)
Holladay 2 – NoPreSurgRef	(73.2%)	(58.5%)	(68.5%)	(74.1%)
SRK/T	(68.3%)	(68.3%)	(75.9%)	(77.8%)
Ladas Super Formula	(80.5%)	(75.6%)	(75.9%)	(72.2%)
Hoffer Q	(63.4%)	(53.7%)	(63.0%)	(61.1%)

*Proportions provided in paper
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

IOL formulas	Number of eyes (proportion) within ±1.0D of the target refraction*			
	Axial length ≤22.0mm (41 eyes)		Axial length ≥26.0mm (54 eyes)	
	PCI - IOLMaster	OLCR - Lenstar	PCI - IOLMaster	OLCR - Lenstar
Olsen_standalone	(95.1%)	(100%)	(98.1%)	(100%)
Haigis	(95.1%)	(100%)	(98.1%)	(98.1%)
T2	(95.1%)	(95.1%)	(98.1%)	(96.3%)
Barrett Universal II	(92.7%)	(95.1%)	(98.1%)	(100%)
Holladay 2 – PreSurgRef	(92.7%)	(92.7%)	(98.1%)	(98.1%)
Holladay 2 – NoPreSurgRef	(87.8%)	(90.2%)	(98.1%)	(98.1%)
SRK/T	(95.1%)	(95.1%)	(98.1%)	(94.4%)
Ladas Super Formula	(92.7%)	(92.7%)	(96.3%)	(96.3%)
Hoffer Q	(87.8%)	(90.2%)	(96.3%)	(96.3%)

*Proportions provided in paper
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

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Full citation	Day AC, Foster PJ, Stevens JD. Accuracy of intraocular lens power calculations in eyes with axial length <22.00mm. Clin Exp Ophthalmol 2012; 40:855-62
Study details	**Country/ies where the study was carried out:** England **Study type:** Retrospective case series **Aim of the study:** To theoretically analyse the accuracy of intraocular lens (IOL) calculation formulas in eyes with an axial length less than 22.00mm using the Haigis, Hoffer Q, SRK/T and Holladay 1 IOL formulas from the IOLMaster, and to assess the accuracy of standard biometry formulas after minimising error due to possible IOL constant inaccuracy **Study dates:** December 2005 to December 2010

Full citation	**Day AC, Foster PJ, Stevens JD. Accuracy of intraocular lens power calculations in eyes with axial length <22.00mm. Clin Exp Ophthalmol 2012; 40:855-62**
	Source of funding: The RD Crusaders Charitable Trust (via Fight for Sight, London; grant reference 1956). Partial financial support for 2 authors from the Department of Health through the National Institute for Health Research for the NIHR Biomedical Research Centre at Moorfields Eye Hospital NHS Foundation Trust and UCL Institute of Ophthalmology
Participants	**Sample size** 163 eyes in 97 people **Diagnostic criteria** Not reported **Inclusion criteria** • People with axial lengths less than 22.00mm undergoing elective uneventful phacoemulsification cataract surgery and implantation of a monofocal IOL (Bausch & Lomb Akreos AO, Akreos Adapt, Corneal ACR6D, Oculentis Lentis L302-1) **Exclusion criteria** • Previous refractive surgery **Baseline characteristics**

IOL model	Bausch & Lomb Akreos AO (32 eyes)	Bausch & Lomb Akreos Adapt (100 eyes)	Corneal ACR6D (19 eyes)	Oculentis Lentis L302-1 (12 eyes)	Total (163 eyes)
Age (years)*	59 ± 8 (46 to 76)	57 ± 11 (33 to 82)	51 ± 10 (36 to 64)	54 ± 9 (33 to 66)	57 ± 10 (33 to 82)
Axial length (mm)*	21.33 ± 0.38 (20.44 to 21.95)	21.41 ± 0.44 (19.95 to 21.98)	20.23 ± 0.52 (19.23 to 21.00)	20.67 ± 0.55 (19.89 to 21.54)	21.20 ± 0.60 (19.23 to 21.98)
Average keratometry (dioptres)*	44.06 ± 1.71 (40.87 to 47.23)	44.25 ± 1.34 (40.62 to 46.78)	43.94 ± 1.15 (41.72 to 46.80)	43.08 ± 1.24 (41.36 to 44.86)	44.09 ± 1.42 (40.62 to 47.23)
Anterior chamber depth (mm)*	2.90 ± 0.38 (2.19 to 3.59)	2.83 ± 0.30 (2.16 to 3.48)	2.80 ± 0.21 (2.46 to 3.27)	2.85 ± 0.25 (2.35 to 3.26)	2.84 ± 0.30 (2.16 to 3.59)
*Data in means ± standard deviations (ranges)					

Methods	**<u>Intervention</u>: IOL constant optimisation** • Lens constant adjustment until the overall mean prediction error was zero was performed using the software on the IOLMaster for each lens type. Predictive refractive outcomes following IOL constant optimisation were recalculated.

	Optimised IOL constants			
IOL constant	**Bausch & Lomb Akreos AO (32 eyes)**	**Bausch & Lomb Akreos Adapt (100 eyes)**	**Corneal ACR6D (19 eyes)**	**Oculentis Lentis L302-1 (12 eyes)**
Haigis a0	1.061	0.741	1.668	0.667
Hoffer Q pACD	5.37	5.00	5.98	5.04
SRK/T A-constant	119.1	118.5	120.3	118.8
NB: Data for Holladay 1 SF have not been extracted as this formula has been identified as no longer in use by the guideline committee				

<u>Comparator</u>: IOLMaster IOL constants

Full citation	**Day AC, Foster PJ, Stevens JD. Accuracy of intraocular lens power calculations in eyes with axial length <22.00mm. Clin Exp Ophthalmol 2012; 40:855-62**

- IOL constants for each formula (Haigis a0, a1 and a2; Hoffer Q pACD; Holladay 1 SF) were the standard values derived by the IOLMaster software using the SRK/T A constant value from the packaging of the appropriate IOL type or nominal value reported on the User Group for Laser Interference Biometry (ULIB) website.

	Standard IOL constants			
IOL constant	**Bausch & Lomb Akreos AO (32 eyes)**	**Bausch & Lomb Akreos Adapt (100 eyes)**	**Corneal ACR6D (19 eyes)**	**Oculentis Lentis L302-1 (12 eyes)**
Haigis a0	1.273	1.273	2.523	1.273
Hoffer Q pACD	4.96	4.96	6.21	4.96
SRK/T A-constant	118.0	118.0	120.0	118.0
NB: Data for Holladay 1 SF have not been extracted as this formula has been identified as no longer in use by the guideline committee				

Biometry and keratometry measurements and formula

- Biometry (axial length, AL and anterior chamber depth, ACD) and keratometry: IOLMaster (Carl Zeiss Meditech Inc)
- Formula: Implanted IOL power based on Haigis, Hoffer Q, SRK/T and Holladay 1 IOL formulas using software in the IOLMaster

Cataract surgery and IOL implantation: 1 surgeon performed cataract surgery through a 2.75mm temporal clear corneal incision using an AMO WhiteStar Signature or Alcon Legacy phacoemulsification system with in-the-bag IOL implantation of Bausch & Lomb Akreos AO, Akreos Adapt, Corneal ACR6D or Oculentis Lentis L302-1

Details

Post-operative assessment: post-operative refractive data assessed at least 2 weeks after surgery using Topcon KR8000 series autorefractor (mean±SD, median, range: 5.3±3.9, 4.0, 2.0 to 17.7 weeks)

Study outcomes:

- Prediction error (difference between post-operative spherical equivalent and predicted spherical equivalent)
- Number of eyes (proportion) within various ranges of target refraction

Group comparisons: paired t test, one way analysis of variance (ANOVA)

Missing data handling/loss to follow up

None reported.

Results

Prediction errors

	Standard IOL constants				
	Mean prediction errors in dioptres*				
IOL formulas	**Bausch & Lomb Akreos AO (32 eyes)**	**Bausch & Lomb Akreos Adapt (100 eyes)**	**Corneal ACR6D (19 eyes)**	**Oculentis Lentis L302-1 (12 eyes)**	**Total (163 eyes)**
Haigis	0.47 ± 0.47 (0.31 to 0.63)	-0.27 ± 0.62 (-0.39 to -0.15)	2.36 ± 1.05 (1.89 to 2.84)	1.45 ± 0.97 (0.91 to 2.00)	0.31 ± 1.13 (0.13 to 0.48)
Hoffer Q	-0.77 ± 0.62 (-0.99 to -0.56)	-0.08 ± 0.60 (-0.19 to 0.04)	0.75 ± 0.94 (0.32 to 1.17)	-0.15 ± 1.05 (-0.75 to 0.45)	-0.12 ± 0.80 (-0.25 to 0)
SRK/T	-1.35 ± 0.66 (-1.58 to 1.12)	-0.58 ± 0.68 (-0.72 to -0.45)	-0.43 ± 1.00 (-0.88 to 0.02)	-1.19 ± 1.05 (-1.78 to -0.60)	-0.76 ± 0.82 (-0.89 to -0.63)

Full citation	Day AC, Foster PJ, Stevens JD. Accuracy of intraocular lens power calculations in eyes with axial length <22.00mm. Clin Exp Ophthalmol 2012; 40:855-62

*Data in means ± standard deviations (ranges)
Comparative data for optimised IOL constants not provided for mean prediction errors
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Mean absolute errors

IOL formulas	Mean absolute errors in dioptres*									
	Bausch & Lomb Akreos AO (32 eyes)		Bausch & Lomb Akreos Adapt (100 eyes)		Corneal ACR6D (19 eyes)		Oculentis Lentis L302-1 (12 eyes)		Total (163 eyes)	
	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant
Haigis	0.37 ± 0.28 (0.28 to 0.47)	0.55 ± 0.36 (0.42 to 0.68)	0.44 ± 0.35 (0.38 to 0.51)	0.53 ± 0.42 (0.45 to 0.61)	0.86 ± 0.58 (0.60 to 1.12)	2.36 ± 1.05 (1.89 to 2.84)	0.77 ± 0.51 (0.48 to 1.06)	1.45 ± 0.97 (0.91 to 2.00)	0.50 ± 0.41 (0.44 to 0.57)	0.82 ± 0.83 (0.69 to 0.94)
Hoffer Q	0.50 ± 0.37 (0.37 to 0.63)	0.84 ± 0.53 (0.66 to 1.02)	0.46 ± 0.39 (0.39 to 0.54)	0.47 ± 0.39 (0.39 to 0.54)	0.74 ± 0.58 (0.48 to 1.00)	0.89 ± 0.80 (0.53 to 1.25)	0.83 ± 0.61 (0.48 to 1.17)	0.88 ± 0.53 (0.58 to 1.19)	0.53 ± 0.44 (0.46 to 0.60)	0.62 ± 0.52 (0.54 to 0.70)
SRK/T	0.50 ± 0.37 (0.37 to 0.63)	1.35 ± 0.66 (1.12 to 1.58)	0.52 ± 0.42 (0.43 to 0.60)	0.72 ± 0.53 (0.62 to 0.83)	0.79 ± 0.56 (0.53 to 1.04)	0.92 ± 0.56 (0.67 to 1.17)	0.85 ± 0.56 (0.53 to 1.16)	1.32 ± 0.87 (0.83 to 1.80)	0.57 ± 0.45 (0.50 to 0.64)	0.91 ± 0.64 (0.81 to 1.01)

*Data in means ± standard deviations (ranges)
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Number of eyes (proportion) within various ranges of target refraction

IOL formulas	Number of eyes (proportion) within ±0.25D of target refraction									
	Bausch & Lomb Akreos AO (32 eyes)		Bausch & Lomb Akreos Adapt (100 eyes)		Corneal ACR6D (19 eyes)		Oculentis Lentis L302-1 (12 eyes)		Total (163 eyes)	
	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant
Haigis	12	8	35	34	3	0	2	1	52	42
Hoffer Q	10	4	39	33	3	2	4	2	55	46
SRK/T	11	2	32	23	2	2	3	2	47	29

IOL formulas	Number of eyes (proportion) within ±0.50D of target refraction									
	Bausch & Lomb Akreos AO (32 eyes)		Bausch & Lomb Akreos Adapt (100 eyes)		Corneal ACR6D (19 eyes)		Oculentis Lentis L302-1 (12 eyes)		Total (163 eyes)	
	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant

Haigis	24	17	68	57	4	0	4	3	101	77
Hoffer Q	18	10	60	62	9	8	4	4	91	85
SRK/T	20	4	54	43	6	5	4	3	85	55

	Number of eyes (proportion) within ±1.00D of target refraction									
	Bausch & Lomb Akreos AO (32 eyes)		**Bausch & Lomb Akreos Adapt (100 eyes)**		**Corneal ACR6D (19 eyes)**		**Oculentis Lentis L302-1 (12 eyes)**		**Total (163 eyes)**	
IOL formulas	**Optimised IOL constant**	**Standard IOL constant**	**Optimised IOL constant**	**Standard IOL constant**	**Optimised IOL constant**	**Standard IOL constant**	**Optimised IOL constant**	**Standard IOL constant**	**Optimised IOL constant**	**Standard IOL constant**
Haigis	31	29	93	86	12	0	7	4	143	119
Hoffer Q	28	23	92	91	14	12	6	6	142	132
SRK/T	28	8	89	72	14	10	6	4	137	95

*Number of eyes (proportion); calculated from reported percentages
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

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Full citation	**Doshi D, Limdi P Parekh N, et al. A comparative study to assess the predictability of different IOL power calculation formulas in eyes of short and long axial length. J Clin Diagnostic Res 2017; 11(1):NC01-04**
Study details	**Country/ies where the study was carried out:** India **Study type:** Prospective case series **Aim of the study:** To compare the predictive ability of 4 intraocular lens (IOL) formulas (SRK/T, Hoffer Q, Holladay I and Haigis) in eyes shorter than 22.0mm and longer than 24.5mm **Study dates:** October 2013 to August 2014 **Source of funding:** None reported
Participants	**Sample size** 80 eyes in 80 people **Diagnostic criteria** Not reported **Inclusion criteria** • People with any type of cataracts and normal anterior and posterior segment, undergoing uneventful phacoemulsification cataract surgery with in-the-bag monofocal IOL implantation with same A constant (118.7) at 1 outpatient department • Eyes with axial length of either <22.0mm or >24.5mm • Post-operative best corrected visual acuity (BCVA) of 6/12 or better at 6 weeks **Exclusion criteria** • Children

Full citation	**Doshi D, Limdi P Parekh N, et al. A comparative study to assess the predictability of different IOL power calculation formulas in eyes of short and long axial length. J Clin Diagnostic Res 2017; 11(1):NC01-04**

- People with psychiatric illness, traumatic cataract, several corneal degeneration, corneal opacity, vitreous degeneration and other vitreous pathology, diabetic retinopathy, developmental and acquired retinal diseases, squint and high corneal astigmatism

Baseline characteristics

	Axial length <22.0mm (40 eyes)	**Axial length >24.5mm (40 eyes)**
Male:female	11:29	25:15
Age (years)*	58.98 ± 9.29	59.23 ± 11.82
Axial length (mm)*	21.39 ± 0.58	24.93 ± 0.80
Mean anterior chamber depth (mm)	2.43	3.56
Keratometry (dioptres)*	46.28 ± 1.22	43.30 ± 1.75
*Data in means ± standard deviations		

Methods

Interventions and comparators: IOL formulas

- Haigis
- Hoffer Q
- SRK/T
- Holladay 1 NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Biometry and keratometry measurements

- Biometry (axial length, AL and anterior chamber depth, ACD): immersion ultrasound A-scan machine ECHORULE 2 (BIOMEDIX)
- Keratometry: IOLMaster
- Formula: Using software of ECHORULE 2 with optimisation of A-constant, Haigis, Hoffer Q, Holladay I and SRK/T formulas were used to calculate IOL power for each axial length subgroup.
- Target in IOL power selection: post-operative refraction nearest to plano erring on the side of myopia. The IOL formula that predicted a lens power with the post-operative refraction nearest to plano was selected.
- IOL constants: optimised A-constant

Cataract surgery and IOL implantation: One surgeon performed uneventful phacoemulsification cataract surgery with in-the-bag monofocal implantation using standard technique (an incision and side-port paracentesis, injection of an ophthalmic viscoelastic device [OVD] into the anterior chamber to create a Continuous Curvilinear Capsulorhexis; hydrodissection using Balanced Salt Solution [BSS]; phacoemulsification, aspiration of cortex and implantation of foldable posterior chamber IOL using the recommended injector system; OVD was removed, surgical wounds hydrated with BSS; no sutures were applied; all wounds were checked for leakage). Subconjunctival gentamycin and dexamethasone injections were given at the end of surgery. Ofloxacin (0.3%) and dexamethasone (0.1%) eye drops were given post-operatively in tapering frequency for 1.5 months.

Details

Post-operative assessment: Actual post-operative spherical equivalent (SE) measured using autorefractometer, retinoscopy and subjective correction at 1.5 months (6 weeks).

Study outcomes:

- Prediction error and mean absolute error in deviation from the predicted post-operative refraction (difference between actual post-operative SE of the subjective refraction and the predicted post-operative SE)

Full citation	**Doshi D, Limdi P Parekh N, et al. A comparative study to assess the predictability of different IOL power calculation formulas in eyes of short and long axial length. J Clin Diagnostic Res 2017; 11(1):NC01-04**
	• Proportion of eyes within various ranges of the predicted post-operative refractive outcome Group comparisons: Kruskal Wallis test Axial length subgroups: <22.0mm and >24.5mm **Missing data handling/loss to follow up** No missing data reported.
Results	**Prediction errors**

IOL formulas	Mean prediction errors in dioptres*	
	Axial length <22.0mm (40 eyes)	**Axial length >24.5mm (40 eyes)**
Haigis	1.32 ± 0.80 (-0.67 to 2.46)	0.70 ± 0.81 (-1.17 to 2.28)
Hoffer Q	-0.15 ± 0.68 (-1.63 to 1.29)	-0.01 ± 0.84 (-1.98 to 1.55)
SRK/T	0.08 ± 0.71 (-1.51 to 1.75)	0.10 ± 0.66 (-1.01 to 1.88)
*Data in means ± standard deviations (ranges) NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee		

Mean absolute errors

IOL formulas	Mean absolute errors in dioptres*	
	Axial length <22.0mm (40 eyes)	**Axial length >24.5mm (40 eyes)**
Haigis	1.36 ± 0.75 (0.07 to 2.50)	0.83 ± 0.67 (0.04 to 2.28)
Hoffer Q	0.59 ± 0.36 (0.02 to 1.63)	0.68 ± 0.48 (0.01 to 1.98)
SRK/T	0.54 ± 0.46 (0.01 to 1.75)	0.51 ± 0.42 (0.01 to 1.88)
*Data in means ± standard deviations (ranges) NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee		

Number of eyes (proportion) within various ranges of the target refraction

IOL formulas	Number of eyes (proportion) within ±0.50D of the target refraction*	
	Axial length <22.0mm (40 eyes)	**Axial length >24.5mm (40 eyes)**
Haigis	7 (17.5%)	17 (42.5%)
Hoffer Q	17 (42.5%)	17 (42.5%)
SRK/T	22(55.0%)	20 (50.0%)
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee		
IOL formulas	**Number of eyes (proportion) within ±1.00D of the target refraction***	
	Axial length <22.0mm (40 eyes)	**Axial length >24.5mm (40 eyes)**
Haigis	14 (35.0%)	27 (675%)
Hoffer Q	36 (90.0%)	30 (75.0%)
SRK/T	33 (82.5%)	34 (85.0%)
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee		
IOL formulas	**Number of eyes (proportion) greater than ±1.00D of the target refraction***	

Full citation	**Doshi D, Limdi P Parekh N, et al. A comparative study to assess the predictability of different IOL power calculation formulas in eyes of short and long axial length. J Clin Diagnostic Res 2017; 11(1):NC01-04**

	Axial length <22.0mm (40 eyes)	Axial length >24.5mm (40 eyes)
Haigis	26 (65.0%)	13 (32.5%)
Hoffer Q	4 (10.0%)	10 (25.0%)
SRK/T	7 (17.5%)	6 (15.0%)
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee		

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Full citation	**El-Nafees R, Moaward A, Kishk H, et al. Intraocular lens power calculation in patients with high axial myopia before cataract surgery. Saudi J Ophthalmol 2010; 24:77-80**
Study details	**Country/ies where the study was carried out:** Egypt **Study type:** Prospective case series **Aim of the study:** To evaluate the accuracy of different formulas used for intraocular lens (IOL) power calculation in people with high axial myopia undergoing cataract surgery **Study dates:** May 2006 to April 2007 **Source of funding:** Not reported
Participants	**Sample size** 53 eyes in 51 people **Diagnostic criteria** Not reported **Inclusion criteria** • People with axial length greater than 25.0mm scheduled for phacoemulsification cataract surgery with IOL implantation **Exclusion criteria** • Previous ocular surgery • Combined surgical procedures • Eventful cataract surgeries • Corneal surface irregularities **Baseline characteristics**

IOL models	I-Medical (53 eyes in 51 people)
Age (years)*	55.04 ± 7.73 (39 to 67)
Male:female^	21:30
Axial length (mm)*	28.20 ± 1.57 (25.5 to 31.4)
Keratometry (dioptres)*	44.33 ± 1.28 (41.50 to 47.29)
Anterior chamber depth (mm)*	3.397 ± 0.37
Senile:pre-senile cataracts^	36:17
Fundus changes:myopic degenerations^	46:19
Posterior staphyloma^	7

Full citation	**El-Nafees R, Moaward A, Kishk H, et al. Intraocular lens power calculation in patients with high axial myopia before cataract surgery. Saudi J Ophthalmol 2010; 24:77-80**

Glasses:contact lens ^	31:1

*Data in means ± standard deviations (ranges) as appropriate
^Number of eyes (proportion)

Methods

Interventions and comparators: IOL formulas

- Haigis
- SRK/T
- Holladay 1 NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Biometry and keratometry measurements

- Biometry (axial length, AL): immersion A-scan ultrasound technique by Hansen scleral shell and B mode with horizontal macular scanning COM—PACT II (Quantel Medical)
- Keratometry: performed using computerised coloured video keratometer, prior to taking axial length measurements
- Formula: Implant IOL power calculated using the Haigis, SRK/T and Holladay 1 formulas by the same person
- IOL constant: not reported.

Cataract surgery and IOL implantation: uneventful phacoemulsification cataract surgery through a sutureless 3.2mm incision was performed; the site of the incision was selected according to the pre-operative corneal astigmatism if present, with IOL in-the-bag implantation of a foldable lens (I-Medical, Germany).

Details

Post-operative assessment: post-operative refraction assessed at 1 day, 1 week, 2 weeks, 1 month, 2 months and 3 months after surgery using Canon (R-30) autorefractometer

Study outcomes:

- Mean errors (difference between the formula predicted refractive error and the actual post-operative refractive error)
- Proportion of eyes within 1.0 dioptre of mean absolute error

Group comparisons: not reported

Axial length subgroups: refractive outcomes were reported in 3 categories: 25 to 27mm, >27 to 29mm, >29 to 31.4mm

Missing data handling/loss to follow up

No missing data reported.

Results

Mean errors

		I-Medical IOL	
		Mean errors in dioptres	
Axial length group (mm)	**Number of eyes**	**Haigis**	**SRK/T**
25-27	15	0.03	0.04
>27-29	23	0.17	0.15
>29-31.4	15	0.46	0.33
All eyes	53	0.21	0.17

NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Full citation	El-Nafees R, Moaward A, Kishk H, et al. Intraocular lens power calculation in patients with high axial myopia before cataract surgery. Saudi J Ophthalmol 2010; 24:77-80

Proportion of eyes within 1.0 dioptre of mean absolute error

I-Medical IOL (53 eyes)	
Proportion of eyes within 1.0 dioptre of mean absolute error*	
Haigis	SRK/T
44	44

*Number of eyes (proportion); calculated from reported percentages
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

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Full citation	Eom Y, Yang SY, Sok JS, et al. Comparison of Hoffer Q and Haigis formulae for intraocular lens power calculation according to the anterior chamber depth in short eyes. Am J Ophthalmol 2014; 157:818-24
Study details	**Country/ies where the study was carried out:** South Korea **Study type:** Retrospective case series **Aim of the study:** To compare the accuracy of the Hoffer Q and Haigis formulas according to the anterior chamber depth (ACD) in cases of short axial length **Study dates:** April 2008 to September 2013 **Source of funding:** None reported
Participants	**Sample size** 75 eyes in 75 people **Diagnostic criteria** Not reported **Inclusion criteria** • People with axial length less than 22mm undergoing uneventful phacoemulsification cataract surgery with in-the-bag IOL implantation of Acrysof IQ at 2 institutions • Axial length measurements determined by the IOLMaster and with at least 3 valid measurements with a signal-to-noise ratio (SNR) above 1.5 for a single measurement and a SNR above 2.0 for the composite signal **Exclusion criteria** • History of traumatic cataracts • Previous ocular surgery (e.g. penetrating keratoplasty or refractive surgery) • Previous complicated cataract surgery (e.g. anterior or posterior capsular ruptures) • Sulcus-fixated lenses • Post-operative complications (e.g. decentred or tilted IOL) • Post-operative best corrected visual acuity less than 20/40 **Baseline characteristics**

IOL model	Acrysof IQ (75 eyes)

Full citation	**Eom Y, Yang SY, Sok JS, et al. Comparison of Hoffer Q and Haigis formulae for intraocular lens power calculation according to the anterior chamber depth in short eyes. Am J Ophthalmol 2014; 157:818-24**

Age (years)	70.1 ± 6.8 (52 to 85)
Male:female^	5:70
Axial length (mm)*	21.69 ± 0.29 (20.32 to 21.99)
Corneal power (dioptres)*	46.34 ± 1.28 (43.67 to 49.46)
Anterior chamber depth (mm)*	2.63 ± 0.39 (1.87 to 3.51)
Right:left^	39:36
*Data in means ± standard deviations (ranges) ^Number of eyes	

Methods

Interventions and comparators: IOL formulas

- Haigis
- Hoffer Q

Biometry and keratometry measurements

- Biometry (axial length, AL and anterior chamber depth, ACD) and keratometry: performed using the IOLMaster (version 5.02 or higher, Carl Zeiss, Germany). At least 3 valid axial length measurements with a signal-to-noise ratio (SNR) above 1.5 for a single measurement and a SNR above 2.0 for the composite signal were accepted.
- Formula: IOL power calculated using the Hoffer Q and Haigis formulas.
- IOL constant: The pseudophakic ACD (pACD) was 5.64 for the Hoffer Q formula and the a0, a1 and a2 constants were =0.767, 0.220 and 0.219 respectively for the Haigis formula. The data adjusted pACD for the Hoffer Q formula was calculated using the Haigis constant optimisation Excel spreadsheet for optical biometry which also optimises the lens constant for Hoffer Q formula.

Cataract surgery and IOL implantation: 3 experienced surgeons performed uneventful phacoemulsification cataract surgery under topical anaesthesia with a 2.2mm or 2.75mm clear temporal corneal incision and a continuous capsulorhexis slight smaller than the IOL optic size using a 26 gauge needle. Standard phacoemulsification technique was used and IOL implantation of Acrysof SA60AT into the capsular bag using an injector system

Details

Post-operative assessment: Post-operative refraction was assessed between 3 and 10 weeks after surgery using an autorefractor/keratometer (RK-F1 Canon, Tokyo)

Study outcomes:

- Prediction errors (difference between the post-operative objective refractive spherical equivalent and pre-operative refraction predicted by the IOLMaster using the Hoffer Q and Haigis formulas)
- Median and mean absolute errors
- Proportion of eyes achieving post-operative predictive refractive error within various ranges of pre-operative predicted refraction

Group comparisons: Wilcoxon signed rank test

Missing data handling/loss to follow up

No missing data reported.

Results

Mean errors

Mean errors in dioptres*

Full citation	Eom Y, Yang SY, Sok JS, et al. Comparison of Hoffer Q and Haigis formulae for intraocular lens power calculation according to the anterior chamber depth in short eyes. Am J Ophthalmol 2014; 157:818-24

Acrysof IQ (75 eyes)	
Haigis	**Hoffer Q**
0.20 (-1.09 to 1.54)	-0.23 (-1.65 to 0.97)
Mean (range)	

Median and mean absolute errors

Absolute errors in dioptres*	
Acrysof IQ (75 eyes)	
Haigis	**Hoffer Q**
0.46 (0.40)	0.49 (0.40)
Mean (median)	

Proportion of eyes achieving post-operative predictive refractive error within various ranges of pre-operative predicted refraction

	Acrysof IQ (75 eyes)	
Proportion of eyes within*	**Haigis**	**Hoffer Q**
±0.25D	28	22
±0.50D	50	47
±1.00D	66	66
>±2.00D	0 (extracted as per text)	0 (extracted as per text)
Number of eyes (proportion); calculated from reported percentages		

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Full citation	Kane JX, Van Heerden A, Atik A, et al. Intraocular lens power formula accuracy: comparison of 7 formulas. J Cataract Refract Surg 2016; 42:1490-1500
Study details	**Country/ies where the study was carried out:** Australia **Study type:** Retrospective case series **Aim of the study:** To assess the accuracy of 7 intraocular lens (IOL) power formulas (Barrett Universal II, Haigis, Hoffer Q, Holladay I, Holladay 2, SRK/T, T2) using IOLMaster biometry and optimised lens constants **Study dates:** February 2010 to November 2015 **Source of funding:** None reported
Participants	**Sample size** 3241 eyes in 3241 people **Diagnostic criteria** Not reported **Inclusion criteria** • People who had uneventful phacoemulsification cataract surgery with in-the-bag IOL implantation of an Acrysof IQ SN60WF at 1 tertiary centre • Pre-operative biometry using IOLMaster (version 5.4, Carl Zeiss Meditec AG) • Randomly selected eye for people undergoing bilateral phacoemulsification cataract surgery

Full citation	**Kane JX, Van Heerden A, Atik A, et al. Intraocular lens power formula accuracy: comparison of 7 formulas. J Cataract Refract Surg 2016; 42:1490-1500**

Exclusion criteria

- Incomplete pre-operative biometry
- Corneal astigmatism greater than 3.0 dioptres
- Complicated cataract surgery, additional procedures during cataract surgery
- Post-operative corrected distance visual acuity (CDVA) worse than 6/12 refraction performed before 14 days post-operatively
- Post-operative complications
- Incomplete documentation
- No formal refraction post-operatively

Baseline characteristics

IOL	Acrysof IQ SN60WF (3241 eyes)
Male:female (%)	45.6:54.4
Right:left eye (%)	51.4:48.6
Axial length (mm)*	23.50 ± 1.06
Keratometry (dioptres)*	43.71 ± 1.51
IOL power (dioptres)*	21.48 ± 2.91
*Data in means ± standard deviations	

Methods

Interventions and comparators: IOL formulas

- Haigis
- Hoffer Q
- SRK/T
- Holladay 2 (via Holladay IOL Consultant software)
- T2 (online)
- Barrett Universal II (online)
- Holladay 1 NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Biometry and keratometry measurements

- Biometry and keratometry: IOLMaster
- IOL constants: for optimised constants for Hoffer Q, Holladay I and SRK/T, the IOL constant for each formula for each patient was varied in 0.001 steps until the difference between the predicted spherical equivalent (SE) and actual SE for the patient was zero. The optimised IOL constant was calculated as the mean of all the individual patients' IOL constants (excluding outliers further than 2 standard deviations from the sample mean). Haigis formula had triple optimisation by calculating the anterior chamber depth constant that would have resulted in the actual post-operative refractive result; a double linear regression analysis was undertaken to find the remaining Haigis constants. The optimised SRK/T constant was used to calculate the T2 formula result. The Holladay 2 formula was optimised in the IOL Consultant program. The recommended lens constant for the Barrett Universal II formula was used as no method currently exists to optimise lens constant using the online calculator.

SRK/T A constant	Hoffer Q personalised anterior chamber depth	Holladay 2 constant	Haigis			Barrett Universal II lens constant
			a_0	a_1	a_2	

Full citation	**Kane JX, Van Heerden A, Atik A, et al. Intraocular lens power formula accuracy: comparison of 7 formulas. J Cataract Refract Surg 2016; 42:1490-1500**

118.824	5.462	5.630	0.996	0.279	0.129	118.99

Cataract surgery and IOL implantation: uneventful phacoemulsification cataract surgery with in-the-bag implantation of an Acrysof IQ SN60WF lens (single piece hydrophobic acrylic with an aspheric biconvex optic) in 1 institution.

Details
Post-operative assessment: Subjective refraction after 14 days post-operatively conducted by orthoptic staff or by optometrists in the community.
Study outcomes:
- Prediction error and mean absolute error in deviation from the predicted post-operative refraction (difference between actual post-operative SE of the subjective refraction and the predicted post-operative SE)
- Proportion of eyes within various ranges of the predicted post-operative refractive outcome

Group comparisons: Friedman test, Conover test for post hoc analysis
Axial length subgroups: ≤22.0mm (short), >22.0 to <24.5mm (medium), ≥24.5 to <26.0mm (medium long) and ≥26.0mm (long)

Missing data handling/loss to follow up
No missing data reported.

Results

Prediction errors and mean absolute errors
NB: no measures of dispersion were reported for prediction errors and mean absolute errors and therefore have not been data extracted.

Number of eyes (proportion) within various ranges of the target refraction

IOL formulas	Number of eyes (proportion) within ±0.25D of the target refraction*				
	Axial length ≤22.0mm (156 eyes)	**Axial length >22.0 to <24.5mm (2638 eyes)**	**Axial length ≥24.5 to <26.0mm (372 eyes)**	**Axial length ≥26.0mm (77 eyes)**	**Any axial length (3241 eyes)^**
Haigis	(36.5%)	(39.0%)	(38.4%)	(36.0%)	(38.8%)
Hoffer Q	(28.2%)	(39.0%)	(34.9%)	(33.3%)	(37.9%)
SRK/T	(32.7%)	(38.6%)	(38.7%)	(38.7%)	(38.3%)
Barrett Universal II	(30.8%)	(42.7%)	(46.2%)	(34.7%)	(43.5%)
T2	(33.3%)	(390%)	(39.5%)	(30.7%)	(39.9%)
Holladay 2	(31.4%)	(379%)	(41.4%)	(32.0%)	(37.9%)

*Proportions provided by paper
^Reported total as 3241 in paper, although subgroups add up to 3243
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

IOL formulas	Number of eyes (proportion) within ±0.50D of the target refraction*				
	Axial length ≤22.0mm (156 eyes)	**Axial length >22.0 to <24.5mm (2638 eyes)**	**Axial length ≥24.5 to <26.0mm (372 eyes)**	**Axial length ≥26.0mm (77 eyes)**	**Any axial length (3241 eyes)^**
Haigis	(62.8%)	(69.0%)	(68.5%)	(57.3%)	(68.3%)
Hoffer Q	(55.8%)	(68.1%)	(68.8%)	(53.3%)	(67.2%)
SRK/T	(59.6%)	(70.8%)	(66.7%)	(62.7%)	(69.6%)
Barrett Universal II	(62.2%)	(71.3%)	(76.6%)	(62.7%)	(72.3%)

Full citation	Kane JX, Van Heerden A, Atik A, et al. Intraocular lens power formula accuracy: comparison of 7 formulas. J Cataract Refract Surg 2016; 42:1490-1500				
T2	(60.3%)	(69.5%)	(71.2%)	(64.0%)	(70.0%)
Holladay 2	(61.5%)	(68.1%)	(67.2%)	(57.3%)	(67.4%)
*Proportions provided by paper ^Reported total as 3241 in paper, although subgroups add up to 3243 NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee					
	Number of eyes (proportion) within ±1.00D of the target refraction*				
IOL formulas	**Axial length ≤22.0mm (156 eyes)**	**Axial length >22.0 to <24.5mm (2638 eyes)**	**Axial length ≥24.5 to <26.0mm (372 eyes)**	**Axial length ≥26.0mm (77 eyes)**	**Any axial length (3241 eyes)^**
Haigis	(91.0%)	(93.0%)	(93.8%)	(88.0%)	(92.9%)
Hoffer Q	(91.0%)	(92.9%)	(94.1%)	(82.7%)	(92.7%)
SRK/T	(92.3%)	(93.9%)	(94.4%)	(92.0%)	(93.8%)
Barrett Universal II	(92.3%)	(94.2%)	(97.8%)	(92.0%)	(94.5%)
T2	(92.9%)	(93.5%)	(94.9%)	(86.7%)	(93.9%)
Holladay 2	(91.7%)	(94.0%)	(93.5%)	(88.0%)	(93.7%)
*Proportions provided by paper ^Reported total as 3241 in paper, although subgroups add up to 3243 NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee					
	Number of eyes (proportion) within ±2.00D of the target refraction*				
IOL formulas	**Axial length ≤22.0mm (156 eyes)**	**Axial length >22.0 to <24.5mm (2638 eyes)**	**Axial length ≥24.5 to <26.0mm (372 eyes)**	**Axial length ≥26.0mm (77 eyes)**	**Any axial length (3241 eyes)^**
Haigis	(100.0%)	(99.6%)	(99.5%)	(98.7%)	(99.6%)
Hoffer Q	(100.0%)	(99.6%)	(99.5%)	(98.7%)	(99.6%)
SRK/T	(99.4%)	(99.8%)	(99.7%)	(97.3%)	(99.7%)
Barrett Universal II	(100.0%)	(99.9%)	(100.0%)	(100.0%)	(99.9%)
T2	(99.4%)	(99.7%)	(99.7%)	(100.0%)	(99.7%)
Holladay 2	(100.0%)	(99.7%)	(99.7%)	(97.3%)	(99.7%)
*Proportions provided by paper ^Reported total as 3241 in paper, although subgroups add up to 3243 NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee					

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Full citation	Mitra A, Jain E, Sen A, et al. A study regarding efficacy of various intraocular lens power calculation formulas in a subset of Indian myopic patients. Indian J Ophthalmol 2014; 62:826-8
Study details	**Country/ies where the study was carried out:** India **Study type:** Retrospective case series **Aim of the study:** To determine the accuracy of the Holladay 1, Hoffer Q, SRK II and SRK/T intraocular lens (IOL) power calculation in people with high myopia in a subset of Indian population undergoing cataract surgery **Study dates:** May to October 2009 **Source of funding:** None reported
Participants	**Sample size**

<table>
<tr><td>Full citation</td><td>Mitra A, Jain E, Sen A, et al. A study regarding efficacy of various intraocular lens power calculation formulas in a subset of Indian myopic patients. Indian J Ophthalmol 2014; 62:826-8</td></tr>
<tr><td></td><td>43 eyes in 43 people

Diagnostic criteria
Not reported

Inclusion criteria
• People with axial length greater than 24.50mm undergoing phacoemulsification cataract surgery with in-the-bag IOL implantation

Exclusion criteria
• Pre-existing astigmatism >3.0 dioptres
• Corneal scar
• Keratoconus
• Complications affecting refractive status (vitreous loss with IOL implanted in sulcus or anterior chamber, high wound induced astigmatism)

Baseline characteristics
<table>
<tr><th>IOL models</th><th>Hydrophilic acrylic foldable IOL (43 eyes)</th></tr>
<tr><td>Axial length (mm)*</td><td>(24.75 to 32.35)</td></tr>
<tr><td>Keratometry (dioptres)</td><td>81% were within the normal range of 42.0 to 46.0 dioptres</td></tr>
<tr><td colspan="2">*Data in means ± standard deviations (ranges) as appropriate</td></tr>
</table></td></tr>
<tr><td>Methods</td><td><u>Interventions and comparators</u>: IOL formulas
• Hoffer Q
• SRK/T
• Holladay 1
• SRK II NB: Data for Holladay 1 and SRK II have not been extracted as these formulas have been identified as no longer in use by the guideline committee

Biometry and keratometry measurements
• <u>Biometry (axial length, AL)</u>: A-scan contact ultrasound using Echorule2
• <u>Keratometry</u>: retrieved from records. No further details provided
• <u>Formula</u>: The implanted IOL power was used to calculate the predicted post-operative refractive error with 4 formulas: Hoffer Q, SRK/T, Holladay 1, SRK II
• <u>IOL constant</u>: not reported.

Cataract surgery and IOL implantation: phacoemulsification cataract surgery with IOL in-the-bag implantation of a hydrophilic acrylic foldable lens in the posterior chamber.

Details
<u>Post-operative assessment</u>: spherical equivalent measured by 1 trained optometrist using an autorefractor and subjective retinoscopy 1 to 2 months after surgery</td></tr>
</table>

Full citation	**Mitra A, Jain E, Sen A, et al. A study regarding efficacy of various intraocular lens power calculation formulas in a subset of Indian myopic patients. Indian J Ophthalmol 2014; 62:826-8**
	Study outcomes: • Mean errors (difference between the formula predicted refractive error and the actual post-operative refractive error) • Proportion of eyes within 1.0 dioptre of mean absolute error Group comparisons: repeated measures analysis of variance (ANOVA) Axial length subgroups: refractive outcomes were reported in 1 category: 24.5 to 26.5mm **Missing data handling/loss to follow up** No missing data reported.
Results	**Mean errors**

Axial length group (mm)	Number of eyes	Hydrophilic acrylic foldable IOL (43 eyes)	
		Mean errors in dioptres*	
		Hoffer Q	SRK/T
24.5-26.5	20	0.47 ± 1.29	0.84 ± 1.31
All eyes (24.75 to 32.35)	43	0.58 ± 1.23	0.92 ± 1.19

*Data in means ± standard deviations
NB: Data for Holladay 1 and SRK II have not been extracted as these formulas have been identified as no longer in use by the guideline committee

Proportion of eyes within 1.0 dioptre of mean absolute error

Axial length group (mm)	Number of eyes	Hydrophilic acrylic foldable IOL	
		Proportion of eyes within 1.0 dioptre of mean absolute error*	
		Hoffer Q	SRK/T
All eyes (24.75 to 32.35)	43	19	17

*Number of eyes (proportion); calculated from reported percentages
NB: Data for Holladay 1 and SRK II have not been extracted as these formulas have been identified as no longer in use by the guideline committee

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Full citation	**Moschos MM, Chatziralli IP, Koutsandrea C. Intraocular lens power calculation in eyes with short axial length. Indian J Ophthalmol 2014; 62:692-4**
Study details	**Country/ies where the study was carried out:** Greece **Study type:** Retrospective case series **Aim of the study:** To compare the predictive capacity of 4 intraocular lens (IOL) power calculation formulas (Haigis, Hoffer Q, SRK/T and Holladay 1) in eyes shorter than 22mm **Study dates:** February to July 2012 **Source of funding:** None reported
Participants	**Sample size** 69 eyes in 69 people **Diagnostic criteria** Not reported

Full citation	**Moschos MM, Chatziralli IP, Koutsandrea C. Intraocular lens power calculation in eyes with short axial length. Indian J Ophthalmol 2014; 62:692-4**

Inclusion criteria

People, aged 40 and over with axial length less than 22mm undergoing phacoemulsification cataract surgery with IOL implantation at 1 institution
Post-operative best corrected visual acuity of 20/40 or better

Exclusion criteria

- Pre-operative best corrected visual acuity of 20/200 or worse
- Corneal abnormalities
- Previous intraocular or corneal surgery (including keratorefractive surgery)
- History of ocular injury or uveitis
- Intraoperative complications e.g. posterior capsule rupture, vitreous loss, lost nucleus, zonule dehiscence and wound leak

Baseline characteristics

IOL model	**Alcon SN60WF (69 eyes)**
Age (years)	73.5 ± 7.2
Male:female^	30:39
Axial length (mm)*	21.50 ± 0.40 (20.20 to 21.99)
Corneal power (dioptres)*	43.7 ± 1.50 (40.31 to 47.88)
Anterior chamber depth (mm)*	2.43 (2.28 to 2.97)
*Data in means ± standard deviations (ranges), as appropriate ^Number of eyes; calculated based on reported ratio	

Methods

Interventions and comparators: IOL formulas

- Haigis
- Hoffer Q
- SRK/T
- Holladay 1 NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Biometry and keratometry measurements

- Biometry (axial length, AL and anterior chamber depth, ACD): performed using the immersion A-scan ultrasonography Ocuscan RxP (Alcon)
- Keratometry: measured using automated keratometer Speedy-K, Righton, Right Mfg Co Ltd
- Formula: Appropriate IOL power was measured for each formula using the software of Ocuscan. Target refraction was plano, erring on the side of myopia.
- IOL constant: Optimised lens constants were used in the Ocuscan, which included customisation for specific IOLs. No details provided on how IOL constants were optimised.

Cataract surgery and IOL implantation: 1 surgeon performed uneventful phacoemulsification cataract surgery with standard technique using topical anaesthesia wand a clear 2.75mm incision and side-port paracentesis. Ophthalmic viscoelastic device was injected into the anterior segment and a continuous curvilinear capsulorhexis was created. Phacoemulsification was conducted using the Infinity Vision System and an Alcon SN60WF IOL implanted into the posterior chamber using the recommended injector system.

Full citation	**Moschos MM, Chatziralli IP, Koutsandrea C. Intraocular lens power calculation in eyes with short axial length. Indian J Ophthalmol 2014; 62:692-4**

Details

Post-operative assessment: Post-operative refraction was assessed 1 month after surgery

Study outcomes:

- Prediction errors (difference between the actual post-operative spherical equivalent and predicted post-operative spherical equivalent) and mean absolute errors
- Proportion of eyes within specified target refraction

Group comparisons: Mann-Whitney U test

Missing data handling/loss to follow up

No missing data reported.

Results

Mean errors

Mean errors in dioptres*		
Alcon SN60WF (69 eyes)		
Haigis	**Hoffer Q**	**SRK/T**
-0.02 ± 0.06 (-1.23 to 1.08)	-0.09 ± 0.10 (-1.73 to 1.75)	0.41 ± 0.23 (-1.59 to 2.14)
Mean ± standard deviation (range) NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee		

Mean absolute errors

Absolute errors in dioptres*		
Alcon SN60WF (69 eyes)		
Haigis	**Hoffer Q**	**SRK/T**
0.43 ± 0.22 (0.25 to 1.25)	0.72 ± 0.51 (0.25 to 2.00)	0.97 ± 0.38 (0.25 to 2.25)
Mean ± standard deviation (range) NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee		

Proportion of eyes within specified target refraction

Proportion of eyes within*	**Alcon SN60WF (69 eyes)**		
	Haigis	**Hoffer Q**	**SRK/T**
±0.50D	50	41	13
±1.00D	64	59	47
Number of eyes (proportion); calculated from reported percentages NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee			

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Full citation	**Ozcura F, Aktas S, Sagdik HM, et al. Comparison of the biometric formulas used for applanation A-scan ultrasound biometry. Int Ophthalmol 2016; 36:707-12**
Study details	**Country/ies where the study was carried out:** Turkey **Study type:** Retrospective case series

<table>
<tr><td>Full citation</td><td>Ozcura F, Aktas S, Sagdik HM, et al. Comparison of the biometric formulas used for applanation A-scan ultrasound biometry. Int Ophthalmol 2016; 36:707-12</td></tr>
<tr><td></td><td>Aim of the study: To compare the accuracy of various biometric formulas for predicting post-operative refraction determined using applanation A-scan ultrasound
Study dates: Not reported
Source of funding: None reported</td></tr>
<tr><td>Participants</td><td>Sample size
485 eyes in 417 people

Diagnostic criteria
Not reported

Inclusion criteria
• People, 18 years and older who had uneventful phacoemulsification cataract surgery with intraocular lens (IOL) implantation at 1 institution
• Post-operative visual acuity of 20/40 or better

Exclusion criteria
• Combined procedures
• Post-operative astigmatism greater than 2.0 dioptres
• Capsule rupture and failure to place the lens in the bag

Baseline characteristics
<table>
<tr><td></td><td>Any axial length (417 people)</td></tr>
<tr><td>Male:female</td><td>247:170</td></tr>
<tr><td>Age (years)*</td><td>65.34 ± 10.64 (26 to 88)</td></tr>
<tr><td colspan="2">*Data in means ± standard deviations (range) as appropriate</td></tr>
</table>
</td></tr>
<tr><td>Methods</td><td><u>Interventions and comparators</u>: IOL formulas
• Hoffer Q
• SRK/T
• Holladay 1
• Binkhorst II
• SRK II NB: Data for Holladay 1, Binkhorst II and SRK II have not been extracted as these formulas have been identified as no longer in use by the guideline committee

Biometry and keratometry measurements
• <u>Biometry</u>: ocular ultrasound biometry (Sonomed EZ Scan AB 5500+, Lake Success, NY USA)
• <u>Keratometry</u>: Autorefractometer
• <u>Target in IOL power selection</u>: lowest myopic value in predicted refractive outcomes.

Cataract surgery and IOL implantation: One surgeon performed uneventful cataract surgery using a peristaltic phacoemulsification machine (Sovereign Compact-WhiteStar; AMO Irvine CA USA) under anaesthesia with 0.5% topical proparacaine solution, 2.4mm clear corneal incision on the steeper corneal</td></tr>
</table>

Full citation	Ozcura F, Aktas S, Sagdik HM, et al. Comparison of the biometric formulas used for applanation A-scan ultrasound biometry. Int Ophthalmol 2016; 36:707-12

meridian, foldable hydrophobic acrylic IOL in the capsular bag. The incision was self-sealing and mild oedema around the incision site was induced by hydration.

Details

Post-operative assessment: Manifest refraction was measured 4 to 6 weeks post-operatively.

Study outcomes:

- Mean absolute error in deviation from the predicted post-operative refraction (absolute values of the difference between actual post-operative SE of the subjective refraction and the predicted post-operative SE)
- Proportion of eyes within various ranges of the predicted post-operative refractive outcome

Group comparisons: one-way repeated measures ANOVA

Axial length subgroups: ≤22.0mm (short), 22.0 to 25.0mm (average) and ≥25.0mm (long)

Missing data handling/loss to follow up

No missing data reported.

Results

Mean absolute errors

IOL formulas	Mean absolute errors in dioptres*			
	Axial length ≤22.0mm (32 eyes)	Axial length 22.0 to 25.0mm (422 eyes)	Axial length ≥25.0mm (31 eyes)	Any axial length (485 eyes)
Hoffer Q	0.76 ± 0.65	0.55 ± 0.44	0.63 ± 0.52	0.57 ± 0.46
SRK/T	0.70 ± 0.64	0.51 ± 0.42	0.61 ± 0.50	0.53 ± 0.44
*Data in means ± standard deviations NB: Data for Holladay 1, Binkhorst II and SRK II have not been extracted as these formulas have been identified as no longer in use by the guideline committee				

Number of eyes (proportion) within various ranges of the target refraction

IOL formulas	Number of eyes (proportion) within ±0.50D of the target refraction			
	Axial length ≤22.0mm (32 eyes)	Axial length 22.0 to 25.0mm (422 eyes)	Axial length ≥25.0mm (31 eyes)	Any axial length (485 eyes)
Hoffer Q	15 (46.9%)	221 (52.4%)	15 (48.4%)	251 (51.8%)
SRK/T	14 (43.8%)	245 (58.1%)	15 (48.4%)	274 (56.5%)
NB: Data for Holladay 1, Binkhorst II and SRK II have not been extracted as these formulas have been identified as no longer in use by the guideline committee				
IOL formulas	**Number of eyes (proportion) within ±1.00D of the target refraction**			
	Axial length ≤22.0mm (32 eyes)	**Axial length 22.0 to 25.0mm (422 eyes)**	**Axial length ≥25.0mm (31 eyes)**	**Any axial length (485 eyes)**
Hoffer Q	26 (81.3%)	374 (88.6%)	24 (77.4%)	424 (87.4%)
SRK/T	24 (75.0%)	374 (88.6%)	23 (74.2%)	421 (86.8%)
NB: Data for Holladay 1, Binkhorst II and SRK II have not been extracted as these formulas have been identified as no longer in use by the guideline committee				
IOL formulas	**Number of eyes (proportion) within ±1.50D of the target refraction**			

Full citation	**Ozcura F, Aktas S, Sagdik HM, et al. Comparison of the biometric formulas used for applanation A-scan ultrasound biometry. Int Ophthalmol 2016; 36:707-12**

	Axial length ≤22.0mm (32 eyes)	Axial length 22.0 to 25.0mm (422 eyes)	Axial length ≥25.0mm (31 eyes)	Any axial length (485 eyes)
Hoffer Q	30 (93.8%)	406 (96.2%)	28 (90.3%)	464 (95.7%)
SRK/T	30 (93.8%)	409 (96.9%)	30 (96.8%)	469 (96.7%)
NB: Data for Holladay 1, Binkhorst II and SRK II have not been extracted as these formulas have been identified as no longer in use by the guideline committee				
	Number of eyes (proportion) within ±2.00D of the target refraction			
IOL formulas	**Axial length ≤22.0mm (32 eyes)**	**Axial length 22.0 to 25.0mm (422 eyes)**	**Axial length ≥25.0mm (31 eyes)**	**Any axial length (485 eyes)**
Hoffer Q	31 (96.9%)	415 (98.3%)	31 (100.0%)	477 (98.4%)
SRK/T	31 (96.9%)	420 (99.5%)	31 (100.0%)	482 (99.4%)
NB: Data for Holladay 1, Binkhorst II and SRK II have not been extracted as these formulas have been identified as no longer in use by the guideline committee				

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Full citation	**Percival SPB, Vyas AV, Setty SS, et al. The influence of implant design on accuracy of post-operative refraction. Eye 2002; 16:309-15**
Study details	**Country/ies where the study was carried out:** England **Study type:** Retrospective case series **Aim of the study:** To assess the degree of accuracy of post-operative refraction that may be achieved with modern techniques and a new lens of modern design, Centerflex lens (Rayner Intraocular Lenses Ltd style 570H) **Study dates:** Not reported **Source of funding:** Not reported
Participants	**Sample size** 500 eyes in 500 people **Diagnostic criteria** Not reported **Inclusion criteria** • Adults undergoing phacoemulsification cataract surgery with in-the-bag IOL placement **Exclusion criteria** • Children • Other intraocular lens implant besides the Centerflex • Surgical complications not permitting bag placement • Corneal pathology that made keratometry uncertain • Extreme dementia • NB: study provided a list of reasons for visual acuity less than 6/9 at 1 month for 57 eyes (36 age-related macular degeneration; 1 retinitis pigmentosa; 1 pre-operatively treated retinal detachment; 8 amblyopia; 1 optic atrophy; 3 central retinal vein occlusion; 1 interstitial keratitis; 5 macular oedema)

Full citation: **Percival SPB, Vyas AV, Setty SS, et al. The influence of implant design on accuracy of post-operative refraction. Eye 2002; 16:309-15**

Baseline characteristics

IOL model	Centerflex lens (500 eyes)
Age (years)*	76.4 (36 to 96)
Male:female	202:298
*Data in mean (range)	

Methods

Interventions and comparators: IOL formulas

- Retrospectively, IOL formulas were assessed for all axial lengths. The following formulas were examined:
  - Hoffer Q
  - SRK/T
  - Mean of Hoffer Q and SRK/T

Biometry and keratometry measurements

- Biometry (axial length, AL): contact A-scan ultrasound (BVI Axis model, Spectrum Ophthalmics) by 1 of 2 orthoptists specialising in the technique
- Keratometry: automated handheld keratometer (Nidek KM-500)
- Target refraction: between -0.1 and -0.8D, but varied according to individual circumstances
- Formula: IOL implant power was calculated using IOL formulas selected depending on axial length: Hoffer Q for AL<22mm; SRK/T for AL>24.5mm and a Mean of the Hoffer Q and SRK/T for AL between 22.0 and 24.5mm.
- IOL constant: A constant used for the Centerflex varied between 117.85 and 117.90 as the study progressed. The manufacturer's recommendation was 118.0. After an initial 20 cases not included in this study, the A constant was personalised to 117.90 with the recommended constant being 117.88.

Cataract surgery and IOL implantation: 4 surgeons (1 consultant: 282; 1 senior house officer: 6; 2 associate specialists: 212) performed phacoemulsification cataract surgery through a 3.0mm clear corneal wound and primary in-the-bag implantation of the Centerflex lens (Rayner Intraocular Lenses Ltd style 570H). Wounds were placed in the steepest meridian for any keratometric cylinder above 1.0D and were otherwise temporal. Paired limbal relaxing incisions were made at the start of surgery where appropriate. The curvilinear capsulorhexis varied between 5.0 and 6.0mm in diameter. Some capsule exhibited an anterior radial team at the end of surgery.

Details

Post-operative assessment: post-operative refraction assessed at 1 week and 1 month after surgery by the study authors using streak retinoscopy when appropriate and subjective fine tuning with trial lenses

Study outcomes:

- Number of eyes within various ranges of the target refractive outcome

Group comparisons: Fisher's exact test and chi-square test

Axial length subgroups: refractive outcomes were reported in 4 categories: <22mm, 22.0 to 24.5mm, 24.5 to 26.0mm, >26mm

Missing data handling/loss to follow up

No missing data reported.

Results

Number of eyes within various ranges of the target refractive outcome

Axial length group (mm)	Number of eyes refracted	Centerflex lens					
		Within ±0.50D			Within ±1.00D		
		Hoffer Q	SRK/T	Mean of Hoffer Q and SRK/T	Hoffer Q	SRK/T	Mean of Hoffer Q and SRK/T

Full citation	Percival SPB, Vyas AV, Setty SS, et al. The influence of implant design on accuracy of post-operative refraction. Eye 2002; 16:309-15							
	<22.00	54	35	25	36	48	43	45
	22.0-24.5	400	Not reported	Not reported	334	Not reported	Not reported	392
	24.5-26.0	26	20	20	21	26	26	26
	>26.0	20	12	16	15	17	19	17
	*Number of eyes (proportion); calculated from reported percentages							

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Full citation	Petermeier K, Gekeler F, Messias A, et al. Intraocular lens power calculation and optimised constants for highly myopic eyes. J Cataract Refract Surg 2009; 35:1575-81
Study details	**Country/ies where the study was carried out:** Germany **Study type:** Retrospective case series **Aim of the study:** To determine whether error in intraocular lens (IOL) calculation in highly myopic patients can be corrected using optimised constants and to evaluate the predictability of different IOL power calculation formulas using the new constants **Study dates:** 2003 to 2007 **Source of funding:** None reported
Participants	**Sample size** 50 eyes in 32 people **Diagnostic criteria** Not reported **Inclusion criteria** • People undergoing phacoemulsification cataract surgery with IOL implantation of Acrysof MA60MA at a single institution • Willing to participate in the study **Exclusion criteria** • Absent partial coherence interferometry biometry data • Pathology that may affect the accuracy of biometry calculations (e.g. retinal detachment surgery, corneal scars) • Severely reduced visual acuity (hand movements or worse) • Unable to participate in refraction because of glaucoma, amblyopia or myopic degeneration **Baseline characteristics**

IOL model	Acrysof MA60MA (50 eyes in 32 people)		
	Positive-dioptre IOL (30 eyes)	Negative-dioptre IOL (18 eyes)	Zero-dioptre IOL (2 eyes)
Age (years)*	57.14 ± 10.27 (35 to 77)		
Axial length (mm)*	31.15 ± 1.69	33.20 ± 2.25	31.37 and 35.34
K value (mm)*	7.56 ± 0.28	7.71 ± 0.33	7.60 and 8.34
Anterior chamber depth, ACD (mm)*	3.72 ± 0.11	3.59 ± 0.12	Not evaluated
*Data in means ± standard deviations (ranges) as appropriate			

Methods	**Intervention: ULIB IOL constant optimisation**

Full citation	**Petermeier K, Gekeler F, Messias A, et al. Intraocular lens power calculation and optimised constants for highly myopic eyes. J Cataract Refract Surg 2009; 35:1575-81**

- Post-operative refractive results were used to calculate individualised IOL constants for positive-dioptre and negative-dioptre ranges within the framework of the User Group for Laser Interference Biometry (ULIB) project to optimise constants for optical biometry. The need to treat plus and minus IOLs differently for optimised outcomes is based on lens geometry changes during the transition from plus to minus dioptres, with the lens' principal planes switching sides relative to the haptic plane. Because the positions of principal planes and IOL constants are directly linked, different constants are needed. No specific details on actual IOL constants were provided.
- The estimated post-operative refractive outcome was re-evaluated by inputting the new constants into the IOLMaster calculation algorithm with the pre-operative anatomic data. In 18 eyes, the ACD was not measured pre-operatively so the target refraction was calculated using the Haigis formula in 32 eyes (18 positive-dioptre IOL, 14 negative-dioptre IOL). For the other formulas, the target refraction was calculated for all eyes.

Comparator: Standard non-ULIB optimised IOL constants

- The constants for AcrySof MA60BM were used as there are no commonly accepted optimised constants for the AcrySof MA60MA. The AcrySof MA60BM has a similar optical design and same constant for ultrasound biometry but a different available range of dioptres.

AcrySof MA60MA IOL (based on data from AcrySof MA60BM)						
IOL formula constant						
Haigis			**Hoffer Q personalised anterior chamber depth, pACD**	**SRK/T A constant, AC**	**Holladay 1 surgeon factor, SF**	**SRK II A constant, SRKIIAC**
a0	**a1**	**a2**				
1.443	0.077	0.163	6.08	119.8	2.33	120.4

- To make allowances for the different geometries of positive and negative dioptre IOLs, 2 sets of optimised constants were derived for each IOL power sign. No further details were provided on how these were derived.

IOL formula constant	Positive-dioptre IOL	Negative-dioptre IOL
Haigis a0	5.74	-4.01
Hoffer Q personalised anterior chamber depth, pACD	16.15	-4.86
SRK/T A constant, AC	126.63	104.43
Holladay 1 surgeon factor, SF	10.46	-6.48
SRK II A constant, SRKIIAC	119.47	120.09

Biometry and keratometry measurements and formula

- Biometry (axial length, AL) and keratometry: IOLMaster (version 3.01.0294), undertaken by a specialist (lead study author)
- Formula: All pre-operative IOL calculations undertaken with the IOLMaster

Cataract surgery and IOL implantation: experienced surgeons performed standard phacoemulsification through a 3.0mm temporal clear corneal tunnel incision and a 5.0 to 5.5mm capsulorhexis with in-the-bag IOL implantation of the acrylic AcrySof MA60MA.

Details

Post-operative assessment: post-operative examination undertaken by the same specialist (lead study author) – no further details provided. However, elsewhere, states that the mean follow-up was 18.92 ± 13.33 months (range 3 to 47 months)

Study outcomes:

- Prediction error i.e. deviation from post-operative refraction from the target refraction (difference between post-operative spherical equivalent and calculated post-operative refraction)

Full citation	**Petermeier K, Gekeler F, Messias A, et al. Intraocular lens power calculation and optimised constants for highly myopic eyes. J Cataract Refract Surg 2009; 35:1575-81**
	• Number of eyes (proportion) achieving target refraction within various ranges Group comparisons: Paired t test **Missing data handling/loss to follow up** None reported.
Results	**Prediction errors**

IOL formulas	Prediction errors					
	Acrysof MA60MA (50 eyes in 32 people)					
	Positive-dioptre IOL (30 eyes)		Negative-dioptre IOL (18 eyes)		Zero-dioptre IOL (2 eyes)	
	ULIB optimised constants*	Non-ULIB optimised constants*	ULIB optimised constants*	Non-ULIB optimised constants*	ULIB optimised constants*	Non-ULIB optimised constants*
Haigis	0 ± 0.21	0.57 ± 0.18	0 ± 0.24	1.14 ± 0.21	0.79 and 1.37	0.79 and 1.37
Hoffer Q	0 ± 0.26	1.25 ± 0.14	0 ± 0.49	2.10 ± 0.19	1.65 and 2.18	1.65 and 2.18
SRK/T	0 ± 0.17	0.59 ± 0.15	0 ± 0.21	1.68 ± 0.19	1.02 and 1.49	1.02 and 1.49

*Data in means ± standard deviations
NB: Data for Holladay 1 and SRK II have not been extracted as these formulas have been identified as no longer in use by the guideline committee
NB: Data in Zero-dioptre IOL correctly extracted. Different results were reported for the 2 groups for the SRK II formula only

Number of eyes (proportion) achieving target refraction within various ranges

	Acrysof MA60MA (50 eyes in 32 people)		
	Haigis*	Hoffer Q*	SRK/T*
±1.00D	32 (84.4%)	50 (100%)	50 (100%)

NB: Data for Holladay 1 and SRK II have not been extracted as these formulas have been identified as no longer in use by the guideline committee
Unclear whether data refers to optimised/non-optimised IOL constants. No other comparative data provided
*Number of eyes (proportion)

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Full citation	**Srivannaboon S, Chirapapaisan C, Chirapapaisan N, et al. Accuracy of the Holladay 2 formula using IOLMaster parameters in the absence of lens thickness value. Graefes Arch Clin Exp Ophthalmol 2013; 251:2563-7**
Study details	**Country/ies where the study was carried out:** Thailand **Study type:** Prospective case series **Aim of the study:** To evaluate the results when using the Holladay 2 formula without the lens thickness value and compare the findings with those obtained using the Haigis and Hoffer Q formulas **Study dates:** June to December 2012 **Source of funding:** None reported
Participants	**Sample size** 163 eyes in 143 people **Diagnostic criteria**

<table>
<tr><td>Full citation</td><td>Srivannaboon S, Chirapapaisan C, Chirapapaisan N, et al. Accuracy of the Holladay 2 formula using IOLMaster parameters in the absence of lens thickness value. Graefes Arch Clin Exp Ophthalmol 2013; 251:2563-7</td></tr>
<tr><td></td><td>Not reported

Inclusion criteria
• People undergoing phacoemulsification cataract surgery with IOL placement

Exclusion criteria
• Other ocular diseases
• Previous ocular surgery

Baseline characteristics
<table>
<tr><th>IOL model</th><th>Hoya PY-60AD (163 eyes in 143 people)</th></tr>
<tr><td>Age (years)*</td><td>69.76 ± 10.08 (44.5 to 89.0)</td></tr>
<tr><td>Axial length (mm)*</td><td>23.34 ± 1.21 (18.77 to 29.26)</td></tr>
<tr><td>Keratometry (dioptres)*</td><td>44.37 ± 1.46 (41.14 to 48.75)</td></tr>
<tr><td>Anterior chamber depth (mm)*</td><td>2.97 ± 0.45 (2.11 to 4.45)</td></tr>
<tr><td>White-to-white (mm)*</td><td>12.17 ± 0.74 (10.60 to 14.40)</td></tr>
<tr><td>Lens thickness (mm)*</td><td>4.90 ± 0.49 (3.18 to 5.79)</td></tr>
<tr><td colspan="2">*Data in means ± standard deviations (ranges)</td></tr>
</table></td></tr>
<tr><td>Methods</td><td><u>Interventions and comparators</u>: IOL formulas
• Haigis
• Hoffer Q
• Holladay 2 with lens thickness reading
• Holladay 2 without lens thickness reading

Biometry and keratometry measurements
• <u>Biometry (axial length, AL; anterior chamber depth, ACD and horizontal white-to-white corneal diameter, WTW) and keratometry</u>: IOLMaster (version 5.4, Carl Zeiss Meditec)
• <u>Biometry (lens thickness measurement)</u>: A-scan ultrasound (Quantel Axis-II, Quantel Medical)
• <u>Biometry and keratometry</u>: All assessments were undertaken by an experienced technician
• <u>Formula</u>: IOL implant power was calculated using the IOLMaster (Haigis formula) and HIC.SOAP (Holladay 2 with lens thickness input, Holladay 2 without lens thickness input) and Hoffer Q formula. IOL power was chosen based on surgeon preferences.
• <u>IOL constant</u>: ULIB optimised IOL constant was used.

Cataract surgery and IOL implantation: 1 surgeon performed uneventful phacoemulsification cataract surgery using standard procedures with IOL implantation of PY-60AD (Hoya).

Details
<u>Post-operative assessment</u>: post-operative manifest refraction assessed at 3 months
<u>Study outcomes</u>:</td></tr>
</table>

Full citation	**Srivannaboon S, Chirapapaisan C, Chirapapaisan N, et al. Accuracy of the Holladay 2 formula using IOLMaster parameters in the absence of lens thickness value. Graefes Arch Clin Exp Ophthalmol 2013; 251:2563-7**

- Mean and median absolute errors (absolute difference between post-operative spherical equivalent refraction and the predicted post-operative spherical equivalent refraction)
- Proportion of eyes within various ranges of the predicted post-operative spherical equivalent refraction

Group comparisons: analysis of variance (ANOVA)
Axial length subgroups: refractive outcomes were reported in 3 categories: <22mm (short), 22.0 to 24.5mm (average), >24.5mm (long)
Sub-classification: in the average axial length group, eyes were categorised into K, ACD and WTW range

Missing data handling/loss to follow up
No missing data reported.

Results

Mean and median absolute errors

Axial length group (mm)	Axial length: mean (range)	Number of eyes	Hoya PY-60AD			
			Absolute errors in dioptres*			
			Haigis	Hoffer Q	Holladay 2 with lens thickness reading	Holladay 2 without lens thickness reading
<22.00	21.44 (18.77 to 21.94)	15	0.44 ± 0.40 (0.50)	0.42 ± 0.33 (0.34)	0.44 ± 0.31 (0.47)	0.45 ± 0.30 (0.46)
22.00-24.50	23.23	124	0.40 ± 0.33 (0.32)	0.39 ± 0.33 (0.31)	0.41 ± 0.31 (0.32)	0.42 ± 0.30 (0.31)
>24.50	25.5 (24.54 to 29.26)	24	0.39 ± 0.32 (0.34)	0.45 ± 0.35 (0.35)	0.38 ± 0.34 (0.27)	0.39 ± 0.33 (0.29)
All eyes	18.77 to 29.26	163	0.41 ± 0.33 (0.35)	0.40 ± 0.34 (0.32)	0.41 ± 0.31 (0.34)	0.41 ± 0.31 (0.32)
*Data in mean ± standard deviation (median)						

Number of eyes within various ranges of the predicted post-operative spherical equivalent refraction

Axial length group (mm)	Number of eyes	Hoya PY-60AD			
		Number of eyes within ±0.25D*			
		Haigis	Hoffer Q	Holladay 2 with lens thickness reading	Holladay 2 without lens thickness reading
<22.00	15	5	6	5	5
22.00-24.50	124	52	50	45	46
>24.50	24	12	10	14	12
Axial length group (mm)	Number of eyes	Number of eyes within ±0.50D*			
		Haigis	Hoffer Q	Holladay 2 with lens thickness reading	Holladay 2 without lens thickness reading
<22.00	15	6	9	7	7
22.00-24.50	124	82	84	87	89
>24.50	24	19	14	17	14
		Number of eyes within ±1.00D*			

Full citation	Srivannaboon S, Chirapapaisan C, Chirapapaisan N, et al. Accuracy of the Holladay 2 formula using IOLMaster parameters in the absence of lens thickness value. Graefes Arch Clin Exp Ophthalmol 2013; 251:2563-7

Axial length group (mm)	Number of eyes	Haigis	Hoffer Q	Holladay 2 with lens thickness reading	Holladay 2 without lens thickness reading
<22.00	15	11	13	13	13
22.00-24.50	124	114	118	118	118
>24.50	24	24	22	20	20
*Number of eyes (proportion); calculated from reported percentages					

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Full citation	Tsang CSL, Chong GSL, Yiu EPF, et al. Intraocular lens power calculation formulas in Chinese eyes with high axial myopia. J Cataract Refract Surg 2003; 29:1358-64
Study details	**Country/ies where the study was carried out:** Hong Kong **Study type:** Retrospective case series **Aim of the study:** To compare the accuracy of intraocular lens (IOL) power calculation formulas in Chinese eyes with high axial myopia **Study dates:** 2000 **Source of funding:** None reported
Participants	**Sample size** 40 eyes **Diagnostic criteria** Not reported **Inclusion criteria** • People with axial length at least 25.0mm undergoing uneventful cataract surgery (phacoemulsification or extracapsular cataract extraction) with posterior chamber IOL implantation at 1 institution NB: Only data on phacoemulsification extracted **Exclusion criteria** • Ocular pathology (marked pre-existing astigmatism >3.0D, corneal scar, keratoconus, obvious posterior staphyloma detected during pre-operative fundal examination) • Operative procedures (combined cataract surgery with astigmatic keratectomy) • Complications significantly affecting refractive status (loss of vitreous with an IOL implanted in the sulcus or anterior chamber, high wound-induced astigmatism) • Cases with missing post-operative refraction data **Baseline characteristics for entire sample (40 had phacoemulsification, 48 had extracapsular cataract extraction)**

IOL models	Foldable (40 eyes): Rigid (48 eyes); Plus power (75 eyes): Minus power (13 eyes)
Age (years)*	(29 to 80)
Male:female^	42:46
Axial length (mm)*	28.32 (25.03 to 36.94)
Keratometry (dioptres)*	43.70 (36.44 to 49.12)
*Data in means ± standard deviations (ranges) as appropriate	

Full citation	**Tsang CSL, Chong GSL, Yiu EPF, et al. Intraocular lens power calculation formulas in Chinese eyes with high axial myopia. J Cataract Refract Surg 2003; 29:1358-64**
	^Number of eyes
Methods	**Interventions and comparators: IOL formulas** • Hoffer Q • SRK/T • Holladay 1 • SRK II NB: Data for Holladay 1 and SRK II have not been extracted as these formulas have been identified as no longer in use by the guideline committee **Biometry and keratometry measurements** • Biometry (axial length, AL): A-scan contact ultrasound (ultrasound velocity 1550m/s) using the Echoscan US 1800 • Keratometry: measurements performed • Formula: The implanted IOL power was used to calculate the predicted post-operative refractive error by 4 IOL power calculation formulas: Hoffer Q, SRK/T, Holladay 1, SRK II, with the help of the Echoscan US 1800 machine • IOL constant: not reported. **Cataract surgery and IOL implantation:** uneventful cataract surgery (phacoemulsification or extracapsular cataract extraction) with posterior chamber IOL implantation. **Details** Post-operative assessment: spherical equivalent measured by optometrists using an autorefractor about 3 months after surgery Study outcomes: • Mean error (difference between the actual and predicted post-operative refractive errors) Group comparisons: Student t test Axial length subgroups: refractive outcomes were reported in 2 categories: 25-28mm, >28mm **Missing data handling/loss to follow up** No missing data reported.
Results	**Mean errors**

		Mean errors in dioptres	
		Hoffer Q	**SRK/T**
All eyes	40	0.62	0.98
NB: Data for Holladay 1 and SRK II have not been extracted as these formulas have been identified as no longer in use by the guideline committee			

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Full citation	**Wang JK, Chang SW. Optical biometry intraocular lens power calculation using different formulas in patients with different axial lengths. Int J Ophthalmol 2013; 6:150-4**
Study details	**Country/ies where the study was carried out:** Taiwan **Study type:** Retrospective case series **Aim of the study:** To investigate the predictability of intraocular lens (IOL) power calculation using the IOLMaster and different IOL power calculation formulas in eyes with various axial length

<table>
<tr><td>Full citation</td><td>Wang JK, Chang SW. Optical biometry intraocular lens power calculation using different formulas in patients with different axial lengths. Int J Ophthalmol 2013; 6:150-4</td></tr>
<tr><td></td><td>Study dates: February 2007 to January 2009
Source of funding: Far Eastern Memorial Hospital (FEMH-970HHC-008), Taiwan</td></tr>
<tr><td>Participants</td><td>Sample size
200 right eyes in 200 people

Diagnostic criteria
Not reported

Inclusion criteria
• People undergoing uneventful phacoemulsification cataract surgery with in-the-bag IOL implantation of 1-piece soft hydrophobic acrylic posterior chamber lens (Acrysof SA60AT) at 1 institution

Exclusion criteria
• Ocular pathology
• Operative complications
• Cases with missing data

Baseline characteristics
<table>
<tr><th>IOL models</th><th>Acrysof SA60AT (200 eyes)</th></tr>
<tr><td>Male:female^</td><td>109:91</td></tr>
<tr><td>Axial length (mm)*</td><td>24.75 ± 2.71 (20.16 to 31.16)</td></tr>
<tr><td>Keratometry (dioptres)*</td><td>43.48 ± 1.66</td></tr>
<tr><td colspan="2">*Data in means ± standard deviations (ranges) as appropriate
^Number of eyes</td></tr>
</table></td></tr>
<tr><td>Methods</td><td><u>Interventions and comparators</u>: IOL formulas
• Haigis
• Hoffer Q
• SRK/T
• Holladay 1 NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Biometry and keratometry measurements
• <u>Biometry (axial length, AL) and keratometry</u>: undertaken by experienced technicians using the IOLMaster (Carl Zeiss, Germany). Only the signal-to-noise ratio value of more than 2.1 was recorded
• <u>Formula</u>: The implanted IOL power was used to calculate the predicted post-operative spherical equivalent by various formulas: Haigis, Hoffer Q, SRK/T and Holladay 1. Pre-operative biometry data and the Haigis formula were used to calculate the power of the implanted IOL and predicted post-operative spherical equivalent.
• <u>IOL constant</u>: Optimisation was conducted according to Nemeth 2012 (Graefes Arch Clin Exp Ophthalmol 250:132-5). The mean numeric error of each formula was adjusted to zero by modifying the IOL constant using the Excel Query/What IF function.</td></tr>
</table>

Full citation	**Wang JK, Chang SW. Optical biometry intraocular lens power calculation using different formulas in patients with different axial lengths. Int J Ophthalmol 2013; 6:150-4**
	Cataract surgery and IOL implantation: 1 surgeon performed uneventful phacoemulsification cataract surgery with in-the-bag IOL implantation of 1-piece soft hydrophobic acrylic posterior chamber lens (Acrysof SA60AT). **Details** Post-operative assessment: Post-operative spherical equivalence was recorded at 3 months after surgery using an autorefractor (Topcon AR, Tokyo) Study outcomes: • Median absolute error (absolute values of the difference between the actual and predicted post-operative spherical equivalent) Group comparisons: Wilcoxon signed rank test Axial length subgroups: refractive outcomes were reported in 3 categories: <22mm, 22-26mm, >26mm **Missing data handling/loss to follow up** No missing data reported.
Results	**Median and mean absolute errors**

Axial length group (mm)	Number of eyes	Absolute errors in dioptres*		
		Haigis	Hoffer Q	SRK/T
<22	33	0.66 ± 0.68 (0.57)	0.67 ± 0.59 (0.58)	0.78 ± 0.66 (0.69)
22-26	92	0.52 ± 0.46 (0.40)	0.57 ± 0.46 (0.45)	0.56 ± 0.46 (0.43)
>26	75	0.44 ± 0.49 (0.39)	0.52 ± 0.41 (0.48)	0.45 ± 0.10 (0.41)
All eyes	200	0.49 ± 0.46 (0.39)	0.55 ± 0.46 (0.45)	0.53 ± 0.46 (0.43)

*Data in means ± standard deviations (medians)
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

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Full citation	**Wang L, Shirayama M, Ma XJ, et al. Optimizing intraocular lens power calculations in eyes with axial lengths above 25.0mm. J Cataract Refract Surg 2011; 37:2018-27**
Study details	**Country/ies where the study was carried out:** USA **Study type:** Retrospective case series **Aim of the study:** To determine the accuracy of refractive prediction of 4 intraocular lens (IOL) calculation formulas (Haigis, Hoffer Q, SRK/T and Holladay 1) in eyes with an axial length greater than 25.0mm and to propose a method of optimising axial lengths to improve prediction accuracy **Study dates:** November 2005 to April 2008 **Source of funding:** In part by an unrestricted grant from Research to Prevent Blindness, New York, USA
Participants	**Sample size** 106 eyes in 78 people **Diagnostic criteria** Not reported **Inclusion criteria** • People with axial lengths greater than 25.0mm undergoing phacoemulsification cataract surgery with IOL implantation of Acrysof SA60AT, SN60AT, SN60T, SN60WF, MA60MA or MA60AC by the same surgeon in 1 institution • Biometric measurements using IOLMaster (Carl Zeiss Meditec Inc)

Full citation	**Wang L, Shirayama M, Ma XJ, et al. Optimizing intraocular lens power calculations in eyes with axial lengths above 25.0mm. J Cataract Refract Surg 2011; 37:2018-27**

- No previous ocular surgery
- No intraoperative or post-operative complications
- Post-operative corrected distance visual acuity of 20/30 or better

Exclusion criteria

- None reported

Baseline characteristics

	Dataset from October 2002 to October 2005 used to develop and validate formulas (n=69)		Dataset from November 2005 to April 2008 to validate formulas (n=78)		
IOL models	**SA60AT/SN60AT**	**MA60MA**	**MA60MA/MA60AC**	**SA60AT/SN60AT/SN60T**	**SN60WF**
Number of eyes	80	14	23	28	55
Age (years)*	62 ± 11 (34 to 88)		65 ± 10 (41 to 85)		
Axial length (mm)*	26.66 ± 0.92 (25.05 to 28.66)	30.41 ± 1.58 (27.14 to 32.98)	27.93 ± 1.00 (26.41 to 30.78)	26.79 ± 1.14 (25.03 to 29.35)	26.50 ± 0.97 (25.01 to 29.56)

*Data in means ± standard deviations (ranges)
NB: Data from second institution located in Germany not extracted as participants had refractive lens exchange. In addition, relevant comparative data for the cohort from October 2002 to October 2005 were not provided and therefore, this group has not been used.

Methods

Intervention1: IOL constant optimisation

- IOL constants for each formula were retrospectively optimised by obtaining a mean numerical error of zero using the IOLMaster (Hoffer Q, SRK/T and Holladay 1) or multiple regression analysis (Haigis). This was done to avoid the offset errors due to systematic errors in biometry, surgical technique and/or formulas.

Comparator1: Standard manufacturer IOL constants

No data provided for this comparison: IOL constant optimisation vs standard manufacturer IOL constants

Intervention2: Axial length optimisation

- For each eye with each IOL formula, the optimised axial length using the manufacturer's IOL constant to produce a refractive prediction error of zero was back-calculated. Manufacturer's IOL constants were used as they serve as standard IOL constants for surgeons.

Comparator2: IOLMaster axial length

Biometry and keratometry measurements and formula

- Biometry (axial length, AL) and keratometry: IOLMaster (Carl Zeiss Meditech Inc)
- Formula: Implanted IOL power based on Holladay 1 formula at USA centre

Cataract surgery and IOL implantation: 1 surgeon performed phacoemulsification cataract surgery through a 3.0 to 3.2mm temporal clear corneal tunnel incision with IOL implantation of Acrysof SA60AT, SN60AT, SN60T, SN60WF, MA60MA or MA60AC

Details

Full citation	**Wang L, Shirayama M, Ma XJ, et al. Optimizing intraocular lens power calculations in eyes with axial lengths above 25.0mm. J Cataract Refract Surg 2011; 37:2018-27**
	Post-operative assessment: post-operative refractive outcomes assessed at least 3 weeks after surgery Study outcomes: • Prediction error (difference between actual post-operative refractive outcome and predicted refraction). A positive refractive prediction error indicates a hyperopic refractive outcome. • Number of eyes (proportion) with a hyperopic refractive outcome (positive prediction error) Group comparisons: Student t test **Missing data handling/loss to follow up** None reported.
Results	**Comparison 2: Optimised axial length vs. IOLMaster axial length (standard manufacturers' IOL constants used in both groups)**

Prediction errors

IOL formulas	Mean prediction errors in dioptres*					
	MA60MA/MA60AC (23 eyes)		SA60AT/SN60AT/SN60T (28 eyes)		SN60WF (55 eyes)	
	Optimised AL	IOLMaster AL	Optimised AL	IOLMaster AL	Optimised AL	IOLMaster AL
Haigis	-0.05 ± 0.40 (-0.63 to 0.99)	0.83 ± 0.39 (0.17 to 1.79)	-0.15 ± 0.71 (-1.09 to 2.40)	0.86 ± 0.67 (-0.36 to 3.04)	-0.05 ± 0.52 (-1.19 to 1.17)	0.62 ± 0.47 (-0.55 to 1.91)
Hoffer Q	-0.03 ± 0.45 (-0.73 to 1.15)	1.08 ± 0.47 (0.06 to 2.06)	0.15 ± 0.77 (-1.10 to 2.25)	0.88 ± 0.70 (-0.37 to 2.78)	-0.08 ± 0.60 (-1.03 to 1.19)	0.55 ± 0.48 (-0.43 to 1.94)
SRK/T	-0.31 ± 0.38 (-1.06 to 0.30)	0.42 ± 0.39 (-0.61 to 1.27)	-0.03 ± 0.67 (-1.20 to 1.61)	0.35 ± 0.61 (-0.82 to 1.79)	-0.08 ± 0.50 (-1.18 to 0.99)	0.22 ± 0.46 (-0.91 to 1.37)

*Data in means ± standard deviations (ranges)
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Number of eyes (proportion) with a hyperopic refractive outcome (positive prediction error)

IOL formulas	Number of eyes (proportion) with a hyperopic refractive outcome*					
	MA60MA/MA60AC (23 eyes)		SA60AT/SN60AT/SN60T (28 eyes)		SN60WF (55 eyes)	
	Optimised AL	IOLMaster AL	Optimised AL	IOLMaster AL	Optimised AL	IOLMaster AL
Haigis	9 (39%)	23 (100%)	15 (54%)	27 (96%)	23 (42%)	52 (95%)
Hoffer Q	11 (48%)	23 (100%)	14 (50%)	26 (93%)	22 (40%)	50 (91%)
SRK/T	6 (26%)	20 (87%)	11 (39%)	18 (64%)	26 (47%)	37 (67%)

*Number of eyes (proportion); calculated from reported percentages
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

63.2.2 Eyes with a history of myopic LASIK/LASEK/PRK

Full citation	**Fam HB, Lim KL. A comparative analysis of intraocular lens power calculation methods after myopic excimer laser surgery. J Refract Surg 2008 24:355-60**
Study details	**Country/ies where the study was carried out:** Not reported; authors from Singapore and Malaysia **Study type:** Retrospective case series

<table>
<tr><td>Full citation</td><td>Fam HB, Lim KL. A comparative analysis of intraocular lens power calculation methods after myopic excimer laser surgery. J Refract Surg 2008 24:355-60</td></tr>
<tr><td></td><td>Aim of the study: To compare the accuracy and predictability of different intraocular lens (IOL) power calculation methods in eyes after myopic excimer laser surgery
Study dates: Not reported
Source of funding: None reported</td></tr>
<tr><td>Participants</td><td>Sample size
37 eyes in 37 people

Diagnostic criteria
Not reported

Inclusion criteria
• People with a history of myopic excimer laser surgery undergoing phacoemulsification cataract surgery with IOL implantation at 6 different clinics

Baseline characteristics
<table>
<tr><td>Keratometry before refractive surgery (dioptres)*</td><td>43.89 ± 1.14 (41.50 to 36.19)</td></tr>
<tr><td>Amount of refractive error corrected during refractive surgery (dioptres)*</td><td>-6.92 ± 3.12 (-2.00 to -13.00)</td></tr>
<tr><td>Laser-assisted in situ keratomileusis (LASIK)/photorefractive keratectomy (PRK)^</td><td>31/6</td></tr>
<tr><td>Axial length before phacoemulsification cataract surgery (mm)*</td><td>26.63 ± 1.42 (23.99 to 30.33)</td></tr>
<tr><td>Resultant manifest refraction spherical equivalent after phacoemulsification cataract surgery (dioptres)*</td><td>-0.05 ± 0.89 (-1.78 to -1.88)</td></tr>
<tr><td>Median (range) best-spectacle corrected Snellen visual acuity after phacoemulsification surgery</td><td>6/7.5 (6/5 to 6/9)</td></tr>
<tr><td colspan="2">*Data in means ± standard deviations (ranges)
^Number of people</td></tr>
</table></td></tr>
<tr><td>Methods</td><td><u>Interventions and comparators</u>: IOL formulas/methods using historical data were programmed into Microsoft Excel spreadsheet (with exception of Holladay 2 DK). The resultant refractive errors using the following methods/formulas were back-calculated.
• Historical data methods
○ IOL power was calculated using Aramberri Double-K (DK) method, where the pre-operative refractive surgery keratometry (K_{PRE}) is used to calculate the effective lens position, and the post-operative refractive surgery keratometry (determined using the clinical history method, K_{CH}) is used to calculate the vergence formula that derives the IOL power. The Double-K method was incorporated into the following formulas to determine IOL power:
- <u>Hoffer Q DK</u>: the K_{PRE} was used in the tangent to calculate the predicted anterior chamber depth. The K_{CH} was used in the vergence formula to derive the IOL power.
- <u>Holladay 1 DK</u>: the K_{PRE} was used to predict the anterior chamber depth. The K_{CH} was used in the vergence formula to derive the IOL power. NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee.
- <u>Holladay 2 DK</u>: the K_{PRE} refractive change from LASIK or PRK and anterior chamber depth (available for 6 eyes) was entered into the Holladay IOL Consultant software (Holladay LASIK Institute, Bellaire, Tex).
- <u>SRK-T DK</u>: the K_{PRE} was used to calculate the computed corneal width and estimated lens position while the K_{CH} was used in the vergence formula to derive the IOL power.
○ <u>SRK-T FM</u>: the Feiz-Mannis (FM) nomogram is a theoretical formula based on the assumption that a change of 1.0D of IOL power will result in a chance of 0.67D of refraction at the spectacle plane. Because LASIK or PRK changes the refractive error by a known amount, the relative change in IOL power can be calculated. The Feiz-Mannis nomogram is used to modify the IOL power calculated using SRK-T.</td></tr>
</table>

Full citation	**Fam HB, Lim KL. A comparative analysis of intraocular lens power calculation methods after myopic excimer laser surgery. J Refract Surg 2008 24:355-60**

- SRK-T LS: the Ladas-Stark or Corneal Bypass (Walter) method. The IOL power for each eye was calculated using the K_{PRE} with the SRK-T formula as if no refractive surgery had been performed. However, the change in spherical equivalent refraction from LASIK or PRK was used as the targeted refraction.
- SRK-T: the standard SRK-T formula was used without any Double-K modification. The K_{CH} was used to determine both the effective lens position and the vergence power of the IOL.

NB: The clinical history method uses pre-refractive surgery keratometry and refractive surgery-induced manifest refraction change to correct bias in conventional keratometry. It subtracts refractive surgery-induced refractive change from the pre-refractive surgery keratometry. Optical vergence model of the eye uses the paraxial approximation of Gaussian optics.

Biometry and keratometry measurements

- Biometry (axial length, AL): not reported.
- Keratometry following LASIK or PRK calculated using the clinical history method , K_{CH}: the refractive change induced by LASIK or PRK (calculated at the corneal plane) is subtracted from the pre-operative LASIK or PRK keratometry (K_{PRE})
- Formula: Using Aramberri technique and SRK-T formula, the post-operative phacoemulsification refraction, implanted IOL power and A-constant, the IOL power that would have resulted in emmetropia was back-calculated.
- IOL constants: A-constant of the implanted IOL.

Cataract surgery and IOL implantation: phacoemulsification cataract surgery with IOL implantation performed at 6 different clinics.

Details

Post-operative assessment: refractive outcome at a minimum of 1 month after phacoemulsification cataract surgery.
Study outcomes:

- Prediction error and mean absolute error
- Proportion of eyes within various ranges of the predicted error

Group comparisons: repeated measures analysis of variance (ANOVA) and Dunnett post-hoc test
Linear regression analysis was undertaken to determine whether any relationship existed between prediction error with each method and the amount of LASIK or PRK correction and axial length of the eye

Missing data handling/loss to follow up

Not relevant.

Results

Mean errors and mean absolute errors (n=37 eyes)

Formulas/methods using historical data	Prediction error*	Mean absolute error*
Hoffer Q DK	0.19 ± 0.90 (-2.11 to 2.08)	0.75 ± 0.52 (0.04 to 2.11)
Holladay 2 DK	-0.04 ± 0.98 (-2.60 to 1.77)	0.75 ± 0.62 (0.09 to 2.60)
SRK-T DK	-0.19 ± 0.95 (-2.54 to 1.54)	0.76 ± 0.60 (0.02 to 2.54)
SRK-T FM	-0.51 ± 1.15 (-3.00 to 1.27)	0.93 ± 0.83 (0.03 to 3.00)
SRK-T LS	-0.01 ± 1.02 (-2.67 to 2.24)	0.80 ± 0.63 (0.01 to 2.67)
SRK-T	1.15 ± 0.99 (-1.51 to 3.41)	1.32 ± 0.73 (0 to 3.41)

*Data in means ± standard deviations (ranges) in dioptres
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Full citation	Fam HB, Lim KL. A comparative analysis of intraocular lens power calculation methods after myopic excimer laser surgery. J Refract Surg 2008 24:355-60

Number of eyes (proportion) within various ranges of the prediction error (n=37 eyes)

Formulas/methods using historical data	Prediction error*		
	Within ±0.5D	Within ±1.0D	Within ±2.0D
Hoffer Q DK	13 (35.1%)	28 (75.7%)	35 (94.6%)
Holladay 2 DK	17 (45.9%)	30 (81.1%)	34 (91.9%)
SRK-T DK	19 (51.4%)	25 (67.6%)	35 (94.6%)
SRK-T FM	15 (40.5%)	23 (62.2%)	32 (86.5%)
SRK-T LS	17 (45.9%)	23 (62.2%)	35 (94.6%)
SRK-T	5 (13.5%)	11 (29.7%)	33 (89.2%)

*Number of eyes (proportion)
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Correlation between refractive prediction error and refractive change induced by LASIK or PRK and axial length

Formulas/methods using historical data	R value			
	Prediction error vs LASIK/PRK change	P value*	Prediction error vs Axial length	P value^
Hoffer Q DK	0.34	<0.05	0.17	>0.05
Holladay 2 DK	0.39	<0.05	0.25	>0.05
SRK-T DK	0.41	>0.05	0.22	>0.05
SRK-T FM	0.65	<0.05	0.38	<0.05
SRK-T LS	0.15	>0.05	0.03	>0.05
SRK-T	0.38	<0.05	0.36	<0.05

*<0.05 indicates that prediction error is significantly correlated to LASIK/PRK change
^<0.05 indicates that prediction error is significantly correlated to axial length
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

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Full citation	Huang D, Tang M, Wang L, et al. Optical coherence tomography-based corneal power measurement and intraocular lens power calculation following laser vision correction (an American Ophthalmological Society thesis). Trans Am Ophthalmol Soc 2013 111:34-45
Study details	**Country/ies where the study was carried out:** USA **Study type:** Prospective case series (NCT00532051) **Aim of the study:** To use optical coherence tomography (OCT) to measure corneal power and improve the selection of intraocular lens (IOL) power in cataract surgeries after myopic laser vision correction **Study dates:** Not reported **Source of funding:** National Institutes of Health, Maryland (grant R01EY018184); research grant from Optovue Inc, California; unrestricted grant to Casey Eye Institute from Research to Prevent Blindness, New York. Authors have significant financial interests in Optovue Inc, a company that may have commercial interest in the results; main author receives research grant, patent royalty, honoraria and stock options from Optovue Inc and patent royalty related to OCT technology licensed to Carl Zeiss Meditech; 2 other authors receive research grants from Optovue Inc, Ziemer Ophthalmic Systems AG; 1 other author is a consultant for AMO Inc and holds stock options in OptiMedica Inc; 4 authors have no financial disclosure

Full citation	**Huang D, Tang M, Wang L, et al. Optical coherence tomography-based corneal power measurement and intraocular lens power calculation following laser vision correction (an American Ophthalmological Society thesis). Trans Am Ophthalmol Soc 2013 111:34-45**
Participants	**Sample size** 46 eyes in 46 people **Diagnostic criteria** Not reported **Inclusion criteria** • People with a history of myopic laser vision correction (laser-assisted in situ keratomileusis [LASIK], laser subepithelial keratomileusis [LASEK], photorefractive keratectomy [PRK]) undergoing uneventful phacoemulsification cataract surgery with monofocal foldable acrylic IOL implantation (Alcon Acrysof SN60AT, SA60AT, SN60WF, SN6AT3/4; AMO ZA9003, ZCB00) at 2 academic eye centres • No other vision-limiting eye disease other than cataract **Baseline characteristics**

Age (years)*	61.5 ± 8.0 (42 to 79)
Known/unknown magnitude of previous myopic correction^	5/41
Magnitude of previous myopic correction in 5 people (dioptres)*	-4.66 ± 1.33
Keratometry after refractive surgery: anterior corneal power[a] (dioptres)*	45.52 ± 3.18
Keratometry after refractive surgery: net corneal power (dioptres)*	40.86 ± 2.85
*Data in means ± standard deviations (ranges) ^Number of people [a]Keratometry after refractive surgery: anterior corneal power obtained by multiplying IOLMaster auto-K output by 0.376/0.3375 (recovering the anterior curvature and then computing the power using corneal index instead of keratometric index)	

Methods	**Interventions and comparators: IOL formulas using no prior data (also known as no-history or regression-based methods). The following formulas estimate the corneal power from standard keratometry using a conversion formula obtained by regression analysis of refractive outcome of cataract surgery after laser vision correction.**
	• **No historical data methods**
	  ○ Haigis-L: used with the American Society of Cataract and Refractive Surgery (ASCRS) IOL calculator (http://iol.ascrs.org). Personalised Haigis constants were derived from the personalised ACD-constant using the formulas provided by Haigis.
	  ○ Shammas-PL: a spreadsheet was created to calculate the results from the formula.
	  ○ Optical coherence tomography-based formula NB: As agreed with the committee, OCT data have not been extracted as not routinely used in the NHS. OCT measures directly anterior and posterior corneal power
	
	Biometry and keratometry measurements
	• Biometry (axial length [AL], anterior chamber depth [ACD]) and keratometry: partial coherence interferometer, IOLMaster (Carl Zeiss Meditec, Inc)
	• Corneal thickness and power: Fourier-domain optical coherence tomography NB: As agreed with the committee, OCT data have not been extracted as not routinely used in the NHS
	• Formula: as described above. Not clear which formula was used to select IOL implant power
	• IOL constants: as described above

Full citation	**Huang D, Tang M, Wang L, et al. Optical coherence tomography-based corneal power measurement and intraocular lens power calculation following laser vision correction (an American Ophthalmological Society thesis). Trans Am Ophthalmol Soc 2013 111:34-45**

Cataract surgery and IOL implantation: uneventful phacoemulsification cataract surgery with IOL implantation performed at 2 eye centres by 5 surgeons using clear corneal incisions.

Details

Post-operative assessment: manifest refraction measured at 1 month post-operative visit (at least 30 days after phacoemulsification cataract surgery).

Study outcomes:

- Prediction error (predicted manifest refraction spherical equivalent [MRSE] minus actual post-cataract surgery MRSE) and mean absolute error (absolute value of prediction error)
- Adjusted mean absolute error (absolute value of prediction error minus mean prediction error)
- Proportion of eyes within various ranges of the predicted refraction

Group comparisons: Wilcoxon signed-rank test for paired samples; Pearson's chi-square test

Power calculation: sample size calculation based on comparison between OCT-based post-refractive surgery IOL calculation and Haigis-L formula.

Missing data handling/loss to follow up

None reported

Results

Mean errors and mean absolute errors (n=46 eyes)

Formulas with no historical data	Prediction error*	Mean absolute error*
Haigis-L	0.14 ± 0.83 (-1.65 to 1.82)	0.67
Shammas-PL	0.24 ± 0.82 (-2.30 to 1.76)	0.67
*Data in means ± standard deviations (ranges) in dioptres NB: As agreed with the committee, OCT data have not been extracted as not routinely used in the NHS		

Number of eyes (proportion) within various ranges of the prediction error (n=46 eyes)

Formulas with no historical data	Prediction error*	
	Within ±0.5D	Within ±1.0D
Haigis-L	21 (46%)	36 (78%)
Shammas-PL	21 (46%)	39 (85%)
*Number of eyes (proportion) NB: As agreed with the committee, OCT data have not been extracted as not routinely used in the NHS		

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Full citation	**Kim EC, Cho K, Hwang HS, et al. Intraocular lens prediction accuracy after corneal refractive surgery using K values from 3 devices. J Cataract Refract Surg 2013 39:1640-6**
Study details	**Country/ies where the study was carried out:** South Korea **Study type:** Retrospective case series **Aim of the study:** To compare methods of intraocular lens (IOL) power calculation using different values of keratometry and topography in people with a history of myopic refractive surgery undergoing phacoemulsification **Study dates:** 2008 to 2010 **Source of funding:** not reported

Full citation	**Kim EC, Cho K, Hwang HS, et al. Intraocular lens prediction accuracy after corneal refractive surgery using K values from 3 devices. J Cataract Refract Surg 2013 39:1640-6**
Participants	**Sample size** 47 eyes in 47 people **Diagnostic criteria** Not reported **Inclusion criteria** • People with a history of laser-assisted in situ keratomileusis (LASIK) or photorefractive keratectomy (PRK) for myopia and subsequent phacoemulsification cataract surgery • People that were examined with all methods (Orbscan II, Pentacam and IOLMaster) **Exclusion criteria** • No manifest refraction after cataract surgery • Missing biometry data such as axial length or keratometry **Baseline characteristics**

Age (years)*	52.4 ± 9.5 (41 to 65)
Male/female^	22 (46.8%) / 25 (53.2%)
Duration from refractive surgery to cataract surgery (years)*	8.67 ± 5.45 (1 to 16)
Spherical equivalent before cataract surgery (dioptres)*	-5.37 ± 2.58 (-9.25 to -1.75)
Mean corrected distance visual acuity	20/100
Axial length (mm)*	27.75 ± 2.19
*Data in means ± standard deviations (ranges) ^Number of people (proportion)	

Methods	**Interventions and comparators: IOL formulas**
	• **No historical data methods**
	  ○ Haigis-L: calculated online using study access provided by Haigis
	  ○ SRK/T: using the PCI system's K value was used to calculate IOL power
	
	Biometry and keratometry measurements
	Keratometry: Partial coherence interferometry (PCI), n=47 (assumed)
	• IOLMaster version 5.0.
	• Keratometry (K; corneal radii) measurements using IOLMaster.
	• Biometry measurements (axial length and anterior chamber depth): immersion ultrasound.
	• IOL formula: SRK/T formula using the PCI system's K value was used to calculate IOL power. In addition, the Haigis-L formula was calculated online using study access provided by Haigis
	• IOL constant optimisation: not reported.
	
	Corneal topography A: Pentacam Scheimpflug, n=47 (assumed)

Full citation	**Kim EC, Cho K, Hwang HS, et al. Intraocular lens prediction accuracy after corneal refractive surgery using K values from 3 devices. J Cataract Refract Surg 2013 39:1640-6**

- Pentacam version 1.17r24.
- Keratometric measurements for cataract surgery were performed 3 times and a central value on the Scheimpflug system's true net corneal power (TNP) map was selected after the centration and alignment of the cornea were confirmed. The exact central value in the TNP map and equivalent K of the Scheimpflug system were selected as the K value and used in the IOL power calculations. The TNP data were preferentially compared with the keratometry data.
- Biometry measurements (axial length): partial coherence interferometry.
- IOL formula: SRK/T formula.
- IOL constant optimisation: not reported.

Corneal topography B: Orbscan II, n=47 (assumed)

- Orbscan II version 3.12.
- This study reports the analysis of the achieved refraction and its deviation from the calculated value using the corneal power measured with the Orbscan II after previous corneal refractive surgery. Corneal power was assessed using: simulated K, 2.0mm diameter central zone of the total mean power (TMP 2.0mm) map and 4.0mm diameter central zone of total optical power (TOP 4.0) maps centred on the pupil.
- Biometry measurements (axial length): partial coherence interferometry.
- IOL formula: SRK/T formula.
- IOL constant optimisation: not reported.

NB: data from corneal topography A and B were not used in the analysis as different keratometry techniques would confound results comparing SRK/T and Haigis-L

Cataract surgery and IOL implantation: 1 experienced surgeon performed uneventful standard phacoemulsification cataract surgery with IOL implantation (Acrysoft SN60AT, Alcon Laboratories Inc) in the capsular bag in all patients.

Details

Post-operative assessment: The target refraction was plano in 37 eyes and -3.00 dioptres in 10 eyes. The manifest refraction was measured 2 months after surgery. Data were collected from primary sources in patient charts.

Study outcomes:

- Mean prediction error (difference between post-operative refraction and expected refraction)
- Absolute median prediction error
- Number of eyes achieving absolute prediction errors within various ranges

Group comparisons: one-way analysis of variance (ANOVA) between prediction errors according to each K value and corneal radius and paired t-tests between estimated refraction and post-operative refraction

Results

Prediction errors and absolute prediction errors

	Keratometry (Haigis-L formula with no historical data), n=47	Keratometry (SRK-T formula with no historical data), n=47	Corneal topography A (Scheimpflug and SRK-T formula)), n=47		Corneal topography A (Orbscan II and SRK-T formula), n=47		
			True net corneal power	Equivalent K	Simulated K	2.0mm diameter central zone of	4.0mm diameter central zone of

Full citation	Kim EC, Cho K, Hwang HS, et al. Intraocular lens prediction accuracy after corneal refractive surgery using K values from 3 devices. J Cataract Refract Surg 2013 39:1640-6

						the total mean power	total optical power
Prediction error*	0.03 ± 1.06 (-1.8 to 1.315)	1.68 ± 1.34 (-0.665 to 4.265)	0.34 ± 1.75 (-1.735 to 3.905)	1.69 ± 1.41 (-1.075 to 5.055)	-0.95 ± 1.61 (-4.01 to 3.28)	0.16 ± 1.90 (-5.065 to 4.515)	0.37 ± 2.18 (-5.135 to 4.715)
Median absolute prediction error^	0.81 ± 0.52 (0.085 to 1.815)	1.73 ± 1.20 (0.02 to 4.265)	1.13 ± 0.95 (0.26 to 3.815)	1.81 ± 1.34 (0.07 to 5.055)	1.25 ± 1.07 (0.005 to 4.01)	0.94 ± 1.09 (0.38 to 4.515)	1.23 ± 1.22 (0.25 to 5.29)
*Data in means ± standard deviations (range) dioptres ^Data in median absolute error ± SD of mean error (range) dioptres							

Mean IOL power implanted (SD, range): 17.63 (4.20, 4.0 to 23.5) dioptres

Number (proportion) of eyes achieving absolute prediction errors within various ranges

	Keratometry (Haigis-L formula with no historical data), n=47	Keratometry (SRK-T formula with no historical data), n=47	Corneal topography A (Scheimpflug and SRK-T formula), n=47		Corneal topography A (Orbscan II and(SRK-T formula), n=47		
			True net corneal power	Equivalent K	Simulated K	2.0mm diameter central zone of the total mean power	4.0mm diameter central zone of total optical power
Within ±0.5 dioptres	30 (64.5%)	5 (11.1%)	15 (31.3%)	10 (22.2%)	6 (13.6%)	17 (36.1%)	9 (19.5%)
Within ±1.0 dioptres	38 (80.6%)	16 (33.3%)	24 (51.7%)	18 (37.5%)	17 (36.4%)	27 (58.3%)	21 (45.2%)
Within ±1.5 dioptres	43 (92.3%)	30 (63%)	32 (68.8%)	23 (48.1%)	21 (45.5%)	33 (69.4%)	27 (58.1%)
Within ±2.0 dioptres	47 (100%)	31 (66.7%)	41 (87.5%)	31 (66.7%)	36 (77.3%)	39 (83.3%)	38 (80.6%)
Numbers calculated from reported percentages in parentheses, assumed n=47 in each group							

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Full citation	Saiki M, Negishi K, Kato N, et al. Modified double-K method for intraocular power calculation after excimer laser corneal refractive surgery. J Cataract Refract Surg 2013 39:556-62
Study details	**Country/ies where the study was carried out:** Japan **Study type:** Retrospective case series **Aim of the study:** To compare the accuracy of the anterior-posterior method (A-P method, a modification of the double-K method) with other intraocular lens (IOL) formulas to calculate IOL power for eyes having phacoemulsification cataract surgery with a history of myopic laser in situ keratomileusis (LASIK) **Study dates:** Not reported

<table>
<tr><td>Full citation</td><td>Saiki M, Negishi K, Kato N, et al. Modified double-K method for intraocular power calculation after excimer laser corneal refractive surgery. J Cataract Refract Surg 2013 39:556-62</td></tr>
<tr><td></td><td>Source of funding: None reported</td></tr>
<tr><td>Participants</td><td>Sample size
28 eyes in 19 people

Diagnostic criteria
Not reported

Inclusion criteria
• People with a history of myopic LASIK undergoing uneventful phacoemulsification cataract surgery with IOL implantation

Baseline characteristics
<table>
<tr><td>IOL model</td><td>Alcon SA60AT (11), SN60WF (6), MA60AC (1)
Abbott Medical Optics ZCB00 (6)
Hoya NY-60 (2), PY-60AD (1), YA65BB (1)</td></tr>
<tr><td>Age (years)*</td><td>54.1 ± 9.8 (30 to 67)</td></tr>
<tr><td>Male/female^</td><td>14/5</td></tr>
<tr><td>Spherical equivalent corrected by LASIK in 16 eyes (dioptres)*</td><td>-6.93 ± 2.57 (-3.50 to -10.63)</td></tr>
<tr><td>Spherical equivalent refraction immediately before cataract surgery (dioptres)*</td><td>-2.29 ± 2.29 (-7.88 to 0.50)</td></tr>
<tr><td>Axial length immediately before cataract surgery (mm)*</td><td>26.19 ± 1.06 (24.18 to 28.49)</td></tr>
<tr><td>Autokeratometry derived K values immediately before cataract surgery (dioptres)*</td><td>40.06 ± 2.39 (35.50 to 45.13)</td></tr>
<tr><td>Scheimpflug system derived (sagittal Km) K values immediately before cataract surgery (dioptres)*</td><td>39.34 ± 2.66 (33.10 to 44.50)</td></tr>
<tr><td>IOLMaster derived K values immediately before cataract surgery (dioptres)*</td><td>39.83 ± 2.37 (35.82 to 44.71)</td></tr>
<tr><td colspan="2">*Data in means ± standard deviations (ranges)
^Number of people</td></tr>
</table></td></tr>
<tr><td>Methods</td><td><u>Interventions and comparators</u>: IOL formulas/methods using no prior data (also known as no-history or regression-based methods) or historical data. The A-P and SRK/T DK methods were programmed into Microsoft Excel 2007. The American Society of Cataract and Refractive Surgery IOL power calculator version 4.0 was used for IOL calculations with the Haigis-L, Shammas-PL, Masket, modified Masket and Feiz-Mannis formulas/methods. IOL calculations using the BESSt formula were performed using the calculator downloaded from the website (http://www.besstformula.com/).
• No historical data methods
○ <u>Anterior-posterior method (A-P method)</u>: no history method that is a modified version of the double-K method in which the pre-LASIK K value is estimated using the post-LASIK posterior corneal power. Km (mean of the K values on the steep and flat meridians in the 3.0mm zone measured by the Scheimpflug system in the front sagittal map/axial power map) is a mean K value calculated from the anterior corneal radius only. K^{6mm} is the mean post-operative posterior corneal power in the 6.00mm zone on the sagittal map. The pre-operative Km was defined as the preKm. Defining the best-fit regression equation, the preKm was estimated based only on the post-LASIK data (the post-operative posterior K^{6mm}) and defined as the Est-preKm.</td></tr>
</table>

Full citation	Saiki M, Negishi K, Kato N, et al. Modified double-K method for intraocular power calculation after excimer laser corneal refractive surgery. J Cataract Refract Surg 2013 39:556-62

This Est-preKm was used as the Kpre in the double-K method to calculate the effective lens position and the post-operative Km on the sagittal map was used as the Kpost for the optical calculation.
  - BESSt
  - Camellin-Calossi
  - Haigis-L
  - Shammas-PL
  - SRK/T DK: SRK/T formula with double-K adjustment using 43.5 dioptres for Kpre
  - SRK/T TNP: SRK/T with true net power (TNP method) measured from the Scheimpflug system
  - Central-peripheral method (C-P method): modification of the double-K method using the SRK/T formula in which the estimated pre-LASIK k value calculated from the post-LASIK keratometric data is used for the Kpre and the post-LASIK anterior sagittal power (or axial power) is used for the Kpost in the SRK/T double-K formula. NB: Data for the C-P method derived from accompanying publication as same comparative cohort used: Saiki M, Negishi K, Kato N, et al. A new central-peripheral corneal curvature method for intraocular lens power calculation after excimer laser refractive surgery. Acta Ophthalmol 2013 91:e133-9.
- **Historical data methods**
  - Double-K method
  - Feiz-Mannis: uses pre-LASIK or photorefractive keratectomy K values and the surgically induced change in refractions; requires the pre-operative and post-operative refractions and K values
  - Masket: use the surgically induced change in refraction to adjust the IOL power using the empiric formula; requires the pre-operative and post-operative manifest refractions
  - Modified Masket: use the surgically induced change in refraction to adjust the IOL power using the empiric formula; requires the pre-operative and post-operative manifest refractions

Biometry and keratometry measurements
- Biometry and keratometry: biometry performed on the date closest to cataract surgery was used to calculate IOL power. Axial length was obtained using the IOLMaster (Carl Zeiss Meditec) for all cases. IOLMaster was used to measure the K value for the Haigis-L and Shammas-PL formulas. IOLMaster was also used to measure the anterior chamber depth for the Haigis-L formula. The ARK10000 system (Nidek) was used to measure the mean axial power in a 3.0mm zone for the Camellin-Calossi formula. An ultrasound A scanner (UD-6000, Tomey) was used to measure the anterior chamber depth from the corneal epithelium and the lens thickness for the Camellin-Calossi formula. The Scheimpflug system was used to measure the corneal thickness for the Camellin-Calossi formula. The Scheimpflug system was used to measure the true net power for the TNP method. The mean anterior and posterior central radii which were the averages of the central radii of the steep and the flat meridians in the 3.0mm zone measured by the Scheimpflug system were used for the BESSt formula. An autokeratometer (ARK-730A, Nidek) was used to measure the pre-operative and post-operative K values for the Masket, modified-Masket and Feiz-Mannis methods. For the central-peripheral method, K was performed using the Pentacam HR anterior segment imaging system Comprehensive Eye Scanner (Oculus Optikgerate, Germany). NB: Data for the C-P method derived from accompanying publication as same comparative cohort used: Saiki M, Negishi K, Kato N, et al. A new central-peripheral corneal curvature method for intraocular lens power calculation after excimer laser refractive surgery. Acta Ophthalmol 2013 91:e133-9.
- Formula: IOL power was calculated using the SRK/T formula and A-P method.
- IOL constants: IOLMaster optimised lens constants were sourced from the User Group for Laser Interference Biometry.

Cataract surgery and IOL implantation: uneventful phacoemulsification cataract surgery with IOL implantation.

Full citation	**Saiki M, Negishi K, Kato N, et al. Modified double-K method for intraocular power calculation after excimer laser corneal refractive surgery. J Cataract Refract Surg 2013 39:556-62**

Details

Post-operative assessment: final manifest refraction measured 1 month post-operative visit.

Study outcomes:

- Median prediction error (difference between estimated post-operative spherical equivalent and the post-operative manifest refraction at the spectacle plane) and median absolute error (absolute value of prediction error)
- Proportion of eyes within various ranges of the targeted refraction

Group comparisons: Signed rank-sum test with Bonferroni method, Chi-square test

Missing data handling/loss to follow up

None reported

Results

Median errors and median absolute errors

Formulas/methods	Median prediction error*	Median absolute error*
No historical data methods		
A-P method (n=28 eyes)	0.16 (-1.41 to 1.73)	0.54 (0.00 to 1.73)
BESSt (n=28 eyes)	1.22	1.22
Camellin-Calossi (n=19 eyes)	-0.48	0.52
Haigis-L (n=25 eyes)	-0.67	0.95
Shammas-PL (n=28 eyes)	-0.41	0.77
SRK/T DK (n=28 eyes)	0.74	0.97
SRK/T TNP (n=28 eyes)	-0.86	0.93
C-P method (n=25 eyes)	0.11 (-1.67 to 1.97)	0.55 (0.02 to 1.97)
Historical data methods		
Double-K method (n=12 eyes)	0.04	0.77
Feiz-Mannis (n=12 eyes)	0.50	1.06
Masket (n=12 eyes)	0.49	0.63
Modified Masket (n=12 eyes)	0.01	0.58

*Median (ranges) in dioptres; graphical measures of dispersion for prediction error only to be extracted from Fig 3 (both publications)
NB: Data for the C-P method derived from accompanying publication as same comparative cohort used: Saiki M, Negishi K, Kato N, et al. A new central-peripheral corneal curvature method for intraocular lens power calculation after excimer laser refractive surgery. Acta Ophthalmol 2013 91:e133-9.

Number of eyes (proportion) within various ranges of the targeted refraction

Formulas/methods	Within ±0.5D*	Within ±1.0D*
No historical data methods		
A-P method (n=28 eyes)	13 (46%)	21 (75%)
BESSt (n=28 eyes)	3 (11%)	12 (43%)
Camellin-Calossi (n=19 eyes)	9 (47%)	14 (74%)
Haigis-L (n=25 eyes)	6 (24%)	13 (52%)
Shammas-PL (n=28 eyes)	7 (25%)	20 (71%)
SRK/T DK (n=28 eyes)	5 (18%)	14 (50%)

Full citation	**Saiki M, Negishi K, Kato N, et al. Modified double-K method for intraocular power calculation after excimer laser corneal refractive surgery. J Cataract Refract Surg 2013 39:556-62**

SRK/T TNP (n=28 eyes)	5 (18%)	17 (61%)
C-P method (n=25 eyes)	12 (48%)	17 (68%)
Historical data methods		
Double-K method (n=12 eyes)	4 (33%)	8 (67%)
Feiz-Mannis (n=12 eyes)	1 (8%)	6 (50%)
Masket (n=12 eyes)	4 (33%)	10 (83%)
Modified Masket (n=12 eyes)	5 (42%)	9 (75%)
*Number of eyes (proportion) calculated from reported percentages in parentheses NB: Data for the C-P method derived from accompanying publication as same comparative cohort used: Saiki M, Negishi K, Kato N, et al. A new central-peripheral corneal curvature method for intraocular lens power calculation after excimer laser refractive surgery. Acta Ophthalmol 2013 91:e133-9.		

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Full citation	**Savini G, Hoffer KJ, Carbonelli M, et al. Intraocular lens power calculation after myopic excimer laser surgery: clinical comparison of published methods. J Cataract Refract Surg 2010 36:1455-65**
Study details	**Country/ies where the study was carried out:** Italy **Study type:** Retrospective case series **Aim of the study:** To compare the accuracy of intraocular lens (IOL) power calculation methods for eyes having phacoemulsification cataract surgery with a history of myopic excimer laser surgery **Study dates:** September 2005 to November 2009 **Source of funding:** None reported
Participants	**Sample size** 28 eyes in 27 people **Diagnostic criteria** Not reported **Inclusion criteria** • People with a history of myopic excimer laser surgery undergoing uneventful phacoemulsification cataract operations • Only the first operated eye was included in people having bilateral cataract surgery unless the 2 eyes were classified into 2 different groups **Exclusion criteria** • Vitreoretinal or corneal disease • History of other ocular surgery, uveitis, trauma or systemic disease affecting vision • Intraoperative complications during refractive or cataract surgery • Eyes with decentred laser treatment that can cause irregular corneal curvatures **Baseline characteristics**

Full citation	**Savini G, Hoffer KJ, Carbonelli M, et al. Intraocular lens power calculation after myopic excimer laser surgery: clinical comparison of published methods. J Cataract Refract Surg 2010 36:1455-65**

	Group 1: pre-operative corneal power and pre- and post-operative refractions available (n=12)	**Group 2: pre-operative corneal power available (n=11)**	**Group 3: surgically induced refractive change known (n=5)**
Age (years)*	52.5 ± 9.6		
Laser-assisted in situ keratomileusis (LASIK)/photorefractive keratectomy (PRK)^	13/15		
Duration between refractive and cataract surgery (years)*	8.4 ± 3.1		
Axial length (mm)*	27.71 ± 1.97	27.78 ± 1.26	28.03 ± 2.46
Pre-operative K (dioptres)*	43.76 ± 1.09	43.17 ± 1.63	Not available
Surgically induced refractive change (dioptres)*	-7.75 ± 3.65	-8.19 ± 3.45	-9.57 ± 4.19
*Data in means ± standard deviations ^Number of eyes			

Methods

Interventions and comparators: IOL formulas/methods were categorised into 3 groups:

1) Group1: pre-operative corneal power available and pre-operative and post-operative refractions (i.e. surgically induced refractive change) were known and certain;
2) Group 2: pre-operative corneal power was available and the surgically induced refractive change was known but uncertain and in most cases because the post-operative refraction was unknown;
3) Group 3: pre-operative corneal power was unknown but the surgically induced refractive change was known even if uncertain; pre-operative corneal power to be entered into the double-K SRK/T formula was calculated by adding the refractive change (at the corneal plane) to the post-operative corneal power calculated according to Speicher method and Seitz and Langenbucher method as modified by Savini et al (Ophthalmology 2006, 113:1271-82) to facilitate lower mean absolute errors than those obtained when using a default pre-operative value close to the mean value of the population i.e. 43.5 dioptres.

NB: Groups 1 and 2 data were analysed together under historical data methods. Only 5 eyes were included in group 3 and therefore data were not extracted from this group

Two methods were used to calculate IOL power:

1) methods that adjust for overestimation of corneal power. Corneal powers obtained from these methods and the simulated K were entered into the double-K SRK/T formula to obtain IOL power, except for the Shammas no-history method that used the Shammas-PL formula, Rosa and Ferrara methods that used values entered into the single-K SRK/T formula, Awwad method that used values entered into the double-K Holladay 1 formula and the clinical history method that entered values into the double-K Hoffer Q, double-K Holladay 1 and double-K SRK/T formulas;
2) methods that directly correct the calculated IOL power and not the corneal power used with the SRK/T formula only.

- **Historical data methods**
  - Simulated K: SRK/T DK
  - ***Methods that adjust for overestimation of corneal power***
    - Clinical history calculated at corneal plane: SRK/T DK, HofferQ DK, Holladay 1 DK
    - Awwad: Holladay 1 DK, SRK/T DK
    - Camellin-Calossi: SRK/T DK
    - Ferrara: SRK/T single-K

Full citation	**Savini G, Hoffer KJ, Carbonelli M, et al. Intraocular lens power calculation after myopic excimer laser surgery: clinical comparison of published methods. J Cataract Refract Surg 2010 36:1455-65**

- Rosa R-factor: SRK/T single-K
- Savini: SRK/T DK
- Seitz/Speicher: SRK/T DK
- Seitz/Speicher/Savini: SRK/T DK
- Shammas no history: Shammas PL NB: no history stated in paper's data tables but as categorised in Group 1, listed here as a historical data method
- Shammas refraction derived: SRK/T DK

○ ***Methods that directly correct the calculated IOL power***

- Diehl: SRK/T
- Feiz (formula): SRK/T
- Feiz (nomogram): SRK/T
- Ladas-Stark or Corneal Bypass: SRK/T
- Latkany: SRK/T
- Masket: SRK/T

Biometry and keratometry measurements

- Biometry and keratometry: For pre-operative and post-operative corneal power measurements obtained by corneal topography, the simulated K value was considered and used for IOL power calculations. Topography was undertaken using the TMS-2 (Tomey), Keratron (Optikon 2000), CM02 (Costruzione Strumenti Oftalmici) and EyeSys System 3000 (EyeSys Vision).
- Formula: IOL power for emmetropia was back-calculated using the double-K SRK/T formula. Target refraction was plano in 24 eyes, -1.00D in 3 eyes and -3.00D in 1 eye
- IOL constants: A-constant of the implanted IOL was 118.4 in 23 eyes, 119.0 in 2 eyes, 119.6 in 1 eye, 118.7 in 1 eye and 118.5 in 1 eye; not optimised.

Cataract surgery and IOL implantation: uneventful phacoemulsification cataract surgery with IOL implantation undertaken by 12 surgeons.

Details

Post-operative assessment: spherical equivalent measured 1 month after cataract surgery

Study outcomes:

- Prediction error (difference between predicted IOL power and back-calculated IOL power for emmetropia) and mean absolute error

Group comparisons: paired *t* test

Missing data handling/loss to follow up

None reported

Results

Prediction errors (n=28 eyes)

Formulas/methods with historical data	Group 1: prediction error*	Group 2: prediction error*	Group 1 and 2: prediction error*
Simulated K (double-K SRK/T)	-0.95 ± 0.93 (-2.37 to 0.59)	-0.79 ± 0.51 (-1.35 to 0.36)	-0.88 ± 0.75 (-2.37 to 0.59)
Methods that adjust for overestimation of corneal power			
Clinical history calculated at corneal plane NB: unclear whether this is calculated using Hoffer Q, double-K SRK/T or Holladay 1	0.76 ± 1.68 (-1.14 to 4.53)	1.42 ± 1.85 (-2.96 to 3.57)	1.08 ± 1.75 (-2.96 to 4.53)
Awwad (double-K Holladay 1)	1.39 ± 0.91 (-0.16 to 2.58)	2.10 ± 1.46 (-0.57 to 4.21)	0.74 ± 1.10 (-1.21 to 3.56)

Full citation	Savini G, Hoffer KJ, Carbonelli M, et al. Intraocular lens power calculation after myopic excimer laser surgery: clinical comparison of published methods. J Cataract Refract Surg 2010 36:1455-65

Awwad (double-K SRK/T)	Not provided	Not provided	1.73 ± 1.23 (-0.57 to 4.21)
Camellin-Calossi (double-K Holladay 1)	1.26 ± 0.80 (-0.34 to 2.71)	1.49 ± 0.88 (-0.07 to 3.34)	0.53 ± 1.00 (-1.37 to 2.69)
Camellin-Calossi (double-K SRK/T)	Not provided	Not provided	1.37 ± 0.83 (-0.34 to 3.34)
Ferrara (single-K SRK/T)	3.75 ± 1.71 (0.65 to 6.05)	3.52 ± 1.17 (1.08 to 6.04)	3.64 ± 1.45 (0.65 to 6.05)
Rosa R-factor (single-K SRK/T)	1.89 ± 1.19 (0.49 to 4.29)	2.00 ± 0.83 (0.39 to 3.56)	1.90 ± 1.10 (-0.55 to 4.29)
Savini (double-K SRK/T)	0.08 ± 0.75 (-1.42 to 1.46)	0.35 ± 0.85 (-1.02 to 2.10)	0.21 ± 0.79 (-1.42 to 2.10)
Seitz/Speicher (double-K SRK/T)	-0.06 ± 0.76 (-1.41 to 1.13)	0.18 ± 0.70 (-0.53 to 1.70)	0.05 ± 0.73 (-1.41 to 1.70)
Seitz/Speicher/Savini (double-K SRK/T)	-0.07 ± 0.68 (-1.19 to 1.15)	0.26 ± 0.71 (-0.97 to 1.51)	0.09 ± 0.70 (-1.19 to 1.51)
Shammas no history (Shammas-PL)	0.31 ± 0.85 (-0.87 to 1.58)	0.70 ± 1.03 (-1.27 to 2.13)	0.50 ± 0.94 (-1.27 to 2.13)
Shammas refraction derived (double-K SRK/T)	1.46 ± 0.89 (0.35 to 2.97)	1.74 ± 1.09 (0.36 to 3.82)	1.60 ± 0.98 (0.35 to 3.82)
Methods that directly correct the calculated IOL power			
Diehl (SRK/T)	0.55 ± 1.24 (-1.33 to 3.03)	1.13 ± 1.72 (-1.82 to 3.65)	0.83 ± 1.48 (-1.82 to 3.65)
Feiz (formula) (SRK/T)	0.83 ± 1.69 (-1.57 to 3.60)	1.96 ± 2.10 (-0.75 to 5.30)	1.37 ± 1.94 (-1.57 to 5.30)
Feiz (nomogram) (SRK/T)	1.83 ± 1.26 (0.37 to 4.35)	2.19 ± 1.83 (-0.44 to 5.50)	2.00 ± 1.53 (-0.44 to 5.50)
Ladas-Stark or Corneal Bypass (SRK/T)	1.83 ± 2.20 (-1.46 to 5.36)	1.83 ± 1.74 (-1.08 to 3.90)	1.83 ± 1.95 (-1.46 to 5.36)
Latkany (SRK/T)	0.63 ± 0.88 (-0.70 to 2.39)	0.99 ± 1.37 (-1.08 to 3.27)	0.80 ± 1.13 (-1.08 to 3.27)
Masket (SRK/T)	-0.39 ± 0.90 (-1.59 to 0.95)	-0.14 ± 0.87 (-1.78 to 1.09)	-0.27 ± 0.88 (-1.78 to 1.09)

*Means ± standard deviations (ranges) in dioptres

Absolute mean errors (n=28 eyes)

Formulas/methods with historical data	Group 1: absolute mean errors*	Group 2: absolute mean errors*	Group 1 and 2: absolute mean errors*
Simulated K (double-K SRK/T)	1.13 ± 0.69 (0.07 to 2.37)	0.86 ± 0.38 (0.32 to 1.35)	1.00 ± 0.57 (0.07 to 2.37)
Methods that adjust for overestimation of corneal power			
Clinical history calculated at corneal plane NB: unclear whether this is calculated using Hoffer Q, double-K SRK/T or Holladay 1	1.29 ± 1.28 (0.31 to 4.53)	1.97 ± 1.17 (0.07 to 3.57)	1.62 ± 1.25 (0.07 to 4.53)
Awwad (double-K Holladay 1)	1.42 ± 0.87 (0.16 to 2.58)	2.20 ± 1.28 (0.57 to 4.21)	1.03 ± 0.82 (0.10 to 3.56)
Awwad (double-K SRK/T)	Not provided	Not provided	1.79 ± 1.13 (0.16 to 4.21)
Camellin-Calossi (double-K Holladay 1)	1.32 ± 0.69 (0.30 to 2.71)	1.50 ± 0.86 (0.07 to 3.34)	0.91 ± 0.65 (0.17 to 2.27)
Camellin-Calossi (double-K SRK/T)	Not provided	Not provided	1.41 ± 0.76 (0.07 to 3.34)
Ferrara (single-K SRK/T)	3.75 ± 1.71 (0.65 to 6.05)	3.52 ± 1.17 (1.08 to 6.04)	3.64 ± 1.45 (0.65 to 6.05)
Rosa R-factor (single-K SRK/T)	1.89 ± 1.19 (0.49 to 4.29)	2.00 ± 0.83 (0.39 to 3.56)	1.94 ± 1.01 (0.39 to 4.29)
Savini (double-K SRK/T)	0.60 ± 0.44 (0.14 to 1.46)	0.65 ± 0.63 (0.05 to 2.10)	0.60 ± 0.52 (0.05 to 2.10)
Seitz/Speicher (double-K SRK/T)	0.58 ± 0.47 (0.08 to 1.41)	0.54 ± 0.45 (0.06 to 1.70)	0.56 ± 0.45 (0.06 to 1.70)
Seitz/Speicher/Savini (double-K SRK/T)	0.51 ± 0.44 (0.00 to 1.19)	0.55 ± 0.50 (0.05 to 1.51)	0.53 ± 0.46 (0.00 to 1.51)
Shammas no history (Shammas-PL)	0.77 ± 0.43 (0.15 to 1.58)	1.11 ± 0.50 (0.32 to 2.13)	0.93 ± 0.48 (0.15 to 2.13)

Full citation	Savini G, Hoffer KJ, Carbonelli M, et al. Intraocular lens power calculation after myopic excimer laser surgery: clinical comparison of published methods. J Cataract Refract Surg 2010 36:1455-65

Shammas refraction derived (double-K SRK/T)	1.46 ± 0.89 (0.35 to 2.97)	1.74 ± 1.09 (0.36 to 3.82)	1.60 ± 0.98 (0.35 to 3.82)
Methods that directly correct the calculated IOL power			
Diehl (SRK/T)	1.08 ± 0.76 (0.23 to 3.03)	1.61 ± 1.23 (0.09 to 3.65)	1.33 ± 1.03 (0.09 to 3.65)
Feiz (formula) (SRK/T)	1.47 ± 1.11 (0.05 to 3.60)	2.30 ± 1.68 (0.39 to 5.30)	1.87 ± 1.44 (0.05 to 5.30)
Feiz (nomogram) (SRK/T)	1.83 ± 1.26 (0.37 to 4.35)	2.27 ± 1.72 (0.44 to 5.50)	2.04 ± 1.48 (0.37 to 5.50)
Ladas-Stark or Corneal Bypass (SRK/T)	2.19 ± 1.81 (0.31 to 5.36)	2.18 ± 1.22 (0.37 to 3.90)	2.18 ± 1.52 (0.31 to 5.36)
Latkany (SRK/T)	0.86 ± 0.63 (0.25 to 2.39)	1.32 ± 1.02 (0.08 to 3.27)	1.08 ± 0.86 (0.08 to 3.27)
Masket (SRK/T)	0.82 ± 0.49 (0.04 to 1.59)	0.69 ± 0.51 (0.03 to 1.78)	0.76 ± 0.49 (0.03 to 1.78)
*Means ± standard deviations (ranges) in dioptres			

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Full citation	Xu K, Hao Y, Qi H. Intraocular lens power calculations using a Scheimpflug camera to measure corneal power. Biotechnic & Histochemistry 2014 89:348-54
Study details	**Country/ies where the study was carried out:** China **Study type:** Retrospective case series **Aim of the study:** To assess the accuracy of the Oculus Pentacam to calculate intraocular lens (IOL) power for eyes having phacoemulsification cataract surgery with a history of myopic refractive surgery **Study dates:** June 2009 to May 2012 **Source of funding:** None reported
Participants	**Sample size** 37 eyes in 22 people (originally 43 eyes in 22 people, 37 of which had phacoemulsification cataract surgery) **Diagnostic criteria** Not reported **Inclusion criteria** • People with a history of myopic laser refractive surgery (laser-assisted in situ keratomileusis [LASIK], laser subepithelial keratomileusis [LASEK], photorefractive keratectomy [PRK]) undergoing uneventful phacoemulsification cataract surgery with in-the-bag IOL implantation **Baseline characteristics**

Age (years)*	49.35 ± 8.0
LASIK/LASEK/PRK^	26/2/15
Pre-keratorefractive surgery refraction (dioptres)*	-11.39 ± 3.96
Pre-cataract surgery refraction (dioptres)*	-8.62 ± 6.61
Axial length (mm)*	29.52 ± 2.12 (25.72 to 33.41)
*Data in means ± standard deviations (ranges) ^Number of eyes	

Methods	**Interventions and comparators: IOL formulas with no historical data**

Full citation	Xu K, Hao Y, Qi H. Intraocular lens power calculations using a Scheimpflug camera to measure corneal power. Biotechnic & Histochemistry 2014 89:348-54

- Hoffer Q
- SRK/T
- Holladay 1 NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Biometry and keratometry measurements

- Biometry and keratometry: Axial length was measured using an immersion ultrasound A scan (OcuScan, Alcon Inc). Corneal power was evaluated using an autokeratometer (Topcon, Tokyo), IOLMaster (Carl Zeiss Meditec) and Pentacam (Oculus). The central true net power (cTNP), mean true net power (mTNP) and 4.5mm equivalent K reading (EKR) were measured using the Pentacam. Using pre-operative data, the clinical history method was used to calculate corneal power for 33 eyes (17 people); however no comparative data using the clinical history method for the different IOL formulas were provided.
- Formula: IOL power was calculated using mTNP and SRK/T formula, with the final IOL power determined by the surgeon
- IOL constants: not reported.

Cataract surgery and IOL implantation: 1 surgeon performed uneventful standard phacoemulsification cataract surgery with in-the-bag IOL implantation.

Details

Post-operative assessment: final refraction was obtained 12 weeks after cataract surgery

Study outcomes:

- Prediction error (difference between actual post-operative refraction and target) and mean absolute error
- Proportion of eyes within various ranges of the refractive predictive error

Group comparisons: one-way analysis of variance (ANOVA) with Bonferroni multiple comparisons, 1 sample t-test

Missing data handling/loss to follow up

None reported

Results

Prediction errors and absolute mean errors (n=37 eyes)

Formulas/methods with no historical data	Prediction error*	Mean absolute error*
Hoffer Q K_{cTNP}	-2.3 ± 1.25 (-4.31 to -1.31)	2.36 ± 1.11 (0.21 to 4.31)
Hoffer Q K_{mTNP}	-0.42 ± 1.11 (-2.54 to 3.00)	0.88 ± 0.79 (0.03 to 3.00)
Hoffer Q EKR	1.58 ± 1.2 (-0.54 to 4.39)	1.61 ± 1.15 (0.03 to 4.39)
SRK/T K_{cTNP}	-1.79 ± 1.11 (-4.47 to 1.28)	1.88 ± 0.95 (0.26 to 0.47)
SRK/T K_{mTNP}	-0.11 ± 0.82 (-2.25 to 2.81)	0.55 ± 0.62 (0.01 to 2.81)
SRK/T EKR	1.64 ± 0.93 (-0.54 to 4.44)	1.67 ± 0.87 (0.08 to 4.4)

*Means ± standard deviations (ranges) in dioptres
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee
NB: cTNP used in network meta-analyses

Number of eyes within various ranges of refractive predictive error (n=37 eyes)

Formulas/methods with no historical data	Within ±0.5D*	Within ±1.0D*
Hoffer Q K_{cTNP}	3 (8.1%)	3 (8.1%)

Full citation	Xu K, Hao Y, Qi H. Intraocular lens power calculations using a Scheimpflug camera to measure corneal power. Biotechnic & Histochemistry 2014 89:348-54		
	Hoffer Q K_{mTNP}	17 (45.9%)	25 (67.6%)
	Hoffer Q EKR	6 (16.2%)	14 (37.8%)
	SRK/T K_{cTNP}	3 (8.1%)	5 (13.5%)
	SRK/T K_{mTNP}	25 (67.6%)	32 (86.5%)
	SRK/T EKR	4 (10.8%)	8 (21.6%)
	* Number of eyes (proportion) calculated from reported percentages in parentheses NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee NB: cTNP used in network meta-analyses		

7E.3.3 Intraocular lens constant optimisation

Full citation	Aristodemou P, Cartwright NEK, Sparrow JM, et al. Intraocular lens formula constant optimization and partial coherence interferometry biometry: refractive outcomes in 8108 eyes after cataract surgery. J Cataract Refract Surg 2011; 37:50-62
Study details	**Country/ies where the study was carried out:** England **Study type:** Retrospective database study **Aim of the study:** To compare the theoretical biometry prediction errors of optimised intraocular lens (IOL) constants with manufacturers' IOL constants for eyes undergoing uneventful phacoemulsification cataract surgery with biometry and keratometry pre-operatively assessed using the IOLMaster, define acceptable levels of error in IOL-constant optimisation, calculate the minimum number of eyes required for IOL-constant optimisation and explore the benefits of personalising IOL constants for individual surgeons **Study dates:** November 2005 to September 2009 **Source of funding:** None reported, but co-author RL Johnston declared as medical director of Medisoft Ltd which supplies the hospital trust included in this study with the Electronic Patient Record for Ophthalmology that was used to collect the data
Participants	**Sample size** 8108 eyes **Diagnostic criteria** Not reported **Inclusion criteria** • People undergoing uneventful phacoemulsification cataract surgery with in-the-bag IOL placement at 1 hospital trust • Biometry and keratometry undertaken using the IOLMaster • Post-operative corrected distance visual acuity (CDVA) of 6/12 or better **Exclusion criteria** • Corneal astigmatism of more than 3.0 dioptres (D) • Concurrent additional surgical procedures e.g. trabeculectomy, vitrectomy, limbal relaxing incisions

Full citation	**Aristodemou P, Cartwright NEK, Sparrow JM, et al. Intraocular lens formula constant optimization and partial coherence interferometry biometry: refractive outcomes in 8108 eyes after cataract surgery. J Cataract Refract Surg 2011; 37:50-62**

- Records with incomplete data set (e.g. missing post-operative refraction and CDVA)

Baseline characteristics

IOL model	L161AO Sofport Advanced Optics IOL (6159 eyes)	Akreos Fit IOL (1949 eyes)
Age (years)*	76.15 ± 9.29	76.30 ± 8.90
Axial length (mm)*	23.51 ± 1.26	23.41 ± 1.17
Keratometry (dioptres)*	43.83 ± 1.52	43.87 ± 1.48
*Data in means ± standard deviations		

Methods

<u>Intervention</u>: IOL constant optimisation

- Optimised IOL constant is defined as the arithmetic mean of all individual IOL constants excluding outliers more than 2 standard deviations from the overall population mean.
  - Three 3rd generation IOL formulas were used depending on axial lengths:
  - Hoffer Q: <22mm
  - Holladay 1: 22 to 25.99mm
  - SRK/T: ≥26mm
- For every eye and formula (Hoffer Q personalised anterior chamber depth, pACD; Holladay 1 surgeon factor, SF; SRK/T A constant, AC), the IOL constants were optimised using an iterative method in which the IOL constant was changed in 0.001 increments until the difference between the predicted and actual spherical equivalent of the post-operative subjective refraction was zero.
- The IOL constants for the 2 IOL models were optimised in a similar manner. An IOL-constant optimisation error analysis was performed using data from each IOL model to identify the critical values containing the maximum range of IOL-constant optimisation error that do not have a significant impact on refractive outcomes. This was done by calculating the theoretical refractive outcomes while varying the IOL constants around their optimised values by set increments (Hoffer Q pACD 0.03, Holladay 1 SF 0.03 and SRK/T AC 0.05). This information can be used to calculate the minimum sample size required for IOL-constant optimisation for each IOL formula.
- Optimised IOL constants were recalculated using eyes within specific ranges of axial lengths (ALs) in groups of 1mm range. For each IOL constant and AL group, an AL-specific IOL constant was defined and compared with the overall optimised IOL constants.
- For each surgeon with adequate number of cases for IOL-constant optimisation, the surgeon personalised IOL constant and standard error was calculated and compared with the overall optimised IOL constant. No comparative post-operative refractive data on the effect of personalised IOL constants and non-personalised IOL constants were provided.
- Refractive outcomes using optimised IOL constants from a randomly selected half of the sample (excluding outliers greater than 2 standard deviation from the mean) and applied to the other half of the sample (no outliers excluded) were compared with the refractive results using the theoretical best optimised IOL constant derived from the whole sample for each IOL model.

	L161AO Sofport Advanced Optics IOL			Akreos Fit IOL		
	IOL formula constant			IOL formula constant		
	pACD	SF	AC	pACD	SF	AC
Total sample (number of eyes)	6159	6159	6159	1949	1949	1949

Full citation	**Aristodemou P, Cartwright NEK, Sparrow JM, et al. Intraocular lens formula constant optimization and partial coherence interferometry biometry: refractive outcomes in 8108 eyes after cataract surgery. J Cataract Refract Surg 2011; 37:50-62**

Excluded eyes outside of 2 standard deviations, n (% of total)	215 (3.5)	134 (2.2)	210 (3.4)	60 (3.1)	41 (2.1)	61 (2.8)
Optimised constant	5.30	1.67	118.76	5.19	1.50	118.52
Standard deviation of optimised constant	0.21	0.37	0.57	0.23	0.37	0.59
Hoffer Q pACD personalised anterior chamber depth (axial length <22mm) Holladay 1 SF surgeon factor, (axial length 22 to 25.99mm) SRK/T AC A constant (axial length ≥26mm)						

Comparator: Manufacturer's IOL constant

	L161AO Sofport Advanced Optics IOL			Akreos Fit IOL		
	IOL formula constant			IOL formula constant		
	pACD	SF	AC	pACD	SF	AC
Manufacturer's IOL constant	4.97	1.22	118	4.97	1.22	118
Hoffer Q pACD personalised anterior chamber depth (axial length <22mm) Holladay 1 SF surgeon factor, (axial length 22 to 25.99mm) SRK/T AC A constant (axial length ≥26mm)						

Biometry and keratometry measurements

- Biometry (axial length, AL) and keratometry: IOLMaster linked to electronic medical record system for automatic data transfer to eliminate transcription errors; prospectively assessed pre-operatively by nurses, surgeon and/or biometry technicians
- Mandatory pre-operative and intraoperative data input fields in the electronic medical records: AL, keratometry, pre-operative visual acuity, ophthalmic comorbidity, IOL model, power and position in the eye, operative complications
- Optional data input fields in the electronic medical records: IOL constant, IOL calculation formula

Cataract surgery and IOL implantation: 66 surgeons performed phacoemulsification cataract surgery with in-the-bag implantation using Bausch & Lomb L161AO Sofport Advanced Optics (3-piece IOL with an aspheric silicone optic, 2 polymethylmethacrylate haptics) or Bausch & Lomb Akreos Fit (1-piece hydrophilic IOL).

Details

Post-operative assessment: subjective post-operative refraction assessed at least 4 weeks after surgery in hospital (~50% of cases) or via a proforma letter from the community optometrist at the individual's nurse-led post-operative clinic visit 6 weeks after surgery.

Study outcomes:

- Mean absolute error in deviation from the predicted post-operative refraction
- Proportion of eyes within various ranges of the target refraction

Group comparisons: one-way analysis of variance (ANOVA)

Full citation	**Aristodemou P, Cartwright NEK, Sparrow JM, et al. Intraocular lens formula constant optimization and partial coherence interferometry biometry: refractive outcomes in 8108 eyes after cataract surgery. J Cataract Refract Surg 2011; 37:50-62**
	Missing data handling/loss to follow up No missing data reported.
Results	**Mean errors and mean absolute errors**

	Index for refractive outcomes with combination of formulas (Hoffer Q for AL<22mm, Holladay 1 for AL between 22 and 25.99mm, SRK/T for AL≥26mm)			
	L161AO Sofport Advanced Optics IOL (6159 eyes)		**Akreos Fit IOL (1949 eyes)**	
	Mean error	**Mean absolute error**	**Mean error**	**Mean absolute error**
Optimised constant[A]	-0.02	0.40	-0.04	0.42
Optimised constant[B]	-0.03	0.40	-0.02	0.42
Manufacturer's constant	0.57	0.66	0.37	0.52

Optimised constant[A] derived from 50% of sample at random (minus 2 standard deviations outliers) and applied to other 50% (no outliers excluded)
Optimised constant[B] derived from and applied to whole sample
L161AO Sofport Advanced Optics IOL Optimised constant[A] and constant[B]: pACD 5.30, SF 1.67, AC 118.76
Akreos Fit IOL Optimised constant[A]: pACD 5.20, SF 1.52, AC 118.53
Akreos Fit IOL Optimised constant[B]: pACD 5.19, SF 1.50, AC 118.52
Note: Optimised IOL constants (pACD, SF and AC) varied significantly with respect to axial length for both IOL models (p<0.00001)

Number of eyes (proportion) within various ranges of the target refraction

	Index for refractive outcomes with combination of formulas (Hoffer Q for AL<22mm, Holladay 1 for AL between 22 and 25.99mm, SRK/T for AL≥26mm)					
	L161AO Sofport Advanced Optics IOL (6159 eyes)			**Akreos Fit IOL (1949 eyes)**		
	±0.25D*	**±0.50D***	**±1.00D***	**±0.25D***	**±0.50D***	**±1.00D***
Optimised constant[A]	2587 (42%)	4373 (71%)	5851 (95%)	1111 (57%)	1384 (71%)	1384 (71%)
Optimised constant[B]	2525 (41%)	4373 (71%)	5851 (95%)	1735 (89%)	1793 (92%)	1813 (93%)
Manufacturer's constant	1170 (19%)	2587 (42%)	4989 (81%)	585 (30%)	1111 (57%)	1735 (89%)

Optimised constant[A] derived from 50% of sample at random (minus 2 standard deviations outliers) and applied to other 50% (no outliers excluded)
Optimised constant[B] derived from and applied to whole sample
L161AO Sofport Advanced Optics IOL Optimised constant[A] and constant[B]: pACD 5.30, SF 1.67, AC 118.76
Akreos Fit IOL Optimised constant[A]: pACD 5.20, SF 1.52, AC 118.53
Akreos Fit IOL Optimised constant[B]: pACD 5.19, SF 1.50, AC 118.52
*Number of eyes (proportion); calculated from reported percentages

Intraocular lens constant optimisation error analysis: critical values and impact on refractive outcomes

IOL constant deviation thresholds within			**Associated reduction in mean absolute error within**	**Associated reduction in proportion of eyes within ±0.50 and ±0.25 dioptres**	**Interpretation of impact on refractive outcomes**
pACD	**SF**	**AC**			
±0.06[a]	±0.06[c]	±0.10[e]	±0.10	1%	clinically trivial
±0.09[b]	±0.09[d]	±0.15[f]	±0.20	2%	marginal clinical significance

Full citation	**Aristodemou P, Cartwright NEK, Sparrow JM, et al. Intraocular lens formula constant optimization and partial coherence interferometry biometry: refractive outcomes in 8108 eyes after cataract surgery. J Cataract Refract Surg 2011; 37:50-62**

>0.09	>0.09	>0.15	further increase (magnitude not reported)	steep decline (magnitude not reported)	clinically relevant

Hoffer Q pACD personalised anterior chamber depth (axial length <22mm)
Holladay 1 SF surgeon factor, (axial length 22 to 25.99mm)
SRK/T AC A constant (axial length ≥26mm)
[a]Sample size required to predict the optimised pACD at 0.06: 50 (within p<0.05) and 86 (within p<0.1)
[b]Sample size required to predict the optimised pACD at 0.09: 24 (within p<0.05) and 40 (within p<0.1)
[c]Sample size required to predict the optimised SF at 0.06: 148 (within p<0.05) and 257 (within p<0.1)
[d]Sample size required to predict the optimised SF at 0.09: 68 (within p<0.05) and 116 (within p<0.1)
[e]Sample size required to predict the optimised AC at 0.10: 141 (within p<0.05) and 243 (within p<0.1)
[f]Sample size required to predict the optimised AC at 0.15: 64 (within p<0.05) and 110 (within p<0.1)

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Full citation	**Charalampidou S, Cassidy L, Ng E, et al. Effect on refractive outcomes after cataract surgery of intraocular lens constant personalization using the Haigis formula. J Cataract Refract Surg 2010; 36:1081-9**
Study details	**Country/ies where the study was carried out:** Ireland **Study type:** Retrospective case series **Aim of the study:** To compare the prediction errors of personalised optimised intraocular lens (IOL) Haigis constants with non-personalised optimised Haigis IOL constants in eyes undergoing uneventful phacoemulsification cataract surgery with biometry and keratometry pre-operatively assessed using the IOLMaster **Study dates:** Not reported **Source of funding:** None reported
Participants	**Sample size** 248 eyes of 195 people **Diagnostic criteria** Not reported **Inclusion criteria** • People undergoing uneventful phacoemulsification cataract surgery by the same surgeon at 1 clinic **Exclusion criteria** • Pre-operative ocular comorbidity that would affect vision • Previous intraocular surgery • Intraoperative complications

Full citation	**Charalampidou S, Cassidy L, Ng E, et al. Effect on refractive outcomes after cataract surgery of intraocular lens constant personalization using the Haigis formula. J Cataract Refract Surg 2010; 36:1081-9**

- Use of a posterior chamber IOL other than the Tecnis ZA9003
- Inability to perform optical coherence biometry
- Inadequate biometry or post-operative refractive data
- Post-operative corrected distance visual acuity (CDVA) worse than 0.5 by subjective refraction performed 6 to 8 weeks after surgery by the individual's optometrist

Baseline characteristics

IOL model	**Tecnis ZA9003 IOL (n=195, 248 eyes)**
Age (years)*	71 ± 9.3
Female^	122 (62.6%)
Axial length: short <22mm^	21 (8.5%)
Axial length: average 22 to 24.5mm^	180 (72.6%)
Axial length: long >24.5mm^	47 (19%)
Right:left eyes	120:128
*Data in means ± standard deviations ^Number (proportion)	

Methods

<u>Intervention</u>: Personalisation of optimised Haigis IOL constants

- Relevant surgical data (unique patient identification number, pre-operative axial length [AL], anterior chamber depth [ACD], corneal radii K1 and K2 measured using the IOLMaster, power of implanted IOL, spherical and cylindrical components of the stable post-operative refraction, surgeon's name or identification number, manufacturer and type of IOL, serial number of IOLMaster, method of determining stable refractive status) from included cases were submitted onto the User Group for Laser Interference Biometry (ULIB) website. Three-variable regression analysis was performed and the personalised a0, a1 and a2 IOL constants for the Tecnis ZA9003 for the ophthalmologist who performed the surgeries were obtained.
- The 3 personalised IOL constants and posterior chamber IOL were entered into the IOLMaster and the putative post-operative target spherical equivalent for the implanted IOL power was calculated using the Haigis formula.

Tecnis ZA9003 IOL		
Personalised optimised Haigis IOL constants (based on 248 sets of post-operative refractive data taken from study's surgeon)		
a0	**a1**	**a2**
-2.341	0.278	0.276

<u>Comparator</u>: Non-personalised optimised Haigis IOL constants

Tecnis ZA9003 IOL		
Non-personalised optimised Haigis IOL constants (based on 421 sets of post-operative refractive data taken from ULIB website)		
a0	**a1**	**a2**
-0.879	0.252	0.220

Biometry and keratometry measurements and formula

Full citation	**Charalampidou S, Cassidy L, Ng E, et al. Effect on refractive outcomes after cataract surgery of intraocular lens constant personalization using the Haigis formula. J Cataract Refract Surg 2010; 36:1081-9**

- Biometry (axial length, AL; anterior chamber depth, ACD; white-to-white distance, WTW) and keratometry: IOLMaster (version V, Carl Zeiss Meditec AG); prospectively assessed pre-operatively by the same experienced operator using a standard technique. For unclear readings, measurements were repeated and only accepted when reproducibility was demonstrated
- Formula: Haigis used to calculate IOL power to achieve the minus post-operative refraction closest to emmetropia
- IOL formula constants: Haigis a0, a1 and a2 constants for the IOL Tecnis ZA9003 were downloaded from the ULIB website onto the IOLMaster device

Cataract surgery and IOL implantation: 1 surgeon performed phacoemulsification cataract surgery using standard technique under topical anaesthesia and a superiorly created clear corneal incision with IOL in-the-bag implantation using the posterior chamber IOL, Tecnis ZA9003. A 10-0 nylon suture was placed in the corneal incision when the surgeon was dissatisfied with wound integrity after stromal hydration.

Details

Post-operative assessment: post-operative refraction assessed at least 4 weeks after removal of corneal suture if present or at least 6 weeks after surgery by a local optometrist, with results forwarded to clinic. People are routinely reviewed in clinic 2 weeks post-operatively where uncorrected distance visual acuity and CDVA are recorded, patient-reported symptoms or problems are evaluated by the ophthalmologist and corneal sutures removed if in situ.

Study outcomes:

- Prediction error (actual post-operative spherical equivalent minus target post-operative spherical equivalent) and mean absolute error
- Proportion of eyes achieving an error of prediction within various ranges

Group comparisons: Student paired *t* test

Subgroup analysis: axial lengths (short: <22mm, average: 22 to 24.5mm, long >24.5mm) using analysis of variance (ANOVA)

Eyes were analysed independently in people who underwent bilateral sequential cataract surgery because it has been demonstrated that the correlation between fellow eyes is weak when evaluating refractive outcome after surgery

Missing data handling/loss to follow up

The IOLMaster-calculated putative post-operative target spherical equivalent for the IOL power that had been implanted was available for 219 eyes; the biometry for 29 eyes had been removed from the IOLMaster and this was not available for recalculation. Data only reported for 214 eyes, unclear whether missing 5 cases are associated with bilateral sequential cataract surgery as no details provided.

Results

Mean errors and mean absolute errors

	Tecnis ZA9003 IOL			
	Personalised optimised Haigis IOL constants		**Non-personalised optimised Haigis IOL constants**	
	Mean error*	**Mean absolute error***	**Mean error***	**Mean absolute error***
All eyes (n=214)	0.01 ± 0.47 (-1.72 to 1.50)	0.36 ± 0.30 (0 to 1.72)	-0.09 ± 0.48 (-1.78 to 1.53)	0.38 ± 0.31 (0.01 to 1.78)
Short eyes (AL<22mm; n=19)	-0.01 ± 0.48 (-1.19 to 0.57)	0.38 ± 0.28 (0.03 to 1.19)	-0.37 ± 0.47 (-1.53 to 0.25)	0.45 ± 0.39 (0.10 to 1.53)
Average eyes (AL 22 to 24.5mm; n=149)	0.02 ± 0.46 (-1.72 to 1.50)	0.37 ± 0.30 (0 to 1.72)	-0.11 ± 0.48 (-1.78 to 1.25)	0.38 ± 0.31 (0 to 1.78)
Long eyes (AL>24.5mm; n=46)	0.05 ± 0.41 (-0.83 to 1.48)	0.32 ± 0.29 (0 to 1.48)	0.08 ± 0.43 (-0.83 to 1.53)	0.32 ± 0.30 (0.01 to 1.53)
*Data in means ± standard deviations (ranges) dioptres				

Full citation	**Charalampidou S, Cassidy L, Ng E, et al. Effect on refractive outcomes after cataract surgery of intraocular lens constant personalization using the Haigis formula. J Cataract Refract Surg 2010; 36:1081-9**

Number of eyes (proportion) achieving an error of prediction within various ranges

	Tecnis ZA9003 IOL					
	Personalised optimised Haigis IOL constants			Non-personalised optimised Haigis IOL constants		
	±0.25D*	±0.50D*	±1.00D*	±0.25D*	±0.50D*	±1.00D*
All eyes (n=214)	94 (44%)	156 (73%)	205 (96%)	92 (43%)	158 (74%)	205 (96%)
Short eyes (AL<22mm; n=19)	7 (37%)	13 (68%)	18 (95%)	8 (42%)	13 (68%)	17 (89%)
Average eyes (AL 22 to 24.5mm; n=149)	63 (42%)	109 (73%)	143 (96%)	60 (40%)	110 (74%)	145 (97%)
Long eyes (AL>24.5mm; n=46)	24 (52%)	36 (78%)	45 (98%)	24 (52%)	36 (78%)	45 (98%)
*Number of eyes (proportion); calculated from reported percentages						

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Full citation	**Day AC, Foster PJ, Stevens JD. Accuracy of intraocular lens power calculations in eyes with axial length <22.00mm. Clin Exp Ophthalmol 2012; 40:855-62**
Study details	**Country/ies where the study was carried out:** England **Study type:** Retrospective case series **Aim of the study:** To theoretically analyse the accuracy of intraocular lens (IOL) calculation formulas in eyes with an axial length less than 22.00mm using the Haigis, Hoffer Q, SRK/T and Holladay 1 IOL formulas from the IOLMaster, and to assess the accuracy of standard biometry formulas after minimising error due to possible IOL constant inaccuracy **Study dates:** December 2005 to December 2010 **Source of funding:** The RD Crusaders Charitable Trust (via Fight for Sight, London; grant reference 1956). Partial financial support for 2 authors from the Department of Health through the National Institute for Health Research for the NIHR Biomedical Research Centre at Moorfields Eye Hospital NHS Foundation Trust and UCL Institute of Ophthalmology
Participants	**Sample size** 163 eyes in 97 people **Diagnostic criteria** Not reported **Inclusion criteria** • People with axial lengths less than 22.00mm undergoing elective uneventful phacoemulsification cataract surgery and implantation of a monofocal IOL (Bausch & Lomb Akreos AO, Akreos Adapt, Corneal ACR6D, Oculentis Lentis L302-1)

Full citation	**Day AC, Foster PJ, Stevens JD. Accuracy of intraocular lens power calculations in eyes with axial length <22.00mm. Clin Exp Ophthalmol 2012; 40:855-62**

Exclusion criteria

- Previous refractive surgery

Baseline characteristics

IOL model	Bausch & Lomb Akreos AO (32 eyes)	Bausch & Lomb Akreos Adapt (100 eyes)	Corneal ACR6D (19 eyes)	Oculentis Lentis L302-1 (12 eyes)	Total (163 eyes)
Age (years)*	59 ± 8 (46 to 76)	57 ± 11 (33 to 82)	51 ± 10 (36 to 64)	54 ± 9 (33 to 66)	57 ± 10 (33 to 82)
Axial length (mm)*	21.33 ± 0.38 (20.44 to 21.95)	21.41 ± 0.44 (19.95 to 21.98)	20.23 ± 0.52 (19.23 to 21.00)	20.67 ± 0.55 (19.89 to 21.54)	21.20 ± 0.60 (19.23 to 21.98)
Average keratometry (dioptres)*	44.06 ± 1.71 (40.87 to 47.23)	44.25 ± 1.34 (40.62 to 46.78)	43.94 ± 1.15 (41.72 to 46.80)	43.08 ± 1.24 (41.36 to 44.86)	44.09 ± 1.42 (40.62 to 47.23)
Anterior chamber depth (mm)*	2.90 ± 0.38 (2.19 to 3.59)	2.83 ± 0.30 (2.16 to 3.48)	2.80 ± 0.21 (2.46 to 3.27)	2.85 ± 0.25 (2.35 to 3.26)	2.84 ± 0.30 (2.16 to 3.59)
*Data in means ± standard deviations (ranges)					

Methods

<u>Intervention</u>: IOL constant optimisation

- Lens constant adjustment until the overall mean prediction error was zero was performed using the software on the IOLMaster for each lens type. Predictive refractive outcomes following IOL constant optimisation were recalculated.

	Optimised IOL constants			
IOL constant	**Bausch & Lomb Akreos AO (32 eyes)**	**Bausch & Lomb Akreos Adapt (100 eyes)**	**Corneal ACR6D (19 eyes)**	**Oculentis Lentis L302-1 (12 eyes)**
Haigis a0	1.061	0.741	1.668	0.667
Hoffer Q pACD	5.37	5.00	5.98	5.04
SRK/T A-constant	119.1	118.5	120.3	118.8
NB: Data for Holladay 1 SF have not been extracted as this formula has been identified as no longer in use by the guideline committee				

<u>Comparator</u>: IOLMaster IOL constants

- IOL constants for each formula (Haigis a0, a1 and a2; Hoffer Q pACD; Holladay 1 SF) were the standard values derived by the IOLMaster software using the SRK/T A constant value from the packaging of the appropriate IOL type or nominal value reported on the User Group for Laser Interference Biometry (ULIB) website.

	Standard IOL constants			
IOL constant	**Bausch & Lomb Akreos AO (32 eyes)**	**Bausch & Lomb Akreos Adapt (100 eyes)**	**Corneal ACR6D (19 eyes)**	**Oculentis Lentis L302-1 (12 eyes)**
Haigis a0	1.273	1.273	2.523	1.273
Hoffer Q pACD	4.96	4.96	6.21	4.96
SRK/T A-constant	118.0	118.0	120.0	118.0
NB: Data for Holladay 1 SF have not been extracted as this formula has been identified as no longer in use by the guideline committee				

Full citation	**Day AC, Foster PJ, Stevens JD. Accuracy of intraocular lens power calculations in eyes with axial length <22.00mm. Clin Exp Ophthalmol 2012; 40:855-62**

Biometry and keratometry measurements and formula

- Biometry (axial length, AL and anterior chamber depth, ACD) and keratometry: IOLMaster (Carl Zeiss Meditech Inc)
- Formula: Implanted IOL power based on Haigis, Hoffer Q, SRK/T and Holladay 1 IOL formulas using software in the IOLMaster

Cataract surgery and IOL implantation: 1 surgeon performed cataract surgery through a 2.75mm temporal clear corneal incision using an AMO WhiteStar Signature or Alcon Legacy phacoemulsification system with in-the-bag IOL implantation of Bausch & Lomb Akreos AO, Akreos Adapt, Corneal ACR6D or Oculentis Lentis L302-1

Details

Post-operative assessment: post-operative refractive data assessed at least 2 weeks after surgery using Topcon KR8000 series autorefractor (mean±SD, median, range: 5.3±3.9, 4.0, 2.0 to 17.7 weeks)

Study outcomes:

- Prediction error (difference between post-operative spherical equivalent and predicted spherical equivalent)
- Number of eyes (proportion) within various ranges of target refraction

Group comparisons: paired t test, one way analysis of variance (ANOVA)

Missing data handling/loss to follow up

None reported.

Results

Prediction errors

IOL formulas	Standard IOL constants Mean prediction errors in dioptres*				
	Bausch & Lomb Akreos AO (32 eyes)	**Bausch & Lomb Akreos Adapt (100 eyes)**	**Corneal ACR6D (19 eyes)**	**Oculentis Lentis L302-1 (12 eyes)**	**Total (163 eyes)**
Haigis	0.47 ± 0.47 (0.31 to 0.63)	-0.27 ± 0.62 (-0.39 to -0.15)	2.36 ± 1.05 (1.89 to 2.84)	1.45 ± 0.97 (0.91 to 2.00)	0.31 ± 1.13 (0.13 to 0.48)
Hoffer Q	-0.77 ± 0.62 (-0.99 to -0.56)	-0.08 ± 0.60 (-0.19 to 0.04)	0.75 ± 0.94 (0.32 to 1.17)	-0.15 ± 1.05 (-0.75 to 0.45)	-0.12 ± 0.80 (-0.25 to 0)
SRK/T	-1.35 ± 0.66 (-1.58 to 1.12)	-0.58 ± 0.68 (-0.72 to -0.45)	-0.43 ± 1.00 (-0.88 to 0.02)	-1.19 ± 1.05 (-1.78 to -0.60)	-0.76 ± 0.82 (-0.89 to -0.63)

*Data in means ± standard deviations (ranges)
Comparative data for optimised IOL constants not provided for mean prediction errors
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Mean absolute errors

Full citation	Day AC, Foster PJ, Stevens JD. Accuracy of intraocular lens power calculations in eyes with axial length <22.00mm. Clin Exp Ophthalmol 2012; 40:855-62

Mean absolute errors in dioptres*

IOL formulas	Bausch & Lomb Akreos AO (32 eyes)		Bausch & Lomb Akreos Adapt (100 eyes)		Corneal ACR6D (19 eyes)		Oculentis Lentis L302-1 (12 eyes)		Total (163 eyes)	
	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant
Haigis	0.37 ± 0.28 (0.28 to 0.47)	0.55 ± 0.36 (0.42 to 0.68)	0.44 ± 0.35 (0.38 to 0.51)	0.53 ± 0.42 (0.45 to 0.61)	0.86 ± 0.58 (0.60 to 1.12)	2.36 ± 1.05 (1.89 to 2.84)	0.77 ± 0.51 (0.48 to 1.06)	1.45 ± 0.97 (0.91 to 2.00)	0.50 ± 0.41 (0.44 to 0.57)	0.82 ± 0.83 (0.69 to 0.94)
Hoffer Q	0.50 ± 0.37 (0.37 to 0.63)	0.84 ± 0.53 (0.66 to 1.02)	0.46 ± 0.39 (0.39 to 0.54)	0.47 ± 0.39 (0.39 to 0.54)	0.74 ± 0.58 (0.48 to 1.00)	0.89 ± 0.80 (0.53 to 1.25)	0.83 ± 0.61 (0.48 to 1.17)	0.88 ± 0.53 (0.58 to 1.19)	0.53 ± 0.44 (0.46 to 0.60)	0.62 ± 0.52 (0.54 to 0.70)
SRK/T	0.50 ± 0.37 (0.37 to 0.63)	1.35 ± 0.66 (1.12 to 1.58)	0.52 ± 0.42 (0.43 to 0.60)	0.72 ± 0.53 (0.62 to 0.83)	0.79 ± 0.56 (0.53 to 1.04)	0.92 ± 0.56 (0.67 to 1.17)	0.85 ± 0.56 (0.53 to 1.16)	1.32 ± 0.87 (0.83 to 1.80)	0.57 ± 0.45 (0.50 to 0.64)	0.91 ± 0.64 (0.81 to 1.01)

*Data in means ± standard deviations (ranges)
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Number of eyes (proportion) within various ranges of target refraction

Number of eyes (proportion) within ±0.25D of target refraction

IOL formulas	Bausch & Lomb Akreos AO (32 eyes)		Bausch & Lomb Akreos Adapt (100 eyes)		Corneal ACR6D (19 eyes)		Oculentis Lentis L302-1 (12 eyes)		Total (163 eyes)	
	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant
Haigis	12	8	35	34	3	0	2	1	52	42
Hoffer Q	10	4	39	33	3	2	4	2	55	46
SRK/T	11	2	32	23	2	2	3	2	47	29

Number of eyes (proportion) within ±0.50D of target refraction

IOL formulas	Bausch & Lomb Akreos AO (32 eyes)		Bausch & Lomb Akreos Adapt (100 eyes)		Corneal ACR6D (19 eyes)		Oculentis Lentis L302-1 (12 eyes)		Total (163 eyes)	
	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant
Haigis	24	17	68	57	4	0	4	3	101	77
Hoffer Q	18	10	60	62	9	8	4	4	91	85
SRK/T	20	4	54	43	6	5	4	3	85	55

Full citation	Day AC, Foster PJ, Stevens JD. Accuracy of intraocular lens power calculations in eyes with axial length <22.00mm. Clin Exp Ophthalmol 2012; 40:855-62

	Number of eyes (proportion) within ±1.00D of target refraction									
	Bausch & Lomb Akreos AO (32 eyes)		Bausch & Lomb Akreos Adapt (100 eyes)		Corneal ACR6D (19 eyes)		Oculentis Lentis L302-1 (12 eyes)		Total (163 eyes)	
IOL formulas	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant	Optimised IOL constant	Standard IOL constant
Haigis	31	29	93	86	12	0	7	4	143	119
Hoffer Q	28	23	92	91	14	12	6	6	142	132
SRK/T	28	8	89	72	14	10	6	4	137	95

*Number of eyes (proportion); calculated from reported percentages
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

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Full citation	Eom Y, Kang SY, Song JS, et al. Use of corneal power-specific constants to improve the accuracy of the SRK/T formula. Ophthalmology 2013; 120:477-81
Study details	**Country/ies where the study was carried out:** South Korea **Study type:** Retrospective case series **Aim of the study:** To evaluate the effect of average corneal power (K) and axial length (AL) on a data-adjusted A-constant for improving the refractive outcome in the Sanders-Retzlaff-Kraff (SRK)/T formula **Study dates:** April 2008 to June 2012 **Source of funding:** None reported
Participants	**Sample size** 237 eyes in 237 people **Diagnostic criteria** Not reported **Inclusion criteria** • People undergoing uneventful phacoemulsification cataract surgery with intraocular lens (IOL) implantation of either Bausch & Lomb Akreos AO or Acrysof IQ SN60WF by a single surgeon at 1 institution • Post-operative best corrected visual acuity (BCVA) ≥20/40 in the operated eye **Exclusion criteria** • Traumatic cataracts

Full citation	**Eom Y, Kang SY, Song JS, et al. Use of corneal power-specific constants to improve the accuracy of the SRK/T formula. Ophthalmology 2013; 120:477-81**

- Previous ocular surgery (e.g. penetrating keratoplasty, refractive surgery)
- Complicated cataract surgery (e.g. anterior or posterior capsular tears)
- Sulcus fixated lenses
- IOL exchanges
- Post-operative complications
- Indwelling silicone oil
- Prior retinal detachment

Baseline characteristics (n=637 comprising 400 people included in the dataset to calculate the data-adjusted A constants)

IOL model	Acrysof IQ SN60WF (314 eyes)	Akreos AO IOL (323 eyes)
Age (years)*	68.2 ± 9.0 (26-90)	65.8 ± 9.1 (37-88)
Female^	197 (62.7%)	203 (62.8%)
Right:left eyes	161:153	157:166
*Data in means ± standard deviations (ranges) ^Number (proportion)		

Methods

Intervention: Data-adjusted A constants

- A different cohort of 400 eyes meeting the study's selection criteria was used to calculate the different data-adjusted A constants based on the K and AL readings. 200 eyes received the Acrysof IQ SN60WF IOL and 200 eyes received the Akreos AO IOL.
- The data-adjusted SRK/T A constants were calculated using the Haigis constant optimisation Excel spreadsheet for optical biometry, which also optimises a lens constant for the SRK/T formula.
- Personalisation of the A-constant for the two IOL models based on the K readings was also undertaken. Data-adjusted A constants were calculated over a range of K values. K value thresholds were then identified where deviations (increasing or decreasing trends) of A-constants were observed. For the Acrysof IQ SN60WF IOL, 2 K thresholds were identified: 43.0D and 44.7D. For the Akreos AO IOL, 2 K thresholds were identified: 43.2D and 45.0D. These K thresholds were used to calculate different data-adjusted A constants as outlined in the table below. No further details were provided on how this was used in the IOL formula calculations.

	SRK/T IOL formula A constants					
	Acrysof IQ SN60WF IOL			Akreos AO IOL		
	AC1	AC2	AC3	AC1	AC2	AC3
1 A constant Data entered into Haigis constant optimisation spreadsheet (Acrysof IQ: 114 eyes; Akreos AO: 123 eyes)	119.04	NR	NR	118.27	NR	NR
2 A constants Cases divided into 2 subgroups based on K thresholds • Acrysof IQ: 200 eyes; K threshold: 44.2D • Akreos AO: 200 eyes; K threshold: 44.0D	119.20	118.79	NR	118.49	118.07	NR
3 A constants	119.33	119.08	118.71	118.57	118.28	117.96

Full citation	**Eom Y, Kang SY, Song JS, et al. Use of corneal power-specific constants to improve the accuracy of the SRK/T formula. Ophthalmology 2013; 120:477-81**

Cases divided into 3 subgroups based on K thresholds
- Acrysof IQ: 200 eyes; K thresholds: 43.0D and 44.7D
- Akreos AO: 200 eyes; K thresholds: 43.2D and 45.0D

Comparator: Traditional A constants

	Acrysof IQ SN60WF IOL (114 eyes)	Akreos AO IOL (123 eyes)
SRK/T IOL formula A constant	119.0	118.3
NB: Due to poor reporting in the manuscript, traditional A constants are assumed to be equivalent to sometimes termed "data-adjusted 1 A constant"		

Biometry and keratometry measurements and formula
- Biometry (axial length, AL) and keratometry: IOLMaster (version 5.02 or higher, Carl Zeiss Meditech); assessed pre-operatively by the same trained biometry technician
- Formula: SRK/T on the IOLMaster used to calculate IOL power

Cataract surgery and IOL implantation: 1 experienced surgeon performed uneventful phacoemulsification cataract surgery under topical anaesthesia and a 2.2mm or 2.75mm temporal clear corneal incision with IOL in-the-bag implantation of either the Acrysof IQ SN60WF or Akreos AO IOL. At the discretion of the surgeon, a single suture was placed in some cases.

Details

Post-operative assessment: post-operative manifest refraction assessed at 3 to 10 weeks after surgery.

Study outcomes:
- Prediction error (observed post-operative spherical equivalent minus pre-operative predicted refraction) and absolute errors
- Proportion of eyes achieving a post-operative predicted refractive error within various ranges

Group comparisons: Wilcoxon signed-rank test

Missing data handling/loss to follow up

None reported.

Results

Absolute errors

	Median absolute error (dioptres)	
	Acrysof IQ SN60WF IOL (114 eyes)	**Akreos AO IOL (123 eyes)**
Traditional A constant (IOL calculation using 1 A constant)	0.29	0.44
IOL calculation using 2 A constants	0.23	0.42
IOL calculation using 3 A constants	0.23	0.38

Full citation	Eom Y, Kang SY, Song JS, et al. Use of corneal power-specific constants to improve the accuracy of the SRK/T formula. Ophthalmology 2013; 120:477-81

Number of eyes (proportion) achieving a post-operative predicted refractive error within various ranges

	Acrysof IQ SN60WF IOL (114 eyes)			Akreos AO IOL (123 eyes)		
	±0.25D*	±0.50D*	±1.00D*	±0.25D*	±0.50D*	±1.00D*
Traditional A constant (IOL calculation using 1 A constant)	49 (43%)	84 (73.7%)	110 (96.5%)	34 (27.6%)	68 (55.3%)	106 (86.2%)
IOL calculation using 2 A constants	59 (51.8%)	88 (77.2%)	111 (97.4%)	34 (27.6%)	68 (55.3%)	111 (90.2%)
IOL calculation using 3 A constants	62 (54.4%)	90 (78.9%)	111 (97.4%)	38 (30.9%)	78 (63.4%)	111 (90.2%)

*Number of eyes (proportion); calculated from reported percentages

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Full citation	Fam HB, Lim KL. Improving refractive outcomes at extreme axial lengths with the IOLMaster: the optical axial length and keratometric transformation. Br J Ophthalmol 2009; 93:678-83
Study details	**Country/ies where the study was carried out:** Singapore **Study type:** Retrospective case series **Aim of the study:** To examine the impact of Haigis' transformation of the optical to acoustic axial length and IOLMaster keratometry with respect to improving the predictability of refractive outcomes in phacoemulsification cataract surgery at all axial lengths **Study dates:** Not reported **Source of funding:** None reported
Participants	**Sample size** 90 eyes in 53 people **Diagnostic criteria** Not reported **Inclusion criteria** • People who underwent phacoemulsification cataract surgery with implantation of either Acrysof toric SN60AT or Tecnis multifocal ZM900 by the same surgeon • No history of previous refractive surgery **Exclusion criteria** • Best corrected visual acuity of 6/9 or better was not achieved following surgery • Presence of ocular pathology other than cataract

Full citation	**Fam HB, Lim KL. Improving refractive outcomes at extreme axial lengths with the IOLMaster: the optical axial length and keratometric transformation. Br J Ophthalmol 2009; 93:678-83**

- Intraoperative complications i.e. posterior capsule rupture or inability to place IOL securely in bag

Baseline characteristics

IOL models	Acrysof toric SN60AT (48 eyes) or Tecnis multifocal ZM900 (42 eyes) in 53 people
Age (years)*	52.4 ± 27.4 (48.5 to 79.5)
Axial length (mm)*	24.38 ± 2.09 (20.60 to 29.55)
Keratometry (dioptres)*	44.59 ± 1.41 (41.55 to 48.14)
Anterior chamber depth (mm)*	3.20 ± 0.44 (2.17 to 4.28)
Right:left eyes	43:47
*Data in means ± standard deviations (ranges)	

Methods

Intervention: IOL constant optimisation

- **Acoustic to optical axial length transformation**
  - **OAL1:** Haigis' AL4 algorithm used to calibrate the optical path length measured by the IOLMaster into the acoustic axial length familiar to A-scan users.
  - **OAL2:** Haigis' AL4 algorithm with compensation for physiological refractive index as proposed by Olsen and Thorwest.
- **Keratometric transformation**
  - **AdjK:** Using a separate cohort of 64 cataractous eyes with no history of refractive surgery or other ocular pathology, keratometry was measured using the IOLMaster and Canon RK-F1 autokeratometer. The relationship between the average keratometry of both devices was derived into an equation which was used for transformations.
  - **OAL1-K:** OAL1 with adjusted keratometry
  - **OAL2-K:** OAL2 with adjusted keratometry
- IOL power calculations using 4 formulas were optimised to take into account variations due to IOL style, surgeon's technique and measurement device. Single and triple optimisation was used for the Haigis method.

	Optimised IOL constants									
	Acrysof toric SN60AT					Tecnis multifocal ZM900				
IOL formulas	**OAL1**	**OAL2**	**AdjK**	**OAL1-K**	**OAL2-K**	**OAL1**	**OAL2**	**AdjK**	**OAL1-K**	**OAL2-K**
Haigis (single)	1.744	1.919	1.483	1.744	1.635	2.408	2.000	1.561	2.408	2.292
Haigis (triple)	-2.345 -0.353 0.373	-3.122 -0.363 0.404	-3.711 -0.385 0.404	-2.217 -0.330 0.355	-1.837 -0.317 0.334	-2.253 -0.359 0.390	-1.678 -0.308 0.355	-2.178 -0.172 0.326	-2.250 -0.358 0.389	-1.678 -0.308 0.355
Hoffer Q	6.266	6.162	5.766	6.005	5.899	6.746	6.631	5.924	6.611	6.487
SRK/T	118.93	118.77	118.26	118.70	118.54	119.81	119.64	119.26	119.91	119.75

Comparator: Standard (non-transformed optimised) IOL constants

	Standard IOLMaster constants	
IOL formulas	**Acrysof toric SN60AT**	**Tecnis multifocal ZM900**

Full citation	Fam HB, Lim KL. Improving refractive outcomes at extreme axial lengths with the IOLMaster: the optical axial length and keratometric transformation. Br J Ophthalmol 2009; 93:678-83

Haigis (single)	1.483	1.859
Haigis (triple)	-4.914 -0.432 0.471	-3.482 -0.339 0.419
Hoffer Q	5.748	6.220
SRK/T	118.15	119.65

Biometry and keratometry measurements and formula

- Biometry (axial length, AL) and keratometry: IOLMaster (version 3.02, Carl Zeiss Meditec AG)
- Formula: IOL power calculations using the Hoffer Q, Holladay I, SRK/T and Haigis formulas. NB: It is unclear whether these formulas were used based on individual axial lengths or for the entire cohort irrespective of axial length.

Cataract surgery and IOL implantation: 1 surgeon performed phacoemulsification cataract surgery with IOL implantation of either Acrysof toric SN60AT or Tecnis multifocal ZM900.

Details

Post-operative assessment: post-operative subjective refraction was undertaken at least 1 month (mean 58.1 days; standard deviation 24 days) after surgery.

Study outcomes:

- Prediction error (difference between achieve spherical equivalent refraction and the calculated spherical equivalent) and mean absolute error. No data were reported for these outcomes.
- Proportion of eyes correct within various refractive ranges

Group comparisons: not reported

Missing data handling/loss to follow up

None reported.

Results

Number of eyes (proportion) correct within various refractive ranges

	Number of eyes (proportion) correct within ±0.50D*					
	Acrysof toric SN60AT (48 eyes) or Tecnis multifocal ZM900 (42 eyes) in 53 people					
	Optimised IOL constants					
IOL formulas	**OAL1**	**OAL2**	**AdjK**	**OAL1-K**	**OAL2-K**	**Standard non-optimised IOLMaster constant**
Haigis (single)	62 (68.8%)	63 (69.9%)	67 (73.9%)	67 (73.9%)	68 (76.1%)	65 (71.7%)
Haigis (triple)	64 (70.7%)	66 (72.8%)	71 (79.3%)	72 (80.4%)	70 (78.3%)	55 (61.3%)
Hoffer Q	59 (65.3%)	60 (67%)	60 (66.7%)	57 (62.9%)	57 (63.5%)	43 (47.6%)
SRK/T	64 (71.6%)	65 (72.6%)	65 (72.6%)	67 (74.5%)	68 (75.5%)	62 (68.4%)

Full citation	Fam HB, Lim KL. Improving refractive outcomes at extreme axial lengths with the IOLMaster: the optical axial length and keratometric transformation. Br J Ophthalmol 2009; 93:678-83

	Number of eyes (proportion) correct within ±1.00D*					
	Acrysof toric SN60AT (48 eyes) or Tecnis multifocal ZM900 (42 eyes) in 53 people					
	Optimised IOL constants					
IOL formulas	OAL1	OAL2	AdjK	OAL1-K	OAL2-K	Standard non-optimised IOLMaster constant
Haigis (single)	80 (89.2%)	80 (89.2%)	82 (91.3%)	82 (91.3%)	82 (91.3%)	82 (91.3%)
Haigis (triple)	82 (91.3%)	82 (91.3%)	82 (91.3%)	82 (91.3%)	82 (91.3%)	80 (89.2%)
Hoffer Q	81 (89.6%)	79 (87.6%)	81 (89.6%)	79 (87.6)	81 (89.6%)	69 (76.7%)
SRK/T	82 (91.6%)	82 (91.6%)	82 (91.6%)	84 (93.6%)	84 (93.6%)	82 (91.6%)
*Number of eyes (proportion); calculated from reported percentages						

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Full citation	Lee TH, Sung MS, Cui L, et al. Factors affecting the accuracy of intraocular lens power calculation with Lenstar. Chonnam Med J 2015; 15:91-6
Study details	**Country/ies where the study was carried out:** South Korea **Study type:** Retrospective case series **Aim of the study:** To compare the refractive outcomes measured by conventional methods and Lenstar biometer and investigate the factors that affect intraocular lens (IOL) power calculation with and without IOL-constant optimisation using the Lenstar **Study dates:** May to October 2013 **Source of funding:** None reported
Participants	**Sample size** 100 eyes in 86 people **Diagnostic criteria** Not reported **Inclusion criteria** • People undergoing uneventful phacoemulsification cataract surgery with in-the-bag posterior chamber IOL implantation by a single surgeon at 1 institution **Exclusion criteria** • Posterior capsule opacification • Mature cataracts • Previous ocular surgery other than cataract surgery • Intraoperative complications • Post-operative visual acuity <6/12

Full citation	Lee TH, Sung MS, Cui L, et al. Factors affecting the accuracy of intraocular lens power calculation with Lenstar. Chonnam Med J 2015; 15:91-6

- Poor cooperation

Baseline characteristics

IOL model	Acrysof IQ SN60WF (n=86, 100 eyes)
Age (years)*	67.62 ± 10.64
Female^	46 (53.5%)
Axial length (mm)*	23.37 ± 1.13
Keratometry (dioptres)*	43.86 ± 1.49
*Data in means ± standard deviations ^Number (proportion)	

Methods

Intervention: Lenstar IOL constant optimisation

- Lenstar optimised A constant of 119.02 obtained from East Valley Ophthalmology (Mesa, AZ, USA; www.doctor-hill.com)

Comparator: Traditional A constant

- Recommended and previously optimised ultrasound A constant of 118.7

Biometry and keratometry measurements and formula

- Biometry (axial length, AL): Lenstar (Haag-Streit AG), Mentor O & O Inc A-scan. Comparison examined in this review question only included biometry and keratometry using the Lenstar biometer
- Keratometry: Lenstar, Topcon KR 8900 automated keratometer, Bausch & Lomb manual keratometer
- Biometry and keratometry measurements undertaken by 1 experienced examiner
- Formula: SRK/T formula on Lenstar used to calculate IOL power to achieve the post-operative refraction target for emmetropia

Cataract surgery and IOL implantation: 1 surgeon performed uneventful sutureless cataract surgery under topical anaesthesia using a temporal corneal incision, continuous curvilinear capsulorrhexis, hydrodissection and phacoemulsification with the Alcon Infinity machine to implant a foldable posterior chamber IOL (Alcon SN60WF, 1-piece acrylic IOL) in the capsular bag.

Details

Post-operative assessment: post-operative final refraction (spherical equivalent) assessed at 2 months after surgery using Topcon KR 8900 autorefractometer.

Study outcomes:

- Mean absolute error (average absolute value of numerical errors i.e. final post-operative spherical equivalent minus predicted post-operative spherical equivalent)
- Proportion of eyes achieving a post-operative predicted refractive error within various ranges

Group comparisons: Kruskal-Wallis test

Full citation	**Lee TH, Sung MS, Cui L, et al. Factors affecting the accuracy of intraocular lens power calculation with Lenstar. Chonnam Med J 2015; 15:91-6**
	Missing data handling/loss to follow up None reported.
Results	**Prediction errors and absolute errors**

	Acrysof IQ SN60WF IOL (100 eyes)	
	Mean prediction errors*	**Mean absolute errors***
Lenstar optimised IOL constant	-0.21 ± 0.61	0.55 ± 0.49
Traditional A constant (non-optimised)	-0.24 ± 0.58	0.67 ± 0.52
*Data in means ± standard deviations (dioptres)		

Number of eyes (proportion) achieving a post-operative predicted refractive error within various ranges

	Acrysof IQ SN60W IOL (100 eyes)			
	±0.50D	**±1.00D**	**±1.50D**	**±2.00D**
Lenstar optimised IOL constant	62	82	94	100
Traditional A constant (non-optimised)	46	76	90	100

Factors that influence IOL power calculation

Factors		**Number of eyes**	**Lenstar optimised IOL constant**		**Traditional A constant (non-optimised)**	
			Mean absolute error (dioptres)	**p value**	**Mean absolute error (dioptres)**	**p value**
Axial length (mm)	**<23**	30	0.56	0.93	0.80	0.03
	23-25	51	0.54		0.59	
	≥25	19	0.51		0.72	
Corneal curvature (dioptres)	**<42**	21	0.60	0.03	0.83	0.31
	42-44	40	0.68		0.68	
	>44	39	0.39		0.62	

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Full citation	**Petermeier K, Gekeler F, Messias A, et al. Intraocular lens power calculation and optimised constants for highly myopic eyes. J Cataract Refract Surg 2009; 35:1575-81**
Study details	**Country/ies where the study was carried out:** Germany **Study type:** Retrospective case series **Aim of the study:** To determine whether error in intraocular lens (IOL) calculation in highly myopic patients can be corrected using optimised constants and to evaluate the predictability of different IOL power calculation formulas using the new constants **Study dates:** 2003 to 2007 **Source of funding:** None reported

Full citation	**Petermeier K, Gekeler F, Messias A, et al. Intraocular lens power calculation and optimised constants for highly myopic eyes. J Cataract Refract Surg 2009; 35:1575-81**
Participants	**Sample size** 50 eyes in 32 people **Diagnostic criteria** Not reported **Inclusion criteria** • People undergoing phacoemulsification cataract surgery with IOL implantation of Acrysof MA60MA at a single institution • Willing to participate in the study **Exclusion criteria** • Absent partial coherence interferometry biometry data • Pathology that may affect the accuracy of biometry calculations (e.g. retinal detachment surgery, corneal scars) • Severely reduced visual acuity (hand movements or worse) • Unable to participate in refraction because of glaucoma, amblyopia or myopic degeneration **Baseline characteristics**

IOL model	**Acrysof MA60MA (50 eyes in 32 people)**		
	Positive-dioptre IOL (30 eyes)	**Negative-dioptre IOL (18 eyes)**	**Zero-dioptre IOL (2 eyes)**
Age (years)*	57.14 ± 10.27 (35 to 77)		
Axial length (mm)*	31.15 ± 1.69	33.20 ± 2.25	31.37 and 35.34
K value (mm)*	7.56 ± 0.28	7.71 ± 0.33	7.60 and 8.34
Anterior chamber depth, ACD (mm)*	3.72 ± 0.11	3.59 ± 0.12	Not evaluated
*Data in means ± standard deviations (ranges) as appropriate			

Methods	**Intervention: ULIB IOL constant optimisation** • Post-operative refractive results were used to calculate individualised IOL constants for positive-dioptre and negative-dioptre ranges within the framework of the User Group for Laser Interference Biometry (ULIB) project to optimise constants for optical biometry. The need to treat plus and minus IOLs differently for optimised outcomes is based on lens geometry changes during the transition from plus to minus dioptres, with the lens' principal planes switching sides relative to the haptic plane. Because the positions of principal planes and IOL constants are directly linked, different constants are needed. No specific details on actual IOL constants were provided. • The estimated post-operative refractive outcome was re-evaluated by inputting the new constants into the IOLMaster calculation algorithm with the pre-operative anatomic data. In 18 eyes, the ACD was not measured pre-operatively so the target refraction was calculated using the Haigis formula in 32 eyes (18 positive-dioptre IOL, 14 negative-dioptre IOL). For the other formulas, the target refraction was calculated for all eyes. **Comparator: Standard non-ULIB optimised IOL constants**

Full citation	**Petermeier K, Gekeler F, Messias A, et al. Intraocular lens power calculation and optimised constants for highly myopic eyes. J Cataract Refract Surg 2009; 35:1575-81**

- The constants for AcrySof MA60BM were used as there are no commonly accepted optimised constants for the AcrySof MA60MA. The AcrySof MA60BM has a similar optical design and same constant for ultrasound biometry but a different available range of dioptres.

AcrySof MA60MA IOL (based on data from AcrySof MA60BM)						
IOL formula constant						
Haigis			**Hoffer Q personalised anterior chamber depth, pACD**	**SRK/T A constant, AC**	**Holladay 1 surgeon factor, SF**	**SRK II A constant, SRKIIAC**
a0	**a1**	**a2**				
1.443	0.077	0.163	6.08	119.8	2.33	120.4

- To make allowances for the different geometries of positive and negative dioptre IOLs, 2 sets of optimised constants were derived for each IOL power sign. No further details were provided on how these were derived.

IOL formula constant	**Positive-dioptre IOL**	**Negative-dioptre IOL**
Haigis a0	5.74	-4.01
Hoffer Q personalised anterior chamber depth, pACD	16.15	-4.86
SRK/T A constant, AC	126.63	104.43
Holladay 1 surgeon factor, SF	10.46	-6.48
SRK II A constant, SRKIIAC	119.47	120.09

Biometry and keratometry measurements and formula

- Biometry (axial length, AL) and keratometry: IOLMaster (version 3.01.0294), undertaken by a specialist (lead study author)
- Formula: All pre-operative IOL calculations undertaken with the IOLMaster

Cataract surgery and IOL implantation: experienced surgeons performed standard phacoemulsification through a 3.0mm temporal clear corneal tunnel incision and a 5.0 to 5.5mm capsulorhexis with in-the-bag IOL implantation of the acrylic AcrySof MA60MA.

Details

Post-operative assessment: post-operative examination undertaken by the same specialist (lead study author) – no further details provided. However, elsewhere, states that the mean follow-up was 18.92 ± 13.33 months (range 3 to 47 months)

Study outcomes:

- Prediction error i.e. deviation from post-operative refraction from the target refraction (difference between post-operative spherical equivalent and calculated post-operative refraction)
- Number of eyes (proportion) achieving target refraction within various ranges

Group comparisons: Paired t test

Missing data handling/loss to follow up

None reported.

Full citation	**Petermeier K, Gekeler F, Messias A, et al. Intraocular lens power calculation and optimised constants for highly myopic eyes. J Cataract Refract Surg 2009; 35:1575-81**

Results

Prediction errors

IOL formulas	Prediction errors					
	Acrysof MA60MA (50 eyes in 32 people)					
	Positive-dioptre IOL (30 eyes)		Negative-dioptre IOL (18 eyes)		Zero-dioptre IOL (2 eyes)	
	ULIB optimised constants*	Non-ULIB optimised constants*	ULIB optimised constants*	Non-ULIB optimised constants*	ULIB optimised constants*	Non-ULIB optimised constants*
Haigis	0 ± 0.21	0.57 ± 0.18	0 ± 0.24	1.14 ± 0.21	0.79 and 1.37	0.79 and 1.37
Hoffer Q	0 ± 0.26	1.25 ± 0.14	0 ± 0.49	2.10 ± 0.19	1.65 and 2.18	1.65 and 2.18
SRK/T	0 ± 0.17	0.59 ± 0.15	0 ± 0.21	1.68 ± 0.19	1.02 and 1.49	1.02 and 1.49

*Data in means ± standard deviations
NB: Data for Holladay 1 and SRK II formulas have not been extracted as these have been identified as no longer in use by the guideline committee
NB: Data in Zero-dioptre IOL correctly extracted. Different results were reported for the 2 groups for the SRK II formula only

Number of eyes (proportion) achieving target refraction within various ranges

	Acrysof MA60MA (50 eyes in 32 people)		
	Haigis*	Hoffer Q*	SRK/T*
±1.00D	32 (84.4%)	50 (100%)	50 (100%)

NB: Data for Holladay 1 and SRK II formulas have not been extracted as these have been identified as no longer in use by the guideline committee
Unclear whether data refers to optimised/non-optimised IOL constants. No other comparative data provided
*Number of eyes (proportion)

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Full citation	**Sharma R, Maharajan P, Kotta S, et al. Prediction of refractive outcome after cataract surgery using partial coherence interferometry: comparison of SRK/T and Haigis formulae. Int Ophthalmol 2014; 34:451-5**
Study details	**Country/ies where the study was carried out:** Not reported **Study type:** Retrospective case series **Aim of the study:** To compare the accuracy of the predictions of SRK/T and Haigis formulas using parameters derived from the IOLMaster and to analyse the effect of updating or optimisation of the constants on the post-operative result **Study dates:** Not reported **Source of funding:** None reported
Participants	**Sample size** 51 eyes in 51 people

Full citation	**Sharma R, Maharajan P, Kotta S, et al. Prediction of refractive outcome after cataract surgery using partial coherence interferometry: comparison of SRK/T and Haigis formulae. Int Ophthalmol 2014; 34:451-5**
	Diagnostic criteria Not reported **Inclusion criteria** • People undergoing phacoemulsification cataract surgery with in-the-bag intraocular lens (IOL) implantation by a single surgeon **Exclusion criteria** • Unable to undergo partial coherence interferometry biometry due to the density of the cataract • Complicated surgery including posterior capsular tear • Implants other than Acrysof MA30 **Baseline characteristics**

IOL model	**Acrysof MA30 (n=51)**
Axial length range (mm)	20.93 to 25.16
Number of people with axial length <22mm, 22-24mm and >24mm	9, 37 and 5

Methods	**Intervention: ULIB constant optimisation** • IOL constants were optimised using the User Group for Laser Interference Biometry (ULIB). The post-operative prediction for the same implant power was retrospectively calculated for the updated SRK/T and Haigis formulas using the optimised constants **Comparator: Non-optimised constants (assumed)** • Standard SRK/T and Haigis formulas (assumed with unaltered constants). Study provided no details. **Biometry and keratometry measurements and formula** • Biometry (axial length, AL and anterior chamber depth, ACD) and keratometry: IOLMaster (Zeiss). • Formula: SRK/T formula used to select pre-operatively the implanted IOL. **Cataract surgery and IOL implantation:** 1 surgeon performed phacoemulsification surgery with 3mm temporal corneal non-sutured incisions with in-the-bag IOL implantation of a single style standard Alcon Acrysof MA30. **Details** Post-operative assessment: post-operative refractive assessment undertaken 4 weeks after surgery. Study outcomes: • Mean absolute error (difference between the predicted value and the actual post-operative spherical equivalent) • Distribution of refractive error

Full citation	**Sharma R, Maharajan P, Kotta S, et al. Prediction of refractive outcome after cataract surgery using partial coherence interferometry: comparison of SRK/T and Haigis formulae. Int Ophthalmol 2014; 34:451-5**
	Group comparisons: Paired t test Axial length subgroups were analysed but data were not provided. Graphical data of errors were provided for the different axial length subgroups but with no measure of dispersion. Therefore, data not extracted. **Missing data handling/loss to follow up** None reported.
Results	**Mean absolute errors**

Acrysof MA30 (51 eyes)					
Mean absolute errors (standard deviation) in dioptres					
SRK/T formula			Haigis formula		
Optimised ULIB constant	**Non-optimised constant**	**P value**	**Optimised ULIB constant**	**Non-optimised constant**	**P value**
0.62 (0.54)	0.75 (0.50)	<0.03	0.49 (0.50)	0.56 (0.40)	0.01
Study reported that overall, Haigis resulted in an average myopia of -0.22 and SRK/T in hypermetropia of 0.6D sphere.					

Distribution of refractive error

Acrysof MA30 (51 eyes)							
Number of eyes (proportion)							
SRK/T formula				Haigis formula			
Optimised ULIB constant		**Non-optimised constant**		**Optimised ULIB constant**		**Non-optimised constant**	
1.00D	**2.00D**	**1.00D**	**2.00D**	**1.00D**	**2.00D**	**1.00D**	**2.00D**
42 (82%)	49 (96%)	40 (78%)	49 (96%)	44 (86%)	51 (100%)	44 (86%)	51 (100%)

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Full citation	**Wang L, Shirayama M, Ma XJ, et al. Optimizing intraocular lens power calculations in eyes with axial lengths above 25.0mm. J Cataract Refract Surg 2011; 37:2018-27**
Study details	**Country/ies where the study was carried out:** USA **Study type:** Retrospective case series **Aim of the study:** To determine the accuracy of refractive prediction of 4 intraocular lens (IOL) calculation formulas (Haigis, Hoffer Q, SRK/T and Holladay 1) in eyes with an axial length greater than 25.0mm and to propose a method of optimising axial lengths to improve prediction accuracy **Study dates:** November 2005 to April 2008 **Source of funding:** In part by an unrestricted grant from Research to Prevent Blindness, New York, USA
Participants	**Sample size** 106 eyes in 78 people **Diagnostic criteria**

Full citation	**Wang L, Shirayama M, Ma XJ, et al. Optimizing intraocular lens power calculations in eyes with axial lengths above 25.0mm. J Cataract Refract Surg 2011; 37:2018-27**

Not reported

Inclusion criteria

- People with axial lengths greater than 25.0mm undergoing phacoemulsification cataract surgery with IOL implantation of Acrysof SA60AT, SN60AT, SN60T, SN60WF, MA60MA or MA60AC by the same surgeon in 1 institution
- Biometric measurements using IOLMaster (Carl Zeiss Meditec Inc)
- No previous ocular surgery
- No intraoperative or post-operative complications
- Post-operative corrected distance visual acuity of 20/30 or better

Exclusion criteria

- None reported

Baseline characteristics

	Dataset from October 2002 to October 2005 used to develop and validate formulas (n=69)		**Dataset from November 2005 to April 2008 to validate formulas (n=78)**		
IOL models	**SA60AT/SN60AT**	**MA60MA**	**MA60MA/MA60AC**	**SA60AT/SN60AT/SN60T**	**SN60WF**
Number of eyes	80	14	23	28	55
Age (years)*	62 ± 11 (34 to 88)		65 ± 10 (41 to 85)		
Axial length (mm)*	26.66 ± 0.92 (25.05 to 28.66)	30.41 ± 1.58 (27.14 to 32.98)	27.93 ± 1.00 (26.41 to 30.78)	26.79 ± 1.14 (25.03 to 29.35)	26.50 ± 0.97 (25.01 to 29.56)

*Data in means ± standard deviations (ranges)
NB: Data from second institution located in Germany not extracted as participants had refractive lens exchange. In addition, relevant comparative data for the cohort from October 2002 to October 2005 were not provided and therefore, this group has not been used.

Methods

Intervention1: IOL constant optimisation

- IOL constants for each formula were retrospectively optimised by obtaining a mean numerical error of zero using the IOLMaster (Hoffer Q, SRK/T and Holladay 1) or multiple regression analysis (Haigis). This was done to avoid the offset errors due to systematic errors in biometry, surgical technique and/or formulas.

Comparator1: Standard manufacturer IOL constants

No data provided for this comparison: IOL constant optimisation vs standard manufacturer IOL constants

Intervention2: Axial length optimisation

- For each eye with each IOL formula, the optimised axial length using the manufacturer's IOL constant to produce a refractive prediction error of zero was back-calculated. Manufacturer's IOL constants were used as they serve as standard IOL constants for surgeons.

Full citation	**Wang L, Shirayama M, Ma XJ, et al. Optimizing intraocular lens power calculations in eyes with axial lengths above 25.0mm. J Cataract Refract Surg 2011; 37:2018-27**

Comparator2: IOLMaster axial length

Biometry and keratometry measurements and formula

- Biometry (axial length, AL) and keratometry: IOLMaster (Carl Zeiss Meditech Inc)
- Formula: Implanted IOL power based on Holladay 1 formula at USA centre

Cataract surgery and IOL implantation: 1 surgeon performed phacoemulsification cataract surgery through a 3.0 to 3.2mm temporal clear corneal tunnel incision with IOL implantation of Acrysof SA60AT, SN60AT, SN60T, SN60WF, MA60MA or MA60AC

Details

Post-operative assessment: post-operative refractive outcomes assessed at least 3 weeks after surgery

Study outcomes:

- Prediction error (difference between actual post-operative refractive outcome and predicted refraction). A positive refractive prediction error indicates a hyperopic refractive outcome.
- Number of eyes (proportion) with a hyperopic refractive outcome (positive prediction error)

Group comparisons: Student t test

Missing data handling/loss to follow up

None reported.

Results

Comparison 2: Optimised axial length vs. IOLMaster axial length (standard manufacturers' IOL constants used in both groups)

Prediction errors

IOL formulas	Mean prediction errors in dioptres*					
	MA60MA/MA60AC (23 eyes)		SA60AT/SN60AT/SN60T (28 eyes)		SN60WF (55 eyes)	
	Optimised AL	IOLMaster AL	Optimised AL	IOLMaster AL	Optimised AL	IOLMaster AL
Haigis	-0.05 ± 0.40 (-0.63 to 0.99)	0.83 ± 0.39 (0.17 to 1.79)	-0.15 ± 0.71 (-1.09 to 2.40)	0.86 ± 0.67 (-0.36 to 3.04)	-0.05 ± 0.52 (-1.19 to 1.17)	0.62 ± 0.47 (-0.55 to 1.91)
Hoffer Q	-0.03 ± 0.45 (-0.73 to 1.15)	1.08 ± 0.47 (0.06 to 2.06)	0.15 ± 0.77 (-1.10 to 2.25)	0.88 ± 0.70 (-0.37 to 2.78)	-0.08 ± 0.60 (-1.03 to 1.19)	0.55 ± 0.48 (-0.43 to 1.94)
SRK/T	-0.31 ± 0.38 (-1.06 to 0.30)	0.42 ± 0.39 (-0.61 to 1.27)	-0.03 ± 0.67 (-1.20 to 1.61)	0.35 ± 0.61 (-0.82 to 1.79)	-0.08 ± 0.50 (-1.18 to 0.99)	0.22 ± 0.46 (-0.91 to 1.37)

*Data in means ± standard deviations (ranges)
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

Full citation	**Wang L, Shirayama M, Ma XJ, et al. Optimizing intraocular lens power calculations in eyes with axial lengths above 25.0mm. J Cataract Refract Surg 2011; 37:2018-27**

Number of eyes (proportion) with a hyperopic refractive outcome (positive prediction error)

IOL formulas	Number of eyes (proportion) with a hyperopic refractive outcome*					
	MA60MA/MA60AC (23 eyes)		SA60AT/SN60AT/SN60T (28 eyes)		SN60WF (55 eyes)	
	Optimised AL	IOLMaster AL	Optimised AL	IOLMaster AL	Optimised AL	IOLMaster AL
Haigis	9 (39%)	23 (100%)	15 (54%)	27 (96%)	23 (42%)	52 (95%)
Hoffer Q	11 (48%)	23 (100%)	14 (50%)	26 (93%)	22 (40%)	50 (91%)
SRK/T	6 (26%)	20 (87%)	11 (39%)	18 (64%)	26 (47%)	37 (67%)

*Number of eyes (proportion); calculated from reported percentages
NB: Data for Holladay 1 have not been extracted as this formula has been identified as no longer in use by the guideline committee

8E.3.4 Other considerations in biometry

8E.3.4.1 Second eye prediction refinement

Full citation	**Aristodemou P, Cartwright NEK, Sparrow JM, et al. First eye prediction error improves second eye refractive outcome. Results in 2129 patients after bilateral sequential cataract surgery. Ophthalmology 2011 118:1701-9**
Study details	**Country/ies where the study was carried out:** UK **Study type:** Retrospective consecutive case series **Aim of the study:** To investigate the relationship between first and second eye prediction errors in order to develop theoretical correction factors based on the prediction error of the first eye that can be applied to the second eye **Study dates:** December 2005 to July 2010 **Source of funding:** not reported
Participants	**Sample size** 2129 people (4258 eyes, first and second eyes defined chronologically) **Diagnostic criteria** Not reported **Inclusion criteria** • People who underwent bilateral sequential uncomplicated phacoemulsification cataract surgery in 1 hospital with the same intraocular lens (IOL) model implanted in the capsular bag in both eyes • Had pre-operative measurement of axial length (AL) and corneal curvature (K) using the IOLMaster (Carl Zeiss Meditec, Germany) • Had a post-operative subjective refraction and corrected distance visual acuity of ≥20/40 **Exclusion criteria**

<table>
<tr><td>Full citation</td><td>Aristodemou P, Cartwright NEK, Sparrow JM, et al. First eye prediction error improves second eye refractive outcome. Results in 2129 patients after bilateral sequential cataract surgery. Ophthalmology 2011 118:1701-9</td></tr>
<tr><td></td><td>• Corneal astigmatism >3.00 dioptres
• People undergoing any concurrent additional procedure such as trabeculectomy, pars plana vitrectomy or limbal relaxing incisions

Baseline characteristics
• Not reported</td></tr>
<tr><td>Methods</td><td>Theoretical correction factors
• Relationship between prediction errors (differences between actual post-operative spherical equivalent of the subjective refraction and the post-operative refraction) for the first and second eyes was analysed using correlation and a significant regression coefficient (RC) of 0.45 was defined for the included 2129 patients (4258 paired eyes).
• Correction factor: corrected absolute prediction error, CAPE = absolute value of the prediction error of the second eye (PE2) minus the prediction error of the first eye (PE1) multiplied by the regression coefficient (RC)
$$CAPE = \left| (PE2) - (PE1 * 0.45) \right|$$
The relationship was plotted to define critical values of interocular differences in axial length and corneal power of paired eyes that are associated with an increase in CAPE (deviations from baseline variation). Data from patients with paired eyes exceeding these critical values were analysed separately. Increasing difference in axial length between paired eyes was not associated with an increase in CAPE. Differences of >0.6 dioptres of corneal power were associated with an increase in CAPE. Therefore, removal of paired eyes with an inter eye difference in corneal power of >0.6 dioptres, resulted in 1867 patients (3734 eyes) used in the theoretical predicted post-operative refraction calculations.
• IOL formula: Theoretical predicted post-operative refraction was calculated using optimised IOL constants and the Hoffer Q, Holladay 1 and SRK/T formulas. The choice of formulas was based on its appropriateness to both eyes:
<table>
<tr><th>IOL formula</th><th>Paired eyes using the same IOL formula</th><th>If paired eyes straddled the axial length thresholds for the preferred choice of IOL formula (in adjacent column), the following criteria were used</th><th>To undertake sensitivity analyses of correction factors around optimised IOL constants, non-optimised IOL constants were used in the theoretical calculations in the following increments and decrements around the individual formula's IOL constant</th></tr>
<tr><td>Hoffer Q (n=83)</td><td>Axial length <21.50mm</td><td>Axial length <26.50mm</td><td>0.06-steps of optimised personalised anterior chamber depth</td></tr>
<tr><td>Holladay 1 (n=1911)</td><td>21.50mm ≤ Axial length < 26.00mm</td><td>21.00mm < Axial length < 26.50mm</td><td>0.06-steps of optimised surgeon factor</td></tr>
<tr><td>SRK/T (n=135)</td><td>Axial length ≥ 26.00mm</td><td>Axial length ≥ 22.00mm</td><td>0.10-steps of optimised A constant</td></tr>
</table>
• Application of the correction factor to the theoretical predicted post-operative refraction of the second eye was tested using a range of correction factors from 10 to 100% in increments of 10%. A 50% correction factor was found to be optimal in improving second eye theoretical refraction outcomes. Sensitivity analyses on the performance of the correction factors when using non-optimised IOL constants were undertaken. With no correction factor applied, increasing deviations from the optimised IOL constant had an adverse effect on the refractive outcome of the second eye. Application of the correction factor progressively from 10% upwards reduced the adverse effects of IOL constant errors on the refractive outcome. The 50% correction factor mitigated the increase in mean absolute errors related to IOL constant errors.</td></tr>
</table>

Full citation	**Aristodemou P, Cartwright NEK, Sparrow JM, et al. First eye prediction error improves second eye refractive outcome. Results in 2129 patients after bilateral sequential cataract surgery. Ophthalmology 2011 118:1701-9**

- First eyes were stratified into groups defined by ranges of their prediction errors and further combined into groups of absolute prediction errors. Comparison of the axial lengths and corneal power between these groups were investigated to identify any groups with unusual biometric characteristics. Vector analysis of post-operative subjective refraction was carried out to detect any significant differences in magnitude and meridian of astigmatism.

Interventions

- Adjusted second eye prediction using 50% correction factor, n=1867
- Unadjusted second eye prediction using no correction factor, n=1867

Measurement and formula

- Biometry and keratometry measurements: axial lengths and keratometry curvature were measured using the IOLMaster (Carl Zeiss Meditec, Germany).

Cataract surgery and IOL implantation: uncomplicated bilateral sequential phacoemulsification cataract surgery with IOL implantation (LI61AO Sofport, Bausch & Lomb) in the capsular bag in all patients. Manufacturer's A constant of 118.0.

Details

Post-operative assessment: subjective refraction was undertaken by an optometrist at the hospital or in the community at least 4 weeks after the surgery. Community optometrists recorded the details of the post-operative assessment in a proforma letter which the patient returned at their post-operative hospital visit 6 weeks after the surgery. Data obtained from anonymised electronic patient records.

Study outcomes:

- Mean absolute error (average of the absolute value of the prediction errors; prediction error is the difference between the actual post-operative spherical equivalent of the subjective refraction and the post-operative refraction)
- Number of eyes within various ranges of the post-operative refraction

Group comparisons: non-parametric tests

Results

Mean absolute errors and number (proportion) of eyes within various ranges of post-operative refraction

First eye prediction error groups	Adjusted second eye prediction using 50% correction factor				Unadjusted second eye prediction using no correction factor			
	MAE	Number (%) within 0.25D*	Number (%) within 0.5D*	Number (%) within 1.00D*	MAE	Number (%) within 0.25D*	Number (%) within 0.5D*	Number (%) within 1.00D*
-0.25 to +0.24 D (n=807)	0.29	428 (53%)	678 (84%)	799 (99%)	0.30	420 (52%)	670 (83%)	791 (98%)
-0.50 to -0.26D and 0.25 to 0.49D (n=583)	0.31	303 (52%)	472 (81%)	566 (97%)	0.34	280 (48%)	455 (78%)	560 (96%)
-0.75 to -0.51D and 0.50 to 0.74D (n=261)	0.38	112 (43%)	193 (74%)	248 (95%)	0.49	81 (31%)	144 (55%)	240 (92%)
-1.00 to -0.76D and 0.75 to 0.99D (n=139)	0.32	60 (43%)	108 (78%)	138 (99%)	0.43	50 (36%)	88 (63%)	131 (94%)

Full citation	**Aristodemou P, Cartwright NEK, Sparrow JM, et al. First eye prediction error improves second eye refractive outcome. Results in 2129 patients after bilateral sequential cataract surgery. Ophthalmology 2011 118:1701-9**

-1.50 to -1.01D and 1.00 to 1.49D (n=69)	0.40	26 (38%)	51 (74%)	63 (91%)	0.61	11 (16%)	29 (42%)	61 (88%)
All eyes (n=1867)	0.32	934 (50%)	1512 (81%)	1811 (97%)	0.36	840 (45%)	1382 (74%)	1792 (96%)

All group sizes are as reported in study paper. There were not enough eyes with prediction errors exceeding ±1.50D for statistically meaningful analysis of outcomes.

D, dioptres; MAE, mean absolute error

*Number calculated from reported percentages in parentheses

Mean absolute errors in different critical levels of interocular corneal power

Interocular corneal power	Adjusted second eye prediction using 50% correction factor	Unadjusted second eye prediction using no correction factor	Wilcoxon signed rank test, *p* value
	Mean absolute errors	Mean absolute errors	
>0.60 dioptres	0.40	0.42	0.20
≤ 0.60 dioptres	0.32	0.36	<0.0001

Comments

Overall risk of bias: This large retrospective case series has a moderate to high risk of bias, due to the lack of reporting of baseline characteristics, inconsistencies in numbers reported in the manuscript, limited reporting of biometry and keratometry measurement procedures and details on how the IOL power was selected at surgery.

Other information: Not relevant

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Full citation	**Covert DJ, Henry CR, Koenig SB. Intraocular lens power selection in the second eye of patients undergoing bilateral, sequential cataract extraction. Ophthalmology 2010 117:49-54**
Study details	**Country/ies where the study was carried out:** USA **Study type:** Retrospective consecutive case series **Aim of the study:** To determine whether prediction errors of the first eye (based on 1 month post-operative refraction assessments) can be used to alter the intraocular lens (IOL) power selection and improve the refractive results for the second eye in people undergoing bilateral, sequential phacoemulsification cataract surgery with IOL implantation **Study dates:** January 2006 to December 2007 **Source of funding:** not reported
Participants	**Sample size** 206 people (412 eyes, assumed first and second eyes defined chronologically) **Diagnostic criteria**

Full citation	**Covert DJ, Henry CR, Koenig SB. Intraocular lens power selection in the second eye of patients undergoing bilateral, sequential cataract extraction. Ophthalmology 2010 117:49-54**

Not reported

Inclusion criteria

- Adults (18 years or older) who underwent bilateral sequential phacoemulsification cataract surgery, separated by at least 7 days, performed by the same surgeon in 1 hospital

Exclusion criteria

- Had post-operative best spectacle-corrected visual acuity worse than 20/40 in 1 or both eyes because of ocular comorbidity
- Inadequate follow-up after the second eye surgery
- IOL implanted was not the SA60AT (Alcon Laboratories Inc) in 1 or both eyes
- Had combined phacoemulsification and an additional procedure
- Had unilateral cataract extraction
- Had manual extracapsular cataract extraction and not phacoemulsification
- Had prior refractive surgery or penetrating keratoplasty

Baseline characteristics

- Mean age at time of first eye surgery (SD, range): 69.9 (13.6, 18 to 91) years
- Male/female: 89 (43.2%) / 117 (56.8%)
- Mean duration between first and second eye surgeries (SD, range): 36.7 (69.4, 7 to 511) days

	First eye	**Second eye**	**Interocular correlation**
Mean axial length in mm (SD, range)	24.0 (1.57, 21.1 to 29.2)	24.0 (1.48, 21.0 to 29.2)	r^2=0.96, p<0.00001
Mean keratometric power in dioptres (SD, range)	44.0 (1.88, 39.0 to 58.9)	43.9 (1.56, 40.0 to 49.3)	r^2=0.88, p<0.00001

Methods

Theoretical correction factors

- Predicted post-operative refractions for the implanted IOL were recorded for the Holladay (1988) and SRK-II formulas. Data only reported for Holladay formula but study reported similar results were observed for the SRK-II formula.
- First eye error of predicted refraction (PE1) was defined as the difference between the observed 1 month post-operative refractive spherical equivalent and the spherical equivalent refraction predicted by the IOLMaster for the implanted using the Holladay or SRK-II formula.
- Unadjusted second eye error of predicted refraction (PEunadj) was defined as the difference between the observed 1 month post-operative refractive spherical equivalent and the spherical equivalent refraction predicted by the IOLMaster for the implanted using the Holladay or SRK-II formula.
- Hypothetical fully adjusted second eye error (PEfull) = PEunadj – PE1

Full citation	**Covert DJ, Henry CR, Koenig SB. Intraocular lens power selection in the second eye of patients undergoing bilateral, sequential cataract extraction. Ophthalmology 2010 117:49-54**

- Hypothetical partially adjusted second eye error (PEpartial) = PEunadj – (C * PE1), where C varied from 0 to 1. The optimal partial adjustment was determined to be 0.5 or 50%.

Interventions

- Adjusted second eye prediction using 100% correction factor: PEfull, n=206
- Adjusted second eye prediction using 50% correction factor: PEpartial50%, n=206
- Unadjusted second eye prediction using no correction factor: PEunadj, n=206

Measurement and formula

- Biometry and keratometry measurements: axial lengths and keratometric corneal powers were measured using the same IOLMaster (version 3.0, Carl Zeiss Meditech, Germany) for all patients by a trained ophthalmic technician.
- IOL formula: lens power calculation was determined using the Holladay formula for both eyes.

Cataract surgery and IOL implantation: 1 surgeon performed temporal clear corneal phacoemulsification cataract surgery and selected the lens model in all cases. Placement of sutures was at the discretion of the operating surgeon. No patients had intraoperative complications.

Details

Post-operative assessment: post-operative manifest subjective refraction was undertaken by the same group of trained technicians.

Study outcomes:

- Mean absolute error (average of the absolute value of the prediction errors)
- Number (proportion) of eyes achieving post-operative spherical equivalent refractions within various ranges of the predicted refraction

Group comparisons: paired sample t-tests

Results

Mean absolute errors and number (proportion) of eyes achieving post-operative spherical equivalent refractions within various ranges of the predicted refraction

	Mean prediction error (SD, range)	Mean absolute error (SD, range)	Number (%) within ≤0.5D*	Number (%) within ≤1.0D*
First eye error (PE1, n=206)	-0.017 (0.61, -1.93 to 1.87)	0.47 (0.39, 0 to 1.93)	134 (65%)	182 (88.3%)
Adjusted second eye prediction using 100% correction factor (PEfull, n=206)	-0.014 (0.59, -1.85 to 2.16)	0.42$ (0.41, 0 to 2.16)	138 (67%)	187 (90.8%)
Adjusted second eye prediction using 50% correction factor (PEpartial50%, n=206)	-0.022 (0.50, -1.67 to 2.04)	0.36^ (0.34, 0.05 to 2.04)	153 (74.3%)	193 (93.7%)

Full citation	**Covert DJ, Henry CR, Koenig SB. Intraocular lens power selection in the second eye of patients undergoing bilateral, sequential cataract extraction. Ophthalmology 2010 117:49-54**

Unadjusted second eye prediction using no correction factor (PEunadj, n=206)	-0.031 (0.57, -1.60 to 2.13)	0.44 (0.37, 0 to 2.13)	137 (66.5%)	186 (90.3%)

D, dioptres; MAE, mean absolute error
*Number calculated from reported percentages in parentheses
$p=0.66 PEfull vs PEunadj
^p<0.0001 PEpartial50% vs PEunadj; p=0.001 PEpartial50% vs PEfull

Mean absolute errors in patients experiencing myopic or hyperopic first eye error

	Mean absolute errors		
	Adjusted second eye prediction using 100% correction factor (PEfull)	**Adjusted second eye prediction using 50% correction factor (PEpartial50%)**	**Unadjusted second eye prediction using no correction factor (PEunadj)**
Myopic first eye error (n=94)	0.46 dioptres	0.38 dioptres*	0.46 dioptres
Hyperopic first eye error (n=112)	0.39 dioptres	0.35 dioptres^	0.42 dioptres

*p=0.01 PEpartial50% vs PEunadj; p=0.008 PEpartial50% vs PEfull
^p=0.002 PEpartial50% vs PEunadj; p=0.07 PEpartial50% vs PEfull

Asymmetric biometry in first and second eyes

No definitive improvement using either full or 50% partial adjustment was observed in paired eyes that differed in axial lengths or average keratometry.

Comments	**Overall risk of bias:** This small retrospective case series has a high risk of bias due to inconsistencies between the timing of first and second eye surgeries and post-operative refractive assessment of the first eye. **Other information:** Not relevant

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Full citation	**Jabbour J, Irwig L, Macaskill P, et al. Intraocular lens power in bilateral cataract surgery: whether adjusting for error of predicted refraction in the first eye improves prediction in the second eye. J Cataract Refract Surg 2006 32:2091-7**
Study details	**Country/ies where the study was carried out:** Australia **Study type:** Retrospective consecutive case series **Aim of the study:** To determine whether the retrospectively calculated case-derived intraocular lens (IOL) position value in the first eye reduces the error of the predicted refraction in the second eye **Study dates:** February 1996 to March 2005 **Source of funding:** Not reported

<table>
<tr><td>Full citation</td><td>Jabbour J, Irwig L, Macaskill P, et al. Intraocular lens power in bilateral cataract surgery: whether adjusting for error of predicted refraction in the first eye improves prediction in the second eye. J Cataract Refract Surg 2006 32:2091-7</td></tr>
<tr><td>Participants</td><td>
Sample size
121 people (242 eyes)

Diagnostic criteria
Not reported

Inclusion criteria
• People who underwent bilateral phacoemulsification cataract surgery with implantation of the same IOL model performed by the same surgeon in 1 hospital

Exclusion criteria
• IOL inserted in the ciliary sulcus
• Stabilised post-operative best-corrected visual acuity worse than 6/12
• Previous or concurrent ocular surgery such as trabeculectomy or anterior vitrectomy
• No recorded measurement of the post-operative spherical equivalent
• Pre-operative corneal astigmatism >3.00 dioptres

Baseline characteristics
• Male/female: 44 (36.4%) / 77 (63.6%)
• Median duration between first and second eye surgeries (range): 3 (0.93 to 48) months
• Number of left eyes operated first / number of right eyes operated first: 53 / 68
<table>
<tr><th></th><th>Overall mean ± SD</th><th>Interocular correlation</th><th>Mean difference between eyes ± SD</th></tr>
<tr><td>Axial length in mm</td><td>23.15 ± 0.91</td><td>r^2=0.97, p<0.05</td><td>-0.0028 ± 0.24; p>0.05</td></tr>
<tr><td>Corneal power in dioptres</td><td>43.48 ± 1.51</td><td>r^2=0.97, p<0.05</td><td>-0.0470 ± 0.36; p>0.05</td></tr>
</table>
</td></tr>
<tr><td>Methods</td><td>
Theoretical correction factors
• The predicted refraction in each eye was generated using the SRK/T formula and the axial length vergence formula.
• Prediction error (post-operative spherical equivalent – predicted refraction).
• The case-derived A-constant (IOL position value) for the SRK/T formula in each eye was back-calculated using a stepwise numeric approach. The A-constant was adjusted until the predicted refraction was equal to the post-operative spherical equivalent, while the power of the IOL implanted, axial length and corneal power remained constant.
• The effective lens position (ELP) of the axial length vergence formula was calculated as suggested by Holladay 1997. This value was converted to the A-constant equivalent (axial length vergence).
• Unadjusted second eye error of predicted refraction (PEunadj) was calculated using the manufacturer’s A-constant.
</td></tr>
</table>

Full citation	**Jabbour J, Irwig L, Macaskill P, et al. Intraocular lens power in bilateral cataract surgery: whether adjusting for error of predicted refraction in the first eye improves prediction in the second eye. J Cataract Refract Surg 2006 32:2091-7**

- Adjusted second eye error of predicted refraction (PEadj) was calculated using the case-derived A-constant.
- Sensitivity analyses were undertaken comparing the adjusted and adjusted second eye prediction errors in patients in whom the absolute prediction error in the first eye was greater than 0.5 dioptres and in datasets where biometrically extreme or asymmetric pairs of eyes were removed as suggested by Holladay 1998 (criteria outlined below):

Parameter	Restriction
Individual eye	Axial length <20.0 or >25.0mm Corneal power <40.00 or >47.00 dioptres Emmetropic IOL power >3.00 dioptres from the calculated mean emmetropic IOL power
Between eyes	Axial length difference >0.3mm Corneal power difference >1.00 dioptres Emmetropic lens power difference >1.00 dioptres

Interventions

- Adjusted second eye prediction using case-derived A-constant (100%): PEadj, n=121
- Unadjusted second eye prediction using the manufacturer's A-constant: PEunadj, n=121

Measurement and formula

- Biometry and keratometry measurements: axial lengths were measured using 2 calibrated ultrasonic biometers (Quantel Cine AB Scanner, Quantel Medical and the model 820 A-scanner, Allergan Humphrey). Keratometric corneal powers were measured using 2 calibrated identical keratometers (Bausch & Lomb). Measurements were always performed bilaterally with the same instrument and repeated by a different operator.

Cataract surgery and IOL implantation: 1 surgeon performed bilateral phacoemulsification cataract surgery with implantation of the same IOL model SI-30NB (Advanced Medical Optics) in the capsular bag.

Details

Post-operative assessment: post-operative spherical equivalent was the optimally measured subjective spherocylindrical refraction.

Study outcomes:

- Prediction error (post-operative spherical equivalent – predicted refraction)
- Mean absolute error (average of the absolute value of the prediction errors)

Group comparisons: paired *t*-tests

Results

Prediction errors and mean absolute errors

	SRK/T formula	Axial length vergence formula

Full citation	**Jabbour J, Irwig L, Macaskill P, et al. Intraocular lens power in bilateral cataract surgery: whether adjusting for error of predicted refraction in the first eye improves prediction in the second eye. J Cataract Refract Surg 2006 32:2091-7**

	Mean prediction error ± SD	Mean absolute error	Mean prediction error ± SD	Mean absolute error
Adjusted second eye prediction using case-derived A-constant (PEadj, n=121)	-0.076 ± 0.85	0.65	-0.66 ± 0.89	0.91
Unadjusted second eye prediction using the manufacturer's A-constant (PEunadj, n=121)	-0.12 ± 0.79	0.63	-0.47 ± 0.90	0.83

Comments	**Overall risk of bias:** This small retrospective case series has a high risk of bias due to unclear timing of post-operative assessments and details on how the IOL power was selected at surgery. **Other information:** Not relevant

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Full citation	**Jivrajka RV, Shammas MC, Shammas HJ. Improving the second-eye refractive error in patients undergoing bilateral sequential cataract surgery. Ophthalmology 2012 119:1097-1101**
Study details	**Country/ies where the study was carried out:** USA **Study type:** Prospective case series **Aim of the study:** To assess the refractive error in the second eye when adjusted to correct 50% of the first-eye refractive error compared to no adjustments **Study dates:** January 2010 to May 2010 **Source of funding:** not reported
Participants	**Sample size** 97 people (194 eyes) **Diagnostic criteria** Not reported **Inclusion criteria** • Consecutive people who underwent first eye phacoemulsification cataract surgery 1 to 3 months prior to the scheduled second eye surgery, providing informed consent • People with a first eye refractive error greater than 0.5 dioptres **Exclusion criteria** • Any underlying retinal or corneal pathology

<table>
<tr><td>Full citation</td><td>Jivrajka RV, Shammas MC, Shammas HJ. Improving the second-eye refractive error in patients undergoing bilateral sequential cataract surgery. Ophthalmology 2012 119:1097-1101</td></tr>
<tr><td></td><td>Baseline characteristics
• Mean age (SD, range): 77.57 (7.95, 51 to 94) years
• Male/female: 48 (49%) / 49 (51%)
<table><tr><th></th><th>Overall mean ± SD (range)*</th></tr><tr><td>Axial length in mm</td><td>23.49 ± 1.01 (21.23 to 27.07)</td></tr><tr><td>Average keratometry readings in dioptres</td><td>43.77 ± 1.60 (38.27 to 47.61)</td></tr><tr><td colspan="2">*Assumed data based on 250 consecutive people available for eligibility screening</td></tr></table></td></tr>
<tr><td>Methods</td><td>Correction factors
• The first eye refractive error (FERE) was evaluated before the second eye’s surgery. It was calculated by subtracting the predicted refraction from the post-operative refraction measured 6 to 8 weeks after surgery. In the presence of astigmatism, the spherical equivalent values were used.
• 50% correction: calculations were adjusted to correct 50% of the error from the first eye when choosing the IOL power for the second eye.
• Theoretical unadjusted second eye error of predicted refraction (PEunadj) was calculated by subtracting the second eye predicted refraction with no correction from the post-operative refraction.
• Adjusted second eye error of predicted refraction (PEpartial50%) was evaluated 6 to 8 weeks after surgery by subtracting the second eye predicted refraction with 50% correction from the post-operative refraction.
• Theoretical adjusted second eye error of predicted refraction (PEfull) was calculated by subtracting the second eye predicted refraction with adjustments to correct for the total first eye error from the post-operative refraction.

Interventions
• Adjusted second eye error of predicted refraction: PEpartial50%, n=97
• Adjusted second eye error of predicted refraction: PEfull, n=97
• Unadjusted second eye error of predicted refraction: PEunadj, n=97

Measurement and formula
• Biometry and keratometry measurements: axial lengths and keratometric corneal powers were measured at the same time using the IOLMaster, version 5.2 (Carl Zeiss Meditech, Germany) before the first eye’s surgery.
• IOL formula: Haigis formula was used for all IOL power calculations.

Cataract surgery and IOL implantation: 1 surgeon performed 2.75mm limbal incision, phacoemulsification cataract surgery with implantation of an SN60WF IOL (Alcon Laboratories Inc) in the capsular bag.

Details
Post-operative assessment: post-operative refraction was assessed 6 to 8 weeks after surgery. No further details provided.</td></tr>
</table>

Full citation

Jivrajka RV, Shammas MC, Shammas HJ. Improving the second-eye refractive error in patients undergoing bilateral sequential cataract surgery. Ophthalmology 2012 119:1097-1101

Study outcomes:

- Prediction error
- Number (proportion) of eyes achieving post-operative refraction within ±1.00 dioptres

Group comparisons: 2-tailed Wilcoxon Mann-Whitney *U* test

Results

Prediction errors and number (proportion) of eyes achieving post-operative refraction within ±1.00 dioptres

First eye refractive error groups	Adjusted second eye error of predicted refraction (PEpartial50%)		Adjusted second eye error of predicted refraction (PEfull)		Unadjusted second eye error of predicted refraction (PEunadj)	
	Mean prediction error (SD, range)	Number (%) within ±1.00D*	Mean prediction error (SD, range)	Number (%) within ±1.00D*	Mean prediction error (SD, range)	Number (%) within ±1.00D*
-0.5 to -1.00 D (n=47)	-0.086 (0.62, -1.43 to 1.47)	42 (89%)	0.269 (0.64, -1.14 to 1.95)	38 (81%)	-0.440 (0.62, -1.81 to 0.99)	39 (83%)
> -1.00D (n=15)	-0.464 (1.00, -2.75 to 0.68)	12 (80%)	0.305 (0.93, -1.58 to 1.34)	11 (73%)	-1.232 (1.14, -3.91 to 0.55)	9 (60%)
+0.5 to +1.00 D (n=24)	-0.082 (0.42, -1.32 to 0.61)	23 (96%)	-0.425 (0.42, -1.65 to 0.32)	23 (96%)	0.260 (0.44, -0.99 to 1.01)	23 (96%)
> +1.00D (n=11)	-0.124 (0.79, -1.61 to 1.19)	9 (82%)	-0.799 (0.81, -2.23 to 0.42)	6 (81%)	0.552 (0.85, -0.98 to 1.98)	7 (64%)
All eyes (n=97)^	-0.189 (0.689)	86 (88.7%)	-0.162 (0.798)	78 (80.4%)	-0.215 (0.907)	78 (80.4%)
^Values calculated by reviewer						

Median prediction errors in patients experiencing myopic or hyperopic first eye error

First eye refractive error groups	Improvement in median prediction errors in people with myopic first eye error (n=not reported)	Improvement in median prediction errors in people with hyperopic first eye error (n=not reported)
	Adjusted second eye prediction using 50% correction factor (PEpartial50%)	Adjusted second eye error of predicted refraction (PEpartial50%)
-0.5 to -1.00 D	-0.48 to -0.12 dioptres	0.31 to -0.03 dioptres
> -1.00D	-0.93 to -0.12 dioptres	0.48 to -0.29 dioptres

Comments

Overall risk of bias: This small prospective case series has a high risk of bias, due to the limited reporting of biometry and keratometry measurement procedures and lack of reporting of post-operative assessment procedures.

Other information: Not relevant

8E.3.5 Risk stratification

Full citation	**Blomquist P, Sargent J, Winslow H. Validation of Najjar-Awwad cataract surgery risk score for resident phacoemulsification surgery. Journal of cataract and refractive surgery. 2010;36(10):1753-1757**
Study details	Country/ies where the study was carried out: USA Study type: Retrospective cohort study Aim of the study: To validate the Najjar-Awwad cataract surgery risk score for residents, which has been proposed to predict surgical complexity and risk. Study dates: January 2005 to April 2008 Sources of funding: Supported in part by an unrestricted research grant from Research to Prevent Blindness, Inc., New York, New York, USA.
Participants	Sample size 1,833 people Inclusion criteria Not reported Exclusion criteria Cases with incomplete documentation, traumatic, congenital, and polar cataract and lenses with dislocation or phacodonesis noted preoperatively.
Methods	All phacoemulsification cataract surgeries performed by second or third year ophthalmology residents (n=33) at Parkland Memorial Hospital (n=1,273 operations) or John Peter Smith Hospital (n=560 operations) between January 2005 and April 2008 were retrospectively reviewed. The Najjar-Awwad cataract risk score was calculated for included cases and intraoperative complications recorded. Intervention Cataract surgery using phacoemulsification
Results	Intraoperative complications in phacoemulsification cataract surgeries (n=1833)

Complication	Number (%)
Posterior capsule tear with vitreous prolapse	48 (2.6)
Posterior capsule tear with intact anterior hyaloid face	15 (0.8)
Zonular dehiscence with vitreous prolapse	8 (0.4)
Zonular dehiscence without vitreous prolapse	6 (0.3)
Dropped nucleus	8 (0.4)
Anterior capsule tear	29 (1.6)
Could not complete CCC	14 (0.8)

Full citation	**Blomquist P, Sargent J, Winslow H. Validation of Najjar-Awwad cataract surgery risk score for resident phacoemulsification surgery. Journal of cataract and refractive surgery. 2010;36(10):1753-1757**

Phacoemulsification wound burn	0
Conversion to manual ECCE	8 (0.4)
Any complication*	120 (6.2)

CCC = continuous curvilinear capsulorhexis; ECCE = extracapsular cataract extraction

*Although some cases had multiple complications, the total number of unique cases with complications was 120

Odds ratios for each risk factor in the Najjar-Awwad cataract risk score.

		95% Confidence Limit	
Risk Factor	Odds Ratio (OR)	Lower	Upper
Age (y)			
50-65 vs <50	0.90	0.49	1.64
65-80 vs <50	1.05	0.56	1.96
≥80 vs <50	1.08	0.42	2.76
Anaesthesia			
Local vs general	0.95	0.50	1.81
Topical vs general	0.72	0.09	5.87
Cataract density			
Grade 2 vs Grade 1	0.96	0.60	1.53
Grade 3 vs Grade 1	0.74	0.23	2.44
Grade 4 vs Grade 1	2.08	1.32	3.26
Frontal bossing/sunken globes	0.27	0.04	1.96
High hyperopia/myopia	0.80	0.49	1.30
History of glaucoma, uveitis, or previous intraocular surgery	1.35	0.84	2.17
History of complications in fellow eye	1.90	0.85	4.28
Shallow anterior chamber	1.45	0.57	3.70
Corneal cloudiness	1.17	0.42	3.30
Poor red reflex (possible use of capsule stain)	2.10	1.45	3.06
Pseudoexfoliation	1.10	0.14	8.47
Poor pupil dilation	1.65	0.64	4.24

<table>
<tr><th>Full citation</th><td>Blomquist P, Sargent J, Winslow H. Validation of Najjar-Awwad cataract surgery risk score for resident phacoemulsification surgery. Journal of cataract and refractive surgery. 2010;36(10):1753-1757</td></tr>
<tr><td></td><td>Odds ratios for level of cataract risk score
<table>
<tr><td></td><td></td><td colspan="2">95% Confidence Limit</td><td></td></tr>
<tr><td>Cataract Risk Score</td><td>Odds ratio*</td><td>Lower</td><td>Upper</td><td>P Value</td></tr>
<tr><td>>3</td><td>1.69</td><td>0.23</td><td>12.61</td><td>0.60</td></tr>
<tr><td>>4</td><td>1.13</td><td>0.45</td><td>2.84</td><td>0.80</td></tr>
<tr><td>>5</td><td>1.16</td><td>0.71</td><td>1.88</td><td>0.55</td></tr>
<tr><td>>6</td><td>2.11</td><td>1.42</td><td>3.14</td><td>0.0002</td></tr>
<tr><td>>7</td><td>1.87</td><td>1.28</td><td>2.72</td><td>0.0009</td></tr>
<tr><td>>8</td><td>1.61</td><td>1.06</td><td>2.46</td><td>0.03</td></tr>
<tr><td>>9</td><td>1.94</td><td>1.18</td><td>3.18</td><td>0.008</td></tr>
<tr><td>>10</td><td>2.06</td><td>1.00</td><td>4.24</td><td>0.05</td></tr>
</table>
*Compared to a risk score of ≤2</td></tr>
<tr><td>Outcomes</td><td>Significant preoperative risk factors for intraoperative complications were cataract density (p=0.004) and poor red reflex (p=0.0007).
Complications were not significantly increased until the cataract risk score was 7 or higher (48.3% of cases in the study had a risk score lower than 7)</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Did the authors use an appropriate method to answer their question? Yes
3 Were the cases recruited in an acceptable way? Unclear
4 Was the exposure accurately measured to minimise bias? N/A
5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unclear
6 Do you believe the results? Yes
7 Can the results be applied to the local population? Yes
8 Do the results of this study fit with other available evidence? N/A
At John Peter Smith Hospital, the second-year resident performs most cases, with the third-year resident performing only the most complex cases. At Parkland Memorial Hospital, only third-year residents act as the primary surgeon for cataract extraction.</td></tr>
</table>

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<table>
<tr><th>Full citation</th><td>Muhsaseb M, Kalhoro A, Ionides A. A system for preoperative stratification of cataract patients according to risk of intraoperative complications: a prospective analysis of 1441 cases. British Journal of Ophthalmology. 2004;88:1242-1246</td></tr>
<tr><td>Study details</td><td>Country/ies where the study was carried out: UK
Study type: Prospective cohort study
Aim of the study: To devise a simple, robust scoring system for assessing the risk of intraoperative complications in patients under- going cataract surgery.
Study dates: 15 November 2002 to 9 June 2003
Sources of funding: No financial support was received</td></tr>
<tr><td>Participants</td><td>Sample size
1,000 patients
Inclusion criteria
Patients undergoing phacoemulsification cataract surgery
Exclusion criteria
Planned Extracapsular cataract extraction surgery</td></tr>
<tr><td>Methods</td><td>Data collection
Patients were assessed preoperatively according to the weighted criteria. According to the points of risk they accumulated using this system; the patients were preoperatively allocated to one of four risk groups. Data were prospectively collected on the occurrence of intraoperative complications. The total rate of intraoperative complications for each risk group as well as the rate of each reported complication for each risk group was calculated.

Patient characteristics used in the scoring protocol
<table>
<tr><th>Category A (no points)</th><th>Category B (1 point each)</th><th>Category C (3 points each)</th></tr>
<tr><td>No additional risk factors carried by the patients</td><td>Previous vitrectomy
Corneal scarring
Small pupil (<3mm)
Shallow anterior chamber (depth <2.5mm)
Age >88 years
High ametropia (>6 D of myopia or hyperopia)
Posterior capsule plaque
Posterior polar cataract
Miscellaneous risks assessed by the surgeon (eg. Poor position of eye/patient)</td><td>Dense/total/white or brunescent cataract
Pseudoexfoliation
Phacodonesis</td></tr>
</table>
</td></tr>
</table>

Full citation	**Muhsaseb M, Kalhoro A, Ionides A. A system for preoperative stratification of cataract patients according to risk of intraoperative complications: a prospective analysis of 1441 cases. British Journal of Ophthalmology. 2004;88:1242-1246**
	Intervention Cataract surgery Analysis Chi-squared test or Fishers exact test
Results	Complication rates where a rise occurs through the risk groups

	Group 1 (0 points)			Group 2 (1-2 points)			Group 3 (3-5 months)			Group 4 (6 points or more)			Total		
	n=579	%	95% CI	n=255	%	95% CI	n=141	%	95% CI	n=25	%	95% CI	n=1000	%	p value
Overall	25	4.32	2.8 to 6.3	19	7.45	4.5 to 11.4	19	13.48	8.3 to 20.2	8	32	14.9 to 53.5	71	7.1	<0.001
PCR	9	1.55		4	1.57		7	4.96		2	8		22	2.2	0.015
Vitreous loss	6	1.04		1	0.39		8	5.67		2	8		17	1.7	<0.001
Failed CCC	1	0.17		1	0.39		3	2.13		2	8		7	0.7	<0.001
Zonule dehiscence	1	0.17		3	1.18		3	2.13		2	8		9	0.9	<0.001
Lost nucleus	1	0.17		1	0.39		1	0.71		1	4		4	0.4	<0.001
Wound burn/leak	0	0		0	0		2	1.42		1	4		3	0.3	<0.001

CI = Confidence Interval

PCR = posterior capsule rupture, CCC = continuous curvilinear capsulorrhexis

Odds ratios for level of risk group

		95% Confidence Limit

<table>
<tr><th>Full citation</th><th>Muhsaseb M, Kalhoro A, Ionides A. A system for preoperative stratification of cataract patients according to risk of intraoperative complications: a prospective analysis of 1441 cases. British Journal of Ophthalmology. 2004;88:1242-1246</th></tr>
<tr><td></td><td>
<table>
<tr><td>Risk group</td><td>Odds ratio*</td><td>Lower</td><td>Upper</td></tr>
<tr><td>1-2</td><td>1.78</td><td>0.96</td><td>3.30</td></tr>
<tr><td>3-5</td><td>3.45</td><td>1.84</td><td>6.47</td></tr>
<tr><td>≥6</td><td>10.43</td><td>4.11</td><td>26.46</td></tr>
</table>
*Compared to a risk score of 0
</td></tr>
<tr><td>Outcomes</td><td>The rate of intraoperative complications increased in frequency through the risk groups: 1= 4.32%, 2= 7.45%, 3 = 13.48%, and 4= 32.00% (p<0.001).
The following complications increased in frequency through the risk groups (p<0.05 in each case): posterior capsule rupture, vitreous loss, incomplete capsular rhexis, zonule dehiscence, wound burn/leak and lost nuclear fragment into vitreous cavity.</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the cohort recruited in an acceptable way? Yes
3 Was the exposure accurately measured to minimise bias? Yes
4 Was the outcome accurately measured to minimise bias? Yes
5 (a) Have the authors identified all important confounding factors? Unclear
(b) Have they taken account of the confounding factors in the design and/or analysis? Unclear
6 (a) Was the follow up of subjects complete enough? Yes
(b) Was the follow up of subjects long enough? N/A
7 Do you believe the results? Yes
8 Can the results be applied to the local population? Yes
9 Do the results of this study fit with other available evidence? N/A</td></tr>
</table>

88

<table>
<tr><th>Full citation</th><th>Osborne S, Adams W, Bunce C, Fraser S. Validation of two scoring systems for the prediction of posterior capsule rupture during phacoemulsification surgery. British Journal of Ophthalmology. 2006;90:333-336</th></tr>
<tr><td>Study details</td><td>Country/ies where the study was carried out: UK
Study type: Case-control
Aim of the study: To attempt to validate two scoring systems for the prediction of intraoperative complication during phacoemulsification surgery.
Study dates: 1 January 2001 to 31 December 2003</td></tr>
</table>

<table>
<tr><th>Full citation</th><td>Osborne S, Adams W, Bunce C, Fraser S. Validation of two scoring systems for the prediction of posterior capsule rupture during phacoemulsification surgery. British Journal of Ophthalmology. 2006;90:333-336</td></tr>
<tr><td></td><td>Sources of funding: Not reported</td></tr>
<tr><td>Participants</td><td>Sample size
300 control group and then extrapolated to population of 11,913
Inclusion criteria
Selected case notes from patients from a study population undergoing uncombined phacoemulsification surgery by a consultant
Exclusion criteria
Not reported</td></tr>
<tr><td>Methods</td><td>Data collection
In order to calculate the risk of a complication associated with a particular preoperative potential complication score, three steps were required:
Establish the prevalence of that score in the entire study population; (2) ascertain the number of complicated cases in the entire study population who had the same score; (3) from these results the percentage risk of complication for a particular preoperative score could be calculated.
Using both Muhtaseb and Habib’s scoring systems they established potential complications cores for each patient and then noted complications during surgery from the patients’ case notes in 300 control cases
The scoring systems results were then extrapolated to a population of n=11,913

Point allocation for risk factors using Muhtaseb’s and Habib’s scoring systems
<table>
<tr><td></td><td colspan="2">Score allocated</td></tr>
<tr><td>Risk factors and comorbid situation</td><td>Muhtaseb’s scoring system</td><td>Habib’s scoring system</td></tr>
<tr><td>Miscellaneous risk assessed by the surgeon (eg, poor position of eye/patient)</td><td>1</td><td>-</td></tr>
<tr><td>Unable to lie flat (spinal deformity, asthma, heart failure)</td><td>-</td><td>1</td></tr>
<tr><td>Severe anxiety</td><td>-</td><td>1</td></tr>
<tr><td>Head tremor</td><td>-</td><td>1</td></tr>
<tr><td>Previous vitrectomy</td><td>1</td><td>1</td></tr>
<tr><td>Previous angle closure glaucoma</td><td>-</td><td>1</td></tr>
<tr><td>Corneal scarring/cloudiness</td><td>1</td><td>1</td></tr>
<tr><td>Poor pupillary dilation and/or posterior synechiae</td><td>1</td><td>1</td></tr>
<tr><td>Shallow anterior chamber (depth <2.5mm)</td><td>1</td><td>1</td></tr>
<tr><td>Age (>88 years)</td><td>1</td><td>-</td></tr>
</table>
</td></tr>
</table>

Full citation	Osborne S, Adams W, Bunce C, Fraser S. Validation of two scoring systems for the prediction of posterior capsule rupture during phacoemulsification surgery. British Journal of Ophthalmology. 2006;90:333-336

High ametropia (>6 D of myopia or hyperopia)	1	-
Posterior capsule plaque	1	-
Posterior polar cataract	1	-
Dense/total/white or brunescent cataract	3	3
Pseudoexfoliation	3	1
Phacodonesis/weak zonules	3	1
Previous angle closure glaucoma	-	1
History of complication in fellow eye	-	1
High myopia (axial length .27 mm)	-	1
High hypermetropia (axial length ,20 mm)	-	1
Nuclear density grade 1–2	-	1
Nuclear density grade 3	-	2

Intervention
Cataract surgery

Results

Potential complication scores for patients in the control group and complication group, and the calculated risk of complication according to the potential complication score

Comparative results for control group (n = 300)					
System	Potential complication score	Number of patients in control group with that score	Extrapolated to entire study population (n = 11 913)	Comparative results for all complicated cases (n = 95)	Complication risk (95% CI)
Muhtaseb et al	0	213	8458	54	0.64% (0.48% to 0.83%)
	1	67	2661	20	0.75% (0.46% to 1.16%)
	2	9	357	2	0.56% (0.07% to 1.16%
	3	9	357	11	3.08% (1.55% to 5.45%)
	4	2	80	7	8.75% (3.59% to 17.2%)
	5	0	0	1	Not calculable
Habib et al	1	218	8657	51	0.59% (0.44% to 0.77%)

Full citation	Osborne S, Adams W, Bunce C, Fraser S. Validation of two scoring systems for the prediction of posterior capsule rupture during phacoemulsification surgery. British Journal of Ophthalmology. 2006;90:333-336

	2	52	2065	19	0.92% (0.55% to 1.43%)
	3	26	1032	17	1.65% (0.96% to 2.62%)
	4	3	119	6	5.04% (1.87% to 10.65%)
	5	1	40	2	5.00% (0.61% to 16.92%)

Potential complication scores

		95% Confidence Limit	
Potential complication score (Muhtaseb)	Odds ratio*	Lower	Upper
1	1.18	0.70	1.97
2	0.88	0.21	3.61
3	4.95	2.56	9.55
4	14.92	6.57	33.90
5	Not calculable/estimable		

* Compared to a risk score of 0

		95% Confidence Limit	
Potential complication score (Habib)	Odds ratio*	Lower	Upper
2	1.57	0.92	2.66
3	2.83	1.63	4.91
4	8.96	3.77	21.30
5	8.88	2.09	37.80

* Compared to a risk score of 1

Outcomes	There is an increased risk of complication in patients in group 3 compared with that for patients in risk groups 1 or 2 using the Muhtaseb scoring system. The Habib et al, potential complication scores seem to correlate more closely with the actual complication incidence than with Muhtaseb's system.
Comments	Case notes of 'selected' patients from a study population – no details reported of how 'selected' Authors noted that the population differed significantly from the population examined by Habib et al in order to formulate their ''potential difficulty score'' and they did not use any data from the case notes used in their study.

Full citation	Osborne S, Adams W, Bunce C, Fraser S. Validation of two scoring systems for the prediction of posterior capsule rupture during phacoemulsification surgery. British Journal of Ophthalmology. 2006;90:333-336
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Did the authors use an appropriate method to answer their question? Yes 3 Were the cases recruited in an acceptable way? Unclear 4 Were the controls selected in an acceptable way? Unclear 5 Was the exposure accurately measured to minimise bias? Unclear 6 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unclear 7 Do you believe the results? Yes 8 Can the results be applied to the local population? Yes 9 Do the results of this study fit with other available evidence? N/A

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Full citation	Tsinopoulos I, Lamprogiannis L, Tsaousis T, Mataftsi A et al. Surgical outcomes in phacoemulsification after application of a risk stratification system. Clinical Ophthalmology. 2013;7:895-899
Study details	Country/ies where the study was carried out: Greece Study type: Randomised controlled trial Aim of the study: To determine whether application of a risk stratification system during preoperative assessment of cataract patients and subsequent allocation of patients to surgeons with matching experience may reduce intraoperative complications. Study dates: May 2010 to August 2012 Sources of funding: Not reported
Participants	Sample size 953 patients (1109 eyes) Inclusion criteria Undergoing phacoemulsification cataract surgery Exclusion criteria Planned extracapsular cataract extractions
Methods	Data collection Consecutive patients were randomly assigned to two groups: Group A (n = 498 patients, 578 eyes) and Group B (n = 455 patients, 531 eyes). Patients from group A were allocated to surgeons with varying experience with only a rough estimate of the complexity of their surgery. Patients from group B were assigned to three risk groups (no added risk, low risk, and moderate-high risk) according to risk factors established during their preoperative assessment using the risk scoring system developed by Muhtaseb et al. and were respectively allocated to resident surgeons.

Full citation	**Tsinopoulos I, Lamprogiannis L, Tsaousis T, Mataftsi A et al. Surgical outcomes in phacoemulsification after application of a risk stratification system. Clinical Ophthalmology. 2013;7:895-899**

Patients with a risk score of zero (no added risk) were allocated to resident surgeons, patients with a risk score of 1–5 (low-moderate risk) were allocated to low-volume specialist surgeons, and patients with a risk score of ≥6 (high risk) were allocated to high-volume specialist surgeons*.

* Surgeons were categorized into three groups, ie, resident surgeons, low-volume surgeons (performing fewer than 400 cataract surgeries per year), and high-volume surgeons (performing 400 or more cataract surgeries per year).

Risk factors and comorbid conditions included in the stratification system

Risk factors and comorbid situation	Points
Previous vitrectomy	1
Corneal scarring	1
Small pupil (<3mm)	1
Shallow anterior chamber (depth <2.5mm)	1
Age (>88 years)	1
High ametropia (>6 D of myopia or hyperopia)	1
Posterior capsule plaque	1
Posterior polar cataract	1
Dense/total/white or brunescent cataract	3
Pseudoexfoliation	3
Phacodonesis	3
Miscellaneous risks assessed by surgeon	1

Allocation of patients to surgeons with varying experience

	Group A	Group B
Resident surgeons	277 (47.9%)	259 (48.8)
Low-volume surgeons	207 (35.8%)	181 (34.1%)
High-volume surgeons	94 (16.3%)	91 (17.1%)
Total	578 (100%)	531 (100%)

Full citation	**Tsinopoulos I, Lamprogiannis L, Tsaousis T, Mataftsi A et al. Surgical outcomes in phacoemulsification after application of a risk stratification system. Clinical Ophthalmology. 2013;7:895-899**

Intervention
Cataract surgery

Analysis
Fisher's exact test

Results

Rate of complications for groups A and B and for each group of surgeons

	Resident surgeons		Low-volume surgeons		High-volume surgeons	
	Group A	Group B	Group A	Group B	Group A	Group B
Posterior capsule rupture	2/277, 2.53%	4/259, 1.54%	6/207, 2.90%	3/181, 1.66%	3/94, 3.19%	2/91, 2.20%
Posterior capsule rupture with vitreous loss	6/277, 2.17%	1/259, 0.39%	2/207, 0.97%	1/181, 0.55%	1/94, 1.06%	-
Posterior capsule rupture with nucleus drop	2/277, 0.72%	2/259, 0.77%	-	-	-	2/91, 2.20%
Anterior chamber haemorrhage	1/277, 0.36%	-	-	-	-	-
Unplanned ECCE	-	-	-	-	-	-
Torn iris	2/277, 0.72%	-	-	1/181, 0.55%	-	-
Zonular dehiscence	-	-	-		-	-
Incomplete capsulorhexis	2/277, 0.72%	1/259, 0.39%	-		-	-
Total	20/277, 7.22%	8/259, 3.08%	10/207, 4.83%	6/181, 3.31%	4/94, 4.25%	4/91, 4.40%

ECCE = extracapsular cataract extraction

Posterior capsule ruptures

		95% Confidence Limit	
	Odds ratio	Lower	Upper

<table>
<tr><th>Full citation</th><td>Tsinopoulos I, Lamprogiannis L, Tsaousis T, Mataftsi A et al. Surgical outcomes in phacoemulsification after application of a risk stratification system. Clinical Ophthalmology. 2013;7:895-899
<table>
<tr><td>Resident surgeon (unstratified versus stratified)</td><td>2.06</td><td>0.83</td><td>5.14</td></tr>
<tr><td>Low-volume surgeons (unstratified versus stratified)</td><td>1.79</td><td>0.60</td><td>5.33</td></tr>
<tr><td>High-volume surgeons (unstratified versus stratified)</td><td>0.97</td><td>0.23</td><td>3.99</td></tr>
</table>

Any complication event
<table>
<tr><td></td><td></td><td colspan="2">95% Confidence Limit</td></tr>
<tr><td></td><td>Odds ratio</td><td>Lower</td><td>Upper</td></tr>
<tr><td>Resident surgeon (unstratified versus stratified)</td><td>2.44</td><td>1.06</td><td>5.65</td></tr>
<tr><td>Low-volume surgeons (unstratified versus stratified)</td><td>1.48</td><td>0.53</td><td>4.16</td></tr>
<tr><td>High-volume surgeons (unstratified versus stratified)</td><td>0.97</td><td>0.23</td><td>3.99</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>A statistically significant difference in total complication rate was found between group A and group B.
Group B patients with no added risk and allocated to resident surgeons had a statistically significant lower complication rate than their counterparts in group A allocated to resident surgeons.
No statistically significant difference in complication rates was found between low-volume and high-volume surgeons
Small increase in complication rates for group B patients operated on by high-volume surgeons.</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Did the authors use an appropriate method to answer their question? Yes
3 Were the cases recruited in an acceptable way? Yes
4 Were the controls selected in an acceptable way? Yes
5 Was the exposure accurately measured to minimise bias? Yes
6 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Yes
7 Do you believe the results? Yes
8 Can the results be applied to the local population? Yes
9 Do the results of this study fit with other available evidence? N/A</td></tr>
</table>

9E.3.6 Risk factors for increased cataract surgical complications

Full citation	**Artzen D, Lundstrom M, Behndig A et al. Capsule complication during cataract surgery: Case-control study of preoperative and intraoperative risk factors. Journal of cataract and refractive surgery. 2009;35:1688-1693**
Study details	Country/ies where the study was carried out: Sweden Study type: Case-control Aim of the study: To identify preoperative and intraoperative factors associated with a capsule complication (capsule tear or a zonular dehiscence) during cataract surgery. Study dates: 2003 Sources of funding: Supported by grants from Synfra¨mjandets Forskningsfond and the Hubacz Foundation, Stockholm, Sweden.
Participants	Sample size 655 people Inclusion criteria Patients with a capsule complication Exclusion criteria Not reported Comparator Patients without a capsule complication
Methods	Data collection The medical records of cases with a capsule complication (study group n=324) and cases without a complication (control group n=331) were reviewed retrospectively. Intervention Cataract surgery Analysis Student t- test, chi-square test, Wald test
Results	

Logistic regression of preoperatively recorded variables with the lowest P values in the single factor analyses. *Variable	Regression coefficient	Standard Error	Wald Test	P value
Patient age	-0.009	0.009	0.94	0.33
Patient sex	0.22	0.19	1.38	0.24
Previous trauma	2.75	1.09	6.34	0.012

Full citation	Artzen D, Lundstrom M, Behndig A et al. Capsule complication during cataract surgery: Case-control study of preoperative and intraoperative risk factors. Journal of cataract and refractive surgery. 2009;35:1688-1693

Previous operation	0.48	0.29	2.76	0.097
Ocular comorbidity	0.29	0.19	2.52	0.11
Corneal pathology	-0.50	0.64	0.61	0.43
Miosis	0.47	0.40	1.37	0.24
Synechias	1.31	1.17	1.26	0.26
White cataract	1.13	0.48	5.57	0.018
Brunescent / hard cataract	1.28	0.33	14.92	<0.001
Phacodonesis	2.74	0.54	25.72	<0.001
Inexperienced surgeon	1.12	0.19	35.93	<0.001

* The parameter pseudo exfoliation was not included in the analyses because of too many missing cases.

Calculated Odds Ratios

		95% Confidence Limit	
Variable	Odds Ratio	Lower	Upper
Patient age	0.99	0.97	1.01
Patient sex	1.25	0.86	1.81
Previous trauma	15.64	1.85	132.48
Previous operation	1.62	0.92	2.85
Ocular comorbidity	1.34	0.92	1.94
Corneal pathology	0.61	0.17	2.13
Miosis	1.60	0.73	3.50
Synechias	3.71	0.37	36.72
White cataract	3.10	1.21	7.93
Brunescent / hard cataract	3.60	1.88	6.87
Phacodonesis	15.48	5.37	44.63
Inexperienced surgeon	3.07	2.11	4.45

Outcomes	In the logistic regression analyses, preoperative conditions associated with a capsule complication were previous trauma, white and brunescent/hard cataract, and phacodonesis

Full citation	Artzen D, Lundstrom M, Behndig A et al. Capsule complication during cataract surgery: Case-control study of preoperative and intraoperative risk factors. Journal of cataract and refractive surgery. 2009;35:1688-1693
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Did the authors use an appropriate method to answer their question? Yes 3 Were the cases recruited in an acceptable way? Unclear 4 Were the controls selected in an acceptable way? Unclear 5 Was the exposure accurately measured to minimise bias? N/A 6 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unclear 7 Do you believe the results? Yes 8 Can the results be applied to the local population? Yes 9 Do the results of this study fit with other available evidence? N/A

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Full citation	Beatty S, Lotery A, Kent D, O'Driscoll A et al. Acute intraoperative suprachoroidal haemorrhage in ocular surgery. Eye. 1998;12:815-820
Study details	Country/ies where the study was carried out: UK Aim of the study: To investigate the visual outcomes and patient characteristics that may predispose to suprachoroidal haemorrhage and the clinical features that may be of prognostic significance. Study type: Case-control Study dates: Not reported Sources of funding: None reported
Participants	Sample size Cases (n=33), matched controls (n=66) Inclusion criteria Cases of Acute intraoperative suprachoroidal haemorrhage (AISH) which could be case-control matched Exclusion criteria Not reported
Methods	Data collection Cases of AISH collected from ophthalmic centres in the United Kingdom, Republic of Ireland and Switzerland were reviewed. Two satisfactory controls in terms of operative procedure, surgeon, age (± 5 years) and gender were found for each case. Systemic and ocular characteristics were compared for cases and controls, and the visual results of all cases of AISH were analysed. Intervention Cataract surgery

<table>
<tr><th>Full citation</th><td>Beatty S, Lotery A, Kent D, O'Driscoll A et al. Acute intraoperative suprachoroidal haemorrhage in ocular surgery. Eye. 1998;12:815-820</td></tr>
<tr><td></td><td>Analysis
Chi-squared test or Fisher exact test</td></tr>
<tr><td>Results</td><td>Per-operative details for 33 cases of acute intraoperative suprachoroidal haemorrhage and 66 matched controls
<table>
<tr><td></td><td>AISH cases (n=33)</td><td>Controls (n=66)</td><td>Chi-squared or t-test</td><td>p value</td></tr>
<tr><td>Age (years)</td><td>77.3 ± 11.3</td><td>78.1 ± 7.6</td><td>t = -0.75</td><td>0.45</td></tr>
<tr><td>Gender (male:female)</td><td>6:27</td><td>6:27</td><td></td><td></td></tr>
<tr><td>Ocular comorbidity
Gluacoma
Previous intraocular surgery</td><td>
20 (60.6%)
2 (6%)</td><td>
29 (43.9%)
6 (9.09%)</td><td>
Chi-squared = 2.44
Chi-squared = 0.6</td><td>
0.12
0.27</td></tr>
<tr><td>Last recorded IOP (mean ± SD)</td><td>21.09 ± 10.18 mmHg (range: 11-72 mmHg)</td><td>17.66 ± 5.8 mmHg (range: 8-45mmHg)</td><td>t = 3.66</td><td>0.0005</td></tr>
<tr><td>Axial mean length (mean ± SD)</td><td>23.33 ± 1.32 mm (range: 21.4 – 26.2 mm)</td><td>22.9 ± 1.25mm (range: 21.069 – 26.65mm)</td><td>t = 2.28</td><td>0.026</td></tr>
</table>
IOP = intraocular pressure, SD = standard deviation</td></tr>
<tr><td>Outcomes</td><td>Longer axial length and higher pre-operative intraocular pressure are associated with increased risk of AISH.</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Did the authors use an appropriate method to answer their question? Yes
3 Were the cases recruited in an acceptable way? Yes
4 Were the controls selected in an acceptable way? Yes
5 Was the exposure accurately measured to minimise bias? Yes
6 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Yes
7 Do you believe the results? Yes
8 Can the results be applied to the local population? Yes
9 Do the results of this study fit with other available evidence? N/A</td></tr>
</table>

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Full citation	**Blomquist P, Morales M, Tong L, Ahn C. Risk factors for vitreous complications in resident performed phacoemulsification surgery. Journal of cataract and refractive surgery. 2012;38:208-214**
Study details	Country/ies where the study was carried out: Germany

<table>
<tr><th>Full citation</th><td>Blomquist P, Morales M, Tong L, Ahn C. Risk factors for vitreous complications in resident performed phacoemulsification surgery. Journal of cataract and refractive surgery. 2012;38:208-214</td></tr>
<tr><td></td><td>Study type: Retrospective cohort
Aim of the study: To identify risk factors for intraoperative vitreous complications in resident-performed phacoemulsification surgery.
Study dates: January 4th 2005 to January 8th 2008
Sources of funding: Supported in part by an unrestricted research grant from Research to Prevent Blindness, Inc., New York, New York, USA</td></tr>
<tr><td>Participants</td><td>Sample size
2,434 cases
Inclusion criteria
Not reported
Exclusion criteria
Cases with incomplete data</td></tr>
<tr><td>Methods</td><td>Data collection
All cases of resident-performed phacoemulsification surgery were retrospectively reviewed. The main outcome was the presence or absence of intraoperative vitreous complications defined as vitreous prolapse into the anterior chamber, vitreous loss through the wound, or dropped nucleus into the vitreous cavity. To grade the density of mainly nuclear and posterior sub capsular cataracts, patients with better than 20/50 vision were classified as mild, with 20/50 to 20/400 as moderate, and with worse than 20/400 as dense.
Intervention
Cataract surgery
Analysis
Chi-square or Fisher exact test for categorical variables and 2-sample t -test for continuous variables</td></tr>
<tr><td>Results</td><td>Independent significant preoperative characteristics for vitreous complications in stepwise logistic regression analysis.
<table>
<tr><th>Clinical characteristic</th><th>Odds Ratio (95% Confidence Interval)</th></tr>
<tr><td>Older age</td><td>1.03 (1.0-1.05)</td></tr>
<tr><td>Worse corrected distance Visual acuity (log MAR)</td><td>1.52 (1.14-2.03)</td></tr>
<tr><td>Left eye</td><td>1.63 (1.05-2.51)</td></tr>
<tr><td>Prior pars plana vitrectomy</td><td>1.88 (1.01-3.51)</td></tr>
<tr><td>Dementia</td><td>3.65 (1.20-11.17)</td></tr>
<tr><td>Zonule dehiscence</td><td>8.55 (3.92-18.63)</td></tr>
</table></td></tr>
</table>

Full citation	**Blomquist P, Morales M, Tong L, Ahn C. Risk factors for vitreous complications in resident performed phacoemulsification surgery. Journal of cataract and refractive surgery. 2012;38:208-214**
Outcomes	Older age, logMAR CDVA, left eye, prior vitrectomy surgery, dementia, and zonule dehiscence to be significant independent preoperative factors associated with vitreous complications.
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Did the authors use an appropriate method to answer their question? Yes 3 Were the cases recruited in an acceptable way? Unclear 4 Was the exposure accurately measured to minimise bias? Unclear 5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unclear 6 Do you believe the results? Yes 7 Can the results be applied to the local population? Yes 8 Do the results of this study fit with other available evidence? N/A

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Full citation	**Briszi A, Prahs P, Hillenkamp J, Helbig H. Complication rate and risk factors for intraoperative complications in resident preformed phacoemulsification surgery. Graefes Arch Clin Exp Ophthalmol. 2012;250:1315-1320**
Study details	Country/ies where the study was carried out: Germany Study type: Retrospective cohort Aim of the study: To determine the complication rate and risk factors for intraoperative complications in resident performed phacoemulsification surgery. Study dates: August 2002 to September 2009 Sources of funding: Not reported
Participants	Sample size 600 people Inclusion criteria Any type of phacoemulsification surgery including combined procedures of cataract surgery with intravitreal injection of bevacizumab or triamcinolone or surgical iridectomy. Exclusion criteria None reported
Methods	Data collection Patient charts and surgery reports were reviewed in detail in order to identify intraoperative complications and risk factors for intraoperative complications. Intraoperative complications related to cataract surgery were assessed: posterior capsular tears, vitreous loss, dropped nucleus or lens fragments.

Full citation	**Briszi A, Prahs P, Hillenkamp J, Helbig H. Complication rate and risk factors for intraoperative complications in resident preformed phacoemulsification surgery. Graefes Arch Clin Exp Ophthalmol. 2012;250:1315-1320**
	Intervention Cataract surgery Analysis Univariate analysis: 2×2contingency table. Fisher's exact test. Chi-squared test
Results	Challenging factors for surgery and correlated incidence of intraoperative complications based on univariate analysis

Challenging factors for surgery	Number of cases	Number of cases with complications	P value	Odds Ratio	95% Confidence interval
White cataract	43	5	0.019	3.9	1.4-11.2
Dense nuclear sclerosis	67	8	0.002	4.7	1.9-11.5
Small pupil (<6.0mm)	73	4	0.509	1.6	0.5-4.7
Anterior chamber depth <2.5mm	23	1	0.600	1.1	0.1-8.9
High myopia (axial length >26.0mm)	26	1	1.000	1.0	0.1-7.7
Pseudoexfoliation syndrome	30	2	0.321	1.9	0.4-8.4
Posterior synechia	18	1	0.510	1.5	0.2-11.8
Restless patient	17	2	0.135	3.6	0.8-16.6
Floppy iris syndrome	1	0	1.000	-	-
Zonular pathology	15	0	1.000	-	-
Corneal pathology	5	0	1.000	-	-
History of prior ocular trauma	7	0	1.000	-	-
History of prior ocular surgery	35	0	1.000	-	-
Traumatic cataract	6	0	1.000	-	-

Challenging factors for surgery and selected intraoperative complications

Complications	Posterior capsule tears	Vitreous loss	Dislocation of lenticular fragments in the vitreous

Full citation	**Briszi A, Prahs P, Hillenkamp J, Helbig H. Complication rate and risk factors for intraoperative complications in resident preformed phacoemulsification surgery. Graefes Arch Clin Exp Ophthalmol. 2012;250:1315-1320**

Challenging factors for surgery	n	P value	n	P value	n	P value
White cataract	5	0.019	4	0.027	2	0.084
Dense nuclear sclerosis	8	0.002	6	0.007	2	0.179
Small pupil (<6.0mm)	4	0.509	2	1.000	1	0.599
Anterior chamber depth <2.5mm	1	0.600	1	0.490	0	1.000
High myopia (axial length >26.0mm)	1	1.000	1	0.534	0	1.000
Pseudoexfoliation syndrome	2	0.321	1	0.587	1	0.303
Posterior synechia	1	0.510	1	0.408	1	0.193
Restless patient	2	0.135	1	0.391	1	0.183

Outcomes	White cataracts and dense nuclear sclerosis were identified as significant risk factors for intraoperative complications The odds ratio for posterior capsular tears in cases with white cataract was 3.9 (95% CI 1.4–11.2, p=0.019) and in cases with dense nuclear sclerosis 4.7 (95% CI 1.9–11.5, p=0.002). The odds ratio for vitreous loss in eyes with white cataract was 4.3 (95% CI 1.3–13.8, p=0.027) and for eyes with dense nuclear sclerosis 4.7 (95% CI 1.7–13.1, p=0.007). In multivariate analyses only dense nuclear sclerosis remained predictive for intraoperative complications especially for posterior capsular tears. In eyes with dense nuclear sclerosis, the OR was 3.2 (95% CI 1.1–9.4, p=0.031) for intraoperative complications in general and 3.2 (95%CI, 1.1–9.4, p=0.031) for posterior capsular rupture.
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Did the authors use an appropriate method to answer their question? Yes 3 Were the cases recruited in an acceptable way? Unclear 4 Was the exposure accurately measured to minimise bias? Unclear 5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unclear 6 Do you believe the results? Yes 7 Can the results be applied to the local population? Yes 8 Do the results of this study fit with other available evidence? N/A

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<table>
<tr><th>Full citation</th><th>Chatziralli I, Sergentanis T. Risk factors for Intraoperative Floppy Iris Syndrome: A Meta-analysis. Ophthalmology. 2011;118:730-735</th></tr>
<tr><td>Study details</td><td>Country/ies where the study was carried out: Greece
Study type: Systematic review and meta-analysis
Aim of the study: To evaluate risk factors (hypertension, diabetes mellitus, and current tamsulosin, alfuzosin, terazosin, or doxazosin use) for intraoperative floppy iris syndrome (IFIS) in patients undergoing phacoemulsification cataract surgery.
Study dates: End of search date was 23 May 2010
Sources of funding: None reported</td></tr>
<tr><td>Participants</td><td>Sample size
Seventeen eligible studies (17 588 eyes)
Inclusion criteria
Eligible studies found in PubMed
Not reported
Exclusion criteria
Not reported</td></tr>
<tr><td>Methods</td><td>Data collection
Eligible articles were identified by a search of the bibliographic database in PubMed using the following combination of search terms: (cataract surgery complications) OR (iris AND cataract) OR (floppy iris) OR (iris hypotony) OR (iris tears) OR (iris prolapse). References of relevant reviews and eligible articles that our search retrieved. Language restrictions were not used, and data were extracted from each eligible study by 2 investigators working independently.
Analysis
Fixed-effects (Mantel–Haenszel method) or random-effects (Der Simonian Laird) model was appropriately used to calculate the pooled OR.</td></tr>
<tr><td>Results</td><td>Results of the Meta-Analysis
<table>
<tr><th>Variable</th><th>Odds ratio (95% CI)</th><th>Test for heterogeneity</th><th>Alternative Odds Ratio (95% CI) vs Patients not receiving any α1 - blocker</th><th>Test for heterogeneity</th></tr>
<tr><td>Current tamsulosin use</td><td>393.1 (159.5 – 968.6)*</td><td>P<0.001</td><td>672.0 (216.4 – 2086.7)*</td><td>P<0.001</td></tr>
<tr><td>Current alfuzosin use</td><td>9.7 (2.0 – 48.7)*</td><td>P=0.044</td><td>40.7 (3.2 – 514.8)*</td><td>P=0.001</td></tr>
<tr><td>Current terazosin use</td><td>5.5 (1.3 – 23.0)**</td><td>P=0.206</td><td>15.1 (2.8 – 81.1)**</td><td>P=0.093</td></tr>
<tr><td>Current doxazosin use</td><td>6.4 (0.9 – 44.1)*</td><td>P<0.001</td><td>24.2 (1.7 – 351.7)*</td><td>P<0.001</td></tr>
<tr><td>Hypertension</td><td>2.2 (1.2 – 4.2)**</td><td>P=0.697</td><td>N/A</td><td>N/A</td></tr>
</table></td></tr>
</table>

Full citation	Chatziralli I, Sergentanis T. Risk factors for Intraoperative Floppy Iris Syndrome: A Meta-analysis. Ophthalmology. 2011;118:730-735
	Diabetes mellitus | 1.3 (0.7 – 2.2)** | P=0.736 | N/A | N/A CI = Confidence interval N/A = not applicable *Odds ratio derived from random effects analysis **Odds ratio derived from fixed effects analysis
Outcomes	The pooled OR for IFIS after tamsulosin use was approximately 40-fold greater than that after alfuzosin use. Alfuzosin and terazosin were also associated with IFIS with comparable ORs. Intraoperative floppy iris syndrome was positively associated with hypertension but not with diabetes mellitus.
Study Appraisal using AMSTAR (Assessing the Methodological Quality of Systematic Reviews)	1. Was an 'a priori' design provided? Yes 2. Was there duplicate study selection and data extraction? Yes 3. Was a comprehensive literature search performed? Yes 4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes 5. Was a list of studies (included and excluded) provided? Yes 6. Were the characteristics of the included studies provided? Yes 7. Was the scientific quality of the included studies assessed and documented? Unclear 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Unclear 9. Were the methods used to combine the findings of studies appropriate? Yes 10. Was the likelihood of publication bias assessed? Unclear 11. Was the conflict of interest included? Unclear

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Full citation	Chen A, Kelly J, Bhandari A, Wu M. Pharmacologic prophylaxis and risk factors for intraoperative floppy-iris syndrome in phacoemulsification performed by resident physicians. Journal of cataract and refractive surgery. 2010;36:898-905
Study details	Country/ies where the study was carried out: USA Study type: Retrospective cohort Aim of the study: To determine the incidence of intraoperative floppy-iris syndrome (IFIS) in patients taking tamsulosin who had surgery by resident physicians and the effect of prophylactic lidocaine–epinephrine. Study dates: January 2005 to July 2008 Sources of funding: Not reported
Participants	Sample size 59 patients (81 eyes)

<table>
<tr><th>Full citation</th><td>Chen A, Kelly J, Bhandari A, Wu M. Pharmacologic prophylaxis and risk factors for intraoperative floppy-iris syndrome in phacoemulsification performed by resident physicians. Journal of cataract and refractive surgery. 2010;36:898-905</td></tr>
<tr><td></td><td>Inclusion criteria
Patients taking tamsulosin at the time of cataract surgery
Exclusion criteria
None reported</td></tr>
<tr><td>Methods</td><td>Data collection
Patient preoperative dilated pupil was measured. Cases were divided into 2 categories based on the use of intracameral lidocaine-epinephrine (yes/no). The occurrence of vitreous loss, operative time, use of iris hooks and presence of billowing iris, iris prolapse and pupil constriction were measured.
Intervention
Prophylactic lidocaine–epinephrine was given in 26 eyes and not given in 55 eyes
Comparator
No use of prophylactic lidocaine–epinephrine
Analysis
Fisher exact test</td></tr>
<tr><td>Results</td><td>Incidence of IFIS with and without use of prophylactic intracameral lidocaine–epinephrine.
<table>
<tr><td>Category</td><td>IFS incidence, n (%)</td><td>Risk Ratio (95% CI)</td><td>Odds Ratio (95%)</td><td>P value*</td></tr>
<tr><td>Overall (n=81)</td><td>24 (29.6)</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>No prophylactic ILE (n=55)</td><td>14 (25.5%)</td><td>Reference</td><td>Reference</td><td>Reference</td></tr>
<tr><td>Prophylactic ILE (n=26)</td><td>10 (38.5%)</td><td>1.51 (0.78-2.93)</td><td>1.83 (0.67-4.96)</td><td>0.174</td></tr>
</table>
*Fisher exact test

Preoperative dilated pupil diameter and incidence of IFIS.
<table>
<tr><td>Preop pupil diameter</td><td>IFS incidence, n (%)</td><td>Risk Ratio (95% CI)</td><td>Odds Ratio (95%)</td><td>P value*</td></tr>
<tr><td>≤ 6.5 mm (n=29)</td><td>13 (44.8%)</td><td>2.06 (1.04-4.07)</td><td>2.92 (1.06-8.05)</td><td>0.032</td></tr>
<tr><td>> 6.5mm (n=46)</td><td>10 (21.7%)</td><td>Reference</td><td>Reference</td><td>Reference</td></tr>
</table>
*Fisher exact test</td></tr>
<tr><td>Outcomes</td><td>Use of prophylactic intracameral lidocaine–epinephrine did not reduce the incidence of IFIS.
A preoperative dilated pupil diameter smaller than 6.5 mm was significantly associated with an increased incidence of IFIS</td></tr>
</table>

Full citation	Chen A, Kelly J, Bhandari A, Wu M. Pharmacologic prophylaxis and risk factors for intraoperative floppy-iris syndrome in phacoemulsification performed by resident physicians. Journal of cataract and refractive surgery. 2010;36:898-905
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the cohort recruited in an acceptable way? Yes 3 Was the exposure accurately measured to minimise bias? Yes 4 Was the outcome accurately measured to minimise bias? Yes 5 (a) Have the authors identified all important confounding factors? Unclear (b) Have they taken account of the confounding factors in the design and/or analysis? Unclear 6 (a) Was the follow up of subjects complete enough? Yes (b) Was the follow up of subjects long enough? N/A 7 Do you believe the results? Yes 8 Can the results be applied to the local population? Yes 9 Do the results of this study fit with other available evidence? N/A

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Full citation	Gonzalez N, Quintana J, Bilbao A, Vidal S et al. Factors affecting cataract surgery complications and their effect on the postoperative outcome. Canadian Journal of Ophthalmology. 2014;49:72-79
Study details	Country/ies where the study was carried out: Spain Study type: Prospective cohort Aim of the study: To identify factors associated with the development of complications during or after cataract surgery and to determine the effect of complications on improvements in visual acuity and visual function. Study dates: October 2004 to July 2005 Sources of funding: This study has been supported by grants from the Fondo de Investigación Sanitaria (PI03/0550,PI03/0724,PI03/0471,PI03/0828,PI04/1577), the thematic networks–Red IRYSS of the Instituto de Salud Carlos III (G03/202), Madrid, Spain; the Basque Country Health Department (2003/11045), Vitoria, Spain; and the CIBER Epidemiología y Salud Pública, Barcelona, Spain.
Participants	Sample size 4335 patients Inclusion criteria Patients referred for cataract removal by phacoemulsification Exclusion criteria Older than 90 years, having corneal dystrophy, severe general comorbidities or psychiatric conditions that might have hindered completion of questionnaires. Patients who underwent cataract surgery before receiving the preoperative questionnaires were also excluded.
Methods	Data collection

<table>
<tr><th>Full citation</th><td>Gonzalez N, Quintana J, Bilbao A, Vidal S et al. Factors affecting cataract surgery complications and their effect on the postoperative outcome. Canadian Journal of Ophthalmology. 2014;49:72-79</td></tr>
<tr><td></td><td>Clinical data was taken at the visit before the intervention and about 6 weeks postoperatively. Technical complexity of the surgery, ocular complications during and immediately after surgery was also noted.
To describe the technical complexity a variable was created for each patient from 14 possible complexities reflected in the clinical data, which were then placed into 3 groups: No/low, Moderate, and High.
Intervention
Cataract surgery
Analysis
Multivariate logistic regression</td></tr>
<tr><td>Results</td><td>Factors associated with the presence of perioperative complications
<table>
<tr><td></td><td>Multivariate*</td><td></td></tr>
<tr><td></td><td>Odds Ratio (95% CI)</td><td>p</td></tr>
<tr><td>Age</td><td>1.02 (1.01-1.03)</td><td>0.0088</td></tr>
<tr><td>Preoperative VA
≥1 vs ≤0.3
0.4-0.9 vs ≤0.3</td><td>
1.54 (1.02-2.31)
1.27 (0.88-1.84)</td><td>
0.0384
0.2073</td></tr>
<tr><td>Technical complexity
Moderate vs no/low
High vs no/low</td><td>
2.39 (1.71-3.33)
3.21 (2.35-4.38)</td><td>
<0.0001
<0.0001</td></tr>
</table>
*Only variables with p<0.05 in the univariate analysis are presented in this multivariate final model.</td></tr>
<tr><td>Outcomes</td><td>Age, preoperative visual acuity higher than 1 and a moderate or high technical complexity were significant related to perioperative complexity was significantly related to perioperative complications.</td></tr>
<tr><td>Comments</td><td>No details reported on how the 3 technical complexity groups were derived</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the cohort recruited in an acceptable way? Yes
3 Was the exposure accurately measured to minimise bias? Unclear
4 Was the outcome accurately measured to minimise bias? Yes
5 (a) Have the authors identified all important confounding factors? Unclear
(b) Have they taken account of the confounding factors in the design and/or analysis? Unclear
6 (a) Was the follow up of subjects complete enough? Yes
(b) Was the follow up of subjects long enough? N/A</td></tr>
</table>

Full citation	**Gonzalez N, Quintana J, Bilbao A, Vidal S et al. Factors affecting cataract surgery complications and their effect on the postoperative outcome. Canadian Journal of Ophthalmology. 2014;49:72-79**
	7 Do you believe the results? Yes 8 Can the results be applied to the local population? Yes 9 Do the results of this study fit with other available evidence? N/A

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Full citation	**Ling R, Kamalarajah S, Cole M, James C, Shaw S. Suprachoroidal haemorrhage complicating cataract surgery in the UK: a case-control study of risk factors. British Journal of Ophthalmology. 2004;88:474-477**
Study details	Country/ies where the study was carried out: UK Study type: Case-control Aim of the study: To study the risk factors for suprachoroidal haemorrhage (SCH) complicating cataract surgery in the United Kingdom. Study dates: November 2000 to October 2001 Sources of funding: Torbay Medical Research Fund, and the British Council for Prevention of Blindness
Participants	Sample size 109 cases compared with 449 controls Inclusion criteria Haemorrhage in the suprachoroidal space during cataract surgery, diagnosed by the surgeon Exclusion criteria Cases that combine cataract extraction with another intraocular procedure
Methods	Data collection Cases of SCH cataract surgery were retrospectively collected through the British Ophthalmological Surveillance Unit and compared with 449 controls that underwent cataract extraction from 13 ‘‘control centres’’ throughout UK. Intervention Cataract surgery Analysis Fisher’s exact test, Chi-square test.
Results	Independently significant risk factors for SCH in the multivariate logistic regression model (n = 431, (79 cases and 352 controls))

Variable	Odds ratio	95% Confidence Interval	p value
Age	1.06	1.03-1.10	<0.001
Cardiovascular drugs	1.66	1.27-2.16	<0.001
Glaucoma	5.9	2.9-11.8	<0.001

Full citation	**Ling R, Kamalarajah S, Cole M, James C, Shaw S. Suprachoroidal haemorrhage complicating cataract surgery in the UK: a case-control study of risk factors. British Journal of Ophthalmology. 2004;88:474-477**
	<table><tr><td>Intraocular pressure</td><td>1.09</td><td>1.02-1.17</td><td>0.015</td></tr><tr><td>Posterior capsule rupture before SCH</td><td>3.9</td><td>1.7-8.9</td><td>0.001</td></tr><tr><td>Extracapsular cataract extraction (ECCE)</td><td>2.08</td><td>0.88-4.94</td><td>0.096</td></tr><tr><td>Conversion*</td><td>6.4</td><td>2.2-18.9</td><td>0.001</td></tr></table> *phacoemulsification conversion to ECCE
Outcomes	Multivariate logistic regression analysis identified the following significant independent risk factors: older age, taking at least one cardiovascular medication, glaucoma, elevated preoperative intraocular pressure, PC rupture before SCH, elective ECCE, and phacoemulsification conversion.
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Did the authors use an appropriate method to answer their question? Yes 3 Were the cases recruited in an acceptable way? Yes 4 Were the controls selected in an acceptable way? Yes 5 Was the exposure accurately measured to minimise bias? Unclear 6 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unclear 7 Do you believe the results? Yes 8 Can the results be applied to the local population? Yes 9 Do the results of this study fit with other available evidence? N/A

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Full citation	**Narendran N, Jaycock P, Johnston R, Taylor H, Adams M, Tole D, Asria R, Galloway P, Sparrow J. The Cataract National Dataset electronic multicentre audit of 55 567 operations: risk stratification for posterior capsule rupture and vitreous loss. Eye. 2009;23:31-37**
Study details	Country/ies where the study was carried out: UK Study type: Prospective cohort Aim of the study: To identify and quantify risk factors for posterior capsule rupture or vitreous loss or both (PCR or VL or both) during cataract surgery and provide a method of composite risk assessment for individual operations. Study dates: November 2001 to July 2006 Sources of funding: none reported Disclosures: Robert Johnston is a Director of Medisoft Limited. Peter Galloway is an advisor to Medisoft in relation to glaucoma but not cataract.

<table>
<tr><th>Full citation</th><th>Narendran N, Jaycock P, Johnston R, Taylor H, Adams M, Tole D, Asria R, Galloway P, Sparrow J. The Cataract National Dataset electronic multicentre audit of 55 567 operations: risk stratification for posterior capsule rupture and vitreous loss. Eye. 2009;23:31-37</th></tr>
<tr><td>Participants</td><td>Sample size
55,567
Inclusion criteria
Not reported
Exclusion criteria
Not reported</td></tr>
<tr><td>Methods</td><td>Data collection
Analysed all systemic, ocular, and surgeon variables within the Cataract National Dataset (CND) considered by the authors to be candidate variables, which may contribute to an increased risk of PCR or VL or both.
Intervention
Cataract surgery
Analysis
Chi-squared
Fishers exact test</td></tr>
<tr><td>Results</td><td>Adjusted odds ratios (OR) for ‘PCR or VL or both’ obtained from the logistic regression model (n=55 358)
<table>
<tr><th></th><th>Adjusted OR (95% CI)</th><th>Chi-square, p-value</th></tr>
<tr><td>Age
<60
60-69
70-79
80-89
90+</td><td>
1.00
1.14 (0.84-1.54)
1.42 (1.08-1.86)
1.58 (1.20-2.08)
2.37 (1.69-3.34)</td><td>

34.8, p<0.0001

</td></tr>
<tr><td>Gender
Female
Male</td><td>
1.00
1.28 (1.13-1.45)</td><td>

15.1, p=0.0001</td></tr>
<tr><td>Glaucoma
No
Yes</td><td>
1.00
1.30 (1.03-1.64)</td><td>

4.6, p=0.0325</td></tr>
</table></td></tr>
</table>

Full citation	Narendran N, Jaycock P, Johnston R, Taylor H, Adams M, Tole D, Asria R, Galloway P, Sparrow J. The Cataract National Dataset electronic multicentre audit of 55 567 operations: risk stratification for posterior capsule rupture and vitreous loss. Eye. 2009;23:31-37		
	Diabetic Retinopathy No Yes	 1.00 1.63 (1.24-2.14)	 10.9, p=0.0010
	Brunescent/white cataract No Yes	 1.00 2.99 (2.32-3.85)	 57.6, p<0.0001
	No fundal view/vitreous opacities No Yes	 1.00 2.46 (1.70-3.55)	 19.5, p<0.0001
	PXF/phacodonesis No Yes	 1.00 2.92 (2.02-4.22)	 25.5, p<0.0001
	Pupil size Large Medium Small	 1.00 1.14 (0.95-1.38) 1.45 (1.10-1.91)	 7.5, p=0.0231
	Axial length (mm) <26.0 ≥26.0	 1.00 1.47 (1.12-1.94)	 6.8, p=0.0090
	Doxazosin No Yes	 1.00 1.51 (1.09-2.07)	 5.7, p=0.0173
	Able to lie flat Yes No	 1.00 1.27 (1.11-1.45)	 11.7, p=0.0006
	Surgeon Grade Consultant Associate specialist Staff grade	 1.00 0.87 (0.67-1.12) 0.36 (0.17- 0.76)	 198.5, p<0.0001

Full citation	**Narendran N, Jaycock P, Johnston R, Taylor H, Adams M, Tole D, Asria R, Galloway P, Sparrow J. The Cataract National Dataset electronic multicentre audit of 55 567 operations: risk stratification for posterior capsule rupture and vitreous loss. Eye. 2009;23:31-37**
	Fellow: 1.65 (1.29-2.11) Specialist registrar: 1.60 (1.38-1.85) Senior house officer: 3.73 (3.09-4.51)
Outcomes	For patient-related factors, the risk of PCR or VL or both was higher with increasing age, male gender, presence of glaucoma, diabetic retinopathy, brunescent/ white cataract, no fundal view/vitreous opacities, PXF/phacodonesis, reducing pupil size, axial length ≥26.0mm, the use of doxazosin, and inability to lie flat. In terms of surgeon grade, the risk of PCR or VL or both was higher for trainee surgeons than career grades with staff grades showing the lowest risk.
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the cohort recruited in an acceptable way? Unclear 3 Was the exposure accurately measured to minimise bias? Unclear 4 Was the outcome accurately measured to minimise bias? Yes 5 (a) Have the authors identified all important confounding factors? Unclear (b) Have they taken account of the confounding factors in the design and/or analysis? Unclear 6 (a) Was the follow up of subjects complete enough? Yes (b) Was the follow up of subjects long enough? N/A 7 Do you believe the results? Yes 8 Can the results be applied to the local population? Yes 9 Do the results of this study fit with other available evidence? N/A

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Full citation	**Robbie S, Muhtaseb J, Qureshi M, Bunce C, Xing W, Ionides A. Intraoperative complications of cataract surgery in the very old. British Journal of Ophthalmology. 2006;90:1516-1518**
Study details	Country/ies where the study was carried out: UK Study type: Prospective cohort Study dates: 15 November 2002 to 9 June 2003 Sources of funding: None reported
Participants	Sample size 1441 patients Inclusion criteria

<table>
<tr><th>Full citation</th><td>Robbie S, Muhtaseb J, Qureshi M, Bunce C, Xing W, Ionides A. Intraoperative complications of cataract surgery in the very old. British Journal of Ophthalmology. 2006;90:1516-1518</td></tr>
<tr><td></td><td>Patients undertaking phacoemulsification surgery
Exclusion criteria
Planned extracapsular cataract extractions</td></tr>
<tr><td>Methods</td><td>Data collection
Consecutive patients were assessed preoperatively and data on the occurrence of intraoperative complications were collected prospectively
Intervention
Cataract surgery</td></tr>
<tr><td>Results</td><td>Overall complication rates per age group
<table>
<tr><td></td><td colspan="3">Complication at surgery</td><td></td></tr>
<tr><td>Age group (years)</td><td>Yes</td><td>No</td><td>Total</td><td>Percentage (95% Confidence Interval)</td></tr>
<tr><td>≤50</td><td>1</td><td>28</td><td>29</td><td>3.45 (0.087 to 17.77)</td></tr>
<tr><td>50-60</td><td>5</td><td>74</td><td>79</td><td>6.33 (2.09 to 14.15)</td></tr>
<tr><td>60-70</td><td>18</td><td>269</td><td>287</td><td>6.27 (3.76 to 9.73)</td></tr>
<tr><td>70-80</td><td>37</td><td>510</td><td>547</td><td>6.76 (4.81 to 9.20)</td></tr>
<tr><td>80-90</td><td>28</td><td>417</td><td>445</td><td>6.29 (4.22 to 8.97)</td></tr>
<tr><td>>90</td><td>3</td><td>51</td><td>54</td><td>5.56 (1.16 to 15.39)</td></tr>
<tr><td>Total</td><td>92</td><td>1349</td><td>1441</td><td>6.83 (5.18 to 7.77)</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>No significant association was found between age and the risk of an intraoperative complication.</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the cohort recruited in an acceptable way? Yes
3 Was the exposure accurately measured to minimise bias? Yes
4 Was the outcome accurately measured to minimise bias? Yes
5 (a) Have the authors identified all important confounding factors? Unclear
(b) Have they taken account of the confounding factors in the design and/or analysis? Unclear
6 (a) Was the follow up of subjects complete enough? Yes
(b) Was the follow up of subjects long enough? N/A
7 Do you believe the results? Yes
8 Can the results be applied to the local population? Yes</td></tr>
</table>

Full citation	**Robbie S, Muhtaseb J, Qureshi M, Bunce C, Xing W, Ionides A. Intraoperative complications of cataract surgery in the very old. British Journal of Ophthalmology. 2006;90:1516-1518**
	9 Do the results of this study fit with other available evidence? N/A

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Full citation	**Rutar T, Porco T, Naseri A. Risk factors for intraoperative complications in resident performed phacoemulsification surgery. Ophthalmology. 2009;116:431-436**
Study details	Country/ies where the study was carried out: USA Study type: Retrospective cohort Aim of the study: To determine the risk factors for intraoperative complications in resident-performed phacoemulsification surgery and the effect of complications on postoperative visual acuity. Study dates: January 2006 and January 2007 Sources of funding:
Participants	Sample size 320 eyes Inclusion criteria Inclusion criteria were resident surgeon as primary surgeon, planned phacoemulsification surgery, and documentation in the electronic medical record consisting of preoperative history, complete ophthalmic examination, and intraoperative record. If the intraoperative decision was made to convert a planned phacoemulsification case to manual lens expression, the case was still included in this series. Exclusion criteria Planned extracapsular cataract extractions with manual lens expression were excluded.
Methods	Data collection Data were collected by review of patients' electronic medical records. Collected data included the patient demographics, ocular comorbidities, cataract features, resident, resident experience, attending, right or left eye, anaesthesia type, wound type, phacoemulsification technique, preoperative and postoperative visual acuities, and presence of any intraoperative complication. Multivariate models were constructed to determine potential risk factors for intraoperative complications. Intervention Cataract surgery Analysis Fisher exact test
Results	Summary of Characteristics of 320 Resident-performed Phacoemulsification Surgeries at the Veterans Administration Hospital San Francisco

	Number of cases	% of all cases
Attending		

Full citation	Rutar T, Porco T, Naseri A. Risk factors for intraoperative complications in resident performed phacoemulsification surgery. Ophthalmology. 2009;116:431-436

VA attending	279	87.2
Visiting attending	41	12.8
Resident year		
Second year	67	20.9
Third year	253	79.1
Case		
Challenging case*	71	22.2
Not challenging	249	77.8
Wound type		
Clear cornea	265	82.8
Scleral tunnel	56	17.5
Phacoemulsification technique		
Divide and conquer	30	9.4
Chopping	283	88.4
Planned phaco requiring conversion to ECCE	4	1.3
Anaesthesia		
Topical	97	30.3
Peribulbar or retrobulbar	218	68.1
General	4	1.3
Side		
Right eye	170	53.1
Left eye	150	46.9
Complications		
Major	15	4.7
Vitreous loss (a subset of major)	10	3.1
Minor	28	8.8

ECCE = extracapsular cataract extraction via manual lens expression technique; phaco = phacoemulsification; VA = Veterans Administration Hospital.

Full citation	**Rutar T, Porco T, Naseri A. Risk factors for intraoperative complications in resident performed phacoemulsification surgery. Ophthalmology. 2009;116:431-436**

*Challenging cases were categorically classified as small pupil (mydriasis <6 mm and intraoperative floppy iris syndrome), potential zonular pathology (cataracts occurring in patients with a history of ocular trauma or pseudoexfoliation syndrome), mature cataracts (4 + nuclear sclerosis), combined cases (phacoemulsification combined with penetrating keratoplasty, glaucoma filtration surgery, or vitrectomy), shallow chambers (anterior chamber depth <2.5 mm, presence of Ahmed tube, or functional filtering bleb), corneal problems (guttae and Fuchs' endothelial corneal dystrophy, corneal opacities), post-vitrectomy cataracts, and monocular patients (irreversible vision loss in the contralateral eye).

Risk Factors for Major Intraoperative Complications in Resident-performed Phacoemulsification Surgeries Based on Multivariate Analyses

			95% Confidence Interval	
Predictor	P value	Odds Ratio	Low	High
Attending: VA vs visiting	0.58	0.63	0.12	3.29
Resident experience	0.91	1.00	0.99	1.02
Challenging case	0.01	5.96	1.47	24.12
Side: right vs left	0.66	0.74	0.20	2.75
Anaesthesia type	0.35	0.32	0.03	3.58
Wound type	0.99	0.74	0.19	5.27
Phacoemulsification technique	0.06	6.89	0.95	50.02
Preoperative visual acuity (logMAR)	0.31	1.93	0.55	6.78

CI = confidence interval; logMAR = logarithm of the minimum angle of resolution; OR = odds ratio; VA = Veterans Administration Hospital.

Outcomes	In multivariate analyses, only challenging cases were predictive of major complications, whereas VA versus visiting attending, resident experience, right versus left eye, anaesthesia type, wound type, phacoemulsification technique, and preoperative visual acuity were not. Challenging cases predictive of vitreous loss: The odds ratio for vitreous loss in a challenging case compared with a non-challenging case was 7.4 (95% CI, 1.1–48.9, p=0.04). The divide and conquer technique, when compared with nuclear chopping techniques, had an increased odds ratio of major complication. However, the divide and conquer technique did not confer an increased odds of vitreous loss. (P = 0.33). Cases with mature lenses or potential zonular pathology (antecedent trauma or pseudoexfoliation) presented the highest odds of a major complication: 18.9 (95%CI, 3.1–117, p= 0.002) and 26.2 (95%CI, 4.3–159, p= 0.003), respectively. Small pupil cases, including those with intraoperative floppy iris syndrome were the most common challenging feature encountered, but did not lead to statistically significant increased odds of a major complication.

Full citation	Rutar T, Porco T, Naseri A. Risk factors for intraoperative complications in resident performed phacoemulsification surgery. Ophthalmology. 2009;116:431-436
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Did the authors use an appropriate method to answer their question? Yes 3 Were the cases recruited in an acceptable way? Yes 4 Was the exposure accurately measured to minimise bias? Yes 5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unclear 6 Do you believe the results? Yes 7 Can the results be applied to the local population? Yes 8 Do the results of this study fit with other available evidence? N/A

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E.4 Intraocular lens selection

- Are different lens design (aspheric vs. spheric, plate vs. loop) effective in improving postoperative vision (refractive outcomes, optical aberrations) in cataract surgery?
- Are different lens design (square-edged vs. round-edge, plate vs. loop) and material (hydrophilic acrylic, hydrophobic acrylic, collagen, hydroxyethyl methacrylate-based vs. silicone-based) effective in preventing posterior capsule opacification in cataract surgery?
- Are tinted lenses effective in preventing the progression of age-related macular degeneration compared with colourless lenses in cataract surgery?
- What is the optimal strategy to facilitate simultaneous distance and near vision following cataract surgery?
- What is the optimal strategy to address pre-existing astigmatism in people undergoing cataract surgery?

E.4.1 Lens design

Full citation	**Findl O, Buehl W, Bauer P et al. Interventions for preventing posterior capsule opacification. Cochrane Database of Systematic Reviews 2010 2:1-89**
Study details	Country/ies where the study was carried out: N/A Study type: Systematic review Recruitment dates: Studies included up to March 2009 Conflicts of Interest: None
Participants	66 included RCTs 32 of these RCTs met the criteria for our review protocol
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: • Lens material • Square-edge vs round edge • 1-piece vs 3-piece
Outcomes	• Visual acuity • PCO • YAG rate
Risk of bias	• Only included studies with a follow-up time of at least 12 months

Full citation	**Alio JL, Chipont E, BenEzra D. Comparative performance of intraocular lenses in eyes with cataract and uveitis. Journal of Catract Refractory Surgery 2002 28:2096-108**
Study details	Country/ies where the study was carried out: Multinational Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 118 people with chronic uveitis Comparison method: Inter-person comparison Mean age: Not reported
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: PMMA vs hydrophobic acrylic vs silicone Follow-up: 11-13 months
Outcomes	• YAG rate
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

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Full citation	**Baumeister M, Neidhardt B, Strobel J, et al. Tilt and decentration of three-piece foldable high-refractive silicone and hydrophobic acrylic intraocular lenses with 6mm optics in an intraindividual comparison. American Journal of Ophthalmology 2005 140: 1051-8**
Study details	Country/ies where the study was carried out: Germany Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: Funded by AMO
Participants	Sample size: 53 people Comparison method: Fellow-eye study Mean age: 73 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Square-edge vs round-edge, hydrophobic acrylic vs silicone Follow-up: 12 months
Outcomes	• Lens decentration • Lens tilt
Risk of bias	• Participants not blinded to allocation

Full citation	**Baumeister M, Neidhardt B, Strobel J, et al. Tilt and decentration of three-piece foldable high-refractive silicone and hydrophobic acrylic intraocular lenses with 6mm optics in an intraindividual comparison. American Journal of Ophthalmology 2005 140: 1051-8**
	• Assessors not blinded to allocation

117

Full citation	**Baumeister M, Bühren J, Kohnen T. Tilt and decentration of spherical and aspheric intraocular lenses: effect on higher-order aberrations. Journal of Cataract Refractory Surgery 2009 35,1006-12**
Study details	Country/ies where the study was carried out: Germany Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 21 people Comparison method: Fellow-eye study Mean age: 71 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 3-4 months
Outcomes	• Aberrations
Risk of bias	• Assessors not blinded to allocation

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Full citation	**Caporossi A, Martone G, Casprini F, et al. Prospective randomized study of clinical performance of 3 aspheric and 2 spherical intraocular lenses in 250 eyes. Journal of Refractive Surgery 2007 23:639-48**
Study details	Country/ies where the study was carried out: Italy Study type: Randomised control trial Recruitment dates: March 2004-April 2006 Conflicts of Interest: None
Participants	Sample size: 100 people Comparison method: Inter-person comparison Mean age: 70 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 2 months

Full citation	**Caporossi A, Martone G, Casprini F, et al. Prospective randomized study of clinical performance of 3 aspheric and 2 spherical intraocular lenses in 250 eyes. Journal of Refractive Surgery 2007 23:639-48**
Outcomes	• Visual acuity • Aberrations • Contrast sensitivity
Risk of bias	• Assessors not blinded to allocation

119

Full citation	**Chang A, Behndig A, Rønbeck M, et al. Comparison of posterior capsule opacification and glistenings with 2 hydrophobic acrylic intraocular lenses: 5- to 7-year follow-up. Journal of Cataract Refractory Surgery 2013 39:694-9**
Study details	Country/ies where the study was carried out: Sweden Study type: Randomised control trial Recruitment dates: May 2003-April 2005 Conflicts of Interest: None
Participants	Sample size: 80 people Comparison method: Inter-person comparison Mean age: 68 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: 1-piece vs 3-piece Follow-up: 5-7 years
Outcomes	• PCO • YAG rate • Glistenings
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

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Full citation	**Chang A, Kugelberg M. Glistenings 9 years after phacoemulsification in hydrophobic and hydrophilic acrylic intraocular lenses. Journal of Cataract Refractory Surgery 2015 41:1199-1204**
Study details	Country/ies where the study was carried out: Sweden Study type: Randomised control trial Recruitment dates: May 2002-March 2004

Full citation	**Chang A, Kugelberg M. Glistenings 9 years after phacoemulsification in hydrophobic and hydrophilic acrylic intraocular lenses. Journal of Cataract Refractory Surgery 2015 41:1199-1204**
	Conflicts of Interest: None
Participants	Sample size: 78 people Comparison method: Fellow-eye study Mean age: 73 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Hydrophobic acrylic vs hydrophilic acrylic Follow-up: 9 years
Outcomes	• Glistenings
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

121

Full citation	**Chen WR, Ye HH, Qian YY. Comparison of higher-order aberrations and contrast sensitivity between Tecnis Z9001 and CeeOn 911A intraocular lenses: a prospective randomized study. Chinese Medical Journal 2006 119:1779-84**
Study details	Country/ies where the study was carried out: China Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 20 people Comparison method: Fellow-eye study Mean age: Not reported
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 3 months
Outcomes	• Visual acuity • Contrast sensitivity
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

122

Full citation	**Crnej A, Buehl W, Greslechner R, et al. Effect of an aspheric intraocular lens on the ocular wave-front adjusted for pupil size and capsulorhexis size. Acta Ophthalmologica 2014 92:e353-7**
Study details	Country/ies where the study was carried out: Austria Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 30 people Comparison method: Fellow-eye study Mean age: 76 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 2 years
Outcomes	• Visual acuity • PCO • Contrast sensitivity
Risk of bias	• No serious risk

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Full citation	**Cui H, Hu R, Zhang Y, et al. Comparison of pseudophakic visual quality in spherical and aspherical intraocular lenses. Canadian Journal of Ophthalmology 2009 44:274-8**
Study details	Country/ies where the study was carried out: China Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 57 people Comparison method: Inter-person comparison Mean age: 69 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 2 months
Outcomes	• Aberrations • Contrast sensitivity

Full citation	**Cui H, Hu R, Zhang Y, et al. Comparison of pseudophakic visual quality in spherical and aspherical intraocular lenses. Canadian Journal of Ophthalmology 2009 44:274-8**
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

124

Full citation	**Denoyer A, Le Lez M, Majzoub S, et al. Quality of vision after cataract surgery after Tecnis Z9000 intraocular lens implantation: effect of contrast sensitivity and wavefront aberration improvements on the quality of daily vision. Journal of Cataract Refractory Surgery 2007 33:210-6**
Study details	Country/ies where the study was carried out: France Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 20 people Comparison method: Inter-person comparison Mean age: 79 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 6 months
Outcomes	• Visual acuity • Aberrations • Contrast sensitivity
Risk of bias	• No serious risk

125

Full citation	**Espindola RF, Santhiago MR, Kara-Junior N. Effect of aspherical and yellow tinted intraocular lenses on blue-on-yellow perimetry. Archives of Brazilian Ophthalmology 2012 75:316-9**
Study details	Country/ies where the study was carried out: Brazil Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 25 people

Full citation	**Espindola RF, Santhiago MR, Kara-Junior N. Effect of aspherical and yellow tinted intraocular lenses on blue-on-yellow perimetry. Archives of Brazilian Ophthalmology 2012 75:316-9**
	Comparison method: Fellow-eye study Mean age: 63 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 2 years
Outcomes	• Visual acuity • Aberrations • Contrast sensitivity
Risk of bias	• No serious risk

126

Full citation	**Findl O, Hirnschall N, Nishi Y, et al. Capsular bag performance of a hydrophobic acrylic 1-piece intraocular lens. Journal of Cataract Refractory Surgery 2015 41:90-7**
Study details	Country/ies where the study was carried out: UK and Austria Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: Funded by Abbott
Participants	Sample size: 50 people Comparison method: Fellow-eye study Mean age: 71 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: 1-piece vs 3-piece Follow-up: 2 years
Outcomes	• Visual acuity • PCO • YAG rate
Risk of bias	• No serious risk

127

Full citation	**Hayashi K, Harada M, Hayashi H, et al. Decentration and tilt of polymethyl methacrylate, silicone, and acrylic soft intraocular lenses. Ophthalmology 1997 104:793-8**
Study details	Country/ies where the study was carried out: Japan Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 160 people Comparison method: Inter-person comparison Mean age: 68 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Hydrophobic acrylic vs silicone Follow-up: 12 months
Outcomes	• Lens decentration • Lens tilt
Risk of bias	• Participants not blinded to allocation

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Full citation	**Hayashi K, Hayashi H, Nakao F, et al. Comparison of decentration and tilt between one piece and three piece polymethyl methacrylate intraocular lenses. British Journal of Ophthalmology 1998 82:419-22**
Study details	Country/ies where the study was carried out: Japan Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 100 people Comparison method: Fellow-eye study Mean age: 69 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: 1-piece vs 3-piece Follow-up: 6 months
Outcomes	• Lens decentration • Lens tilt
Risk of bias	• Participants not blinded to allocation

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Full citation	Hayashi K, Hayashi H, Nakao F, et al. Anterior capsule contraction and intraocular lens decentration and tilt after hydrogel lens implantation. British Journal of Ophthalmology 2001 85:1294-7
Study details	Country/ies where the study was carried out: Japan Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 100 people Comparison method: Fellow-eye study Mean age: 71 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Hydrophobic acrylic vs hydrophilic acrylic Follow-up: 6 months
Outcomes	• YAG rate • Lens decentration • Lens tilt
Risk of bias	• No serious risk

130

Full citation	Hayashi K, Hayashi H. Comparison of the stability of 1-piece and 3-piece acrylic intraocular lenses in the lens capsule. Journal of Cataract refractory Surgery 2005 31:337-42
Study details	Country/ies where the study was carried out: Japan Study type: Randomised control trial Recruitment dates: July 2002-December 2002 Conflicts of Interest: None
Participants	Sample size: 56 people Comparison method: Fellow-eye study Mean age: 71 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: 1-piece vs 3-piece Follow-up: 6 months
Outcomes	• Lens decentration

Full citation	Hayashi K, Hayashi H. Comparison of the stability of 1-piece and 3-piece acrylic intraocular lenses in the lens capsule. Journal of Cataract refractory Surgery 2005 31:337-42
	• Lens tilt
Risk of bias	• No serious risk

131

Full citation	Hennig A, Puri LR, Sharma H, et al. Foldable vs rigid lenses after phacoemulsification for cataract surgery: a randomised controlled trial. Eye 2014 28:567-75
Study details	Country/ies where the study was carried out: Nepal Study type: Randomised control trial Recruitment dates: September 2010-September 2011 Conflicts of Interest: None
Participants	Sample size: 1,200 people Comparison method: Inter-person comparison Mean age: 57 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: PMMA vs hydrophilic acrylic Follow-up: 12 months
Outcomes	• Visual acuity • PCO
Risk of bias	• Assessors not blinded to allocation

132

Full citation	Hollick EJ, Spalton DJ, Ursell PG, et al. The effect of polymethylmethacrylate, silicon, and polyacrylic intraocular lenses on posterior capsular opacification 3 years after cataract surgery. Ophthalmology 1999 106:49-55
Study details	Country/ies where the study was carried out: UK Study type: Randomised control trial Recruitment dates: September 1993-September July 1994 Conflicts of Interest: None
Participants	Sample size: 81 people Comparison method: Inter-person comparison Mean age: 73 years

Full citation	**Hollick EJ, Spalton DJ, Ursell PG, et al. The effect of polymethylmethacrylate, silicon, and polyacrylic intraocular lenses on posterior capsular opacification 3 years after cataract surgery. Ophthalmology 1999 106:49-55**
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: PMMA vs hydrophilic acrylic vs silicone Follow-up: 3 years
Outcomes	• YAG rate
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

133

Full citation	**Jafarinasab M, Feizi S, Baghi A, et al. Aspheric versus spherical posterior chamber intraocular lenses. Journal of Ophthalmic and Vision Research 2010 5:217-22**
Study details	Country/ies where the study was carried out: Iran Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 34 people Comparison method: Inter-person comparison Mean age: 59 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 3 months
Outcomes	• Visual acuity • Aberrations • Contrast sensitivity
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

134

Full citation	**Kobayashi H, Ikeda H, Imamura S, et al. Clinical assessment of long-term safety and efficacy of a widely implanted polyacrylic intraocular lens material. American Journal of Ophthalmology 2000 130:310-21**
Study details	Country/ies where the study was carried out: Japan

Full citation	**Kobayashi H, Ikeda H, Imamura S, et al. Clinical assessment of long-term safety and efficacy of a widely implanted polyacrylic intraocular lens material. American Journal of Ophthalmology 2000 130:310-21**
	Study type: Randomised control trial Recruitment dates: January 1995-May 1998 Conflicts of Interest: Not reported
Participants	Sample size: 1,202 people Comparison method: Inter-person comparison Mean age: 72 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: PMMA vs hydrophobic acrylic Follow-up: 3 years
Outcomes	• Visual acuity • YAG rate
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

135

Full citation	**Kucuksumer Y, Bayraktar S, Sahin S, et al. Posterior capsule opacification 3 years after implantation of an AcrySof and a MemoryLens in fellow eyes. Journal of Cataract Refractory Surgery 2000 26:1176-82**
Study details	Country/ies where the study was carried out: Turkey Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 50 people Comparison method: Fellow-eye study Mean age: 67 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Hydrophobic acrylic vs hydrophilic acrylic Follow-up: 3 years
Outcomes	• Visual acuity • PCO • YAG rate

Full citation	**Kucuksumer Y, Bayraktar S, Sahin S, et al. Posterior capsule opacification 3 years after implantation of an AcrySof and a MemoryLens in fellow eyes. Journal of Cataract Refractory Surgery 2000 26:1176-82**
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

136

Full citation	**Kugelberg M, Wejde G, Jayaram H, et al. Two-year follow-up of posterior capsule opacification after implantation of a hydrophilic or hydrophobic acrylic intraocular lens. Acta Ophthalmologica 2008 86:533-6**
Study details	Country/ies where the study was carried out: Sweden Study type: Randomised control trial Recruitment dates: 2002-2004 Conflicts of Interest: Funded by Bausch & Lomb
Participants	Sample size: 120 people Comparison method: Inter-person comparison Mean age: Not reported
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Hydrophobic acrylic vs hydrophilic acrylic Follow-up: 2 years
Outcomes	• Visual acuity • YAG rate
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

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Full citation	**Luo M, Ji J, Zhao C, et al. Clinical study of Acrysof IQ aspheric intraocular lenses. Clinical and Experimental Ophthalmology 2010 38:358-62**
Study details	Country/ies where the study was carried out: China Study type: Randomised control trial Recruitment dates: May 2006-June 2008 Conflicts of Interest: None
Participants	Sample size: 260 people Comparison method: Inter-person comparison

Full citation	Luo M, Ji J, Zhao C, et al. Clinical study of Acrysof IQ aspheric intraocular lenses. Clinical and Experimental Ophthalmology 2010 38:358-62
	Mean age: 73 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 90 days
Outcomes	• Visual acuity • Contrast sensitivity
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

138

Full citation	Moorfields IOL Study Group. Binocular implantation of the Tecnis Z9000 or AcrySof MA60AC intraocular lens in routine cataract surgery. Journalk of Cataract Refractory Surgery 2007 33:1559-64
Study details	Country/ies where the study was carried out: UK Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: Funded by AMO
Participants	Sample size: 300 people Comparison method: Inter-person comparison Mean age: 71 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 8 months
Outcomes	• Visual acuity • Aberrations • Contrast sensitivity
Risk of bias	• No serious risk

139

Full citation	**Morales EL, Rocha KM, Chalita MR, et al. Comparison of optical aberrations and contrast sensitivity between aspheric and spherical intraocular lenses. Journal of Refractive Surgery 2011 27:723-28**
Study details	Country/ies where the study was carried out: Brazil Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 40 people Comparison method: Fellow-eye study Mean age: 69 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 90 days
Outcomes	• Visual acuity • Aberrations
Risk of bias	• No serious risk

140

Full citation	**Mutlu FM, Erdurman C, Sobaci G, et al. Comparison of tilt and decentration of 1-piece and 3-piece hydrophobic acrylic intraocular lenses. Journal of Cataract Refractory Surgery 2005 31:343-7**
Study details	Country/ies where the study was carried out: Turkey Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 88 people Comparison method: Inter-person comparison Mean age: 69 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: 1-piece vs 3-piece Follow-up: 6 months
Outcomes	• Lens decentration • Lens tilt

Full citation	**Mutlu FM, Erdurman C, Sobaci G, et al. Comparison of tilt and decentration of 1-piece and 3-piece hydrophobic acrylic intraocular lenses. Journal of Cataract Refractory Surgery 2005 31:343-7**
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

141

Full citation	**Mylonas G, Prskavec M, Baradaran-Dilmaghani R, et al. Effect of a single-piece and a three-piece acrylic sharp-edged IOL on posterior capsule opacification. Current Eye Research 2013 38:86-90**
Study details	Country/ies where the study was carried out: Austria Study type: Randomised control trial Recruitment dates: January 2009-July 2009 Conflicts of Interest: None
Participants	Sample size: 28 people Comparison method: Fellow-eye study Mean age: 76 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: 1-piece vs 3-piece Follow-up: 90 days
Outcomes	• PCO • YAG rate
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

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Full citation	**Nanavaty MA, Spalton DJ, Boyce J, et al. Wavefront aberrations, depth of focus, and contrast sensitivity with aspheric and spherical intraocular lenses: fellow-eye study. Journal of Cataract refractory Surgery 2009 35:663-71**
Study details	Country/ies where the study was carried out: UK Study type: Randomised control trial Recruitment dates: November 2006-July 2007 Conflicts of Interest: Funded by Alcon
Participants	Sample size: 47 people Comparison method: Fellow-eye study

Full citation	**Nanavaty MA, Spalton DJ, Boyce J, et al. Wavefront aberrations, depth of focus, and contrast sensitivity with aspheric and spherical intraocular lenses: fellow-eye study. Journal of Cataract refractory Surgery 2009 35:663-71**
	Mean age: 72 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 6 months
Outcomes	• Visual acuity • Aberrations • Depth of focus
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

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Full citation	**Nanavaty MA, Spalton DJ, Gala KB, et al. Effect of intraocular lens asphericity on posterior capsule opacification between two intraocular lenses with same acrylic material: a fellow-eye study. Acta Ophthalmologica 2012 90:e104-8**
Study details	Country/ies where the study was carried out: UK Study type: Randomised control trial Recruitment dates: November 2006-July 2007 Conflicts of Interest: Funded by Alcon
Participants	Sample size: 47 people Comparison method: Fellow-eye study Mean age: 76 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 24 months
Outcomes	• Visual acuity • PCO • YAG rate
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

144

Full citation	**Papaliodis GN, Nguyen QD, Samson M, et al. Intraocular lens tolerance in surgery for cataract complications: assessment of four implant materials. Seminars in Ophthalmology 2002 17:120-3**
Study details	Country/ies where the study was carried out: USA Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 36 people with chronic uveitis Comparison method: Inter-person comparison Mean age: 52 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: PMMA vs hydrophobic acrylic vs silicone Follow-up: 360 days
Outcomes	• YAG rate
Risk of bias	• No serious risk

145

Full citation	**Prinz A, Neumayer T, Buehl W, et al. Rotational stability and posterior capsule opacification of a plate-haptic and an open-loop-haptic intraocular lens. Journal of Cataract Refractory Surgery 2011 37:251-7**
Study details	Country/ies where the study was carried out: Austria Study type: Randomised control trial Recruitment dates: August 2006-September 2007 Conflicts of Interest: Funded by Zeiss
Participants	Sample size: 40 people Comparison method: Fellow-eye study Mean age: 74 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Plate vs 3-piece Follow-up: 12 months
Outcomes	• Visual acuity • PCO • YAG rate • Lens tilt

Full citation	**Prinz A, Neumayer T, Buehl W, et al. Rotational stability and posterior capsule opacification of a plate-haptic and an open-loop-haptic intraocular lens. Journal of Cataract Refractory Surgery 2011 37:251-7**
Risk of bias	• No serious risk

146

Full citation	**Prinz A, Vecsie-Marlovits PV, Sonderhof D, et al. Comparison of posterior capsule opacification between a 1-piece and a 3-piece microincision intraocular lens. British Journal of Ophthalmology 2012 00:1-5**
Study details	Country/ies where the study was carried out: Austria Study type: Randomised control trial Recruitment dates: May 2009-August 2009 Conflicts of Interest: None
Participants	Sample size: 40 people Comparison method: Fellow-eye study Mean age: 72 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: 1-piece vs 3-piece Follow-up: 12 months
Outcomes	• Visual acuity • PCO • YAG rate
Risk of bias	• No serious risk

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Full citation	**Rocha KM, Soriano ES, Chalita MR, et al. Wavefront analysis and contrast sensitivity of aspheric and spherical intraocular lenses: a randomised prospective study. American Journal of Ophthalmology 2006 142:750-6**
Study details	Country/ies where the study was carried out: Brazil Study type: Randomised control trial Recruitment dates: February 2005-October 2005 Conflicts of Interest: Not reported
Participants	Sample size: 60 people Comparison method: Fellow-eye study Mean age: 70 years

Full citation	**Rocha KM, Soriano ES, Chalita MR, et al. Wavefront analysis and contrast sensitivity of aspheric and spherical intraocular lenses: a randomised prospective study. American Journal of Ophthalmology 2006 142:750-6**
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 90 days
Outcomes	• Visual acuity • Aberrations • Contrast sensitivity
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

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Full citation	**Roesel M, Heinz C, Heimes B, et al. Uveal and capsular biocompatibility of two foldable acrylic intraocular lenses in patients with endogenous uveitis – a prospective randomized study. Archives of Clinical and Experimental Ophthalmology 2008 246:1609-15**
Study details	Country/ies where the study was carried out: Germany Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 60 people with chronic uveitis Comparison method: Inter-person comparison Mean age: 51 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Hydrophobic acrylic vs hydrophilic acrylic Follow-up: 6 months
Outcomes	• Visual acuity • PCO • YAG rate
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

149

Full citation	**Sandoval HP, de Castro LEF, Vroman DT, et al. Comparison of visual outcomes, phototopic contrast sensitivity, wavefront analysis, and patient satisfaction following cataract extraction and IOL implantation: aspheric vs spherical acrylic lenses**
Study details	Country/ies where the study was carried out: USA Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: Funded by Alcon
Participants	Sample size: 27 people Comparison method: Inter-person comparison Mean age: 70 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 3 months
Outcomes	• Visual function • Contrast sensitivity
Risk of bias	• No serious risk

150

Full citation	**Santhiago MR, Netto MV, Barreto J, et al. Wavefront analysis, contrast sensitivity, and depth of focus after cataract surgery with aspherical intraocular lens implantation. American Journal of Ophthalmology 2010 149:383-9**
Study details	Country/ies where the study was carried out: Brazil Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 25 people Comparison method: Fellow-eye study Mean age: 57 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 3 months
Outcomes	• Visual acuity • Contrast sensitivity

Full citation	**Santhiago MR, Netto MV, Barreto J, et al. Wavefront analysis, contrast sensitivity, and depth of focus after cataract surgery with aspherical intraocular lens implantation. American Journal of Ophthalmology 2010 149:383-9**
Risk of bias	• No serious risk

151

Full citation	**Shentu X, Tang X, Yao K. Spherical aberration, visual performance and pseudoaccommodation of eyes implanted with different aspheric intraocular lens. Clinical and Experimental Ophthalmology 2008 36:620-4**
Study details	Country/ies where the study was carried out: China Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: Not reported
Participants	Sample size: 196 people Comparison method: Inter-person comparison Mean age: 68 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 3 months
Outcomes	• Visual acuity • Contrast sensitivity
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

152

Full citation	**Takmaz T, Genc I, Yildiz Y, et al. Ocular wavefront analysis and contrast sensitivity in eyes implanted with AcrySof IQ or AcrySof Natural intraocular lenses. Acta Ophthalmologica 2009 87:759-63**
Study details	Country/ies where the study was carried out: Turkey Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: Not reported
Participants	Sample size: 60 people Comparison method: Inter-person comparison Mean age: 66 years

Full citation	**Takmaz T, Genc I, Yildiz Y, et al. Ocular wavefront analysis and contrast sensitivity in eyes implanted with AcrySof IQ or AcrySof Natural intraocular lenses. Acta Ophthalmologica 2009 87:759-63**
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 30 days
Outcomes	• Aberrations • Contrast sensitivity
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

153

Full citation	**Trueb PR, Albach C, Montes-Mico R, et al. Visual acuity and contrast sensitivity in eyes implanted with aspheric and spherical intraocular lenses. Ophthalmology 2009 116:890-5**
Study details	Country/ies where the study was carried out: Switzerland Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 262 people Comparison method: Inter-person comparison Mean age: 76 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 3 months
Outcomes	• Visual acuity • Contrast sensitivity
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

154

Full citation	**Tzelikis P, Akaishi L, Trindade FC, et al. Ocular aberrations and contrast sensitivity after cataract surgery with AcrySof IQ intraocular lens implantation. Journal of Cataract Refractory Surgery 2007 33:1918-24**
Study details	Country/ies where the study was carried out: Brazil

Full citation	**Tzelikis P, Akaishi L, Trindade FC, et al. Ocular aberrations and contrast sensitivity after cataract surgery with AcrySof IQ intraocular lens implantation. Journal of Cataract Refractory Surgery 2007 33:1918-24**
	Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 25 people Comparison method: Fellow-eye study Mean age: 68 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 3 months
Outcomes	• Visual acuity • Aberrations • Contrast sensitivity
Risk of bias	• No serious risk

155

Full citation	**Tzelikis P, Akaishi L, Trindade FC, et al. Spherical aberration and contrast sensitivity in eyes implanted with aspheric and spherical intraocular lenses: a comparative study. American Journal of Ophthalmology 2008 145:827-833**
Study details	Country/ies where the study was carried out: Brazil Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 25 people Comparison method: Fellow-eye study Mean age: 65 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 3 months
Outcomes	• Visual acuity • Aberrations • Contrast sensitivity

Full citation	**Tzelikis P, Akaishi L, Trindade FC, et al. Spherical aberration and contrast sensitivity in eyes implanted with aspheric and spherical intraocular lenses: a comparative study. American Journal of Ophthalmology 2008 145:827-833**
Risk of bias	• No serious risk

156

Full citation	**van Gallen KW, Koopmans SA, Jansonius NM, et al. Clinical comparison of the optical performance of aspheric and spherical intraocular lenses. Journal of Cataract Refractory Surgery 2010 36:34-43**
Study details	Country/ies where the study was carried out: Netherlands Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 30 people Comparison method: Fellow-eye study Mean age: 69 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 6 weeks
Outcomes	• Visual acuity • Aberrations
Risk of bias	• No serious risk

157

Full citation	**Vasavada AR, Raj SM, Shah A, et al. Comparison of posterior capsule opacification with hydrophobic acrylic and hydrophilic acrylic intraocular lenses. Journal of Cataract Refractory Surgery 2011 37: 1050-9**
Study details	Country/ies where the study was carried out: India Study type: Randomised control trial Recruitment dates: January 2006-March 2007 Conflicts of Interest: None
Participants	Sample size: 68 people Comparison method: Fellow-eye study Mean age: 67 years
Methods	Intervention: Phacoemulsification cataract surgery

Full citation	**Vasavada AR, Raj SM, Shah A, et al. Comparison of posterior capsule opacification with hydrophobic acrylic and hydrophilic acrylic intraocular lenses. Journal of Cataract Refractory Surgery 2011 37: 1050-9**
	Relevant lens comparisons: Hydrophobic acrylic vs hydrophilic acrylic Follow-up: 3 years
Outcomes	• YAG rate
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

158

Full citation	**Vock L, Crnej A, Findl O, et al. Posterior capsule opacification in silicone and hydrophobic intraocular lenses with sharp-edge optics six year after surgery. American Journal of Ophthalmology 2009 147:683-90**
Study details	Country/ies where the study was carried out: Austria Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 22 people Comparison method: Fellow-eye study Mean age: 75 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Hydrophobic acrylic vs silicone Follow-up: 3 years
Outcomes	• Visual acuity • YAG rate
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

159

Full citation	**Yamaguchi T, Negishi K, Ohnuma K, et al. Correlation between contrast sensitivity and higher-order aberration based on pupil diameter after cataract surgery. Clinical Ophthalmology 2011 5:1701-7**
Study details	Country/ies where the study was carried out: Japan Study type: Randomised control trial Recruitment dates: October 2007-December 2009

Full citation	**Yamaguchi T, Negishi K, Ohnuma K, et al. Correlation between contrast sensitivity and higher-order aberration based on pupil diameter after cataract surgery. Clinical Ophthalmology 2011 5:1701-7**
	Conflicts of Interest: None
Participants	Sample size: 92 people Comparison method: Inter-person study Mean age: 69 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 1 month
Outcomes	• Contrast sensitivity
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

160

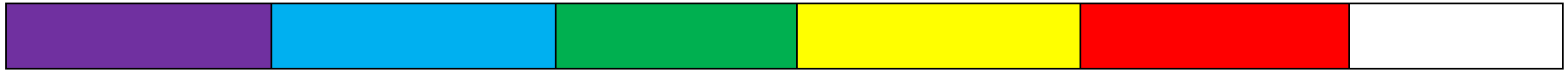
Full citation	**Zemaitiene R, Jasinskas V. Prevention of posterior capsule opacification with 3 intraocular lens models: a prospective, randomized, long-term clinical trial. Medicina (Kaunas) 2011 47:595-9**
Study details	Country/ies where the study was carried out: Lithuania Study type: Randomised control trial Recruitment dates: Not reported Conflicts of Interest: None
Participants	Sample size: 89 people Comparison method: Inter-person study Mean age: 67 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Hydrophobic acrylic vs silicone, 1-piece vs 3-piece Follow-up: 3 years
Outcomes	• Visual acuity • PCO • YAG rate
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

Full citation	Zeng M, Liu Y, Liu X, et al. Aberration and contrast sensitivity comparison of aspherical and monofocal and multifocal intraocular lens eyes. Clinical and Experimental Ophthalmology 2007 35:355-60
Study details	Country/ies where the study was carried out: China Study type: Randomised control trial Recruitment dates: May 2005-December 2005 Conflicts of Interest: None
Participants	Sample size: 124 people Comparison method: Inter-person study Mean age: 66 years
Methods	Intervention: Phacoemulsification cataract surgery Relevant lens comparisons: Aspheric vs spheric Follow-up: 3 months
Outcomes	• Visual acuity • Contrast sensitivity
Risk of bias	• Participants not blinded to allocation • Assessors not blinded to allocation

6.24.1.1 Contrast sensitivity results

Methods

A considerable amount of poor reporting was identified in the data on contrast sensitivity for aspheric versus spheric intraocular lenses. In particular, data were often only reported as graphs, with an accompanying list of the data points where the differences between the two lens types were statistically significant. Whilst some of these graphs also contained error bars which would have enabled estimation of standard deviations, it was felt that doing so would be likely to introduce reporting bias, as there appeared to be a trend towards studies finding larger difference being more likely to report measures of uncertainty. Therefore, it was decided to report the contrast sensitivity results in a simple fashion, according to the following key:



Significantly better	Non-significantly better	Measured but not reported	Non-significantly worse	Significantly worse	Not measured

For each study and lighting level (mesopic or phototopic, with or without glare), and each spatial frequency, it is simply reported whether aspheric lenses provide significantly better, non-significantly better, non-significantly worse or significantly worse contrast sensitivity than spheric lenses in that study. If a study did not report results at one of the spatial frequencies specified below, results from the nearest spatial frequency were included instead, provided they were within 1.5 cycle per degree of visual angle.

Results

Mesopic lighting conditions

Paper	Light level	1.5 cpd	3 cpd	6 cpd	12 cpd	18 cpd
Caporossi 2007	6cd/m^2					
Chen 2006	6cd/m^2					
Crnej 2014	6cd/m^2					
Denoyer 2007	0.15cd/m^2					
Espindola 2012	3cd/m^2					
Jafarinasab 2010	5cd/m^2					
Luo 2010	5cd/m^2					
Rocha 2006	3cd/m^2					
Santhiago 2010	3cd/m^2					
Takmaz 2009	2.7cd/m^2					
Trueb 2009	6cd/m^2					
Tzelikis 2007	5cd/m^2					
Tzelikis 2008	5cd/m^2					
Yamaguchi 2011	3cd/m^2					

Mesopic lighting conditions (with glare)

Paper	Light level	1.5 cpd	3 cpd	6 cpd	12 cpd	18 cpd
Chen 2006	6cd/m^2					
Rocha 2006	3cd/m^2					

Takmaz 2009	2.7cd/m^2					
Tzelikis 2007	5cd/m^2					
Tzelikis 2008	5cd/m^2					
Yamaguchi 2011	3cd/m^2					

178 **Phototopic lighting conditions**

Paper	Light level	1.5 cpd	3 cpd	6 cpd	12 cpd	18 cpd
Caporossi 2007	85cd/m^2					
Chen 2006	85cd/m^2					
Cui 2009	Not reported					
Denoyer 2007	80cd/m^2					
Espindola 2012	85cd/m^2					
Jafarinasab 2010	85cd/m^2					
Luo 2010	80cd/m^2					
Rocha 2006	85cd/m^2					
Sandoval 2008	Not reported					
Santhiago 2010	85cd/m^2					
Shentu 2008	Not reported					
Takmaz 2009	85cd/m^2					
Trueb 2009	85cd/m^2					
Tzelikis 2007	85cd/m^2					
Tzelikis 2008	85cd/m^2					
Yamaguchi 2011	85cd/m^2					
Zeng 2007	85cd/m^2					

179 **Phototopic lighting conditions (with glare)**

Paper	Light level	1.5 cpd	3 cpd	6 cpd	12 cpd	18 cpd
Chen 2006	85cd/m^2					
Cui 2009	Not reported					
Denoyer 2007	80cd/m^2					

Shentu 2008	Not reported					
Tzelikis 2007	85cd/m^2					
Tzelikis 2008	85cd/m^2					
Yamaguchi 2011	85cd/m^2					
Zeng 2007	85cd/m^2					

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18E.4.2 Tinted vs colourless lenses

Full citation	**Brondsted A, Sander B, Scient C, Haargaard B et al. The effect of cataract surgery on circadian photoentrainment. Ophthalmology. 2015;122:2115-2124**
Study details	Country/ies where the study was carried out: USA Study type: RCT Aim of the study: To investigate the effect of cataract surgery on circadian photoentrainment and to determine any difference between blue-blocking and neutral intraocular lenses. Study dates: Not reported Sources of funding: Not reported
Participants	Sample size 76 patients Inclusion criteria Patients who were referred for bilateral senile cataract eligible for cataract surgery and informed written consent obtained. Only the first eye was included in the study, that is, the eye with the lowest visual acuity according to the department's guidelines Exclusion criteria Any ophthalmological disease with an expected effect on the retina, optic disc, or cornea, including advanced age related macular degeneration, glaucoma, diabetic retinopathy, corneal dystrophy, ocular trauma, and recurrent uveitis. Furthermore, patients with severe systemic disease, including diabetes, cancer of any kind, and known sleep disturbances, were excluded. Pre-operative characteristics

	Blue –blocking IOL (n=38)	Neutral IOL (n=35)	P value
Age (yrs), mean (range)	74 (65-94)	73 (50-88)	0.637*
Sex (F/M)	16/22	22/13	0.124**
BCDVA (logMAR)	0.29±0.14	0.40±0.41	0.127*

*Student t-test, **Chi-square test, BCDVA = Best corrected distance visual acuity

Methods	Randomization was performed on the day of the surgery using automated, computerized block-randomization lists with a 1:1 allocation ratio and a block size of 9. The participants were masked to IOL type. Due to the different colours of the blue-blocking and neutral IOLs, it was not possible to keep the investigator masked to IOL type. Sleep efficiency was measured by Actigraphy before surgery and 3 weeks post-operatively as a percentage of sleep during the night. Subjective sleep quality was measured 1 to 4 weeks before surgery and 3 weeks after using the Danish version of the Pittsburgh Sleep Quality Index (PSQI). A value of zero indicates perfect sleep quality; poor sleepers were identified with a score of ≥5. Intervention

<table>
<tr><th>Full citation</th><td>Brondsted A, Sander B, Scient C, Haargaard B et al. The effect of cataract surgery on circadian photoentrainment. Ophthalmology. 2015;122:2115-2124</td></tr>
<tr><td></td><td>cataract surgery by phacoemulsification</td></tr>
<tr><td>Results</td><td>Actigraphy Measures before and after Cataract Surgery
<table>
<tr><th></th><th>Before surgery</th><th>n</th><th>After 3 weeks</th><th>n</th></tr>
<tr><td>Sleep efficiency (%)</td><td>86.22 ± 6.88</td><td>74</td><td>86.60 ± 7.33</td><td>70</td></tr>
<tr><td>Neutral IOL</td><td>86.01 ± 7.49</td><td>34</td><td>85.85 ± 8.80</td><td>33</td></tr>
<tr><td>Blue-blocking IOL</td><td>86.21 ± 6.48</td><td>38</td><td>87.27 ± 5.75</td><td>37</td></tr>
</table>
Subjective Sleep Quality before and after Surgery
<table>
<tr><th>PSQI</th><th>Before surgery</th><th>n</th><th>After 3 weeks</th><th>n</th></tr>
<tr><td>Global score</td><td>4.61 ± 2.65</td><td>72</td><td>4.89 ± 3.57</td><td>66</td></tr>
<tr><td>Neutral IOL</td><td>4.52 ± 2.75</td><td>33</td><td>5.16 ± 3.82</td><td>32</td></tr>
<tr><td>Blue-blocking IOL</td><td>4.7 ± 2.64</td><td>37</td><td>4.65 ± 3.35</td><td>34</td></tr>
<tr><td>Poor sleepers (PSQI ≥5)</td><td>35</td><td>72</td><td>29</td><td>66</td></tr>
<tr><td>Neutral IOL</td><td>17</td><td>33</td><td>16</td><td>32</td></tr>
<tr><td>Blue-blocking IOL</td><td>17</td><td>37</td><td>13</td><td>34</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>The IOL type had no effect on the change in sleep efficiency (mixed model ANOVA, F68 = 1.15, P = 0.287).
Subjective sleep quality assessed by the PSQI questionnaire was not affected by the surgery (mixed-model ANOVA, F64 = 0.91, P = 0.345) or by IOL type (mixed-model ANOVA, F63 = 2.04, P = 0.158).
The number of poor sleepers was not affected by surgery (chi-square test, X2 = 0.03, P = 0.856).</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Yes
3 Were the patients, health workers and study personnel blinded? Yes (although assessor not blinded)
4 Were the groups similar at the start of the trial? Yes
5 Aside from the experimental intervention, were the groups treated equally? Yes
6 Were all of the patients who entered the trial properly accounted for sat its conclusion? Yes
7 Can the results be applied to the local population? Yes
8 Were all clinically important outcomes considered? N/A</td></tr>
</table>

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Full citation	**Brondsted A, Haargaard B, Sander B et al. The effect of blue-blocking and neutral intraocular lenses on circadian photoentrainment and sleep one year after cataract surgery. Acta Ophthalmologica. 2016;1-8**
Study details	Country/ies where the study was carried out: Denmark Study type: RCT Aim of the study: To investigate the effect of blue-blocking and neutral intraocular lenses on circadian photoentrainment and sleep one year after cataract surgery. Study dates: Not reported Sources of funding: Danish Association of the Blind and the Velux Foundation
Participants	Sample size 67 patients Inclusion criteria Patients who were referred for bilateral cataract eligible for cataract surgery. Only the first eye was included in the study, that is, the eye first scheduled for cataract surgery. Exclusion criteria Any ophthalmological disease with an expected effect on the retina, optic disc, or cornea, including advanced age related macular degeneration, glaucoma, diabetic retinopathy, corneal dystrophy, ocular trauma, and recurrent uveitis. Furthermore, patients with severe systemic disease, including diabetes, cancer of any kind, and known sleep disturbances, were excluded.
Methods	Randomization was performed on the day of the surgery using automated, computerized block-randomization lists with a 1:1 allocation ratio. The participants were masked to IOL type until completion of the 1-year follow up examination. Sleep efficiency was measured by Actigraphy as a percentage of sleep during the night. Subjective sleep quality was measured at the time of the pre-operative visit and 1 year after using the Danish version of the Pittsburgh Sleep Quality Index (PSQI). A value of zero indicates perfect sleep quality; poor sleepers were identified with a score of ≥5. Intervention Cataract surgery by phacoemulsification
Results	Actigraphy Measures before and after Cataract Surgery Sleep efficiency (%) | Before surgery | n | After 1 year | n Neutral IOL | 87 (85-89) | 31 | 86 (84-89) | 31 Blue-blocking IOL | 86 (84-88) | 36 | 88 (86-89) | 36

<table>
<tr><th>Full citation</th><td>Brondsted A, Haargaard B, Sander B et al. The effect of blue-blocking and neutral intraocular lenses on circadian photoentrainment and sleep one year after cataract surgery. Acta Ophthalmologica. 2016;1-8</td></tr>
<tr><td></td><td>Subjective Sleep Quality before and after Surgery
<table>
<tr><th>PSQI</th><th>Before surgery</th><th>n</th><th>After 1 year</th><th>n</th></tr>
<tr><td>Global score
Neutral IOL
Blue-blocking IOL</td><td>
4.4 (3.4-5.4)
4.8 (3.9-5.6)</td><td>
31
36</td><td>
4.8 (3.6-6.0)
4.8 (3.4-6.1)</td><td>
31
36</td></tr>
<tr><td>Number of Poor sleepers (PSQI ≥5)
Neutral IOL
Blue-blocking IOL</td><td>
9
12</td><td></td><td>
12
9</td><td></td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>For the entire population, sleep efficiency was unaffected but an increase of 2% was detected for blue-blocking IOL participants.
Global PSQI score was unchanged 1 year after surgery</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Yes
3 Were the patients, health workers and study personnel blinded? Yes
4 Were the groups similar at the start of the trial? Yes
5 Aside from the experimental intervention, were the groups treated equally? Yes
6 Were all of the patients who entered the trial properly accounted for sat its conclusion? Yes
7 Can the results be applied to the local population? Yes
8 Were all clinically important outcomes considered? N/A</td></tr>
</table>

185

Full citation	**Espindle D, Crawford B, Maxwell A, Rajagopalan K, Barnes R, Harris B and Hileman K. Quality of life improvements in cataract patients with bilateral blue light-filtering intraocular lenses: Clinical trial. Journal of cataract refract surg. 2005;31:1952-1959**
Study details	Country/ies where the study was carried out: USA Study type: RCT Aim of the study: To compare change in patient-reported vision related and health related functioning and quality of life (HRQOL) following bilateral implantation with a new blue light-filtering IOL's Study dates: Not reported Sources of funding: Alcon Laboratories

<table>
<tr><th>Full citation</th><td>Espindle D, Crawford B, Maxwell A, Rajagopalan K, Barnes R, Harris B and Hileman K. Quality of life improvements in cataract patients with bilateral blue light-filtering intraocular lenses: Clinical trial. Journal of cataract refract surg. 2005;31:1952-1959</td></tr>
<tr><td>Participants</td><td>Sample size
257 patients
Inclusion criteria
Requiring bilateral cataract surgery, at least 60 years old, in good general and ocular health, expected to achieve at least 20/40 post-operative visual acuity and pass both the Farnsworth D-15 panel test and the Ishihara colour test.
Exclusion criteria
Patients with other eye conditions (incl. colour blindness or other colour vision deficiencies) or taking other medications that could interfere with the results. Also patients with alcoholism, Alzheimer’s or terminal cancer.</td></tr>
<tr><td>Methods</td><td>Patients were randomly assigned to 1 of 2 IOL groups for the first eye (Blue light-filtering or clear). The second eye was later implanted with the same type of IOL. Patients and HRQOL data collectors were masked to treatment however clinical investigators were not.
Data collection
HRQOL were measured preoperatively and postoperatively (120-180 days) using the NEI VQF-39 scales and SF-12 component scales
Intervention
Cataract surgery
Analysis
Two tailed t-test</td></tr>
<tr><td>Results</td><td>Mean change on HRQOL measures
<table>
<tr><th></th><th colspan="2">Blue-light filtering IOL (n=131)*</th><th colspan="2">Clear IOL (n=126)*</th><th></th></tr>
<tr><th></th><th>Mean change (95% CI)</th><th>P value</th><th>Mean change (95% CI)</th><th>P value</th><th>P value
for treatment comparison</th></tr>
<tr><td>NEI-VFQ-39 series
Composite</td><td>20.04 (17.58, 22.50)</td><td><0.0001</td><td>22.01 (19.28, 24.75)</td><td><0.0001</td><td>0.1742</td></tr>
<tr><td>SF-12 component scales
Physical
Mental</td><td>
3.47 (1.78, 5.15)
1.60 (-0.05, 3.26)</td><td>
<0.0001
0.0571</td><td>
2.36 (0.71, 4.01)
1.59 (0.10, 3.09)</td><td>
0.0054
0.0373</td><td>
0.3545
0.9920</td></tr>
</table>
*exact n varies slightly by scale depending on amount of missing data</td></tr>
<tr><td>Outcomes</td><td>Improvements in HRQOL measures were observed in both treatment groups from baseline.
No statistically significant difference in HRQOL measures between each lens group.</td></tr>
<tr><td>Comments</td><td>Dr Rajagopalan was employed by Alcon laboratories at the time the research was conducted.</td></tr>
</table>

Full citation	**Espindle D, Crawford B, Maxwell A, Rajagopalan K, Barnes R, Harris B and Hileman K. Quality of life improvements in cataract patients with bilateral blue light-filtering intraocular lenses: Clinical trial. Journal of cataract refract surg. 2005;31:1952-1959**
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Unsure 3 Were the patients, health workers and study personnel blinded? Yes (but not clinical staff) 4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for sat its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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Full citation	**Kara-Junior N, Espindola R, Gomez B, Ventura B, Smadja D and Santhiago M. Effects of blue light-filtering intraocular lenses on the macula, contrast sensitivity, and colour vision after a long-term follow-up. Journal of Cataract Refract Surg. 2011;37:2115-2119**
Study details	Country/ies where the study was carried out: Brazil Study type: RCT Aim of the study: To evaluate the possible side effects and potential protection 5 years after implantation of an intraocular lens with a blue light-filter. Study dates: Not reported Sources of funding: Not reported
Participants	Sample size 25 patients (50 eyes) Inclusion criteria Patients with visually significant bilateral cataracts and no history of colour vision deficiency. Exclusion criteria Ocular disease such as corneal opacity or irregularity, dry eye, amblyopia, anisometropia, glaucoma, retinal abnormalities, surgical complications, IOL tilt, previous or current use of medications known to cause colour vision deficiencies, and incomplete follow up.
Methods	Patients randomly received an ultraviolet and blue light filtering IOL in 1 eye and an acrylic UV light filtering only IOL in the fellow eye. Data collection Colour vision was measured 5 years post-operatively using the Farnsworth-Munsell test Intervention Cataract surgery Analysis

Full citation	**Kara-Junior N, Espindola R, Gomez B, Ventura B, Smadja D and Santhiago M. Effects of blue light-filtering intraocular lenses on the macula, contrast sensitivity, and colour vision after a long-term follow-up. Journal of Cataract Refract Surg. 2011;37:2115-2119**
	Mann-Whitney U
Results	Colour discrimination test – 5 years post-operatively IOL type: Mean ± SD Blue light-filtering: 112 ± 23 Clear: 105 ± 21
Outcomes	No statistically significant differences were found between the 2 IOL groups for the colour discrimination test. (p=0.674) There was no statistically significant difference in the mean CDVA (p=0.714), corrected near visual acuity (p=0.735) or mean astigmatism (p=0.810) after surgery. There were no significant clinical or OCT findings with respect to AMD in any case. The mean central macular thickness was 205 ± 21 µm in the tinted IOL group and 203 ± 18µm in the untinted IOL group; the difference was not statistically significant (p=0.712).
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Unsure 3 Were the patients, health workers and study personnel blinded? Unsure 4 Were the groups similar at the start of the trial? Unsure 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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Full citation	**Marshall J, Cionni R, Davison J, Ernest P, Lehmann R, Maxwell A, Solomon K. Clinical results of the blue-light filtering AcrySof Natural foldable acrylic intraocular lens. Journal of Cataract Refract Surg. 2005;31:2319-2323**
Study details	Country/ies where the study was carried out: USA Study type: RCT Aim of the study: To verify the safety and effectiveness of the new AcrySoft Natural (Alcon laboratories Inc.) blue-light filtering intraocular lens. Study dates: September 5 2000 to December 17 2001 Sources of funding: Sponsored by Alcon laboratories Inc.
Participants	Sample size 297 patients (150 blue-filter lens, 147 clear control lens)

<table>
<tr><th>Full citation</th><td>Marshall J, Cionni R, Davison J, Ernest P, Lehmann R, Maxwell A, Solomon K. Clinical results of the blue-light filtering AcrySof Natural foldable acrylic intraocular lens. Journal of Cataract Refract Surg. 2005;31:2319-2323</td></tr>
<tr><td></td><td>Inclusion criteria
Healthy adults older than 60 years with bilateral age-related cataracts. Willing to wait at least 30 days (but no longer than 60) between cataract extractions and successfully passed the Ishihara colour test and Farnsworth-Munsell D-15 colour perception test pre-operatively.
Exclusion criteria
Retinal abnormalities, glaucoma, diabetic retinopathy and previous or current use of medications known to cause colour-vision deficiencies.</td></tr>
<tr><td>Methods</td><td>Bilateral implantation occurred in 2 phases. The eye with the denser cataract was chosen randomly to receive the test or control lens with patient follow up for 1 to 2 months post-operatively. The second eye was implanted with the same lens model as the first eye which was randomised to the test or control lens at a ratio of 1:1
Data collection
Best corrected distance visual acuity determined post-operatively (1 to 2 days, 7 to 14 days, 30 to 60 days, 120 to 180 days and 330 to 420 days after the first procedure)
Colour perception measured post-operatively (30 to 60 days and 120 to 180 days)
Intervention
Cataract surgery</td></tr>
<tr><td>Results</td><td>Best corrected distance acuity after first-eye implantation – 1 year post-operative
<table>
<tr><td></td><td colspan="5">BCDVA</td></tr>
<tr><td></td><td colspan="3">Overall</td><td colspan="3">Best Case*</td></tr>
<tr><td>IOL</td><td>n</td><td>≥20/40 (%)</td><td>FDA Grid (%)</td><td>n</td><td>≥20/40 (%)</td><td>FDA Grid (%)</td></tr>
<tr><td>SB30AL (Blue-filtering)</td><td>135</td><td>99.3</td><td>92.5</td><td>114</td><td>100</td><td>96.7</td></tr>
<tr><td>SA30AL (Control)</td><td>127</td><td>98.4</td><td>92.5</td><td>102</td><td>99.0</td><td>96.7</td></tr>
</table>
*Excluding eyes with pre-existing pathology or postoperative macular degeneration

Colour perception – 120 to 180 day after first-eye implantation
<table>
<tr><td></td><td colspan="2">Pass</td><td colspan="2">Fail</td></tr>
<tr><td>IOL</td><td>n</td><td>(%)</td><td>n</td><td>(%)</td></tr>
<tr><td>SB30AL (Blue-filtering) First eye</td><td>107</td><td>98.2</td><td>2</td><td>1.8</td></tr>
<tr><td>SA30AL (Control) First eye</td><td>97</td><td>95.1</td><td>5</td><td>4.9</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>No difference in best corrected distance acuity between the 2 lenses (p=0.6123, Fisher exact test) at 1 year post-operative examination.</td></tr>
</table>

Full citation	**Marshall J, Cionni R, Davison J, Ernest P, Lehmann R, Maxwell A, Solomon K. Clinical results of the blue-light filtering AcrySof Natural foldable acrylic intraocular lens. Journal of Cataract Refract Surg. 2005;31:2319-2323**
	No difference in those who passed the colour perception test at 120 to 180 day follow up from the first eye implantation (p=0.2669, Fisher exact test)
Comments	Drs. Cionni, Lehmann and Maxwell are consultants to Alcon Laboratories Inc. No details of loss to follow up patients given No details of how patients and or lens given randomised
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Unsure 3 Were the patients, health workers and study personnel blinded? No 4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for at its conclusion? No 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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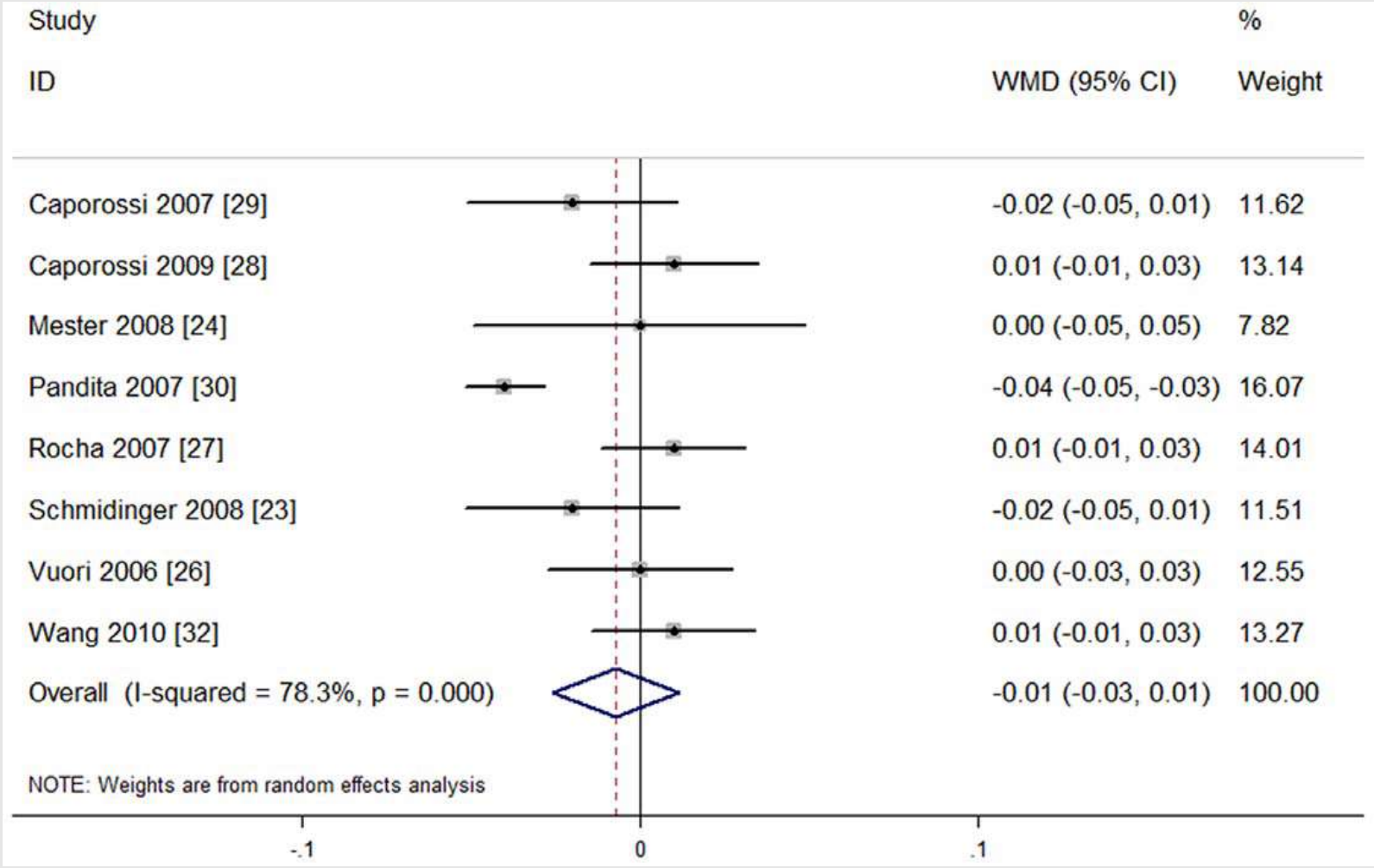
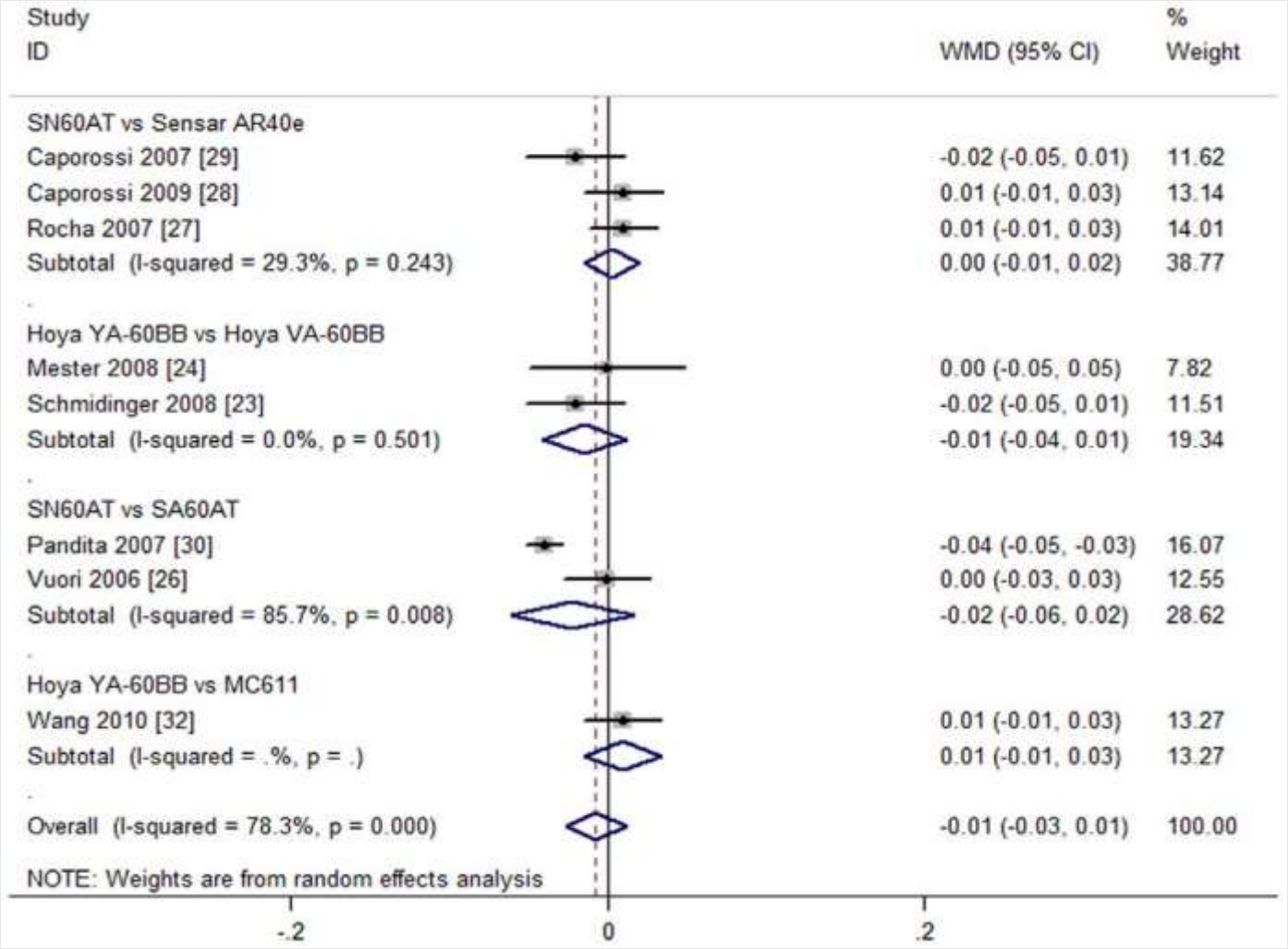
Full citation	**Zhu X, Zou H, Yu Y, Sun Q, Zhao N. Comparison of Blue Light-Filtering IOLs and UV Light-Filtering IOLs for Cataract Surgery: A Meta-Analysis. PLoS ONE . 2012;7(3): e33013**
Study details	Country/ies where the study was carried out: China Study type: Systematic review Aim of the study: To compare blue-light filtering IOLs and UV light filtering IOL's for cataract surgery. Study dates: Literature search of publications from 20000 to June 30th 2011 Sources of funding: Not reported
Participants	Sample size 15 RCT studies Inclusion criteria Eligibility criteria were randomized controlled clinical trials comparing postoperative visual performance of blue-light filtering IOL's and UV filtering IOL's Exclusion criteria Simulation experiments with blue light filtering IOL's and clinical trials containing aspherical and multifocal IOL's.
Methods	Systematic literature search conducted in the Embase, PubMed.gov, and Cochrane Central Library databases and the Chinese Biomedical Literature (CBM) using the MeSH terms: "cataract extraction" or "phacoemulsification" or "lens" or "intraocular" or "implantation" or "blue light

Full citation	**Zhu X, Zou H, Yu Y, Sun Q, Zhao N. Comparison of Blue Light-Filtering IOLs and UV Light-Filtering IOLs for Cataract Surgery: A Meta-Analysis. PLoS ONE . 2012;7(3): e33013**
	filtering" or "blue blocking" or AcrySof Natural" or "SN60AT" or yellow intraocular lens" or YA60BB" In addition, the reference lists of potentially relevant manuscripts were scanned backwards to obtain extra eligible studies. No language restrictions were applied.
Results	Meta-analysis of postoperative best corrected visual acuity (BCVA).



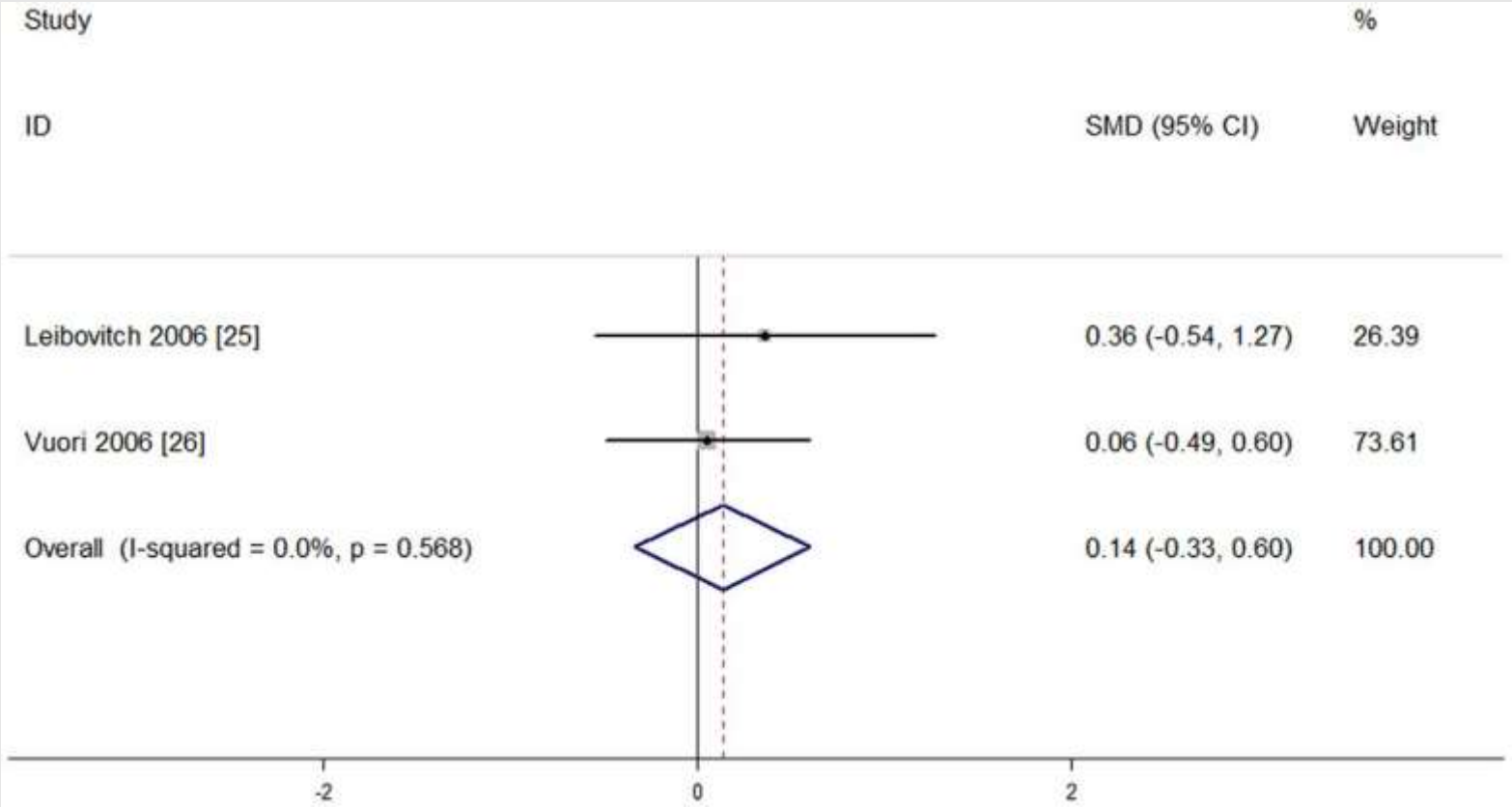
Full citation	**Zhu X, Zou H, Yu Y, Sun Q, Zhao N. Comparison of Blue Light-Filtering IOLs and UV Light-Filtering IOLs for Cataract Surgery: A Meta-Analysis. PLoS ONE . 2012;7(3): e33013**

Subgroup analysis of postoperative best corrected distance visual acuity (BCVA).



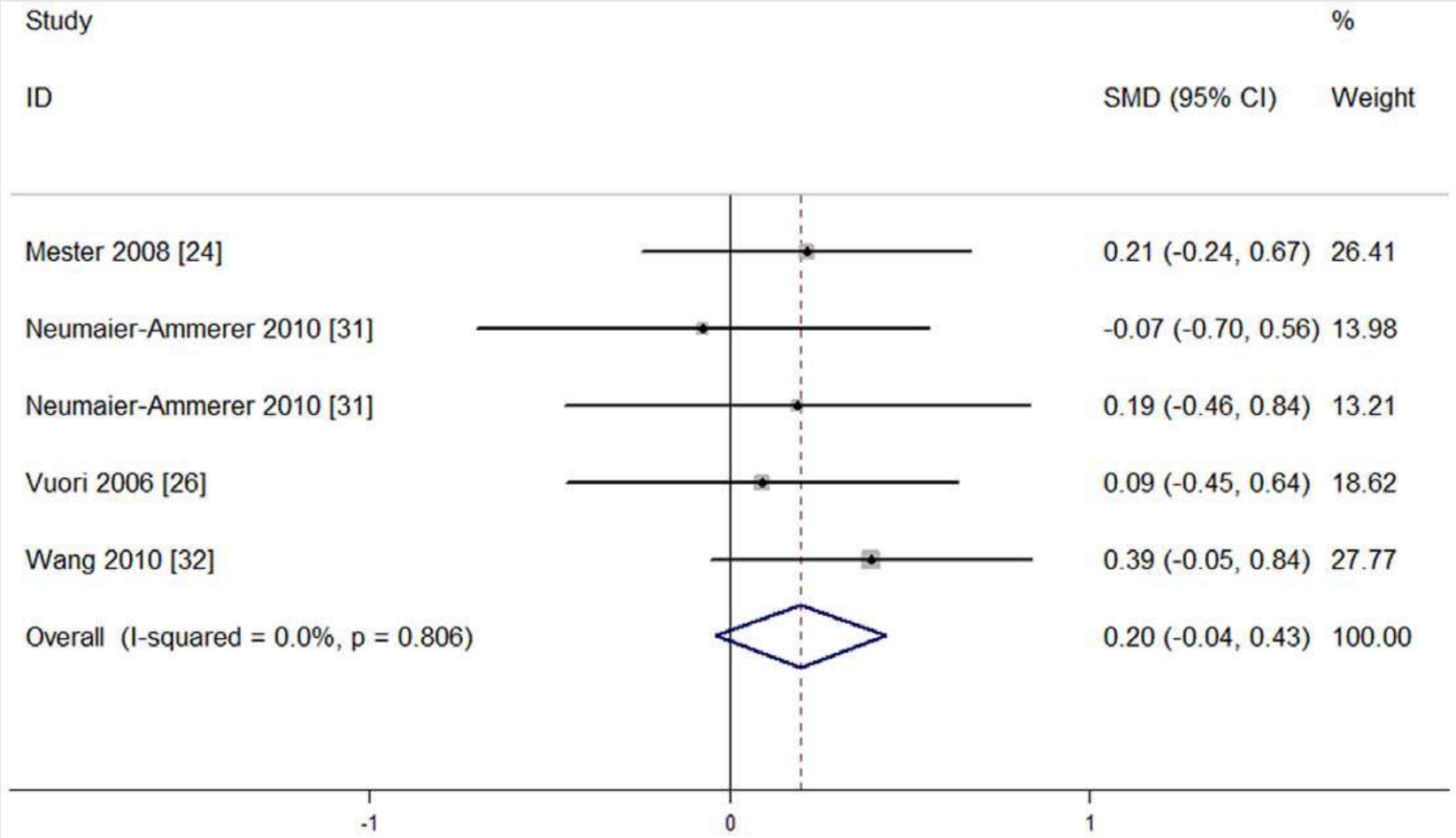
Full citation	**Zhu X, Zou H, Yu Y, Sun Q, Zhao N. Comparison of Blue Light-Filtering IOLs and UV Light-Filtering IOLs for Cataract Surgery: A Meta-Analysis. PLoS ONE . 2012;7(3): e33013**

Meta-analysis of postoperative overall colour vision.



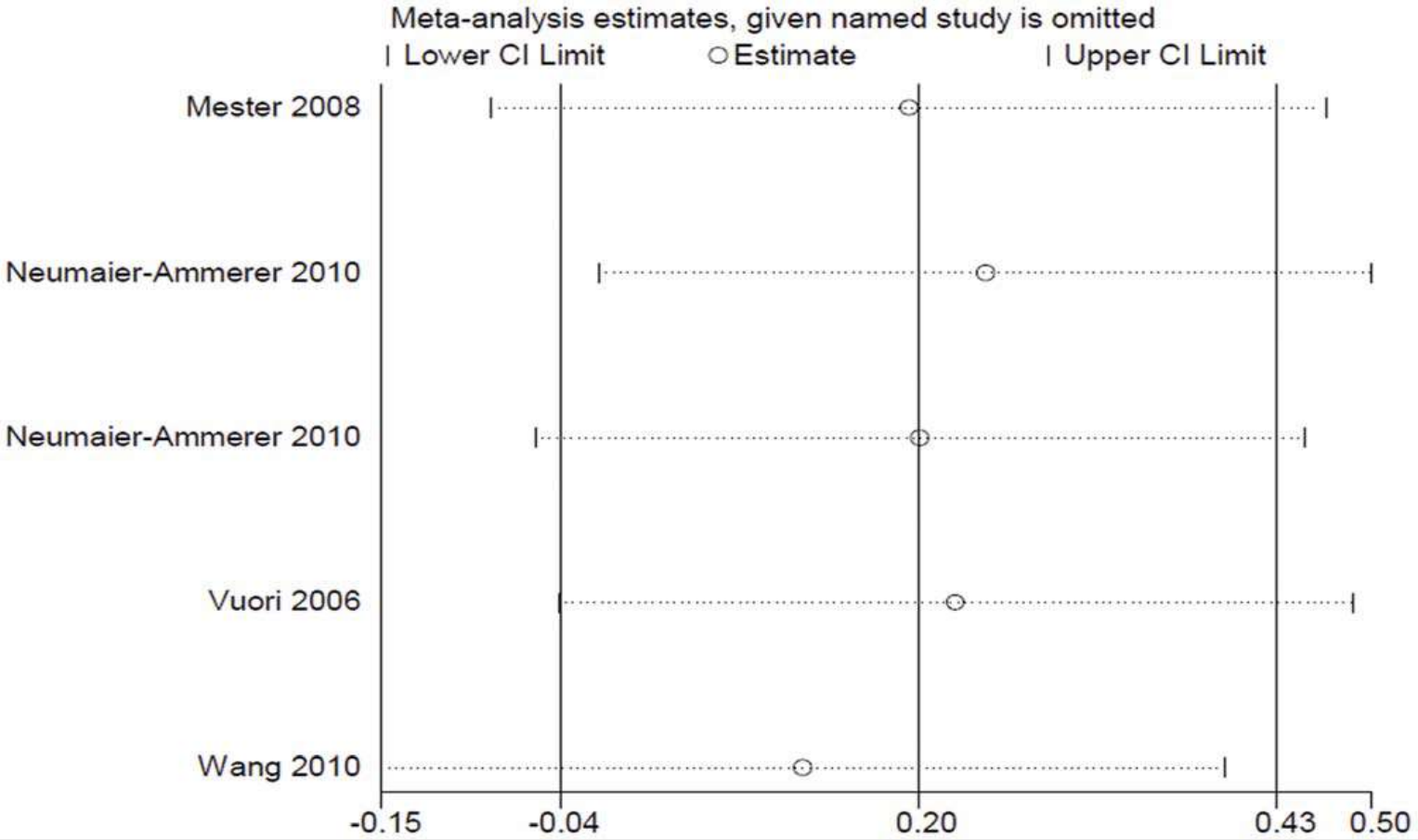
Full citation	**Zhu X, Zou H, Yu Y, Sun Q, Zhao N. Comparison of Blue Light-Filtering IOLs and UV Light-Filtering IOLs for Cataract Surgery: A Meta-Analysis. PLoS ONE . 2012;7(3): e33013**

Meta-analysis of postoperative colour vision in the blue light spectrum under photopic light condition.



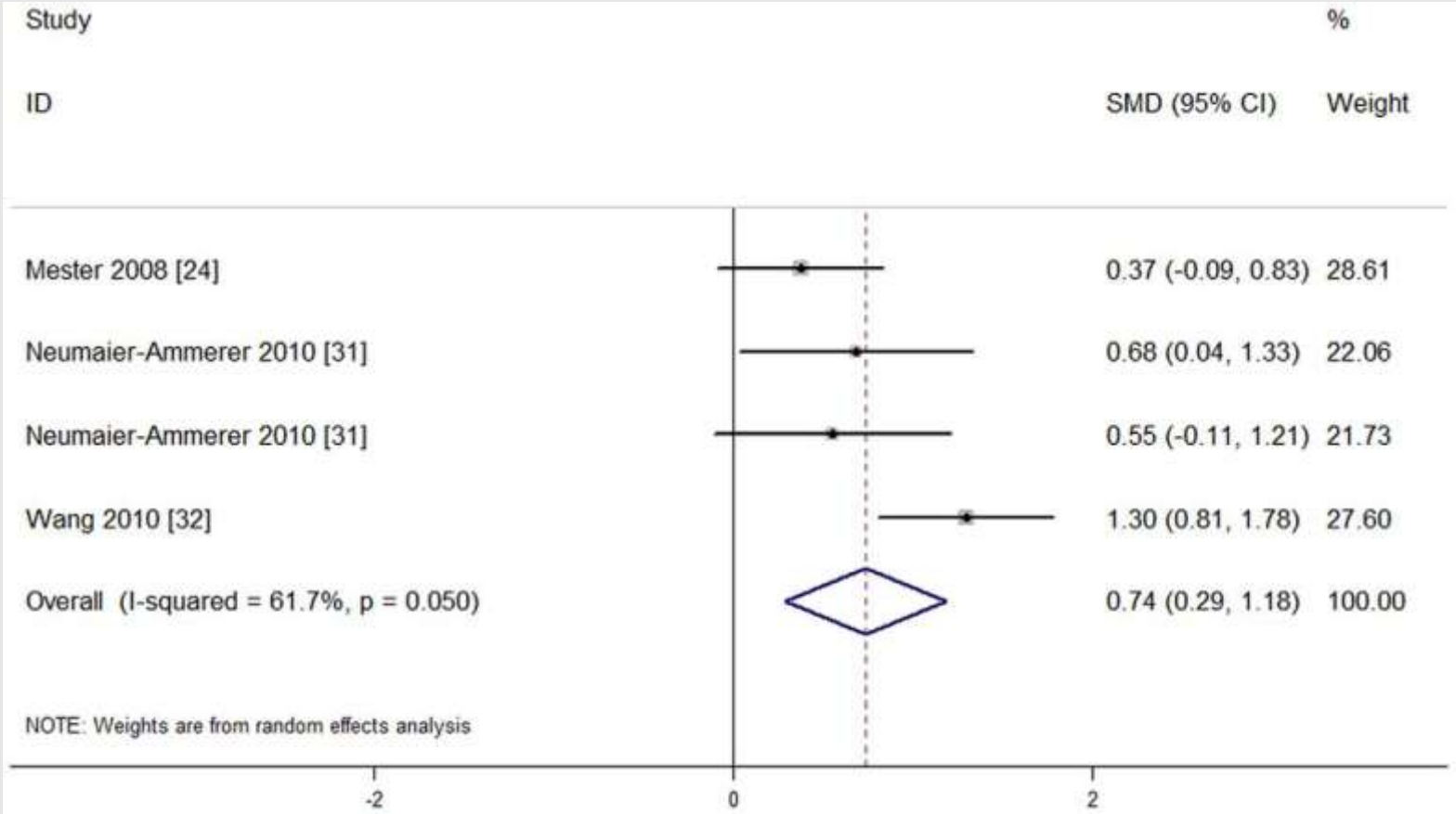
Full citation	**Zhu X, Zou H, Yu Y, Sun Q, Zhao N. Comparison of Blue Light-Filtering IOLs and UV Light-Filtering IOLs for Cataract Surgery: A Meta-Analysis. PLoS ONE . 2012;7(3): e33013**

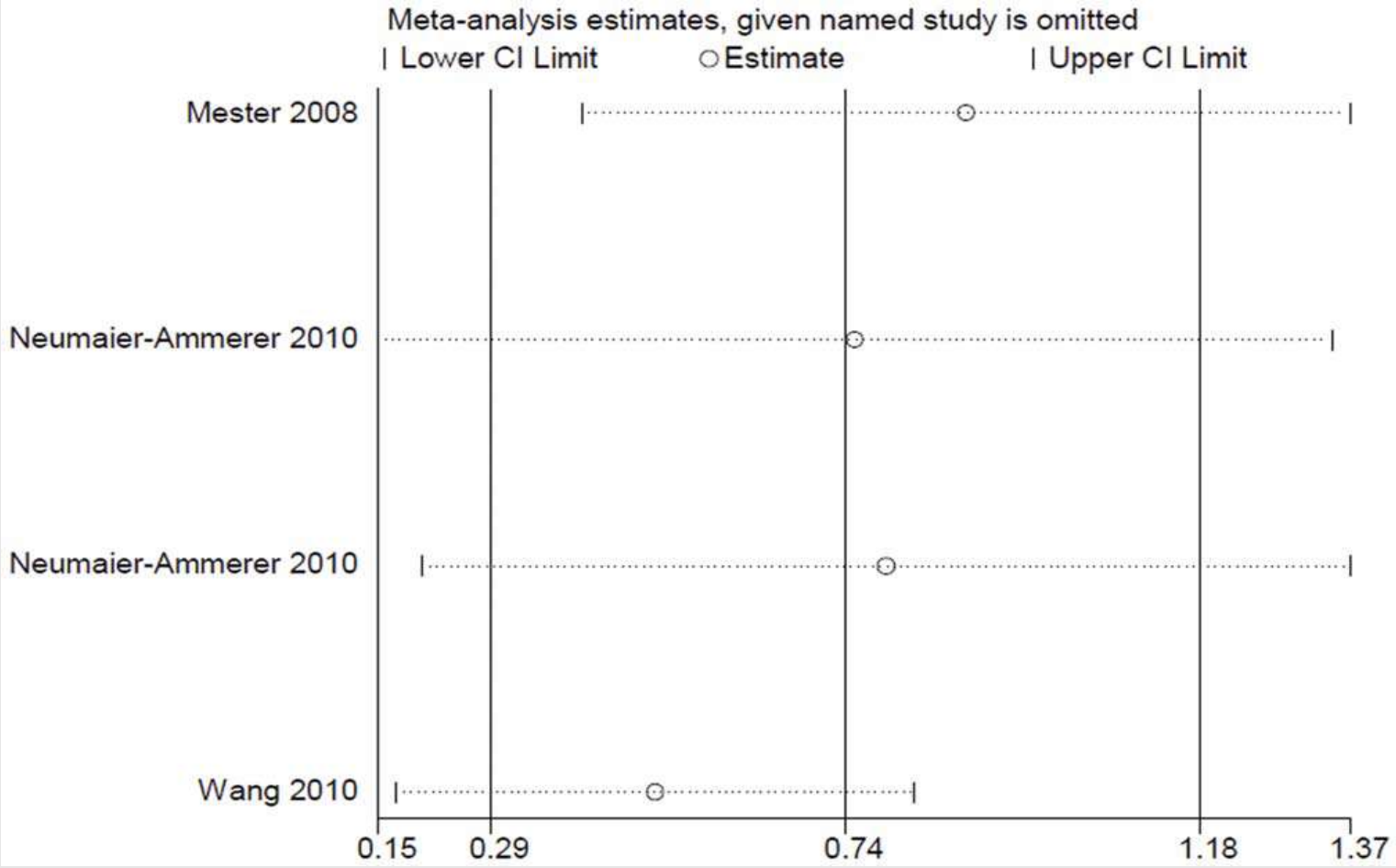
Sensitivity analysis of postoperative colour vision in the blue light spectrum under photopic light condition.



Full citation	**Zhu X, Zou H, Yu Y, Sun Q, Zhao N. Comparison of Blue Light-Filtering IOLs and UV Light-Filtering IOLs for Cataract Surgery: A Meta-Analysis. PLoS ONE . 2012;7(3): e33013**

Meta-analysis of postoperative colour vision in the blue light spectrum under mesopic light condition.



Full citation	**Zhu X, Zou H, Yu Y, Sun Q, Zhao N. Comparison of Blue Light-Filtering IOLs and UV Light-Filtering IOLs for Cataract Surgery: A Meta-Analysis. PLoS ONE . 2012;7(3): e33013**
	Sensitivity analysis of postoperative colour vision in the blue light spectrum under mesopic light condition. 
Outcomes	Blue light filtering IOL groups and UV light-filtering IOL groups were not significantly different in postoperative colour vision.

Full citation	Zhu X, Zou H, Yu Y, Sun Q, Zhao N. Comparison of Blue Light-Filtering IOLs and UV Light-Filtering IOLs for Cataract Surgery: A Meta-Analysis. PLoS ONE . 2012;7(3): e33013
	Blue light filtering IOL groups and UV light-filtering IOL groups were not significantly different in postoperative colour vision in the blue light spectrum under photopic light conditions. There was a significant difference between the two groups [SMD=0.74, 95%CI (0.29, 1.18), P=0.001], indicating that colour vision for blue with blue light-filtering IOLs was significantly reduced under mesopic conditions. I one study 3 of 24 patients noticed a difference and all could correctly identify the eye implanted with the blue light-filtering IOL. However, all 3 patients said that they were not disturbed in binocular vision. In one study, incidence of patients who noticed cyanopsia was significantly less in the blue light-filtering IOL group than in the UV light-filtering IOL group at 2 weeks after surgery (p= 0.0234), but no patients reported cyanopsia at 3 months. Four studies found no significant differences in subjective satisfaction of visual quality or lens related adverse events in either group after surgery
Study Appraisal using AMSTAR (Assessing the Methodological Quality of Systematic Reviews)	1. Was an 'a priori' design provided? Yes 2. Was there duplicate study selection and data extraction? Yes 3. Was a comprehensive literature search performed? Yes 4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes 5. Was a list of studies (included and excluded) provided? Yes 6. Were the characteristics of the included studies provided? Yes 7. Was the scientific quality of the included studies assessed and documented? Unclear 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Unclear 9. Were the methods used to combine the findings of studies appropriate? Yes 10. Was the likelihood of publication bias assessed? Unclear 11. Was the conflict of interest included? Unclear

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E.4.3 Multifocal vs monofocal intraocular lenses

The evidence tables on multifocal lenses versus monofocal lenses and multifocal lenses versus monovision in this section were produced by the Cochrane Eyes and Vision Group, as part of a collaboration with the NICE Internal Clinical Guidelines Team.

Reference	Cillino 2008
Methods	Parallel-group RCT
Participants	Baseline Characteristics Multifocal 1: Array SA40N, AMO Number of people (eyes) randomised: Not reported Number of people (eyes) excluded after randomisation: Not reported Number of people (eyes) lost to follow-up: Not reported Number of people (eyes) analysed (at longest time point): 16 (32) Average age in years (range) : 57 % female: 56 Ethnic group: Not reported Multifocal 2: ReZoom, AMO Number of people (eyes) randomised: Not reported Number of people (eyes) excluded after randomisation: Not reported Number of people (eyes) lost to follow-up: Not reported Number of people (eyes) analysed (at longest time point): 15 (30) Average age in years (range) : 65 % female: 47 Ethnic group: Not reported Multifocal 3: Tecnis ZM900, AMO Number of people (eyes) randomised: Not reported Number of people (eyes) excluded after randomisation: Not reported Number of people (eyes) lost to follow-up: Not reported Number of people (eyes) analysed (at longest time point): 16 (32) Average age in years (range) : 60 % female: 63 Ethnic group: Not reported Monofocal: AR40, AMO Number of people (eyes) randomised: Not reported

Reference	Cillino 2008
	Number of people (eyes) excluded after randomisation: Not reported Number of people (eyes) lost to follow-up: Not reported Number of people (eyes) analysed (at longest time point): 15 (30) Average age in years (range) : 68 % female: 47 Ethnic group: Not reported Inclusion criteria: Bilateral juvenile or senile cataract; visually significant (ie, Snellen visual acuity <20/30) in at least 1 eye; corneal astigmatism not >1.0 diopter (D); and capability of understanding and signing the informed consent. Exclusion criteria: Age less than 21 years; pre-cataract myopia or hyperopia >3 D; history of amblyopia; fundus abnormalities that could cause significant vision impairment; previous surgical intraocular procedures; and ocular comorbidities, such as previous trauma, glaucoma, diabetic retinopathy, pseudoexfoliation syndrome, chronic uveitis, corneal opacities, senile miosis or hyporeactive pupil, or alpha-antagonist (tamsulosin) treatment, which might induce floppy iris syndrome. Intraoperative exclusion criteria were iris pupillary trauma; vitreous loss; and inability to place the IOL in the capsular bag.
Interventions	Intervention Characteristics Multifocal 1 Name of lens: Array SA40N, AMO Type of lens: refractive Target: Emmetropia Multifocal 2 Name of lens: ReZoom, AMO Type of lens: refractive Target: Emmetropia Multifocal 3 Name of lens: Tecnis ZM900, AMO Type of lens: diffractive Target: Emmetropia Monofocal Name of lens: AR40, AMO Type of lens: NA Target: Emmetropia Both eyes operated on

Reference	Cillino 2008
Outcomes	Outcomes: Distance, near, and intermediate visual acuity, defocusing curves, contrast sensitivity, patient satisfaction, and spectacle independence. Eyes: outcomes measured by eye, unclear number of eyes reported (we have assumed both eyes reported without adjustment for within-person correlation) Maximum follow-up: 12 months
Notes	Sponsorship source: Not reported Declaration of interest: "The authors have no proprietary or commercial interest in any materials discussed in this article" Country: Italy Date study conducted: January 2005 to January 2006 Trial registration ID number: Not reported

193 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization used a 1:1:1:1 block randomization scheme generated by SPSS statistical software for Windows (version 14.0, SPSS Inc, Chicago, IL)
Allocation concealment (selection bias)	Low risk	The randomization code was maintained only at the central data facility and was not broken until all data analysis was complete.
Blinding of participants and personnel (performance bias)	Low risk	The patients and the medical staff who collected functional data and quality-of-life data were masked to the type of lens that each patient received." Judgement Comment: Not possible to mask the operating surgeon but we judged that this would not have important effect on risk of bias.
Blinding of outcome assessment (detection bias)	Low risk	The patients and the medical staff who collected functional data and quality-of-life data were masked to the type of lens that each patient received." Judgement Comment: Outcome assessors were masked
Incomplete outcome data (attrition bias)	Unclear risk	Four patients withdrew after randomization or during the postoperative period. Two patients were excluded from the analysis because of the presence of capsular fibrosis at 1 week postoperatively." Judgement Comment: 91% of patients followed-up but some exclusions after randomisation and unclear which group these were in
Selective reporting (reporting bias)	Unclear risk	No protocol or trials registry entry

194

Reference	El Maghraby 1992
Methods	Parallel-group RCT
Participants	Baseline Characteristics Multifocal 1: 815LE, 3M Vision Care, St Paul, Minnesota Number of people (eyes) randomised: 39 (39) Number of people (eyes) excluded after randomisation: 4 (4) Number of people (eyes) lost to follow-up: 1 (1) Number of people (eyes) analysed (at longest time point): 28 (28) Average age in years (range) : 57 (45-90) % female: 59 Ethnic group: Not reported Monofocal Number of people (eyes) randomised: 38 (38) Number of people (eyes) excluded after randomisation: 0 (0) Number of people (eyes) lost to follow-up: 2 (2) Number of people (eyes) analysed (at longest time point): 33 (33) Average age in years (range) : 56 (45-70) % female: 47 Ethnic group: Not reported Inclusion criteria: candidates for cataract extraction by phacoemulsification and IOL to be implanted was within the range of +17:00 to +23:00 D for emmetropia Exclusion criteria: evidence or history of uveitis; active progressive corneal disease; history of previous intraocular surgery in the eye to be studies; intraocular pressure above 23mmHg or on glaucoma medication; diabetic retinopathy; macular degeneration; amblyopia; or any other known disease that would decrease postoperative BCVA to worse than 20/40; non age-related cataracts; blind in contralateral eye Pre-treatment: Similar characteristics except for more women (59%) in MF compared to MO group (47%)
Interventions	Intervention Characteristics Multifocal: Name of lens: 815LE, 3M Vision Care, St Paul, Minnesota Type of lens: Diffractive Target: Emmetropia Monofocal Name of lens: 15LE, 3M Vision Care, St Paul, Minnesota

Reference	El Maghraby 1992
	Type of lens: Target: Emmetropia One eye operated on
Outcomes	Outcomes: Distance and near visual acuity, refractive error Eyes: Study eye (one eye operated per person) Maximum follow-up: 2-4 months
Notes	Sponsorship source: Saudi Eye Foundation Declaration of interest: Not reported Country: Saudi Arabia Date study conducted: Not reported Trial registration ID number: Not reported

195 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization schedules were generated using Prodas, a statistical software package"
Allocation concealment (selection bias)	Low risk	Not reported but confirmed by author correspondence
Blinding of participants and personnel (performance bias)	High risk	Masking not reported and lenses different.
Blinding of outcome assessment (detection bias)	High risk	Masking not reported and lenses different.
Incomplete outcome data (attrition bias)	High risk	Some exclusions after randomisation 4/39 in multifocal group, one of these due to PCO and one due to high astigmatism, 2 due to pre-existing maculopathy. Overall follow-up at 2-4 months was 28/39 (71%) for multifocal group and 33/38 (87%) for monofocal group.
Selective reporting (reporting bias)	Unclear risk	No access to trial registry entry or protocol.

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Reference	Haaskjold 1998
Methods	Parallel-group RCT
Participants	Baseline Characteristics Multifocal 1: 808X, Pharmacia Number of people (eyes) randomised: Not reported Number of people (eyes) excluded after randomisation: Not reported Number of people (eyes) lost to follow-up: Not reported Number of people (eyes) analysed (at longest time point): 115 (115) Average age in years (range) : 67 (max age 88) % female: Not reported Ethnic group: Not reported Monofocal: 808D, Pharmacia Number of people (eyes) randomised: Not reported Number of people (eyes) excluded after randomisation: Not reported Number of people (eyes) lost to follow-up: Not reported Number of people (eyes) analysed (at longest time point): 106 (106) Average age in years (range) : 67 (max age 90) % female: Not reported Ethnic group: Not reported Inclusion criteria: Age-related uncomplicated cataracts, 47 years or older; pre-operative astigmatism < 1.5 D Exclusion criteria: Eye pathology other than cataract Pre-treatment: Not described
Interventions	Intervention Characteristics Multifocal 1 Name of lens: 808X (Pharmacia) Type of lens: Diffractive, bifocal Target: NR Monofocal Name of lens: 808D (Pharmacia) Type of lens: NA Target: NR One eye operated on

Reference	Haaskjold 1998
Outcomes	Outcomes: Distance and near visual acuity, contrast sensitivity, patient satisfaction, spectacle independence, adverse effects (halos, glare etc). Eyes: Study eye (one eye operated per person) Maximum follow-up: 5 months
Notes	Sponsorship source: Not reported Declaration of interest: Not reported Country: Europe (UK, Finland, Germany, Norway, Portugal, Sweden) Date study conducted: Not reported Trial registration ID number: Not reported

197 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Study was described as "randomized" but no further details given
Allocation concealment (selection bias)	Low risk	Not reported but confirmed by author correspondence
Blinding of participants and personnel (performance bias)	High risk	Study was described as "open". No information on masking
Blinding of outcome assessment (detection bias)	High risk	Study was described as "open" No information on masking.
Incomplete outcome data (attrition bias)	Unclear risk	Follow-up not clearly described
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials register entry

198

Reference	Harman 2008
Methods	Parallel-group RCT
Participants	Baseline Characteristics Multifocal 1: Array SA40N, AMO Number of people (eyes) randomised: 30 (60) Number of people (eyes) excluded after randomisation: 3 (6) Number of people (eyes) lost to follow-up: 3 (6) Number of people (eyes) analysed (at longest time point): 24 (48) Average age in years (range) : 73

Reference	Harman 2008
	% female: 50 Ethnic group: Not reported Monofocal: Clariflex, AMO Number of people (eyes) randomised: 30 (60) Number of people (eyes) excluded after randomisation: 2 (4) Number of people (eyes) lost to follow-up: 9 (18) Number of people (eyes) analysed (at longest time point): 19 (38) Average age in years (range) : 71 % female: 60 Ethnic group: Not reported Inclusion criteria: Age over 21 years; bilateral visually significant cataract; axial length < 25 mm Exclusion criteria: Mature cataract; anterior segment pathology such as pseudoexfoliation or zonular dialysis; previous ocular surgery, and any ocular pathology that might limit the postoperative VA to <6/9 (e.g., amblyopia, corneal opacity, macular disease; preoperative corneal astigmatism of >2 diopters (D) in either eye.
Interventions	Intervention Characteristics Multifocal 1 Name of lens: Array SA40N, AMO Type of lens (eg refractive/diffractive): Refractive Target: Emmetropia Monofocal Name of lens: Clariflex, AMO Type of lens: NA Target: Emmetropia Both eyes operated on There was a third treatment arm in this study that was not included in this review (accommodative lenses, 1CU). Quote "Patients who had >1 D (and <2 D) of corneal astigmatism also underwent limbus-relaxing incisions (LRIs), using the modified Gills nomogram (21) at the time of surgery, aiming for postoperative astigmatism of <1 D." Quote "Ten patients required LRIs at the time of surgery: 5 from the 1CU group [not included in this review], 3 from the multifocal, and 2 from the monofocal. Of these, only 1 patient from the multifocal group required bilateral LRIs."
Outcomes	Outcomes: Distance and near visual acuity, refraction, contrast sensitivity, accommodation (defocus, near point), spectacle independence, reading ability, adverse effects (halos, glare etc). Eyes: Both eyes operated, binocular outcomes reported except for refraction and glare disability (right eye only)

Reference	Harman 2008
	Maximum follow-up: 18 months Note: Patients were asked to practice reading every day without spectacle correction until 3 months
Notes	Sponsorship source: Hillingdon Hospital Research and Development Fund, Uxbridge, United Kingdom. Declaration of interest: "No author has any conflict of interest with the products investigated." Country: UK Date study conducted: Not reported Trial registration ID number: Not reported

199 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Patients were randomly allocated to 1 of the 3 types of lenses by sealed envelopes opened on the day of surgery; they received the same IOL in each eye, and the second eye was operated on within 6 weeks of the first. Sequence generation not reported
Allocation concealment (selection bias)	Low risk	Patients were randomly allocated to 1 of the 3 types of lenses by sealed envelopes opened on the day of surgery; they received the same IOL in each eye, and the second eye was operated on within 6 weeks of the first.
Blinding of participants and personnel (performance bias)	High risk	Patients were masked as to the nature of the IOL inserted until the 3-month review, and all were asked to practice reading every day without spectacle correction until this time. Patients were not masked for the 18 month visit.
Blinding of outcome assessment (detection bias)	Low risk	All examiners were masked at the 3- and 18-month reviews. A subjective masked assessment was made of PCO in the right eye at the 18-month review, graded as none, mild, moderate, or severe.
Incomplete outcome data (attrition bias)	Unclear risk	"Of the 90 patients entering the trial, 82 completed follow-up at 3 months; withdrawals were all before second-eye surgery (development of subretinal neovascular membranes, n 2; cystoid macular edema, 2; corneal decompensation secondary to undiag- nosed Fuchs' endothelial dystrophy, 1; severe local allergic reac- tion to preoperative tropicamide drops, 1; IOL selection error, 1; anterior capsule tear at time of surgery, 1). Two patients withdrew from the 1CU group and 3 from each of the other groups. There were no cases of a posterior capsule tear or vitreous loss. A further 18 patients were lost to follow-up by 18 months (data from these patients were included in the 3-month results), with 21 patients remaining in the 1CU group, 24 in the multifocal, and 19 in the monofocal."
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials register entry

200

Reference	Javitt 2000
Methods	Parallel-group RCT
Participants	Baseline Characteristics Multifocal 1: Array SA40N, AMO Number of people (eyes) randomised: 134 (268) Number of people (eyes) excluded after randomisation: 7 (14) Number of people (eyes) lost to follow-up: 3 (6) Number of people (eyes) analysed (at longest time point): 124 (248) Average age in years (range) : 74 % female: 51 Ethnic group: NR Monofocal: PhacoFlex II S140NB, AMO Number of people (eyes) randomised: 127 (254) Number of people (eyes) excluded after randomisation: 9 (18) Number of people (eyes) lost to follow-up: 7 (14) Number of people (eyes) analysed (at longest time point): 111 (222) Average age in years (range) : 75 % female: 61 Ethnic group: NR Inclusion criteria: Aged 50-85 years with bilateral cataracts; < 1.5 D of keratometric cylinder; 20/30 of better potential VA Exclusion criteria: Any pre-existing ocular pathology other than cataract Pre-treatment: No important differences at baseline between both groups
Interventions	Intervention Characteristics Multifocal 1 Name of lens: Array SA40N, AMO Type of lens: Zonal-progressive Target: +3.5 D for near Monofocal Name of lens: PhacoFlex II S140NB, AMO Type of lens: Monofocal

Reference	Javitt 2000
	Target: NR Both eyes operated on
Outcomes	Outcomes: Distance and near visual acuity, refraction, spectacle independence, satisfaction, visual function (modified Cataract TyPE questionnaire), adverse effects (halos, glare etc). Eyes: Both eyes operated, binocular outcomes reported Maximum follow-up: 3 to 6 months after second eye surgery
Notes	Sponsorship source: Allergan, Inc. Declaration of interest: "Dr. Javitt and Dr. Steinert are consultants to Allergan, Inc., but do not have a proprietary interest in the company or its products" Country: USA Date study conducted: February 1996 to March 1998 Trial registration ID number: Not reported

201 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A block randomization schedule by patient was prepared for each site using SAS software, (SAS Institute, Cary, NC)"
Allocation concealment (selection bias)	Unclear risk	Quote: "assigned in blocks of two. For each block of two patients, either the first patient or the second (in random order) received a multifocal lens. The randomization schedule" Quote: "The randomization schedule was drawn up by site before the start of the study, and the assignment of each patient was placed in a sealed container that was not opened until the patient was actually in the operating room. Differences between the ultimate size of the monofocal and multifocal groups resulted from patients withdrawing from study after just one implant, sites stopping ahead of schedule, and chance outcomes." Judgement Comment: Although efforts make to conceal the allocation a block size of two may have been very easy to second guess.
Blinding of participants and personnel (performance bias)	Low risk	"The patients, the ophthalmic technicians who collected clinical data, and the interviewers who collected the quality-of-life data were all masked as to the type of lens that each patient received."
Blinding of outcome assessment (detection bias)	Low risk	"The patients, the ophthalmic technicians who collected clinical data, and the interviewers who collected the quality-of-life data were all masked as to the type of lens that each patient received. Patients"

Bias	Authors' judgement	Support for judgement
Incomplete outcome data (attrition bias)	Unclear risk	Slightly lower follow-up in monofocal group (85%) compared to 92% in multifocal group. A higher proportion of monofocal group participants did not undergo second eye surgery because of problems in the first eye 8/127 (6%) compared to 2/134 (1%)
Selective reporting (reporting bias)	Unclear risk	No access to trial protocol and trial not registered.

202

Reference	Ji 2013
Methods	Parallel-group RCT
Participants	Baseline Characteristics Multifocal 1: Acrysof ReSTOR, Alcon Laboratories, Irvine, CA Number of people (eyes) randomised: NR Number of people (eyes) excluded after randomisation: NR Number of people (eyes) lost to follow-up: NR Number of people (eyes) analysed (at longest time point): 24 (30) Average age in years (range) : 63 (52-71) % female: 58 Ethnic group: NR Monofocal: Acrysof Natural, Alcon Laboratories, Irvine, CA Number of people (eyes) randomised: NR Number of people (eyes) excluded after randomisation: NR Number of people (eyes) lost to follow-up: NR Number of people (eyes) analysed (at longest time point): 27 (34) Average age in years (range) : 63 (55-75) % female: 56 Ethnic group: NR Inclusion criteria: Age between 50 and 75 years old; age-associated cataracts. Exclusion criteria: Corneal astigmatism > 1.5 D; glaucoma; retinal abnormalities; surgical complications Pre-treatment: Not reported
Interventions	Intervention Characteristics Multifocal 1

Reference	Ji 2013
	Name of lens: Acrysof ReSTOR, Alcon Laboratories, Irvine, CA Type of lens: NR Target: NR Monofocal Name of lens: Acrysof Natural, Alcon Laboratories, Irvine, CA Type of lens: NA Target: NR One or both eyes operated on
Outcomes	Outcomes: Distance and near visual acuity, contrast sensitivity, refraction, accommodation, aberrometry Eyes: Probably reported by eye without adjustment for within-person correlation Maximum follow-up: 90 days after surgery
Notes	Sponsorship source: Shanghai Leading Academic Discipline Project (S30205) Declaration of interest: Not reported Country: China Date study conducted: January 2009 to December 2011 Trial registration ID number: Not reported

203 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The method of sequence generation is not described.
Allocation concealment (selection bias)	Unclear risk	The method of allocation concealment is not described.
Blinding of participants and personnel (performance bias)	Unclear risk	Surgeon masking is not feasible for the study methodology described. No masking of participants is described.
Blinding of outcome assessment (detection bias)	Unclear risk	No masking of the outcome assessment is described.
Incomplete outcome data (attrition bias)	Unclear risk	There is no reporting of reporting of data attrition to permit judgment.
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry (trial was not registered).
Other bias	Low risk	"The authors declare no conflicts of interest."

204

Reference	Jusufovic 2011
Methods	Parallel-group RCT
Participants	Baseline Characteristics Multifocal 1: ReZoom NXG1, AMO Number of people (eyes) randomised: NR Number of people (eyes) excluded after randomisation: NR Number of people (eyes) lost to follow-up: NR Number of people (eyes) analysed (at longest time point): 50 (50) Average age in years (range) : 43 (20-57) % female: 46 Ethnic group: NR Monofocal: AcrySof MA60BM, Alcon Number of people (eyes) randomised: NR Number of people (eyes) excluded after randomisation: NR Number of people (eyes) lost to follow-up: NR Number of people (eyes) analysed (at longest time point): 50 (50) Average age in years (range) : 50 (26-64) % female: 42 Ethnic group: NR Inclusion criteria: Age of participant between 14 and 80 years; astigmatism less than 1D. Exclusion criteria: Chronic inflammatory and degenerative diseases of the posterior eye segment; previous surgery on the eye; high refractive anomalies; and systemic diseases, which can cause changes in the eye, which significantly influence on the vision quality outcome after the operation. Pre-treatment: Small difference in age
Interventions	Intervention Characteristics Multifocal 1 Name of lens: ReZoom NXG1, AMO Type of lens: Refractive Target: NR Monofocal Name of lens: AcrySof MA60BM (Alcon) Type of lens: NA

Reference	Jusufovic 2011
	Target: NR One eye operated on
Outcomes	Outcomes: Distance and near visual acuity, stereo vision Eyes: Binocular Maximum follow-up: 6 weeks after surgery
Notes	Sponsorship source: Sponsorship source: Not reported Decalaration of interests: "The authors declare no competing interests." Country: Bosnia and Herzegovina Date study conducted: February 2006 to January 2007 Trial registration ID number: Not reported

205 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Included 50 patients with implanted monofocal IOL's. Randomization was performed as follows: 100 small folded pieces of paper on which "multi" or "mono" was written, are folded and placed in an opaque bag."
Allocation concealment (selection bias)	Low risk	"The nurse who did not participate in the study picked papers from the bag and divided patients into two groups. Also, surgeon who carried out the operations did not know which group does the patient belong, until the very moment of intraocular lens implantation"
Blinding of participants and personnel (performance bias)	High risk	Masking not reported
Blinding of outcome assessment (detection bias)	High risk	Masking not reported
Incomplete outcome data (attrition bias)	Unclear risk	Follow-up not reported
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry

206

Reference	Kamlesh 2001
Methods	Parallel-group RCT

Reference	Kamlesh 2001
Participants	Baseline Characteristics Multifocal 1: Progress 3, Laboratoires Domilens, Lyon, France Number of people (eyes) randomised: Not reported Number of people (eyes) excluded after randomisation: Not reported Number of people (eyes) lost to follow-up: Not reported Number of people (eyes) analysed (at longest time point): 20 (Not reported) Average age in years (range) : 56 % female: Not reported Ethnic group: Not reported MonofocalL Flex 65, Laboratoires Domilens, Lyon, France Number of people (eyes) randomised: Not reported Number of people (eyes) excluded after randomisation: Not reported Number of people (eyes) lost to follow-up: Not reported Number of people (eyes) analysed (at longest time point): 20 (Not reported) Average age in years (range) : 54 % female: Not reported Ethnic group: Not reported Inclusion criteria: Age-related cataract Exclusion criteria: Known disease likely to interfere with post-operative visual outcome; pre-operative astigmatism > 1.50 D; axial length beyond that requiring an estimated IOL power of 18.00 D to 24.00 D for emmetropia; previous eye surgery Pre-treatment: Quite large differences in near vision with 90% of multifocal group having distance-corrected near vision better than or equal to N9 compared to 10% of the monofocal group. Monofocal group had worse distance visual acuity as well.
Interventions	Intervention Characteristics Multifocal 1 Name of lens: Progress 3, Laboratoires Domilens, Lyon, France Type of lens: NR Target: + 3.00 D Monofocal Name of lens: Flex 65, Laboratoires Domilens, Lyon, France Type of lens: NA

Reference	Kamlesh 2001
	Target: Emmetropia One eye operated on
Outcomes	Outcomes: Contrast sensitivity, depth of focus, satisfaction, spectacle use, adverse effects (glare, halo etc) Eyes: Unclearly reported, probably by eye as unilateral surgery Maximum follow-up: 3 months after surgery
Notes	Sponsorship source: Not reported Declaration of interest: "The authors do not have any financial interest in any of the products mentioned in this article" Country: India Date study conducted: Not reported Trial registration ID number: Not reported

207 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Sequence generation not reported
Allocation concealment (selection bias)	High risk	Allocation concealment not reported and considerable baseline imbalance in groups with respect to near vision
Blinding of participants and personnel (performance bias)	High risk	Masking not reported
Blinding of outcome assessment (detection bias)	High risk	Masking not reported
Incomplete outcome data (attrition bias)	Unclear risk	Follow-up not reported
Selective reporting (reporting bias)	Unclear risk	No access to trial protocol or registry entry

208

Reference	Labiris 2015
Methods	Study design: Parallel-group RCT
Participants	Baseline Characteristics Multifocal: Isert PY60MV, Hoya Surgical Optics, Inc Number of people (eyes) randomised: 37 (74) Number of people (eyes) excluded after randomisation: NR

Reference	Labiris 2015
	Number of people (eyes) lost to follow-up: NR Number of people (eyes) analysed (at longest time point): NR Average age in years (range) : 61 (NR) % female: NR Ethnic group: NR Monofocal: SN60WF, Alcon Laboratories, Inc Number of people (eyes) randomised: 38 (76) Number of people (eyes) excluded after randomisation: NR Number of people (eyes) lost to follow-up: NR Number of people (eyes) analysed (at longest time point): NR Average age in years (range) : 60(NR) % female: NR Ethnic group: NR Inclusion criteria: age-related cataract with grade 2 nuclear opalescence according to the Lens Opacities Classification System III grading scale Exclusion criteria: manifest astigmatism more than 1.00 D; reports of headaches and/or eyestrain associated with visual activities; positive pathologic ocular cover test (near and distance), and/or the Mallett disparity test (near and distance) and the double Maddox rod test; endothelial cell count less than 1900 cells/mm2; glaucoma; intraocular pressure lowering medications; former incisional surgery; former diagnosis of corneal disease; former diagnosis of fundus disease; diabetes; autoimmune or mental diseases Pre-treatment: No major imbalances in age and grade of cataract
Interventions	Intervention Characteristics Multifocal Name of lens: Isert PY60MV, Hoya Surgical Optics, Inc Type of lens: Refractive Target: + 3.00 D of near addition Monofocal Name of lens: SN60WF, Alcon Laboratories, Inc Type of lens: NA Target: targeting -0.50 D in the dominant eye and -1.25 D in the non-dominant eye. Both eyes operated

Reference	Labiris 2015
Outcomes	Outcomes: Dysphotopsia, need for spectacles, Visual Function Index-14, binocular uncorrected distance and near visual acuity, contrast sensitivity and stereo acuity, Eyes: both eyes operated, measurements binocular Maximum follow-up: 6 months after surgery
Notes	Sponsorship source: Not reported Declaration of interest: "No author has a financial or proprietary interest in any material or method mentioned." Country: Greece Date study conducted: January 2013 to July 2013 Trial registration ID number: Not reported

209 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Using a custom computer randomization program, all patients randomly populated 2 study groups according to the cataract extraction technique used: monovision and multifocal IOL."
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias)	High risk	Masking not described. On clinical trials registry entry described as "open label"
Blinding of outcome assessment (detection bias)	Unclear risk	Quote: "All preoperative and postoperative assessments were done by the same ophthalmologist, who had no direct involvement in the study." Unclear if this person was masked or not.
Incomplete outcome data (attrition bias)	Unclear risk	Not reported
Selective reporting (reporting bias)	Low risk	All outcomes on clinical trials registry entry reported.

210

Reference	Leyland 2002
Methods	Parallel-group RCT
Participants	Baseline Characteristics Multifocal 1: Array SA40NB, AMO

Reference	Leyland 2002
	Number of people (eyes) randomised: 31 (62) Number of people (eyes) excluded after randomisation: 2 (4) Number of people (eyes) lost to follow-up: 0 (0) Number of people (eyes) analysed (at longest time point): 29 (58) Average age in years (range) : 75 % female: 53 Ethnic group: Not reported Multifocal 2: TrueVista 68STUV, Storz Number of people (eyes) randomised: 19 (38) Number of people (eyes) excluded after randomisation: 4 (8) Number of people (eyes) lost to follow-up: 0 (0) Number of people (eyes) analysed (at longest time point): 15 (30) Average age in years (range) : 74 % female: 60 Ethnic group: Not reported Monofocal: Phacoflex S140N, AMO Number of people (eyes) randomised: 19 (38) Number of people (eyes) excluded after randomisation: 3 (6) Number of people (eyes) lost to follow-up: 0 (0) Number of people (eyes) analysed (at longest time point): 16 (32) Average age in years (range) : 76 % female: 44 Ethnic group: Not reported Inclusion criteria: >18 years of age; bilateral visually significant cataracts with extraction indicated; informed consent; ability to understand and complete TyPE questionnaire Exclusion criteria: Macular or other pathology considered likely to limit post-operative acuity to worse than 6/9 in either eye; corneal astigmatism >1.5 dioptres in either eye ; required IOL power outside range available for multifocal IOL (16-24 dioptres). Pre-treatment: There were no significant intergroup differences in age, sex, preoperative best corrected visual acuity and visual satisfaction.
Interventions	Intervention Characteristics Multifocal 1

Reference	Leyland 2002
	Name of lens: Array SA40NB, AMO Type of lens: Refractive Target: Emmetropia Multifocal 2 Name of lens: TrueVista 68STUV, Storz Type of lens: Bifocal Target: Emmetropia Monofocal Name of lens: Phacoflex S140N, AMO Type of lens: NA Target: Emmetropia Both eyes operated on
Outcomes	Outcomes: Distance and near visual acuity, refraction, contrast sensitivity, depth of focus, satisfaction and visual function (TyPE questionnaire including bother from glare/halos), spectacle use Eyes: Binocular for acuity outcomes, monocular not adjusted with within-person correlation for refractive outcomes Maximum follow-up: 12 months after surgery
Notes	Sponsorship source: Not reported Declaration of interest: "The authors have no financial interest in any of the products described in this paper" Country: UK Date study conducted: Not reported Trial registration ID number: Not reported

211 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Low risk	Sealed envelopes opened on the day of surgery
Blinding of participants and personnel (performance bias)	Unclear risk	Patients were informed that the IOL type implanted would not be revealed to them until completion of the trial but a proportion of patients were reported to be unmasked.

Bias	Authors' judgement	Support for judgement
Blinding of outcome assessment (detection bias)	Low risk	The hospital optometrist and the ophthalmic nurse specialist carrying out these tests were masked as to the nature of the IOL implanted.
Incomplete outcome data (attrition bias)	Unclear risk	Follow-up less than 80% at one year.
Selective reporting (reporting bias)	Unclear risk	No access to protocol or trials registry entry

212

Reference	Nijkamp 2004
Methods	Parallel-group RCT
Participants	Baseline Characteristics Multifocal 1: Array SA40N, AMO Number of people (eyes) randomised: 93 Number of people (eyes) excluded after randomisation: 11 Number of people (eyes) lost to follow-up: 14 Number of people (eyes) analysed (at longest time point): 68 Average age in years (range) : 72 % female: 67 Ethnic group: Not reported Monofocal: PhacoFlexII, AMO Number of people (eyes) randomised: 97 Number of people (eyes) excluded after randomisation: 19 Number of people (eyes) lost to follow-up: 9 Number of people (eyes) analysed (at longest time point): 69 Average age in years (range) : 72 % female: 64 Ethnic group: Not reported Inclusion criteria: Bilateral senile cataract; astigmatism < 1.5 D; spectacle sphere between -6.0 and +4.0 D; axial length between 19.5 mm and 26 mm; ability to complete questionnaires in Dutch Exclusion criteria: Professional night driver; mental retardation (diagnosed in the medical file or concluded by contact by telephone); any eye disease other than cataract that might limit post-operative vision Pre-treatment: Slightly more astigmatism in the monofocal group

Reference	Nijkamp 2004
Interventions	Intervention Characteristics Multifocal 1 Name of lens: Array SA40N, AMO Type of lens: NR Target: Emmetropia Monofocal Name of lens: PhacoFlexII, AMO Type of lens: NA Target: Emmetropia Both eyes operated
Outcomes	Patients with a postoperative refractive error in spherical equivalent (SE) of >1.5 D from emmetropia (in at least one eye) were excluded from further analyses (monofocal, n = 8; multifocal,n = 3). Outcomes: Distance and near visual acuity, refraction, contrast sensitivity, depth of focus, satisfaction, visual function and quality of life (including VF14 and VQOL), Cataract Symptom Score, spectacle dependence. Eyes: Largely unclear how dealt with eyes, measurements monocular Maximum follow-up: 3 months after surgery
Notes	Sponsorship source: Eye Research Institute Maastricht (Maastricht, The Netherlands) Declaration of interest: "None of the authors has a financial or proprietary interest in any product or device mentioned." Country: The Netherlands Date study conducted: August 1999 to January 2001 Trial registration ID number: Not reported

213

Reference	Percival 1993
Methods	Parallel-group RCT
Participants	Baseline Characteristics Multifocal 1: MPC25, AMO Number of people (eyes) randomised: Not reported Number of people (eyes) excluded after randomisation: Not reported Number of people (eyes) lost to follow-up: Not reported Number of people (eyes) analysed (at longest time point): 25 (25)

Reference	Percival 1993
	Average age in years (range) : 77 (59-89) % female: 58 Ethnic group: Not reported Monofocal: PC25, AMO Number of people (eyes) randomised: Not reported Number of people (eyes) excluded after randomisation: Not reported Number of people (eyes) lost to follow-up: Not reported Number of people (eyes) analysed (at longest time point): 25 (25) Average age in years (range) : 78 (60-92) % female: 58 Ethnic group: Not reported Inclusion criteria: Not specified Exclusion criteria: Any other ocular pathology Pre-treatment: 5 patients dropped out of study (due to death, undiagnosed diabetic retinopathy and undiagnosed macular degeneration) and replaced by other randomised patients - unclear which groups these patients were lost from
Interventions	Intervention Characteristics Multifocal 1 Name of lens: MPC25, AMO Type of lens: Refractive Target: SE between -0.50 and +0.50 D with cylinder of less than 1.00 D Monofocal Name of lens: PC25, AMO Type of lens: NA Target: SE between -0.30 and -1.30 D with cylinder of 1.00 to 1.75 D One eye operated on
Outcomes	Outcomes: Distance and near visual acuity, refraction, contrast sensitivity, satisfaction, operative and postoperative complications, adverse effects (including glare etc) Eyes: One eye operated per person Maximum follow-up: 4 to 6 months after surgery
Notes	Sponsorship source: Not reported

Reference	Percival 1993
	Declaration of interest: Not reported Country: UK Date study conducted: Not reported Trial registration ID number: Not reported

214 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Block randomization by means of a computerized random number generator was used to keep the number of subjects in the different groups balanced."
Allocation concealment (selection bias)	Low risk	"After the preoperative assessments, a technical ophthalmic assistant allocated the treatment condition via a sealed envelope that contained a card identifying the lens type. The envelope was opened by a nurse not involved in the study. This was done after biometry and just before surgery, to enable the ophthalmologist to choose the correct lens power."
Blinding of participants and personnel (performance bias)	High risk	"Patients were masked with respect to the type of lens until the first postoperative visit. It was unfeasible to keep patients masked postoperatively, because they were aware of the characteristics of both types of IOL from their description in the patient information they received." Quote: "Interviewers and ophthalmologists were unaware of the treatment group of the patient at the preoperative tests. However, because there were perceptible differences between the 2 types of lenses during the slit-lamp examination, masking of interviewers and ophthalmologists was not feasible postoperatively."
Blinding of outcome assessment (detection bias)	High risk	"Interviewers and ophthalmologists were unaware of the treatment group of the patient at the preoperative tests. However, because there were perceptible differences between the 2 types of lenses during the slit-lamp examination, masking of interviewers and ophthalmologists was not feasible postoperatively."
Incomplete outcome data (attrition bias)	High risk	Rather high loss to follow-up (approx 30%) potentially linked to outcome although similar loss to follow-up in both groups. Excluded people with high astigmatism after surgery. "Patients with a postoperative refractive error in spherical equivalent (SE) of >1.5 D from emmetropia (in at least one eye) were excluded from further analyses (Fig 1; monofocal, n=8; multifocal, n=3)."
Selective reporting (reporting bias)	Unclear risk	No access to protocol or trials registry entry

215

Reference	Palmer 2008
Methods	Parallel-group RCT

Reference	Palmer 2008
Participants	Baseline Characteristics Multifocal 1: Tecnis ZM900, AMO Number of people (eyes) randomised: Not reported Number of people (eyes) excluded after randomisation: Not reported Number of people (eyes) lost to follow-up: Not reported Number of people (eyes) analysed (at longest time point): 26 (52) Average age in years (range) : 73 % female: 61 Ethnic group: Not reported Multifocal 2: ReZoom, AMO Number of people (eyes) randomised: Not reported Number of people (eyes) excluded after randomisation: Not reported Number of people (eyes) lost to follow-up: Not reported Number of people (eyes) analysed (at longest time point): 32 (64) Average age in years (range) : 72 % female: 69 Ethnic group: Not reported Multifocal 3: TwinSet, Acri Tec Number of people (eyes) randomised: Not reported Number of people (eyes) excluded after randomisation: Not reported Number of people (eyes) lost to follow-up: Not reported Number of people (eyes) analysed (at longest time point): 32 (64) Average age in years (range) : 74 % female: 67 Ethnic group: Not reported Monofocal: Tecnis Z9000, AMO Number of people (eyes) randomised: Not reported Number of people (eyes) excluded after randomisation: Not reported Number of people (eyes) lost to follow-up: Not reported Number of people (eyes) analysed (at longest time point): 24 (48) Average age in years (range) : 75

Reference	Palmer 2008
	% female: 53 Ethnic group: Not reported Inclusion criteria: Both eyes healthy with no disease except cataract. Exclusion criteria: Professional drivers Pre-treatment: Some differences in gender and spherical equivalent between groups .
Interventions	Intervention Characteristics Multifocal 1 Name of lens: Tecnis ZM900, AMO Type of lens: Diffractive Target: NR Multifocal 2 Name of lens: ReZoom, AMO Type of lens: Refractive Target: NR Multifocal 3 Name of lens: TwinSet, Acri Tec Type of lens: Diffractive Target: NR Monofocal Name of lens: Tecnis Z9000, AMO Target: NR Both eyes operated on
Outcomes	Outcomes: Distance and near visual acuity, refraction, contrast sensitivity, visual symptoms, spectacle dependence for near tasks Eyes: Binocular and monocular, no adjustment for within-person correlation Maximum follow-up: 3 months after surgery
Notes	Sponsorship source: Not reported Declaration of interest: "The authors have no financial interest in the materials presented herein" Country: Spain Date study conducted: June 2004 to March 2005 Trial registration ID number: Not reported

216 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	High risk	"Sealed envelope method" but not enough detail to be clear what they did and some differences between groups in terms of gender and preoperative spherical equivalent
Blinding of participants and personnel (performance bias)	Unclear risk	Patients were not told which lens they would receive but unclear whether any of them could have guessed. This was not discussed.
Blinding of outcome assessment (detection bias)	Unclear risk	Quote: "Refraction measurements were performed by a single independent observer who was unaware of the purpose of the study." Judgement Comment: This judgement applies to refraction outcomes only.
Incomplete outcome data (attrition bias)	Unclear risk	Not reported
Selective reporting (reporting bias)	Unclear risk	No access to trial registry entry or study protocol

217

Reference	Peng 2012
Methods	Parallel-group RCT
Participants	Baseline Characteristics Multifocal 1: AcrySof ReSTOR SN6AD1, Alcon Number of people (eyes) randomised: 51 (102) Number of people (eyes) excluded after randomisation: 1 (2) Number of people (eyes) lost to follow-up: 0 (0) Number of people (eyes) analysed (at longest time point): 50 (100) Average age in years (range) : 66 % female: 58 Ethnic group: Not stated (presume Chinese?) Monofocal: AcrySof IQ SN60WF, Alcon Number of people (eyes) randomised: 51 (102) Number of people (eyes) excluded after randomisation: 0 (0) Number of people (eyes) lost to follow-up: 0 (0) Number of people (eyes) analysed (at longest time point): 51 (102)

Reference	Peng 2012
	Average age in years (range) : 67 % female: 47 Ethnic group: Not stated (presume Chinese?) Inclusion criteria: Bilateral cataract; age between 50 and 75 years; axial length between 22.0 and 24.0 mm; preoperative corneal astigmatism <2.0 dioptre (D); nuclear hardness from grade II to IV based on the Emery-Little classification; corneal endothelium cell count >2000 cells/mm2. Exclusion criteria: Myopia or hyperopia >3.00 D; history of amblyopia; fundus abnormalities; previous corneal or intraocular surgery; ocular comorbidity (e.g. previous trauma, glaucoma, abnormal iris, chronic uveitis, macular degeneration or retinopathy, neuro-ophthalmic disease). Intraoperative exclusion criteria: iris pupil trauma; vitreous loss; IOL tilt. Pre-treatment: Some differences between study groups in pupil size and intraocular straylight
Interventions	Intervention Characteristics Multifocal 1 Name of lens: AcrySof ReSTOR SN6AD1, Alcon Type of lens: Diffractive Target: Emmetropia Monofocal Name of lens: AcrySof IQ SN60WF, Alcon Type of lens: NA Target: Emmetropia Both eyes operated on
Outcomes	Outcomes: Distance, near and intermediate visual acuity, refraction, contrast sensitivity, defocus curves, aberrations, visual problems, satisfaction, spectacle independence, adverse effects (including PCO, glare etc) Eyes: Binocular acuity, other measures largely unclear, no adjustment for within-person correlation Maximum follow-up: 6 months after surgery
Notes	Sponsorship source: Education Department of Liaoning Province grants, China (2009R53); and Science and Technology Department of Liaoning Province grants, China (2009225011-3). Declaration of interest: "No author has a proprietary or commercial interest in the materials or methods mentioned here" Country: China Date study conducted: Not reported Trial registration ID number: Not reported

218 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not described. Opaque envelopes were selected.
Allocation concealment (selection bias)	Low risk	"Patients were randomized to each of the IOLs by selecting an unmarked, opaque envelope for each patient from a total of 102 envelopes evolving the type of one of the IOLs. The envelope was opened by a staff not involved in our study."
Blinding of participants and personnel (performance bias)	Unclear risk	Quote: "This prospective, randomized, comparative, and observer-masked trial recruited 204 eyes (102 patients)" Judgement Comment: It was not clear how the masking was done
Blinding of outcome assessment (detection bias)	Unclear risk	Quote: "This prospective, randomized, comparative, and observer-masked trial" Judgement Comment: It was not clear how the masking was done
Incomplete outcome data (attrition bias)	Low risk	Quote: "A total of 101 patients were available at 6 month postoperatively, owing to the presence of posterior capsular opacities in the multifocal IOL group. Therefore, 50 patients (100 eyes) in the multifocal IOL group and 51 patients (102 eyes) in the monofocal IOL group were available for analysis." Judgement Comment: 100/101 patients followed to 6 months
Selective reporting (reporting bias)	Unclear risk	No protocol or trials registry entry

219

Reference	Rasp 2012
Methods	Parallel RCT
Participants	Baseline Characteristics Multifocal 1: Acrysof Restor SN6AD3, Alcon Number of people (eyes) randomised: NR Number of people (eyes) excluded after randomisation: NR Number of people (eyes) lost to follow-up: NR Number of people (eyes) analysed (at longest time point): 28 (56) Average age in years (range) : 76 (62-91) % female: NR Ethnic group: NR Multifocal 2: AT LISA 366D, Carl Zeiss

Reference	Rasp 2012
	Number of people (eyes) randomised: NR Number of people (eyes) excluded after randomisation: NR Number of people (eyes) lost to follow-up: NR Number of people (eyes) analysed (at longest time point): 30 (60) Average age in years (range) : 74 (63-89) % female: NR Ethnic group: NR Multifocal 3: Rezoom, AMO Number of people (eyes) randomised: NR Number of people (eyes) excluded after randomisation: NR Number of people (eyes) lost to follow-up: NR Number of people (eyes) analysed (at longest time point): 30 (60) Average age in years (range) : 79 (66-89) % female: NR Ethnic group: NR Multifocal 4: Tecnis ZMA00, AMO Number of people (eyes) randomised: NR Number of people (eyes) excluded after randomisation: NR Number of people (eyes) lost to follow-up: NR Number of people (eyes) analysed (at longest time point): 29 (58) Average age in years (range) : 75 (62-87) % female: NR Ethnic group: NR Monofocal: Acri.Smart 48S (a.k.a. CT Spheris 209M), Carl Zeiss Number of people (eyes) randomised: NR Number of people (eyes) excluded after randomisation: NR Number of people (eyes) lost to follow-up: NR Number of people (eyes) analysed (at longest time point): 29 (58) Average age in years (range) : 76 (63-80) % female: NR Ethnic group: NR

Reference	Rasp 2012
	Inclusion criteria: Age more than 60 year; and patients seeking bilateral cataract refractive surgery for presbyopia in the presence of significant nuclear sclerosis. Exclusion criteria: Additional ocular disease; and illiteracy. Pre-treatment: There were statistically significant between-group differences in sphere, cylinder, corrected distance visual acuity (CDVA), axial length, anterior chamber depth, and IOL power. These differences were the result of the randomization process and do not represent selection bias.
Interventions	Intervention Characteristics Multifocal 1 Name of lens: Acrysof Restor SN6AD3, Alcon Type of lens: Refractive/diffractive Target: NR Multifocal 2 Name of lens: AT LISA 366D, Carl Zeiss Type of lens: Refractive -diffractive bifocal Target: NR Multifocal 3 Name of lens: Rezoom, AMO Type of lens: Refractive Target: NR Multifocal 4 Name of lens: Tecnis ZMA00, AMO Type of lens: Diffractive Target: NR Monofocal Name of lens: Acri.Smart 48S (a.k.a. CT Spheris 209M), Carl Zeiss Type of lens: NA Target: NR Both eyes operated on
Outcomes	Outcomes: Distance visual acuity, refraction, reading ability Eyes: Monocular, no adjustment for within-person correlation Maximum follow-up: 12 months after surgery

Reference	Rasp 2012
Notes	Sponsorship source: Sponsorship source: Not reported Declaration of interest: "Drs.Grabner and Dexl were patent owners of the Salzburg Reading Desk technology (now owned by SRD-Vision, LLC). No other author has a financial or proprietary interest in any material or method mentioned." Country: Austria Date study conducted: Not reported Trial registration ID number: Not reported

220 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	High risk	Not reported
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Unclear risk	Not reported
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry

221

Reference	Rossetti 1994
Methods	Parallel-group RCT
Participants	Baseline Characteristics Multifocal 1: 3M/Vision Care multifocal IOL, St Paul, MN Number of people (eyes) randomised: NR Number of people (eyes) excluded after randomisation: NR Number of people (eyes) lost to follow-up: NR Number of people (eyes) analysed (at longest time point): 38 (38) Average age in years (range) : 72 (55-84) % female: 61 Ethnic group: NR Monofocal, not specified Number of people (eyes) randomised: NR

Reference	Rossetti 1994
	Number of people (eyes) excluded after randomisation: NR Number of people (eyes) lost to follow-up: NR Number of people (eyes) analysed (at longest time point): 42 (42) Average age in years (range) : 70 (50-90) % female: 57 Ethnic group: NR Inclusion criteria: astigmatism less than or equal to 2.5D; spherical equivalent in the fellow eye of no more than 2.5D; cataract in one eye and clear lens or early cataract in the fellow eye that would not require surgery during the study Exclusion criteria: astigmatism of more than 1.5D; IOL in fellow eye; fundus abnormalities causing significant vision impairment; could not be followed for one year Pre-treatment: No group differences
Interventions	Intervention Characteristics Multifocal 1 Name of lens: 3M/Vision Care multifocal IOL, St Paul, MN Type of lens: Refractive and diffractive Target: Emmetropia Monofocal Name of lens: NR Type of lens: NA Target: Emmetropia One eye operated on
Outcomes	Outcomes: Distance and near visual acuity, contrast sensitivity, satisfaction, spectacle dependence, adverse effects (including glare, halos etc) Eyes: One eye operated per patient Maximum follow-up: 12 months after surgery
Notes	Sponsorship source: Not reported Declaration of interest: Not reported Country: Italy Date study conducted: Not reported Trial registration ID number: Not reported

222 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	High risk	No information on masking.
Blinding of outcome assessment (detection bias)	High risk	No information on masking.
Incomplete outcome data (attrition bias)	Unclear risk	Not reported
Selective reporting (reporting bias)	Unclear risk	No access to trials registry entry or study protocol

223

Reference	Sen 2004
Methods	Parallel group RCT
Participants	Baseline Characteristics Multifocal 1: Array SA40N, AMO Number of people (eyes) randomised: 40 (Not reported) Number of people (eyes) excluded after randomisation: 5 (Not reported) Number of people (eyes) lost to follow-up: 0 (0) Number of people (eyes) analysed (at longest time point): 35 (53) Average age in years (range) : 69 (48-84) % female: 74 Ethnic group: Not reported Monofocal: SI-40NB, AMO Number of people (eyes) randomised: 40 (Not reported) Number of people (eyes) excluded after randomisation: 0 (0) Number of people (eyes) lost to follow-up: 0 (0) Number of people (eyes) analysed (at longest time point): 40 (67) Average age in years (range) : 72 (41-88) % female: 63 Ethnic group: Not reported Inclusion criteria: both eyes had to be healthy, with no disease except cataract; required to understand the possible benefit of having implantation of a multifocal IOL instead of a monofocal IOL; have potential good vision in both eyes after cataract surgery and IOL implantation.

Reference	Sen 2004
	Exclusion criteria: Patients who would likely be more sensitive to glare, halos, and changes in contrast sensitivity; and who did not have realistic expectations of the new technology. Pre-treatment: There were no significant between-group differences in demographics including age, sex, education, and profession. Visual acuity and the type of cataract were comparable between groups, and no patient in either group had ocular comorbidity in addition to cataract. The VF-7 and CS-5 values were almost identical in the 2 groups preoperatively, and the percentages of those reporting being dissatisfied with their vision (43.1% multifocal group and 57.6% monofocal group) or very dissatisfied with their vision (19.6% and 18.2%, respectively) were comparable. The proportion of patients with moderate (35.3% and 25.8%, respectively) or a great deal (25.5% and 21.2%, respectively) of self-reported trouble with vision was also comparable between the 2 groups.
Interventions	Intervention Characteristics Multifocal 1 Name of lens: Array SA40N, AMO Type of lens: Refractive Target: NR Monofocal Name of lens: SI-40NB, AMO Type of lens: NA Target: NR One or both eyes operated on
Outcomes	Outcomes: Distance and near visual acuity, refraction, contrast sensitivity, range of accommodation, visual function (VF-7), visual symptoms, satisfaction, adverse effects (glare, halos etc) Eyes: Monocular acuity, no adjustment for within-person correlation Maximum follow-up: 1 month after surgery
Notes	Sponsorship source: Supported by a special government grant for research (TYH 3234),Helsinki University Eye Hospital, and a grant from the Finnish Eye Foundation, Helsinki Finland, and a grant to help in statistical analysis from Allergan Norden. Declaration of interest: "None of the authors has a financial or proprietary interest in any material or method mentioned" Country: Finland Date study conducted: February 1998 to August 2002 Trial registration ID number: NR

224 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Sealed-envelope method was used but no further details given.
Blinding of participants and personnel (performance bias)	High risk	Participants and personnel were not blinded.
Blinding of outcome assessment (detection bias)	High risk	No blinding was done.
Incomplete outcome data (attrition bias)	High risk	5/40 patients in multifocal group only excluded after randomisation
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry

225

Reference	Steinert 1992
Methods	Parallel group RCT
Participants	Baseline Characteristics Multifocal 1: MPC-25NB Array, AMO Number of people (eyes) randomised: 40 Number of people (eyes) excluded after randomisation: NR Number of people (eyes) lost to follow-up: 8 Number of people (eyes) analysed (at longest time point): 32 (32) Average age in years (range) : 72 % female: 55 Ethnic group: NR Monofocal: PC-26NB, AMO Number of people (eyes) randomised: 40 Number of people (eyes) excluded after randomisation: NR Number of people (eyes) lost to follow-up: 10 Number of people (eyes) analysed (at longest time point): 30 (30) Average age in years (range) : 71 % female: 78 Ethnic group: NR Inclusion criteria: Functionally disabling cataracts; potential acuity of 20/25 or better; pre-operative cylinder of 1.5 D or less; axial myopia < 26 mm; phakic fellow eye

Reference	Steinert 1992
	Exclusion criteria: Non-cataract ocular pathology Pre-treatment: Significant gender difference between both study groups (p = 0.033)
Interventions	Intervention Characteristics Multifocal 1 Name of lens: MPC-25NB Array, AMO Type of lens: Refractive Target: NR Monofocal Name of lens: PC-26NB, AMO Type of lens: NA Target: NR One eye operated on
Outcomes	Outcomes: Distance and near, refraction, contrast sensitivity, visual problems (including glare, halos etc), satisfaction, spectacle use, Eyes: Only one eye operated Maximum follow-up: 3 to 6 months after surgery (mean follow-up approximately 4 months)
Notes	Sponsorship source: "Supported in part by Allergan Medical Optics, Irving, California" Declaration of interest: "None of the authors has any proprietary or financial interest in the devices used in this study. Dr Steinert is a member of the Allergan Scientific Advisory committee, for which a stipend is received. Drs Steinert and Oksman are unpaid medical monitors for the multifocal intraocular lens used in this study." Country: USA Date study conducted: Not reported Trial registration ID number: Not reported

226 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised block design but no further details
Allocation concealment (selection bias)	Unclear risk	Not reported

Bias	Authors' judgement	Support for judgement
Blinding of participants and personnel (performance bias)	Low risk	"The lenses were centrally encoded and labelled such that the patient record did not indicate which IOL was implanted. Both the patient and ophthalmic technical staff performing objective measures were masked regarding the identity of the implant. "
Blinding of outcome assessment (detection bias)	Low risk	"The lenses were centrally encoded and labelled such that the patient record did not indicate which IOL was implanted. Both the patient and ophthalmic technical staff performing objective measures were masked regarding the identity of the implant. "
Incomplete outcome data (attrition bias)	High risk	Only 77% followed up and not clear if equal between groups
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry

227

Reference	Wilkins 2013
Methods	Parallel group RCT
Participants	Baseline Characteristics Multifocal 1: Tecnis ZM900, AMO Number of people (eyes) randomised: 106 (212) Number of people (eyes) excluded after randomisation: 6 (12) Number of people (eyes) lost to follow-up: 6 (12) Number of people (eyes) analysed (at longest time point): 94 (188) Average age in years (range) : 67 (Not reported) % female: 56 Ethnic group: Not reported Monofocal: Akreos AO, Bausch & Lomb Number of people (eyes) randomised: 105 (210) Number of people (eyes) excluded after randomisation: 2 (4) Number of people (eyes) lost to follow-up: 10 (20) Number of people (eyes) analysed (at longest time point): 93 (186) Average age in years (range) : 69 (Not reported) % female: 58 Ethnic group: Not reported

Reference	Wilkins 2013
	Inclusion criteria: bilateral cataract surgery; age range 30 to 90 years; axial length measureable using the Zeiss IOLMaster (Oberkochen,Germany) Exclusion criteria: IOL power available to achieve emmetropia with IOL or -1.5D with the Akreos AO IOL (Bausch & Lomb, Rochester, NY); significant co-pathology likely to reduce acuity or visual field; keratometric astigmatism likely to be >=1.0 D in either eye after surgery; amblyopia; congenital or traumatic cataracts; poor comprehension of written or spoken English; inability to give informed consent Pre-treatment: The 2 arms of the study were similar in age (68.7±12.0 years for monovision vs. 67.0±11.2 for multifocal) and sex (female 57.5% for monovision vs. female 55.7% for multifocal).
Interventions	Intervention Characteristics Multifocal 1 Name of lens: Tecnis ZM900, AMO Type of lens: Diffractive Target: Emmetropia Monofocal Name of lens: Akreos AO, Bausch & Lomb Type of lens: Monovision Target: Emmetropia in distance eye; myopia -1.0 to -1.5D in the near eye Both eyes operated on
Outcomes	Outcomes: Distance, near and intermediate visual acuity, refraction, contrast sensitivity, straylight, aberrations, stereo acuity, visual problems (dysphopsia), satisfaction, spectacle dependence, visual function (VF-14) Eyes: Binocular acuity or right eye only Maximum follow-up: 4 months after surgery
Notes	Sponsorship source: : "Funded by an unrestricted grant from Abbott Medical Optics and Bausch &Lomb. The funding organizations had no role in the design or conduct of this research. This work was supported in part by the UK National Institute for Health Research Biomedical Research Centre in Ophthalmology at Moorfields Eye Hospital and UCL Institute of Ophthalmology." Declaration of interest: "The author(s) have no proprietary or commercial interest in any materials discussed in this article." Country: UK Date study conducted: April 2007 to August 2010 Trial registration ID number: ISRCTN37400841

228 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization was conducted using minimization that incorporated a single factor, hospital site, using Minim, a free minimization program (available at www-users.york.ac.uk/wmb55/guide/ minim.htm, accessed July 22, 2013)."
Allocation concealment (selection bias)	Low risk	"Access to the procedure was via a medical statistician within the Research and Development department at Moorfields Eye Hospital. The statistician was phoned shortly before surgery after patients had provided written informed consent and been registered into the trial. Sequentially numbered sealed opaque envelopes were available as a backup facility."
Blinding of participants and personnel (performance bias)	Low risk	"The surgeons performing the surgery and staff reviewing the patient at 4 months were not masked to the IOL inserted. However, patients were masked to the lens group."
Blinding of outcome assessment (detection bias)	High risk	The surgeons performing the surgery and staff reviewing the patient at 4 months were not masked to the IOL inserted. However, patients were masked to the lens group.
Incomplete outcome data (attrition bias)	Low risk	"We planned to conduct the analysis according to the intent-to-treat principal. Primary outcome data were not available on 12% of patients. We compared missing rates between treatment groups and assessed whether missingness was associated with any baseline covariate. We then conducted an available case analysis."
Selective reporting (reporting bias)	High risk	Some differences between outcomes on trial register and those reported eg, reading speed.

229

Reference	Zhao 2010
Methods	Parallel group RCT
Participants	Baseline Characteristics Multifocal 1: AcrySof ReSTOR SA60D3, Alcon Number of people (eyes) randomised: Not reported Number of people (eyes) excluded after randomisation: Not reported Number of people (eyes) lost to follow-up: Not reported Number of people (eyes) analysed (at longest time point): 72 (72) Average age in years (range) : 65 (34-80) % female: 49 Ethnic group: Not reported

Reference	Zhao 2010
	Monofocal: AcrySof SA60AT, Alcon Number of people (eyes) randomised: Not reported Number of people (eyes) excluded after randomisation: Not reported Number of people (eyes) lost to follow-up: Not reported Number of people (eyes) analysed (at longest time point): 89 (72) Average age in years (range) : 67 (51-92) % female: 46 Ethnic group: Not reported Inclusion criteria: Corrected distance VA and uncorrected distance VA worse than 10/25; nuclear hardness from grade II to IV (Emery-Little classification); corneal astigmatism < 1.50 D; corneal endothelium cell count > 2000 cells/mm square; ability to understand and sign an informed consent form Exclusion criteria: Age < 21 years; myopia or hyperopia > 3.00 D; history of amblyopia; fundus abnormalities that could cause significant visual impairment; previous intraocular surgery; ocular comorbidity (e.g. previous trauma, glaucoma, diabetic retinopathy, pseudoexfoliation syndrome, chronic uveitis, corneal opacity, senile miosis hyporeactive pupil; alpha-antagonist (tamsulosin) treatment because of risk of floppy-iris syndrome; intraoperative iris pupil trauma, vitreous loss and IOL implantation outside the capsular bag Pre-treatment: No important differences between study groups
Interventions	Intervention Characteristics Multifocal 1 Name of lens: AcrySof ReSTOR SA60D3, Alcon Type of lens: Diffractive Target: NR Monofocal Name of lens: AcrySof SA60AT, Alcon Type of lens: Target: NR One eye operated on
Outcomes	Outcomes: Distance and near visual acuity, contrast sensitivity, defocus curves, aberrations, visual function (VF-7), satisfaction, spectacle independence, adverse effects (including PCO, glare etc) Eyes: One eye per person Maximum follow-up: 6 months after surgery
Notes	Sponsorship source: Not reported

Reference	Zhao 2010
	Declaration of interest: "No author has a financial or proprietary interest in any material or method mentioned." Country: China Setting: Department of Ophthalmology, Affiliated Hospital of Qingdao University Medical College Date study conducted: October 2005 and March 2007 Trial registration ID number: Not reported

230 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Immediately preoperatively, the patients were randomized with a coin toss to receive an AcrySof SA60AT single-piece monofocal IOL (monofocal group) or an AcrySof ReSTOR SA60D3 multifocal IOL (multifocal group) (both Alcon, Inc.)."
Allocation concealment (selection bias)	Unclear risk	not described
Blinding of participants and personnel (performance bias)	Unclear risk	Patients and medical staff collecting data were masked to the IOL. However no description of masking of staff providing care.
Blinding of outcome assessment (detection bias)	Low risk	The patients and the medical staff who collected visual function and quality-of-life data were masked to the type of IOL each patient received.
Incomplete outcome data (attrition bias)	Unclear risk	Follow-up not reported
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry

231 The evidence tables on bifocal versus trifocal lenses and diffractive multifocal lenses versus refractive multifocal lenses below were conducted by
232 the NICE Internal Clinical Guidelines Team, separate from the results of the Cochrane review presented above.

233 **Bifocal versus trifocal lenses**

Full citation	Gunderson J, Potvin R. Comparison of visual outcomes after implantation of diffractive trifocal toric intraocular lens and a diffractive apodized bifocal toric intraocular lens. Clinical Ophthalmology 2016;10:455-461
Study details	Country/ies where the study was carried out: Norway Study type: RCT Aim of the study: To compare

<table>
<tr><th>Full citation</th><td>Gunderson J, Potvin R. Comparison of visual outcomes after implantation of diffractive trifocal toric intraocular lens and a diffractive apodized bifocal toric intraocular lens. Clinical Ophthalmology 2016;10:455-461</td></tr>
<tr><td></td><td>Study dates: Not reported
Sources of funding: Funded with a grant from FineVision, Liege, Belgium</td></tr>
<tr><td>Participants</td><td>Sample size
22 patients
Inclusion criteria
Patients who were >50 years old, presented with uncomplicated cataract surgery and interested in reducing their spectacle dependence in daily life. Had to have regular astigmatism and have a calculated IOL power that was within the available range for each IOL
Exclusion criteria
Patients who the surgeon felt (after evaluation of their interest in spectacle independence, their affect and expectations) the patient’s expectations were unrealistic. Ocular pathology (besides cataract) and previous refractive surgery. If the surgeon felt there were factors that would be likely to affect the subjects postoperative vision (eg, amblyopia and history of uveitis)</td></tr>
<tr><td>Methods</td><td>Patients were randomised to receive either bilateral implantation of a trifocal toric IOL in one group and a bifocal toric IOL in the other group during one session
Data collection
Uncorrected and corrected (logMAR) v11isual acuity were measured 3 months postoperatively
Intervention
Cataract surgery with bilateral implantation of trifocal or bifocal toric lens
Analysis
Fishers exact test</td></tr>
<tr><td>Results</td><td>Visual acuity 3 months postoperatively
<table>
<tr><td></td><td>Trifocal</td><td>Bifocal</td><td>p-value</td></tr>
<tr><td>Uncorrected distance VA (logMAR)</td><td>0.03 ± -0.10 (-0.20 to 0.32)</td><td>0.08 ± 0.13 (-0.18 to 0.42)</td><td>0.16</td></tr>
<tr><td>Corrected distance VA (logMAR)</td><td>-0.01± -0.06 (-0.20 to 0.10)</td><td>0.01 ± 0.07 (-0.18 to 0.16)</td><td>0.44</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>Postoperative distance visual acuity at 3 months were similar between the groups</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Unsure
3 Were the patients, health workers and study personnel blinded? Not all (examiner taking readings not blinded)
4 Were the groups similar at the start of the trial? Yes
5 Aside from the experimental intervention, were the groups treated equally? Yes</td></tr>
</table>

Full citation	Gunderson J, Potvin R. Comparison of visual outcomes after implantation of diffractive trifocal toric intraocular lens and a diffractive apodized bifocal toric intraocular lens. Clinical Ophthalmology 2016;10:455-461
skills programme)	6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

234

Full citation	Jonker S, Bauer N, Makhotkina N et al. Comparison of a trifocal intraocular lens with a +3.0 D bifocal IOL: Results of a prospective randomised clinical trial. J Cataract Refract Surg. 2015;41:1631-1640
Study details	Country/ies where the study was carried out: Netherlands Study type: RCT Aim of the study: To compare visual outcomes in patients with cataract surgery and bilateral implantation of a trifocal or bifocal intraocular lens (IOL) Study dates: Not reported Sources of funding: Supported by Physiol S.A., Liege, Belgium. Dr Bauer received grants from Alcon laboratories, Carl Zeiss Meditec AG, Dr Nuijts is a consultant to Alcon Surgical Inc, Thea Pharma, ASICO LLC.
Participants	Sample size 28 patients (trifocal group n=15), (bifocal group n=13) Inclusion criteria Patients with bilateral cataract, less than 1.0 dioptre (D), corneal astigmatism in both eyes, age over 42 years, and an expected postoperative corrected distance visual acuity (CDVA) of 0.3 logMAR or less Exclusion criteria Combined ocular pathology that would limit postoperative visual outcome, suturing of the incision during surgery, and complications during surgery in the first eye.
Methods	Random allocation was undertaken to receive bilateral implantation of a trifocal IOL (trifocal group) or a bifocal IOL (bifocal group) Data collection Photopic visual acuity (logMAR) for uncorrected and distance –corrected were measured 6 months postoperatively. Spectacle independence was also measured Intervention Trifocal and Bifocal IOL implantation during cataract surgery Analysis Chi-squared, Student t -test

<table>
<tr><th>Full citation</th><td>Jonker S, Bauer N, Makhotkina N et al. Comparison of a trifocal intraocular lens with a +3.0 D bifocal IOL: Results of a prospective randomised clinical trial. J Cataract Refract Surg. 2015;41:1631-1640</td></tr>
<tr><td>Results</td><td>6 months postoperative measurements – Mean ± SD
<table>
<tr><td>Measurement</td><td>Trifocal</td><td>Bifocal</td><td>P value</td></tr>
<tr><td>Photopic visual acuity (logMAR)</td><td></td><td></td><td></td></tr>
<tr><td colspan="4">Uncorrected</td></tr>
<tr><td>UDVA at 4m</td><td>0.09 ± 0.16</td><td>0.08 ± 0.11</td><td>0.88</td></tr>
<tr><td>UIVA at 70cm</td><td>0.45 ± 0.18</td><td>0.41 ± 0.15</td><td>0.46</td></tr>
<tr><td>UNVA at 40cm</td><td>0.25 ± 0.17</td><td>0.20 ± 0.09</td><td>0.19</td></tr>
<tr><td>15UNVA at PP</td><td>0.20 ± 0.17</td><td>0.19 ± 0.10</td><td>0.77</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="4">Distance-corrected</td></tr>
<tr><td>CDVA at 4m</td><td>0.01 ± 0.11</td><td>0.02 ± 0.08</td><td>0.93</td></tr>
<tr><td>DCIVA at 70cm</td><td>0.43 ± 0.15</td><td>0.42 ± 0.14</td><td>0.89</td></tr>
<tr><td>DCNVA at 40cm</td><td>0.19 ± 0.14</td><td>0.17 ± 0.08</td><td>0.53</td></tr>
<tr><td>DCNVA at PP</td><td>0.14 ± 0.14</td><td>0.16 ± 0.08</td><td>0.55</td></tr>
</table>
CDVA= corrected distance visual acuity; DCIV= distance-corrected intermediate visual acuity; DCNVA= distance-corrected near visual acuity; PP= patient-preferred distance; UDVA= uncorrected distance visual acuity; UIVA= uncorrected intermediate visual acuity; UNVA= uncorrected near visual acuity</td></tr>
<tr><td>Outcomes</td><td>No statistical difference found between the 2 groups for monocular measurements (photopic and mesopic visual acuities)
At 6 months all patients were spectacle-free for distance with 12 trifocal patients (80%) and 9 bifocal patients (75%) also reporting spectacle independence at near vision</td></tr>
<tr><td>Study appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Unsure
3 Were the patients, health workers and study personnel blinded? Yes
4 Were the groups similar at the start of the trial? Yes
5 Aside from the experimental intervention, were the groups treated equally? Yes
6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes
7 Can the results be applied to the local population? Yes</td></tr>
</table>

Full citation	Jonker S, Bauer N, Makhotkina N et al. Comparison of a trifocal intraocular lens with a +3.0 D bifocal IOL: Results of a prospective randomised clinical trial. J Cataract Refract Surg. 2015;41:1631-1640
	8 Were all clinically important outcomes considered? N/A

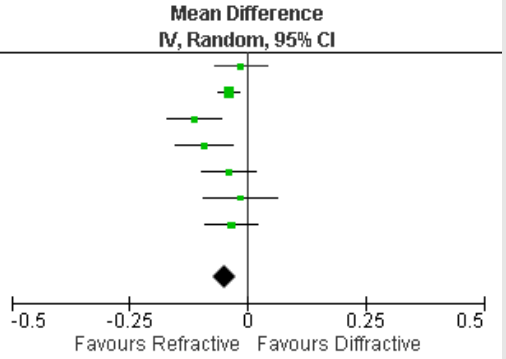
235 **Refractive vs diffractive multifocal lenses**

Full citation	Xu X, Zhu M, Zou H. Refractive versus diffractive multifocal IOL in cataract surgery: A Meta-analysis of randomised controlled trials. J Cataract Refract Surg. 2014;30:634-644
Study details	Country/ies where the study was carried out: China Study type: Systematic review Aim of the study: To compare the effectiveness of refractive multifocal IOLs versus diffractive multifocal IOLs in bilateral cataract surgery Study dates: 2000 to April 4, 2014 Sources of funding: Not reported
Participants	Sample size 8 RCTs containing 621 patients (1,242 eyes) Inclusion criteria RCTs that compared the postoperative visual performance of patients with refractive IOLs and diffractive IOLs. Patients with age-related cataracts who underwent phacoemulsification and bilateral implantation with a single type of multifocal IOL Exclusion criteria Simulation experiments. Patients with coexisting ocular pathologies, such as amblyopia, glaucoma, age-related macular degeneration, pre-existing systemic disease such as diabetes, or a history of intraocular surgery that may affect the postoperative visual outcome.
Methods	Search limited to RCTs in PubMed, Medline, Embase and the Cochrane Central Register of Controlled Trials using the following search terms: cataract, multifocal, intraocular lenses and phacoemulsification. Restricted to English. Data collection Primary outcomes: postoperative uncorrected distance, intermediate and near visual acuity Secondary outcomes: spectacle independence Intervention Bilateral cataract surgery
Results	Postoperative uncorrected distance visual acuity

Full citation	**Xu X, Zhu M, Zou H. Refractive versus diffractive multifocal IOL in cataract surgery: A Meta-analysis of randomised controlled trials. J Cataract Refract Surg. 2014;30:634-644**

Study or Subgroup	Refractive Mean	SD	Total	Diffractive Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Alio 2011	0.12	0.13	35	0.134	0.115	41	12.9%	-0.01 [-0.07, 0.04]
Chiam 2007	0.025	0.055	50	0.064	0.059	50	30.0%	-0.04 [-0.06, -0.02]
Cillino 2008	0.06	0.129	31	0.173	0.106	32	12.1%	-0.11 [-0.17, -0.05]
Gil 2012	0.04	0.06	11	0.131	0.087	12	11.5%	-0.09 [-0.15, -0.03]
Martinez Palmer 2008	0.14	0.12	32	0.18	0.1	26	12.6%	-0.04 [-0.10, 0.02]
Mester 2007	0.675	0.126	24	0.69	0.144	23	7.9%	-0.01 [-0.09, 0.06]
Rasp 2012	0.11	0.11	30	0.144	0.104	27	13.0%	-0.03 [-0.09, 0.02]
Total (95% CI)			**213**			**211**	**100.0%**	**-0.05 [-0.07, -0.02]**

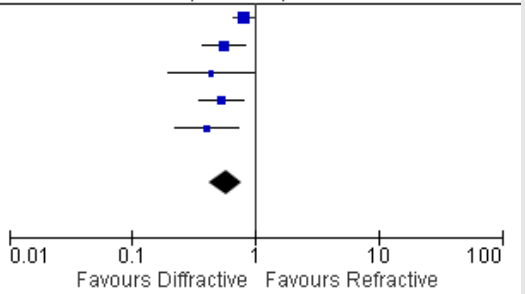
Heterogeneity: Tau² = 0.00; Chi² = 9.64, df = 6 (P = 0.14); I² = 38%
Test for overall effect: Z = 3.89 (P < 0.0001)



Postoperative spectacle independence

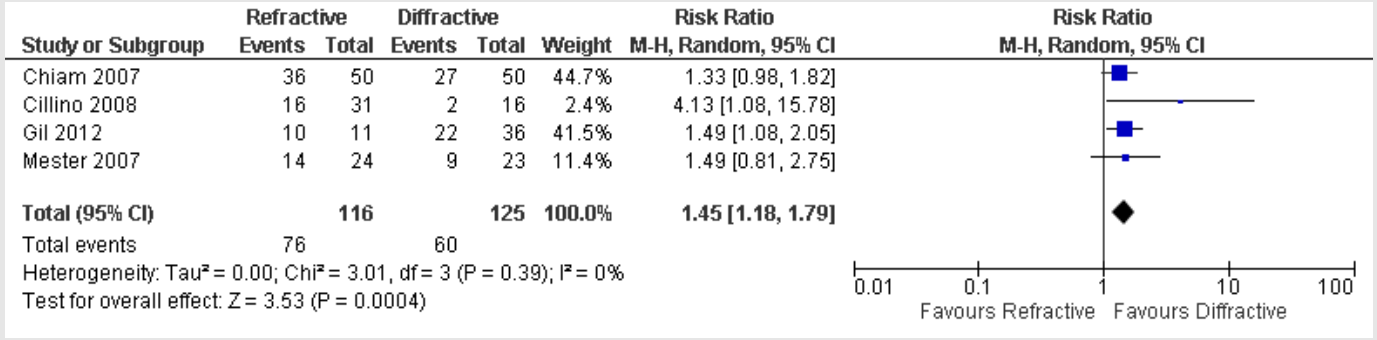
Study or Subgroup	Refractive Events	Total	Diffractive Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Chiam 2007	35	50	43	50	29.9%	0.81 [0.66, 1.01]
Cillino 2008	15	31	14	16	21.9%	0.55 [0.37, 0.83]
Gil 2012	4	11	30	36	10.8%	0.44 [0.20, 0.97]
Martinez Palmer 2008	14	32	48	58	21.9%	0.53 [0.35, 0.80]
Mester 2007	8	24	19	23	15.5%	0.40 [0.22, 0.73]
Total (95% CI)		**148**		**183**	**100.0%**	**0.57 [0.42, 0.78]**
Total events	76		154			

Heterogeneity: Tau² = 0.07; Chi² = 10.78, df = 4 (P = 0.03); I² = 63%
Test for overall effect: Z = 3.49 (P = 0.0005)

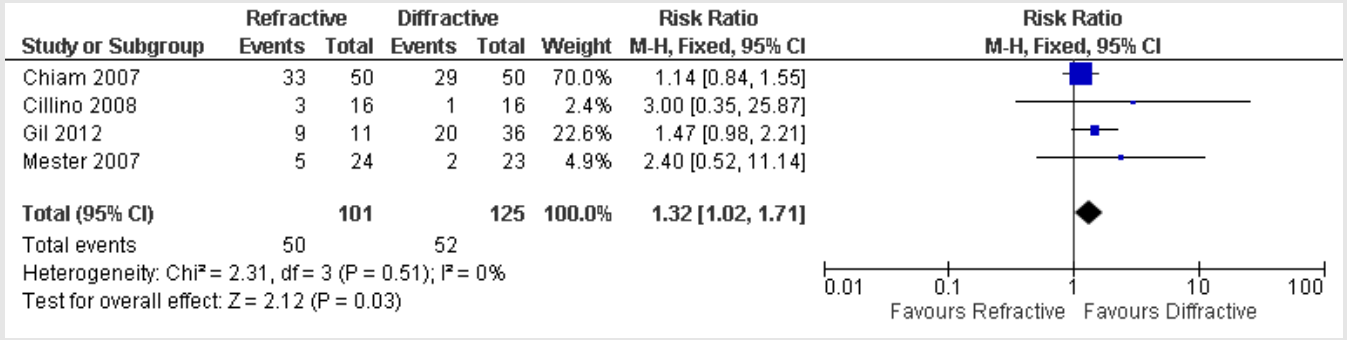


Postoperative Halo

Full citation	**Xu X, Zhu M, Zou H. Refractive versus diffractive multifocal IOL in cataract surgery: A Meta-analysis of randomised controlled trials. J Cataract Refract Surg. 2014;30:634-644**



Postoperative Glare



Outcomes	Refractive multifocal IOL group exhibited better uncorrected distance visual acuity than diffractive Diffractive multifocal IOL group exhibited better uncorrected near visual acuity, spectacle independence, halo and glare rate than diffractive No significant difference between the 2 groups in uncorrected intermediate visual acuity
Study appraisal using AMSTAR	1. Was an 'a priori' design provided? Yes 2. Was there duplicate study selection and data extraction? Yes 3. Was a comprehensive literature search performed? Yes 4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes 5. Was a list of studies (included and excluded) provided? Yes 6. Were the characteristics of the included studies provided? Yes

Full citation	**Xu X, Zhu M, Zou H. Refractive versus diffractive multifocal IOL in cataract surgery: A Meta-analysis of randomised controlled trials. J Cataract Refract Surg. 2014;30:634-644**
	7. Was the scientific quality of the included studies assessed and documented? Unclear 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Unclear 9. Were the methods used to combine the findings of studies appropriate? Yes 10. Was the likelihood of publication bias assessed? Unclear 11. Was the conflict of interest included? Unclear

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23E.4.4 Optimal strategy to address pre-existing astigmatism

Full citation	**Emesz M, Dexl A, Krall E, Bachernegg A et al. Randomized controlled clinical trial to evaluate different intraocular lenses for the surgical compression of low to moderate-to-high regular corneal astigmatism during cataract surgery. Journal of cataract refract surg. 2015;41:2683-2694**
Study details	Country/ies where the study was carried out: Austria Study type: RCT Aim of the study: To evaluate vector analysis, rotational stability and visual outcomes after implantation of low and moderate-to-high toric IOL's vs non-toric IOL's Study dates: Not reported Sources of funding: Fuchs Foundation for the promotion of Research in Ophthalmology. Alcon Inc. financially supports the Fuchs Foundation (Grant number 2010-37)
Participants	Sample size 39 patients (78 eyes) Inclusion criteria Bilateral senile cataract and pre-existing regular topographic corneal astigmatism demanding a toric IOL implantation with cylindric values between 1.5 diopters (D) and 6.0 D Exclusion criteria Pregnancy, lactation, irregular corneal astigmatism, diabetic retinopathy, iris neovascularization, congenital eye abnormality, glaucoma, pseudo exfoliation syndrome, amblyopia, uveitis, long-term anti-inflammatory treatment, advanced age-related macular degeneration, retinal detachment, previous ocular surgery, severe corneal and retinal disease, and history of eye trauma.
Methods	Consecutive patients had binocular randomised implantation of a non toric IOL, a low toric IOL, or a medium-to-high toric IOL after phacoemulsification. Patients received the same IOL type in both eyes. Data collection UDVA, CDVA and refractive astigmatism were measured preoperatively and postoperatively (1 day and 6 weeks) Intervention Cataract surgery Analysis Bonferroni procedure
Results	Visual and refractive outcomes

Parameter	Pre-op Mean ± SD	6 weeks postop Mean ± SD	P value, pre-op to 6 weeks postop (Bonferroni)	P value, LT group (≤2.25D), MHT group (≥3.0D) and non toric group 6 weeks postop (Bonferroni)

Full citation	Emesz M, Dexl A, Krall E, Bachernegg A et al. Randomized controlled clinical trial to evaluate different intraocular lenses for the surgical compression of low to moderate-to-high regular corneal astigmatism during cataract surgery. Journal of cataract refract surg. 2015;41:2683-2694				
	UDVA (logMAR)				
	LT IOL group	0.90 ± 0.35	0.02 ± 0.08	0.000	MHT vs LT = 0.753
	MHT IOL group	0.84 ± 0.45	0.06 ± 0.13	0.000	MHT vs NonT = 0.001
	Non toric IOL group	0.70 ± 0.37	0.2 ± 0.18	0.000	LT vs NonT = 0.000
	CDVA (logMAR)				
	LT IOL group	0.26 ± 0.18	-0.02 ± 0.07	0.000	MHT vs LT = 0.365
	MHT IOL group	0.26 ± 0.19	0.02 ± 0.13	0.000	MHT vs NonT = 1.0
	Non toric IOL group	0.35 ± 0.25	0.03 ± 0.10	0.000	LT vs NonT = 0.163
	Refractive cylinder (D)				
	LT IOL group	1.45 ± 1.18	0.36 ± 0.44	0.000	MHT vs LT = 1.0
	MHT IOL group	1.92 ± 1.09	0.31 ± 0.46	0.000	MHT vs NonT = 0.000
	Non toric IOL group	0.97 ± 0.89	1.13 ± 0.93	0.469	LT vs NonT = 0.000
Outcomes	Significant increase in UDVA in all 3 groups No difference between toric groups but low-toric and medium-to-high toric IOL patients achieved significantly better UDVA than non toric Significant increase in CDVA in all 3 groups No statistically significant difference in CDVA between toric groups Mean refractive astigmatism reduced significantly in both toric groups but did not show any significant changes in patients with nontoric IOLs				
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Yes 3 Were the patients, health workers and study personnel blinded? Unsure 4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for sat its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A				

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<table>
<tr><th>Full citation</th><th>Kaufmann C, Peter J, Ooi K et al. Limbal relaxing incisions versus on-axis incisions to reduce corneal astigmatism at the time of cataract surgery. Journal of cataract refract surg. 2005;31:2261-2265</th></tr>
<tr><td>Study details</td><td>Country/ies where the study was carried out: Australia
Study type: RCT
Aim of the study: To compare limbal relaxing incisions with placement of the corneal incision on the steepest keratometric axis for the reduction of pre-existing astigmatism.
Study dates: Not reported
Sources of funding: None reported</td></tr>
<tr><td>Participants</td><td>Sample size
71 patients (71 eyes)
Inclusion criteria
Patients having 1.5 D or more keratometric astigmatism in a healthy corneal.
Exclusion criteria
Previous corneal or anterior segment surgery, previous corneal trauma, irregular astigmatism and a cataract unsuitable for phacoemulsification.</td></tr>
<tr><td>Methods</td><td>Patients were randomised by a 2 stage randomisation process (no details reported of the process)
Data collection
Refractive astigmatism were measured preoperatively and 6 months postoperatively
Intervention
Cataract surgery (limbal relaxing incisions vs on-axis incisions)
Analysis
Mann-Whitney U test</td></tr>
<tr><td>Results</td><td>Treatment analysis 6 months postoperatively. Data represents median and interquartile range
<table>
<tr><th>Parameter</th><th>Limbal relaxing incisions (LRI)</th><th>On-axis incisions (OAI)</th><th>Significance level (Mann-Whitney U)</th></tr>
<tr><td>Postoperative cylinder (D)</td><td>1.5 (1.00 to 2.25)</td><td>1.75 (1.00 to 2.75)</td><td>0.298</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>Post-operative astigmatism was non-significantly lower with the LRI technique.</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Unsure
3 Were the patients, health workers and study personnel blinded? Unsure
4 Were the groups similar at the start of the trial? Yes</td></tr>
</table>

Full citation	**Kaufmann C, Peter J, Ooi K et al. Limbal relaxing incisions versus on-axis incisions to reduce corneal astigmatism at the time of cataract surgery. Journal of cataract refract surg. 2005;31:2261-2265**
skills programme)	5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for sat its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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Full citation	**Kessel L, Andresen J, Tendal B, et al. Toric Intraocular Lenses in the correction of Astigmatism during cataract surgery. Ophthalmology. 2016;123:275-286**
Study details	Country/ies where the study was carried out: USA Study type: Systematic review Aim of the study: To evaluate the benefit and harms associated with implantation of toric intraocular lenses (IOLs) during cataract surgery. Study dates: Literature search undertaken on 26 August 2015 Sources of funding: Not reported
Participants	Sample size 13 RCT studies Inclusion criteria Eligibility criteria were randomized controlled clinical trials comparing the result after toric versus non-toric IOL implantation in patients with preoperative regular corneal astigmatism and cataract. Exclusion criteria References that reported only on outcome after toric IOL implantation in patients with corneal ectasia, such as keratoconus, or marginal pellucid degenerations were excluded.
Methods	Systematic literature search conducted in the Embase, PubMed.gov, and Cochrane Central Library databases using the search term: (((((cataract) AND surgery) AND toric iol)) OR (((cataract) AND surgery) AND toric intraocular lens)) OR (((cataract) AND surgery) AND toric intraocular lens). References of relevant reviews and eligible articles were retrieved and data was extracted and risk of bias assessed from each eligible study by 2 investigators working independently. GRADE was undertaken for each included study.
Results	Uncorrected distance visual acuity (UCDVA) of Toric vs non-toric intraocular lens

Full citation	**Kessel L, Andresen J, Tendal B, et al. Toric Intraocular Lenses in the correction of Astigmatism during cataract surgery. Ophthalmology. 2016;123:275-286**

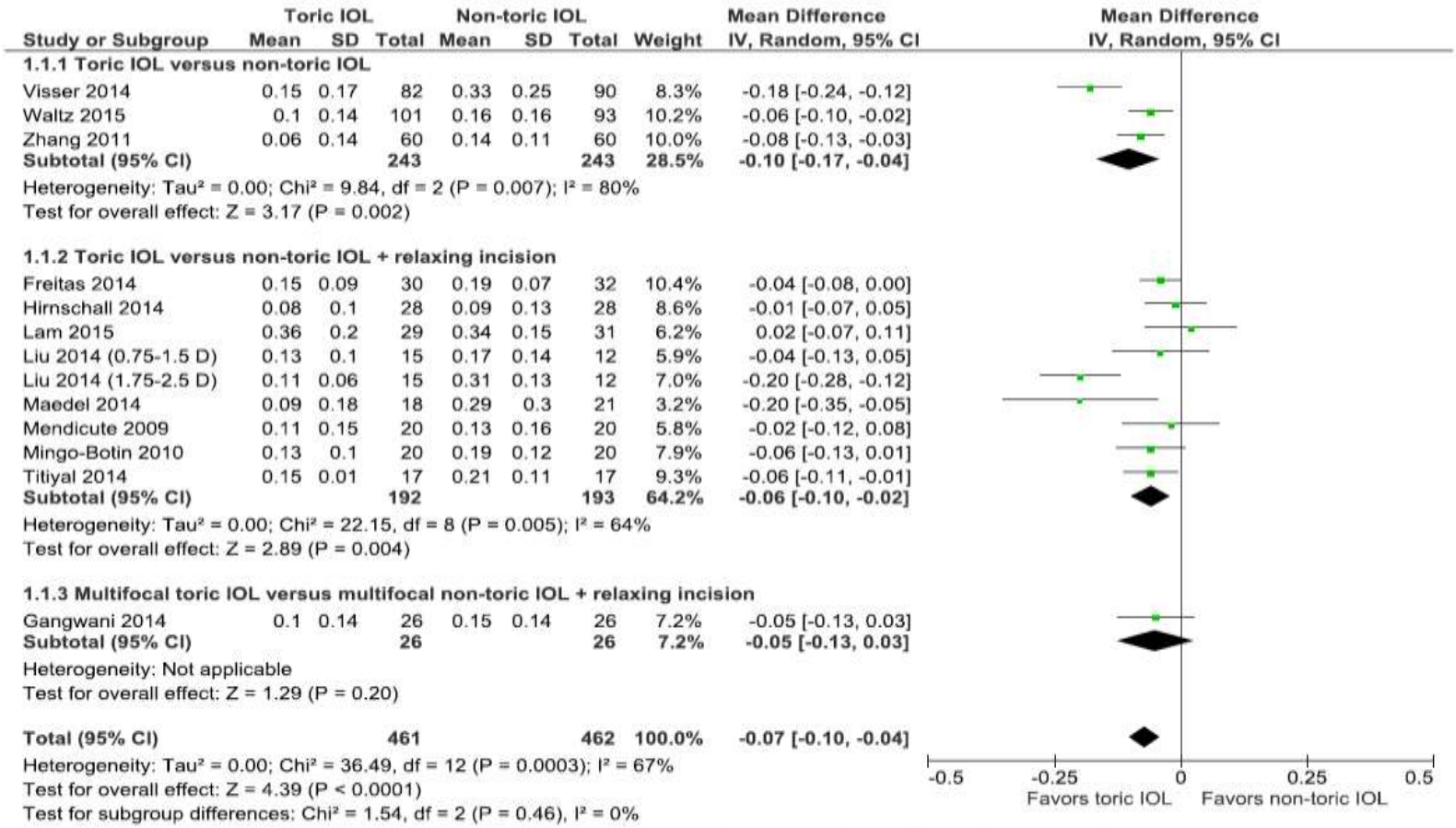

Figure 1. Forest plot comparing uncorrected distance visual acuity (UCDVA) in eyes randomized to implantation with a toric or non-toric intraocular lens (IOL). Visual acuity was 0.07 logarithm of the minimum angle of resolution (logMAR) better in the toric group compared with the non-toric groups. CI = confidence interval; IV = inverse variance; SD = standard deviation.

Residual astigmatism in people with Toric vs non-toric intraocular lens

Full citation	**Kessel L, Andresen J, Tendal B, et al. Toric Intraocular Lenses in the correction of Astigmatism during cataract surgery. Ophthalmology. 2016;123:275-286**

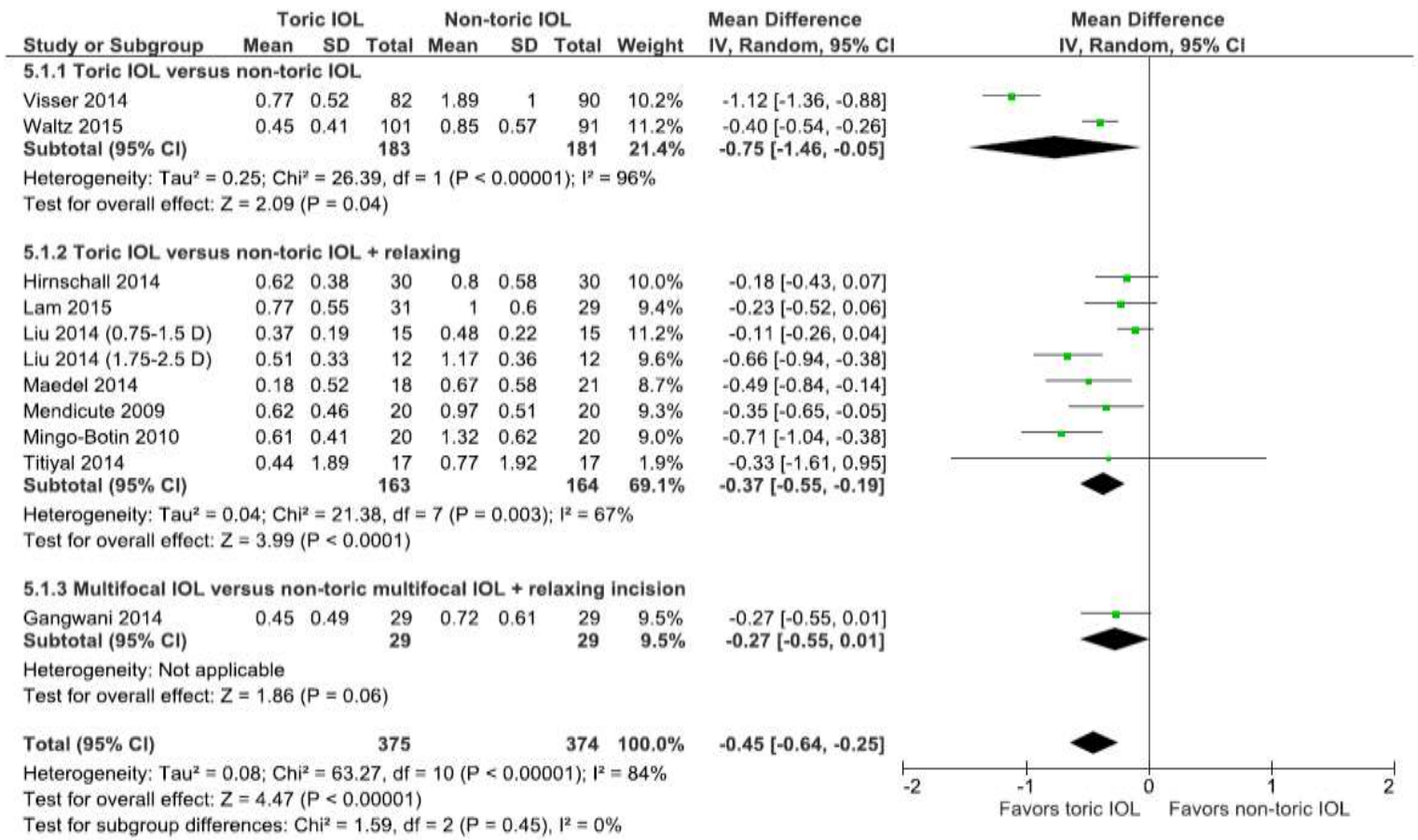

Figure 5. Forest plot demonstrating the residual astigmatism in patients randomized to toric or non-toric IOL implantation. Residual astigmatism was on average 0.5 diopters (D) lower in the toric group. CI = confidence interval; IOL = intraocular lens; IV = inverse variance; SD = standard deviation.

Full citation	**Kessel L, Andresen J, Tendal B, et al. Toric Intraocular Lenses in the correction of Astigmatism during cataract surgery. Ophthalmology. 2016;123:275-286**

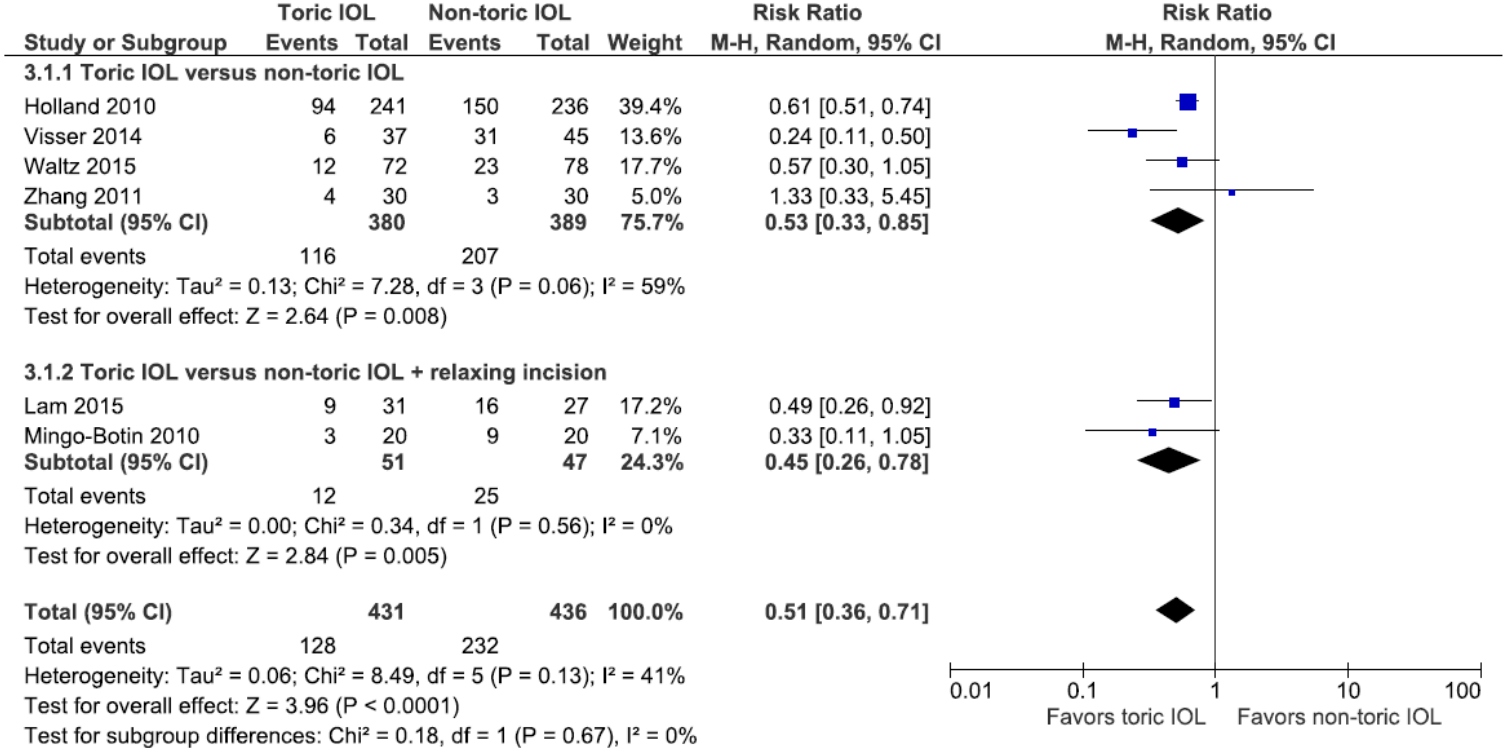

Figure 3. Forest plot showing the number of patients who reported that they required spectacles for distance viewing, as well as the RRs for needing spectacles for distance viewing. Spectacle independence was significantly greater in the toric group. CI = confidence interval; IOL = intraocular lens; M-H = Mantel–Haenszel.

Outcomes	High-quality evidence that UCDVA was better in the toric IOL group [logMAR] mean difference, -0.07; 95% confidence interval [CI], -0.10 to -0.04) Residual astigmatism was lower in the toric IOL group than in the non-toric IOL plus relaxing incision group (mean difference, 0.37 dioptres [D]; 95% CI, -0.55 to -0.19). The number of patients who required spectacles for distance viewing was significantly lower in patients randomized to toric IOL implantation (29.7%) than in patients randomized to non-toric IOL implantation (53.2%) (RR, 0.51; 95% CI, 0.36-0.71)

Full citation	**Kessel L, Andresen J, Tendal B, et al. Toric Intraocular Lenses in the correction of Astigmatism during cataract surgery. Ophthalmology. 2016;123:275-286**
Study Appraisal using AMSTAR (Assessing the Methodological Quality of Systematic Reviews)	1. Was an 'a priori' design provided? Yes 2. Was there duplicate study selection and data extraction? Yes 3. Was a comprehensive literature search performed? Yes 4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes 5. Was a list of studies (included and excluded) provided? Yes 6. Were the characteristics of the included studies provided? Yes 7. Was the scientific quality of the included studies assessed and documented? Unclear 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Unclear 9. Were the methods used to combine the findings of studies appropriate? Yes 10. Was the likelihood of publication bias assessed? Unclear 11. Was the conflict of interest included? Unclear

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Full citation	**Leon P, Pastore M, Zanei A, Umari I et al. Correction of low corneal astigmatism in cataract surgery. International Journal of Ophthalmology. 2015;8(4):719-724**
Study details	Country/ies where the study was carried out: Italy Study type: RCT Aim of the study: To evaluate and compare aspheric toric intraocular lens (IOL) implantation and aspheric monofocal IOL implantation with limbal relaxing incisions (LRI) to manage low corneal astigmatism (1.0-2.0 D) in cataract surgery. Study dates: Between January and June 2013 Sources of funding: None stated – co conflicts of interest
Participants	Sample size 102 patients (102 eyes) Inclusion criteria Significant cataract (II-IV group LOCS III The Lens Opacities Classification System III [21]), regular corneal astigmatism (1.0-2.0 D), with-the-rule (WTR) astigmatism, mean axial length 23-24 mm 依0.81, regular and symmetric astigmatism shape at the corneal topographic map, regular and WTR astigmatism of the posterior corneal surface, pharmacologic mydriasis >6.00 mm diameter to allow intraoperative and postoperative visualization of axis marks on the toric IOLs. Exclusion criteria

<table>
<tr><th>Full citation</th><td>Leon P, Pastore M, Zanei A, Umari I et al. Correction of low corneal astigmatism in cataract surgery. International Journal of Ophthalmology. 2015;8(4):719-724</td></tr>
<tr><td></td><td>Previous surgery in the eye under study, irregular astigmatisms of the anterior or the posterior corneal surfaces, against-the-rule (ATR) astigmatism, ocular diseases (pupil or zonular abnormalities, corneal scaring, uveitis, glaucoma, neuro-ophthalmic diseases, significant macular disease or other retinopathy).
Demographic and biometric data
<table>
<tr><td>Characteristics</td><td colspan="2">Groups</td><td>P value</td></tr>
<tr><td></td><td>LRI</td><td>Toric IOL</td><td></td></tr>
<tr><td>Age (range)</td><td>70.9±7.3 (62-88)</td><td>69.6±5.9 (53-85)</td><td>0.29</td></tr>
<tr><td>Sex (M/F)</td><td>22/28</td><td>26/26</td><td>-</td></tr>
<tr><td>Axial Length (mm)</td><td>22.90±1.15</td><td>23.04±0.97</td><td>0.13</td></tr>
</table></td></tr>
<tr><td>Methods</td><td>Patients were randomly assigned to one of the two treatments via computer. A randomized number was assigned to each patient before being randomly divided into two groups which received either toric IOL or monofocal IOL.
Data collection
Pre-operative and post-operative (1 day, 1 month, 3 months and 6 months) uncorrected distance visual acuity (UDVA) and best corrected visual acuity (BCVA) were measured.
Intervention
cataract surgery by phacoemulsification
Analysis
Wilcoxon, Mann-Whitney and t-test</td></tr>
<tr><td>Results</td><td>Preoperative and postoperative visual acuity (logMAR)
<table>
<tr><td>Groups</td><td>Preoperative</td><td colspan="4">Post-operative follow up</td><td>P value</td></tr>
<tr><td></td><td></td><td>1 day</td><td>1 month</td><td>3 month</td><td>6 month</td><td></td></tr>
<tr><td>Uncorrected visual acuity
Toric IOL
Limbal relaxing incisions
P value</td><td>
0.75±0.27
0.79±0.31
0.44</td><td>
0.28±0.15
0.32±0.19
0.28</td><td>
0.21±0.11
0.19±0.14
0.37</td><td>
0.18±0.14
0.23±0.09
<0.01</td><td>
0.15±0.08
0.22±0.12
<0.01</td><td>
<0.01
<0.01</td></tr>
<tr><td>Best corrected visual acuity
Toric IOL
Limbal relaxing incisions</td><td>
0.35±0.20
0.39±0.13</td><td>
0.15±0.12
0.22±0.14</td><td>
0.07±0.05</td><td>
0.05±0.03</td><td>
0.04±0.03</td><td>
<0.01
<0.01</td></tr>
</table></td></tr>
</table>

<table>
<tr><th>Full citation</th><td colspan="7">Leon P, Pastore M, Zanei A, Umari I et al. Correction of low corneal astigmatism in cataract surgery. International Journal of Ophthalmology. 2015;8(4):719-724</td></tr>
<tr><td></td><td colspan="7">
<table>
<tr><td>P value</td><td>0.59</td><td>0.72</td><td>0.07±0.6
0.64</td><td>0.07±0.0
6
0.87</td><td>0.05±0.0
4
0.83</td><td></td></tr>
</table>

Refractive astigmatism
<table>
<tr><td>Groups</td><td colspan="2">Pre-operative refractive cylinder (D) ±SD</td><td colspan="2">Post-operative at 6 months refractive cylinder (D) ±SD</td><td>P value</td></tr>
<tr><td></td><td>Sphere (D)</td><td>Cylinder (D)</td><td>Sphere</td><td>Cylinder (D)</td><td></td></tr>
<tr><td>Toric IOL</td><td>-1.95±1.37</td><td>1.59±0.52</td><td>-0.35±0.95</td><td>0.4±0.20</td><td>p<0.01</td></tr>
<tr><td>Limbal relaxing incisions</td><td>-1.80±1.42</td><td>1.91±0.63</td><td>-0.43±0.44</td><td>1.1±0.38</td><td>p<0.01</td></tr>
<tr><td>P value</td><td>n.s.</td><td>n.s.</td><td>n.s.</td><td>p<0.01</td><td></td></tr>
</table>
</td></tr>
<tr><td>Outcomes</td><td colspan="7">Both groups had a significant increase in UCVA and BCVA during the follow up period.
UCVA was statistically higher in the group with of the toric IOL’s compared to LRI, while BCVA did not demonstrate statistically significant differences between the both groups.
The refractive astigmatism variation from baseline were statistically significant (<0.01) in the two groups.
Both groups presented a reduction of the refractive astigmatism at the end of the follow-up resulting in 0.4 D ±0.20 for the toric group and 1.1 D ±0.38 for the LRI group (<0.01)</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td colspan="7">1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Yes
3 Were the patients, health workers and study personnel blinded? Unsure
4 Were the groups similar at the start of the trial? Yes
5 Aside from the experimental intervention, were the groups treated equally? Yes
6 Were all of the patients who entered the trial properly accounted for sat its conclusion? Yes
7 Can the results be applied to the local population? Yes
8 Were all clinically important outcomes considered? N/A</td></tr>
</table>

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<table>
<tr><th>Full citation</th><td>Ouchi M, Kinoshita S. Prospective randomised trial of limbal relaxing incisions combined with microincision cataract surgery. Journal of Cataract & Refractive Surgery 2010;26(8):594-599</td></tr>
<tr><td>Study details</td><td>Country/ies where the study was carried out: Japan
Study type: RCT
Aim of the study:
Study dates: Between September 2007 and July 2008
Sources of funding: None stated</td></tr>
<tr><td>Participants</td><td>Sample size
157 patients (189 eyes)
Inclusion criteria
Patients with ≥0.75 dioptres of keratometric astigmatism in the healthy cornea and a corticonuclear cataract of grade 3 to 4.
Exclusion criteria
Perioperative complications such as failure to place the IOL in the capsular bag, suturing of the wound and any complication necessitating enlargement of the incision or insertion of another IOL.</td></tr>
<tr><td>Methods</td><td>Patients were randomly assigned to one of the two groups by placing the patients ID numbers in an envelope. One group received cataract surgery with limbal relaxing incisions and the other cataract surgery without limbal relaxing incisions
Data collection
Pre-operative and post-operative (6 months) uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA) and cylindrical refraction in CDVA were measured.
Intervention
cataract surgery by phacoemulsification with and without limbal relaxing incisions
Analysis
2 sided paired t-test, Cravy vector analysis</td></tr>
<tr><td>Results</td><td>Mean postoperative results
<table>
<tr><td></td><td colspan="2">Mean ± SD (Range)</td><td></td></tr>
<tr><td>Parameter</td><td>LRI Group</td><td>Non-LRI Group</td><td>P value</td></tr>
<tr><td>UDVA (decimal converted from logMAR)</td><td>0.94±0.34 (0.4 to 1.5)</td><td>0.71±0.52 (0.08 to 1.5)</td><td>0.009</td></tr>
<tr><td>CDVA (decimal converted from logMAR)</td><td>1.12±0.30 (0.6 to 1.5)</td><td>1.18±0.31 (0.5 to 1.5)</td><td>0.53</td></tr>
<tr><td>Cylindrical refraction in CDVA</td><td>0.56±0.87 (0 to 1.75)</td><td>1.51±0.79 (0.75 to 3.00)</td><td>0.0004</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>Uncorrected distance visual acuity was significantly higher in the LRI group than the non-LRI group
No difference seen in CDVA in either group
Postoperative cylindrical error was significantly lower in the LRI group than in the non-LRI group</td></tr>
</table>

Full citation	**Ouchi M, Kinoshita S. Prospective randomised trial of limbal relaxing incisions combined with microincision cataract surgery. Journal of Cataract & Refractive Surgery 2010;26(8):594-599**
	Cravy analysis showed the vector change in cylinder was 1.44 D in the LRI group and 0.18 D in the non-LRI group (p=0.0007)
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Yes 3 Were the patients, health workers and study personnel blinded? Unsure 4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for sat its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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E.5 Wrong lens implant errors

- What are the procedural causes of wrong lens implant errors?
- What strategies should be adopted to reduce the risk of wrong lens implant errors?

Full citation	Kelly SP, Astbury NJ. Patient safety in cataract surgery. Eye 2006; 20(3):275-82
Study details	**Country/ies where the study was carried out:** UK (NHS) **Study type:** Qualitative review **Aim of the study:** To review patient safety issues relevant to cataract care. Causation and consequences of incidents in cataract surgery, with implications for policy, are discussed. **Study dates:** Partly informed by a focus group at the National Patient Safety Agency in Feb 2004 **Source of funding:** Not specified
Participants	**Sample size** Not specified **Inclusion criteria** Not specified **Exclusion criteria** Not specified **Baseline characteristics** Not specified
Methods	Models of accident causation from other domains were drawn on and empirically applied to cataract care. Consultation was undertaken with experts in cataract surgery, patient safety, and in risk management. Feedback on patient safety was included from presentations made to staff and patients and from personal insights.
Thematic analysis: causes of wrong lens implant errors	• Incorrect measurement of axial length. • Incorrect keratometry readings. • Data entry errors into the intraocular lens (IOL) calculation program or use of incorrect formulas. • Incorrect labelling or packaging of IOL by manufacturer. • Mistakes in providing the correct IOL, such as mix-ups with an IOL for another patient or not having the correct implant in stock on the day.
Thematic analysis: strategies to reduce the risk of wrong lens implant errors	No strategies specific to wrong lens implant errors are identified, although the authors note that “Adverse events relating to medical devices, medical device/user interface issues in England and Wales should be reported to the MHRA Devices Adverse Incident Centre (see www.mhra.gov.uk). The MHRA has been successful in improving designs or processes in many such matters. An annual report describes device related adverse incidents and how these were dealt with. Safety information from the MHRA is communicated to device users through Medical Device Alerts. All acute NHS Trusts have an MHRA Liaison Officer (usually located in the clinical risk department); he/she should be informed of all medication and device incidents.”

<table>
<tr><th>Full citation</th><td>Kelly SP, Jalil A. Wrong intraocular lens implant; learning from reported patient safety incidents. Eye 2011; 25(6):730-4</td></tr>
<tr><th>Study details</th><td>Country/ies where the study was carried out: England and Wales (NHS)
Study type: Thematic retrospective review of wrong intraocular lens (IOL) implantation incidents
Aim of the study: To consider wrong IOL implant events in cataract surgical care reported through a national incident reporting database. To propose potential solutions for such events where possible.
Study dates: 2003-2010
Source of funding: Not specified</td></tr>
<tr><th>Participants</th><td>Sample size 22,569 ophthalmic Patient Safety Incident (PSI) reports from England, 1289 from Wales. 164 cases identified as wrong IOL implantation incidents.
Inclusion criteria: All IOL related incidents reported in the National Patient Safety Agency (NPSA) National Reporting and Learning System database (NRLS)
Exclusion criteria: Ophthalmic PSI reports not relating to wrong IOL implantation.
Baseline characteristics: Not stated</td></tr>
<tr><th>Methods</th><td>Records identified through a keyword search using the terms; ‘cataract’, ‘dioptre’; ‘intraocular lens’, ‘IOL’, plus any of the following terms present in the same PSI report: ‘wrong’, ‘incorrect’, ‘error’. All selected records then sifted to ensure they related to IOL implant error. A thematic analysis of narrative detail contained in the selected reports is provided.</td></tr>
<tr><th>Thematic analysis: causes of wrong lens implant errors</th><td>“Broadly speaking, where a theme was discernible, safety issues include: problems obtaining accurate biometry; problems matching biometry to patients; problems matching correct IOL implant to correct patient and to laterality.”
“Patients’ details with the IOL power were written on the white board. However, either because of a change in surgical list order or otherwise, such details on whiteboards were not updated after the previous patient’s surgery, the wrong lens power was thus implanted.”
“Several errors occurred as a result of change in the order of the planned surgical list and mixing up of sequential patients and IOL powers”
“Several cases were because of biometry errors including use of incorrect biometry detail and including use of incorrect biometry formulae. Misfiling of biometry results in incorrect patient clinical records contributed to some such errors. Mixing of IOL powers for right and left eyes of patients and misidentification of correct patient at biometry visit examination also occurred. A biometry error attributed to failure to remove rigid contact lenses in adequate time before outpatient biometric examination was reported in one case. In several PSI reports, the wrong IOL had to be implanted because of depletion of IOL bank stock, with the correct IOL power not being available in stock on the day of elective surgery.”
“Other incidents occurred when cataract surgery was complicated by posterior capsular rupture and the IOL implant, which was implanted was of incorrect power.”
“Transcription confusions included mixing up handwritten IOL powers.”
“Technological, socio-organizational and team training factors have some role in IOL event causation”. Of the reports identified, the causal factors can categorised as:

<table>
<tr><th>Thematic Reasons for ‘Wrong’ IOL implantation</th><th>Number of reports</th></tr>
<tr><td>Inaccurate Biometry</td><td>29</td></tr>
</table>
</td></tr>
</table>

Full citation	**Kelly SP, Jalil A. Wrong intraocular lens implant; learning from reported patient safety incidents. Eye 2011; 25(6):730-4**
	Wrong IOL selection: 21 Transcription errors: 10 Handwriting misinterpretations: 7 Change in list order: 8 Right/left eye confusion: 5 Patient identification issues: 4 Misfiled biometry: 4 Wrong IOL written on theatre white board: 4 Optimal IOL power unavailable in stock: 3 Wrong IOL power implantation after complicated surgery: 3 Wrong patient notes: 2 Communication errors: 2 No causal reason documented.: 62 "Many incidents (n= 62) simply reported 'wrong IOL implantation'"
Thematic analysis: strategies to reduce the risk of wrong lens implant errors	• Follow best practice in capturing biometry and in IOL power calculations. • Only rely on biometry source documents. • Consider use of electronic patient records. • Reduce potential for handwriting misinterpretations of IOL powers. Write IOL power required clearly and in full. • Consider circling or highlighting the correct IOL power required on the source IOL calculation print out page. • Beware that abbreviation 'D' for dioptre and '-' for minus may confuse. • Avoid use of operating theatre 'white boards' for IOL powers selection. • Use of cataract pre-operative checklist (e.g. RCO & NPSA) and pre-operative 'time out'. • Ensure adequate stock of IOLs ranges is in place in operating department. • Follow patient safety guidance on cataract surgery (e.g. RCO)
Comments	**Other information:** Authors note that medical incidents tend to be underreported, that there are barriers to incident reporting, and that reporting is often nurse led. Root causation of IOL implant errors is problematic as PSI causation is not described in a standard format, or at all. Often free-text or anecdotal opinion. Severity of patient harms is self-declared by the reporter. Device related incidents (such as opaque IOLs) are reported to the MHRA and therefore don't appear in the database.

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Full citation	**Kelly SP, Steeples LR, Smith R, et al. Surgical checklist for cataract surgery: progress with the initiative by the Royal College of Ophthalmologists to improve patient safety. Eye 2013; 27(7):878-82**
Study details	**Country/ies where the study was carried out:** Survey respondents from England (75%), Scotland (11%), Wales (5%), Northern Ireland (2%), Republic of Ireland (1%) and Overseas (6%).

Full citation	**Kelly SP, Steeples LR, Smith R, et al. Surgical checklist for cataract surgery: progress with the initiative by the Royal College of Ophthalmologists to improve patient safety. Eye 2013; 27(7):878-82**
	Study type: Analysis of a survey of Royal College of Ophthalmologists (RCO) members **Aim of the study:** To ascertain the use of surgical checklists in cataract surgery in 2012 **Study dates:** 2012 **Source of funding:** Not specified
Participants	**Sample size** Electronic survey sent to 2856 RCO members. 46% completed the survey. 296 (60%) Consultant ophthalmologists, 133 (27%) trainees/fellows, 65 (13%) non-consultant career grade doctors. Overall response rate = 18% **Inclusion criteria:** Not stated **Exclusion criteria:** Not stated **Baseline characteristics:** Not stated.
Methods	College members were asked to respond anonymously to questions on surgical checklist and 'team-brief' use before cataract surgery. The questions included grade of the responder, the location of base hospital, and the type of checklist used. Surgeons were asked of their opinion on the value of a checklist, including whether they considered a checklist to be 'too time consuming'. Those not using a checklist were asked to detail their reasons for not doing so. Free text comments were also invited.
Thematic analysis: causes of wrong lens implant errors	None given
Thematic analysis: strategies to reduce the risk of wrong lens implant errors	"It is recognised that a large proportion of adverse clinical events is due to organisational or human behavioural factors. Although there is no evidence to date that use of a checklist has reduced the incidence of adverse events in cataract care, the use of a checklist has been associated with reduction of morbidity and mortality in other surgical areas." "Direct evaluation of the impact of a pre-operative checklist in cataract surgery is difficult, because significant avoidable adverse events occur infrequently" "The cataract patient checklist includes a 'time-out', which provides a vital final opportunity to check the patient, site, procedure, and the IOL required against source biometry documents before each operation." "Using a surgical checklist: **Advantages:** Increased patient and refractive outcome safety. Formal reminder to prompt thorough review before cataract surgery Alerts staff to higher risk cases Aids communication, especially when unfamiliar staff/environment **Disadvantages:**

Full citation	**Kelly SP, Steeples LR, Smith R, et al. Surgical checklist for cataract surgery: progress with the initiative by the Royal College of Ophthalmologists to improve patient safety. Eye 2013; 27(7):878-82**
	Risk of automated approach or 'box-ticking' exercise. Time consumption Repetitive questions and duplication of documentation, for example, care pathways The process may be performed after anaesthetic is given and is this too late to ask about equipment/IOL availability? **Personal experiences:** Introduction of a checklist has avoided 'near misses' 'Use of a checklist has become a good habit' and 'organises my thoughts prior to surgery' 'Once familiar with the format the time to perform the checklist reduces' Enhanced 'flow and 'good practice' 67% of cataract surgeons responded that they undertake a preoperative team briefing. 36% of surgeons reported using a locally designed checklist (modified from the RCO version)." "Checklist use is associated with reduced surgical morbidity and mortality, and positive impact on team working and non-technical skills, which are imperative to improving patient safety. We suggest further investigation of the impact of checklists in cataract surgery safety, particularly in relation to 'never events.'"
Comments	**Other information:** No survey of non-surgical members of cataract teams.

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Full citation	**Schein OD, Banta JT, Chen TC, et al. Lessons learned: wrong intraocular lens. Ophthalmology 2012; 119(10):2059-64**
Study details	**Country/ies where the study was carried out:** USA **Study type:** Retrospective small case series, convenience sample. **Aim of the study:** To report cases involving the placement of the wrong intraocular lens (IOL) at the time of cataract surgery where human error occurred. **Study dates:** 2012 **Source of funding:** None declared.
Participants	**Sample size** Seven surgical cases **Inclusion criteria:** Cases identified as relating to the implantation of a wrong IOL that resulted in a formal review or root cause analysis. **Exclusion criteria:** Not stated **Baseline characteristics:** Not stated.
Methods	An informal consortium of faculty responsible for quality and safety programs at their respective institutions was formed to discuss areas of common interest and concern. The faculty identified 7 cases related to the implantation of a wrong IOL. All cases shared the use of a multidisciplinary team approach to document the event, explore multiple possible contributing causes, and outline specific plans to reduce the likelihood of recurrence. These cases, their review, and resulting changes in clinical policy were summarized

Full citation	Schein OD, Banta JT, Chen TC, et al. Lessons learned: wrong intraocular lens. Ophthalmology 2012; 119(10):2059-64
Thematic analysis: causes of wrong lens implant errors	"Although not an exhaustive list, it is critical to recognize the multitude of potential causes for IOL selection errors, such as the following: 1. An IOL calculation sheet for a different patient with a similar or same name is in the medical record. 2. The previous patient's IOL is inserted. 3. The IOL power for the wrong eye is inserted. 4. The wrong IOL A-constant or formula is used in IOL calculations. 5. The surgeon misreads intended IOL power (e.g.,28.0 instead of 23.0). 6. The power for an ACIOL is selected instead of the intended PCIOL power. 7. The wrong IOL model is picked from IOL calculation sheet. 8. The axial length is confused with the IOL power on the printout. 9. The wrong IOL is chosen when multiple IOL types are present in the OR. 10. A minus is confused with a plus in choosing the target refraction or IOL power. 11. A transcription error is made when transferring data for keratometry or axial length data into IOL calculation software. 12. The patient specifically requests myopia or monovision, but the surgeon targets emmetropia. 13. The patient requested (and paid for) a different type of premium IOL than implanted. 14. The patient did not want a toric or presbyopia-correcting IOL, but one was implanted, or vice versa. 15. The requested special-order IOL was not available in the OR after lens extraction."
Thematic analysis: strategies to reduce the risk of wrong lens implant errors	"Although it is acknowledged that the most critical moments in preventing IOL error occur in the OR, it has become equally apparent that the path to IOL error often begins earlier. Errors, once committed, may be propagated downstream and may be more difficult to detect than to prevent in the first instance. "Quality-control efforts must begin at the time of initial measurement and decision for surgery. Because of some variability in practice and patient flow in clinics, preoperative holding areas, and staffing, there is not a single, rigid plan that is optimal for every setting. However, we were able to identify a set of common elements that we believe will minimize IOL errors. These may be summarized as follows: • A surgical plan regarding the type of IOL (e.g., spherical, toric, presbyopia correcting) and general refractive target (e.g., better for distance or near) should be documented in the medical record. • The intended IOL, in particular any special-order IOL, should be verified to be present in the OR before the patient is taken to the OR. • A patient label that contains name, medical record number, and date of birth is present on every IOL calculation printout. Each technician performing IOL calculations should use 2 patient identifiers (name and either date of birth or medical history number) to match the name on the IOL calculation printout to that of the specific patient. If additional calculations on a patient are subsequently requested, 2 patient identifiers are used to confirm that the correct patient has been accessed from the IOL database. • If the difference in axial length between the 2 eyes is >0.3 mm, we recommend that this difference be reconciled clinically by the surgeon or the measurement repeated. • If the axial length is measured by ultrasonography, or corneal power measured manually and then transcribed into an IOL calculation software, the data transcribed should be subsequently confirmed by a technician or the surgeon. The use of IOL order forms that require manual transcription from the IOL printout should be minimized. • If the IOL calculations are missing on the day of surgery, they should be transmitted to the OR properly labelled with name, date of birth, and medical record number before the patient enters the OR.

Full citation	Schein OD, Banta JT, Chen TC, et al. Lessons learned: wrong intraocular lens. Ophthalmology 2012; 119(10):2059-64
	• IOL verification on the day of surgery: The circulating nurse reviews the patient chart with the surgeon and confirms that the IOL calculation sheet matches the patient by name and date of birth or medical record number and that the IOL model and diopter power circled on the printout sheet and signed or initialled by the surgeon has been brought into the OR. Only the IOL for that one patient is brought into the OR. • The "time-out" in the OR that confirms the correct patient, procedure, and site occurs before the first incision. For patients who will be receiving an IOL, all 4 institutions participating in this review concur that an IOL-specific time-out is a necessity. However, there is variability across the institutions as to when this should take place. At one of our institutions, the IOL verification occurs as an integral component of the initial time-out before the first incision, and the intended IOL in its sterile package is typically placed on the Mayo stand in real time. That institution's logic for its timing is that if a concern regarding the IOL is to be discovered, it would rather see that conflict resolved before the incision, rather than have to do so in the middle of surgery. At the other institutions, a separate IOL time-out is held just before the insertion, with the logic that the closer in time the IOL time-out is to the actual insertion, the better. For all 4 institutions, the components of the verification include a matching (visual and auditory) of the patient's name and date of birth (or medical record number) as recorded on the consent form with that on the label of the IOL printout. If a change in IOL is requested intraoperatively, the surgeon and circulating nurse will repeat the IOL verification procedure. • Only the IOL for the patient currently undergoing surgery is present in the OR; any unused IOL is removed from the OR after each case." "The last moment before IOL implantation in the OR is crucial, but often is not the optimal time to prevent errors whose roots begin elsewhere, such as transcription errors occurring in clinic or at scheduling. Improving processes and their accuracy before the day of surgery will reduce errors. However, the final verification steps on the day of surgery will always remain paramount as the last, if not the best, way to prevent the implantation of a wrong IOL."

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Full citation	Steeples LR, Hingorani M, Flanagan D, et al. Wrong intraocular lens events – what lessons have we learned? A review of incidents reported to the National Reporting and Learning System: 2010-2014 versus 2003-10. Eye 2016; 30:1049-55
Study details	**Country/ies where the study was carried out:** United Kingdom **Study type:** Retrospective review of the National Reporting and Learning System (NRLS) **Aim of the study:** To identify the causal factors in wrong IOL events and to compare with similar historical data **Study dates:** 2010-2014 **Source of funding:** Not specified
Participants	**Sample size** 178 wrongs IOL implantation events. **Inclusion criteria:** Wrong lens implantation after cataract surgery between 1 February 2010 and 31 May 2014 **Exclusion criteria:** Not stated **Baseline characteristics:** Not stated.

Full citation	**Steeples LR, Hingorani M, Flanagan D, et al. Wrong intraocular lens events – what lessons have we learned? A review of incidents reported to the National Reporting and Learning System: 2010-2014 versus 2003-10. Eye 2016; 30:1049-55**
Methods	Data were retrospectively extracted and analysed from IOL incident reports. Data were thematically analysed to identify the major reasons for errors. The timing of detection, management and the level of harm reported were also reviewed. These data were compared to similar IOL incident historical data, from the period 2003-2010, extracted and analysed using the same method.
Thematic analysis: causes of wrong lens implant errors	• Checklist procedure failing to recognise non-matched patient and data including incorrect notes or incorrect biometry with patient. • Transcribing IOL selection onto white boards, theatre list and paper notes and not checking intraoperatively with source documents. • Writing lens selection on whiteboard for the next case during an on-going operation. • Failure to refer to source documents. • Surgeon selecting IOL from memory and ignoring notes. • Unclear handwriting or notation of plus/minus status of lens power. • Stockpiling lenses for all cases on the list in theatre. • Not challenging surgeon despite concerns about IOL selected. • Undermining or ignoring established safety procedures and protocols.
Thematic analysis: strategies to reduce the risk of wrong lens implant errors	• Consistent checks and no assumptions: three-stage approach to the sign in, time out, and sign out checks:9,31 (i) identity and document check; (ii) eye (left or right) check and (iii) IOL check (power, type, and model) repeated at each stage. Specifically check all documents, especially biometry data matches the patient and operated eye at each stage. • IOL selection: always refer to source biometry and clinical documents during IOL checks at each stage listed above. Any unusual powers or models or negative powers voiced during the 'team brief' and 'time out' stages. Always check the selection is made using the correct formula, A-constant and pertains to correct eye. • Transcriptions: to avoid mistakes and cascading of errors: (i) no writing of multiple IOL selections onto white boards or theatre lists and the transcription should always be matched to a single patient and their identifying data; (ii) any minus lens powers clearly denoted by the word 'minus' and (iii) transcription onto only locally agreed IOL selection sheets (paper or electronic) and clear handwriting is crucial. • Avoid re-selection during procedure: availability of the selected IOL always confirmed before patient enters theatre and the start of procedure. • Lens collection: (i) IOL only selected from the lens bank once staff and surgeon have confirmed the selection, (ii) only one IOL in theatre with the patient and where the lens bank is in the theatre for a single lens to be selected and removed as suggested and be positioned in a selected place as per local protocol away from the lens bank (no stockpiling). • Change: if change in list order or procedure, entire team pause and repeat brief. If change in staffing during list/procedure: pause, repeat brief, and if new staff involved in IOL selection or collection repeat checks. • Re-selection: if need to reselect different IOL during the procedure: entire team pauses, remove the original IOL from theatre, and repeat process for selection of lens including identity, eye, and IOL check. • Challenge and check: staff encouraged and allowed to challenge any issues, concerns or inconsistencies regarding IOL selection immediately. • Simulation training: scenario-based team training exercises to learn local checklist protocol, improve repeatability, develop non-technical skills and aid recognition of common mistakes (see Table 2 for possible scenarios).

Full citation	**Steeples LR, Hingorani M, Flanagan D, et al. Wrong intraocular lens events – what lessons have we learned? A review of incidents reported to the National Reporting and Learning System: 2010-2014 versus 2003-10. Eye 2016; 30:1049-55**
Comments	**Study conclusion:** What was known before: • Wrong IOL implantation is a serious patient safety incident and is defined by NHS England as a 'never event'. • Learning from patient safety incidents and failures, through incident reporting, causal analysis, and dissemination for wider learning, is a core process for improving patient care quality. What this study adds: • Despite the introduction of surgical checklists and major patient safety initiatives, wrong IOL incidents continue to occur and are probably under-reported. • Human or behavioural factors remain heavily implicated in wrong IOL incidents and need to be addressed through further training and we suggest the importance of simulation training. • Recommendations of important principles to adhere to are provided

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Full citation	**Zamir E, Beresova-Creese K, Miln L. Intraocular lens confusions: a preventable "never event" – the Royal Victorian Eye and Ear Hospital protocol. Survey of Ophthalmology 2012; 57(5):430-447**
Study details	**Country/ies where the study was carried out:** Australia **Study type:** Review of introduced clinical protocol **Aim of the study:** To describe the implementation of an error-detection protocol and provide qualitative data on its performance **Study dates:** 2007-2010 **Source of funding:** Public research funding only
Participants	**Sample size** 14 IOL events and near misses, together with an evaluation of the introduction of the protocol **Inclusion criteria:** All cataract surgery taking place in the hospital over the study period **Exclusion criteria:** Not stated **Baseline characteristics:** Not stated.
Methods	The Royal Victorian Eye and Ear Hospital protocol consists of: • Dual, independent selection of IOLs • Structured preoperative UIOL preparation • A structured in-operating room IOL pathway
Thematic analysis: causes of wrong lens	• Transcription errors • Misfiling of biometry results • Patient's misidentified • Depletion of IOL stock • Incorrectly labelled IOLs

Full citation	**Zamir E, Beresova-Creese K, Miln L. Intraocular lens confusions: a preventable "never event" – the Royal Victorian Eye and Ear Hospital protocol. Survey of Ophthalmology 2012; 57(5):430-447**
implant errors	• Failure to check IOL specifications and patient records
Thematic analysis: strategies to reduce the risk of wrong lens implant errors	10 of the 11 identified IOL errors were regarded as preventable if the full developed protocol had been followed. The specific features of the protocol identified as potentially preventing errors were: • Dual, independent IOL selection • Vernal confirmation that the required IOL is present before any invasive anaesthetic steps are allowed • IOL boxes should not be labelled with patient identification labels • A defined in-operating room IOL pathway, with a surgical "time-out" where the IOL present in the operating room is compared to the IOL selection, confirming the patient's identity, the correct IOL is present and the orthoptist's and surgeon's IOL choices are within 0.5 dioptres
Comments	**Study conclusion:** What was known before: • Wrong IOL implantation is a serious patient safety incident and is defined by NHS England as a 'never event'. • Learning from patient safety incidents and failures, through incident reporting, causal analysis, and dissemination for wider learning, is a core process for improving patient care quality. What this study adds: • Despite the introduction of surgical checklists and major patient safety initiatives, wrong IOL incidents continue to occur and are probably under-reported. • Human or behavioural factors remain heavily implicated in wrong IOL incidents and need to be addressed through further training and we suggest the importance of simulation training. • Recommendations of important principles to adhere to are provided

E.6 Surgical timing and technique

- What is the effectiveness of laser-assisted phacoemulsification cataract surgery compared with standard ultrasound phacoemulsification cataract surgery?
- What is the effectiveness of bilateral simultaneous (rapid sequential) cataract surgery compared with unilateral eye surgery?
- What is the appropriate timing of second eye surgery, taking into account issues such as refractive power after first eye surgery?

E.6.1 Laser-assisted cataract surgery

The evidence tables in this section were produced by the Cochrane Eyes and Vision Group, as part of a collaboration with the NICE Internal Clinical Guidelines Team.

Reference	**Conrad-Hengerer I, Al Juburi M, Schultz T, Hengerer FH, Dick HB. Corneal endothelial cell loss and corneal thickness in conventional compared with femtosecond laser-assisted cataract surgery: three-month follow-up. Journal of Cataract and Refractive Surgery 2013; 39(9):1307-13.**
Methods	Within-person (paired-eye) RCT
Participants	Number of participants randomised: 75 Number of eyes included: 150 Country: Germany Average age: 71 years Sex: 63% female Ethnic group: not described Inclusion criteria: "All patients enrolled had a visually significant cataract, dilated pupil width of 6.0 mm or larger, and were willing to volunteer for the trial after giving informed consent." Exclusion criteria: "The exclusion criteria included a history of serious coexisting ocular disease, uncontrolled glaucoma, optic atrophy or ocular tumours, use of topical or systemic steroids or nonsteroidal anti-inflammatory drugs (NSAIDs) during the previous 3 months, relevant corneal opacities, poorly dilating pupils (pupil % 6.0 mm), known zonular weakness, age less than 22 years, or participation in another clinical study."
Interventions	Laser assisted cataract surgery using the Catalys platform (Catalys Precision Laser System, AMO) or manual phacoemulsification using a Stellaris phaco machine (Bausch & Lomb).
Outcomes	Primary outcome measures: Corneal endothelial cell loss and corneal thickness at up to 3 months. Additional data reported: effective phacoemulsification time, mean irrigation fluid volume, mean surgical time, intra- and postoperative complications.
Notes	Funding source: not reported Declaration of interest: "Dr. Dick is a member of the medical advisory board of Optimedica Corp."

Reference	Conrad-Hengerer I, Al Juburi M, Schultz T, Hengerer FH, Dick HB. Corneal endothelial cell loss and corneal thickness in conventional compared with femtosecond laser-assisted cataract surgery: three-month follow-up. Journal of Cataract and Refractive Surgery 2013; 39(9):1307-13.
	Date study conducted; February 2012 to July 2012 Trial registration number: not reported

263 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The method of sequence generation is not described.
Allocation concealment (selection bias)	Unclear risk	"The surgeon opened the corresponding envelope, receiving information about the procedure to use in each eye; that is, femtosecond laser– assisted or standard phacoemulsification."
Blinding of participants and personnel (performance bias)	Unclear risk	Surgeon masking is not feasible, no efforts to mask participants are described.
Blinding of outcome assessment (detection bias)	Low risk	"All patients had a full clinical examination by the same masked trained technician."
Incomplete outcome data (attrition bias)	Low risk	"Two patients were excluded at the 3-month follow-up because they missed their previous visits. One patient had cancer and was not available for further visits; the other moved to another county."
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry (trial was not registered).
Other bias	High risk	The contact author is on the medical advisory board for the company that makes the Catalys platform evaluated in this study.

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Reference	Conrad-Hengerer I, Hengerer FH, Al Juburi M, Schultz T, Dick HB. Femtosecond laser-induced macular changes and anterior segment inflammation in cataract surgery. Journal of Cataract and Refractive Surgery 2014; 30(4):222-6.
Methods	Within-person (paired-eye) RCT randomised controlled trial
Participants	Number of participants randomised: 104 Number of eyes included: 208 Country: Germany Average age: 71 years

Reference	Conrad-Hengerer I, Hengerer FH, Al Juburi M, Schultz T, Dick HB. Femtosecond laser-induced macular changes and anterior segment inflammation in cataract surgery. Journal of Cataract and Refractive Surgery 2014; 30(4):222-6.
	Sex: 56% female Ethnic group: not described Inclusion criteria: only the exclusion criteria below are given. Exclusion criteria: "history of coexistent ocular disease (e.g. glaucoma, high myopia, retinal diseases affecting the macula, optic atrophy, or ocular tumours), use of topical or systemic steroids or nonsteroidal anti-inflammatory drugs during the prior 3 months, relevant corneal opacities, age younger than 22 years, or participation in another clinical study. "
Interventions	Laser assisted cataract surgery using the Catalys platform (Catalys Precision Laser System, AMO) or manual phacoemulsification using a Stellaris phaco machine (Bausch & Lomb).
Outcomes	Primary outcome measures: laser flare counts and changes in macular thickness and volume. Secondary outcome measures: absolute and effective phacoemulsification time; and intraoperative and postoperative complications. Follow-up was 6 months postoperatively.
Notes	Funding source: not reported. Declaration of interest: "Dr. Dick was a member of the medical advisory board of OptiMedica. The remaining authors have no financial or proprietary interest in the materials presented herein." Date study conducted; March 2012 to October 2012 Trial registration number: not reported

265 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The method of sequence generation is not described.
Allocation concealment (selection bias)	Unclear risk	"After positioning the patient on the operating bed, the surgeon opened the corresponding envelope indicating which procedure to choose (ie, femtosecond laser-assisted or standard phacoemulsification)."
Blinding of participants and personnel (performance bias)	Unclear risk	Surgeon masking is not feasible, no efforts to mask participants are described.
Blinding of outcome assessment (detection bias)	Unclear risk	No masking of the outcome assessment is described.

Bias	Authors' judgement	Support for judgement
Incomplete outcome data (attrition bias)	Low risk	"Two hundred two eyes (97%) were included and analysed at 6 months postoperatively." No further information is given.
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry (trial was not registered).
Other bias	High risk	The contact author is on the medical advisory board for the company that makes the Catalys platform evaluated in this study.

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Reference	Conrad-Hengerer I, Al Sheikh M, Hengerer FH, Schultz T, Dick HB. Comparison of visual recovery and refractive stability between femtosecond laser-assisted cataract surgery and standard phacoemulsification: Six-month follow-up. Journal of Cataract and Refractive Surgery 2015; 41(7):1356-64.
Methods	Within-person (paired-eye) RCT
Participants	Number of participants randomised: 100 Number of eyes included: 200 Country: Germany Average age: 72 years Sex: 56% female Ethnic group: not described Inclusion criteria: "a potential corrected visual acuity of 0.8 (20/25) in both eyes." Exclusion criteria: "amblyopia, a history of serious coexistent ocular disease (e.g. pseudoexfoliation, uncontrolled glaucoma, macular pathologies, high myopia, or hyperopia, defined as an axial length [AL] <21.5mm or >27.5 mm), corneal astigmatism of more than 1.5 diopters (D), optic atrophy, ocular tumours, use of topical or systemic steroids or nonsteroidal anti-inflammatory drugs during the previous 3 months, relevant corneal opacities, Fuchs dystrophy, cornea guttata, an age younger than 22 years, and participation in another clinical study. Furthermore, a dilated pupil of at least 6.0 mm preoperatively was necessary."
Interventions	Laser assisted cataract surgery using the Catalys platform to produce capsulotomy and lens fragmentation; or manual phacoemulsification cataract surgery.
Outcomes	"Primary outcome measures were early and late corrected distance visual acuity (CDVA) and the deviation from the target refraction using the spherical equivalent (SE) refraction. Secondary outcome measures were anterior chamber depth (ACD) and keratometry values."
Notes	Funding source: not reported

Reference	Conrad-Hengerer I, Al Sheikh M, Hengerer FH, Schultz T, Dick HB. Comparison of visual recovery and refractive stability between femtosecond laser-assisted cataract surgery and standard phacoemulsification: Six-month follow-up. Journal of Cataract and Refractive Surgery 2015; 41(7):1356-64.
	Declaration of interest: "Dr. Dick is a member of the medical advisory board of Abbott Medical Optics, Inc. No other author has a financial or proprietary interest in any material or method mentioned." Date study conducted; not reported Trial registration number: not reported

267 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The method of sequence generation is not described.
Allocation concealment (selection bias)	Unclear risk	"After placing the patient on the laser system's operating bed, the surgeon opened the corresponding envelope providing the information about which procedure to use; that is, femtosecond laser–assisted cataract surgery or regular phacoemulsification."
Blinding of participants and personnel (performance bias)	Unclear risk	Surgeon masking is not feasible, no efforts to mask participants are described.
Blinding of outcome assessment (detection bias)	Unclear risk	No masking of the outcome assessment is described.
Incomplete outcome data (attrition bias)	Low risk	"Six months postoperatively, 196 eyes were included and analysed." No further details are given.
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry (trial was not registered).
Other bias	High risk	Dr. Dick is a member of the medical advisory board of Abbott Medical Optics, Inc. No other author has a financial or proprietary interest in any material or method mentioned.

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Reference	Dick HB, Conrad-Hengerer I, Schultz T. Intraindividual capsular bag shrinkage comparing standard and laser-assisted cataract surgery. Journal of Refractive Surgery 2014; 30(4):228-33.
Methods	Within-person (paired-eye) RCT
Participants	Number of participants randomised: 53 Number of eyes included: 106

Reference	Dick HB, Conrad-Hengerer I, Schultz T. Intraindividual capsular bag shrinkage comparing standard and laser-assisted cataract surgery. Journal of Refractive Surgery 2014; 30(4):228-33.
	Country: Germany Average age: 71 years old Sex: 57% female Ethnic group: not described Inclusion criteria: "a visually significant cataract (corrected distance visual acuity <20/25) in both eyes, dilated pupil width of 6.0 mm or greater, and were willing to volunteer for the trial after giving an informed consent." Exclusion criteria: "included corneal scars, corneal diseases, corneal astigmatism of 1.5 dioptres or greater, reduced endothelial cells, glaucoma, pseudoexfoliation syndrome, zonular weakness, single eye, malformations, history of ocular surgery, intraocular tumours, active or past inflammations, age-related macular degeneration, diabetic retinopathy, axial length difference (greater than 0.5 mm and less than 21.5 mm or greater than 26 mm), pregnancy, reduced compliance, age younger than 22 years, or participation in another clinical study. "
Interventions	Laser assisted cataract surgery using the Catalys platform (Catalys Precision Laser System, AMO) or manual phacoemulsification using a Stellaris phaco machine (Bausch & Lomb).
Outcomes	Primary outcome measures: absolute capsular bag diameters and intra-individual difference in millimetres. Additional data reported: phacoemulsification energy used. Follow-up was 3 months.
Notes	Funding source: not reported. Declaration of interest: "The authors have no financial or proprietary interest in the materials presented herein." Date study conducted; not reported Trial registration number: not reported

269 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The method of sequence generation is not described.
Allocation concealment (selection bias)	Unclear risk	"For randomization, the patient was placed on the operating bed of the laser system and a corresponding envelope with the information about the receiving procedure was opened by the surgeon."
Blinding of participants and personnel (performance bias)	Unclear risk	Surgeon masking is not feasible for the study methodology described.
Blinding of outcome assessment (detection bias)	Low risk	"All slit-lamp measurements were done by a single trained technician who was blinded to the surgical technique."

Bias	Authors' judgement	Support for judgement
Incomplete outcome data (attrition bias)	Low risk	All patients were included in the 3 month follow up.
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry (trial was not registered).
Other bias	Low risk	"The authors have no financial or proprietary interest in the materials presented herein."

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Reference	**Filkorn T, Kovács I, Takács A, Horváth E, Knorz MC, Nagy ZZ. Comparison of IOL power calculation and refractive outcome after laser refractive cataract surgery with a femtosecond laser versus conventional phacoemulsification. Journal of Refractive Surgery 2012; 28(8):540-44.**
Methods	Parallel-group RCT
Participants	Number of participants randomised: 134 (77 laser arm, 57 control arm). Number of eyes included: 134 (77 laser arm, 57 control arm) Country: Hungary Average age: 65 years laser arm, 64 years control arm Ethnic group: not described Inclusion criteria: not described Inclusion criteria: previous ocular surgery, corneal diseases such as keratoconus, known zonular weakness, corneal astigmatism 3.00 dioptres (D), anterior capsule tear, posterior capsule rupture, severe macular disease, and amblyopia.
Interventions	Surgical intervention: Laser assisted cataract surgery using the LenSx (Alcon Laboratories Inc) or manual phacoemulsification (Accurus, Alcon Laboratories Inc).
Outcomes	IOL power calculation, visual and refractive outcomes.
Notes	Funding source: not reported. Declaration of interest: "Drs Knorz and Nagy are consultants to Alcon LenSx Inc. All remaining authors have no financial interest in the materials presented herein." Date study conducted: not reported Trial registration number: not reported

271 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Patients were randomly assigned to each group using a computer randomisation chart.
Allocation concealment (selection bias)	Unclear risk	The method of allocation concealment is not described.
Blinding of participants and personnel (performance bias)	Unclear risk	Surgeon masking is not feasible for the study methodology described. No masking of participants is described.
Blinding of outcome assessment (detection bias)	Unclear risk	No masking of the outcome assessment is described.
Incomplete outcome data (attrition bias)	Low risk	Based on the number of patients/eyes reported in figure 2, there was no loss to follow up.
Selective reporting (reporting bias)	Unclear risk	"Patients with CDVA 20/40 or worse were excluded (one patient in each group) to avoid errors in manifest refraction." No access to study protocol or trials registry entry (trial was not registered).
Other bias	High risk	Two of the study authors are consultants for the manufacturer of the LenSx platform evaluated in this study.

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Reference	**Hida WT, Chaves MA, Gonçalves MR, Tzeliks PF, Nakano CT, Motta AF, et al. Comparison between femtosecond laser capsulotomy and manual continuous curvilinear digital image guided capsulorrhexis [Comparação entre capsulotomia assistida por laser de femtossegundoe capsulorrexe curvilínea contínua guiada por imagem digita]. Revista Brasileira de Oftalmologia 2014; 73(6):329-34.**
Methods	Parallel-group RCT
Participants	Number of participants randomised: 80 (40 laser arm, 40 control arm) Number of eyes included: 80 (40 laser arm, 40 control arm) Country: Brazil Average age: 67 years laser arm, 65 years control arm Ethnic group: not described Inclusion criteria: not described Exclusion criteria: not described
Interventions	Surgical intervention: Laser assisted cataract surgery using the LenSx (Alcon Laboratories Inc) or manual phacoemulsification (phacoemulsification system not described).

Reference	Hida WT, Chaves MA, Gonçalves MR, Tzeliks PF, Nakano CT, Motta AF, et al. Comparison between femtosecond laser capsulotomy and manual continuous curvilinear digital image guided capsulorrhexis [Comparação entre capsulotomia assistida por laser de femtossegundoe capsulorrexe curvilínea contínua guiada por imagem digita]. Revista Brasileira de Oftalmologia 2014; 73(6):329-34.
Outcomes	Capsulotomy/capsulorhexis circularity and postoperative spherical equivalent.
Notes	Funding source: not reported. Declaration of interest: "The authors declare no conflicts of interest." Date study conducted; October 2013 to January 2014 Trial registration number: not reported

273 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The method of sequence generation is not described.
Allocation concealment (selection bias)	Unclear risk	The method of allocation concealment is not described.
Blinding of participants and personnel (performance bias)	Unclear risk	Surgeon masking is not feasible for the study methodology described. No masking of participants is described.
Blinding of outcome assessment (detection bias)	Unclear risk	No masking of the outcome assessment is described.
Incomplete outcome data (attrition bias)	Unclear risk	There is no reporting of reporting of data attrition to permit judgment.
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry (trial was not registered).
Other bias	Low risk	"The authors declare no conflicts of interest."

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Reference	Kovács I, Kránitz K, Sándor GL, Knorz MC, Donnenfeld ED, Nuijts RM, et al. The effect of femtosecond laser capsulotomy on the development of posterior capsule opacification. Journal of Refractive Surgery 2014; 30(3):154-8.
Methods	Parallel-group RCT
Participants	Number of participants randomised: 79 (40 laser arm, 39 control arm) Number of eyes included: 79 (40 laser arm, 39 control arm) Country: Hungary Average age: 66 years laser arm, 69 years control arm

Reference	Kovács I, Kránitz K, Sándor GL, Knorz MC, Donnenfeld ED, Nuijts RM, et al. The effect of femtosecond laser capsulotomy on the development of posterior capsule opacification. Journal of Refractive Surgery 2014; 30(3):154-8.
	Sex: 70% female laser arm, 74% female control arm Ethnic group: not described Inclusion criteria: only exclusion criteria are given. Exclusion criteria: "previous ocular surgery, trauma, active ocular disease (e.g. pseudo-exfoliation syndrome and uveitis), poorly dilated pupils, or known zonular weakness "
Interventions	Surgical intervention: Laser assisted cataract surgery using the LenSx (Alcon Laboratories, Inc.) or manual phacoemulsification using the Infinity Vision System (Alcon Laboratories, Inc.)
Outcomes	Subgroup analysis of previous RCT (no further data on this given). Primary outcome measure: quantification of posterior capsule opacification at 18-26 months postoperatively. Additional data: intraocular lens tilt and decentration.
Notes	"All patients from a previous prospective, randomised study on femtosecond laser surgery with a minimum follow-up time of 18 months were identified in our database and their data were processed for further statistical analyses." No publication reference is given for the original RCT. Funding source: not reported. Declaration of interest: "Drs. Nagy, Donnenfeld, and Knorz are consultants of LenSx Lasers, Inc. The remaining authors have no financial or proprietary interest in the materials presented herein. " Date study conducted; not reported Trial registration number: not reported

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Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The method of sequence generation is not described. Patients included were those with a minimum follow-up time of 18 months from a previous RCT.
Allocation concealment (selection bias)	Unclear risk	The method of allocation concealment is not described.
Blinding of participants and personnel (performance bias)	Unclear risk	Surgeon masking is not feasible for the study methodology described. No masking of participants is described.
Blinding of outcome assessment (detection bias)	Low risk	Masking of the outcome assessment is described.
Incomplete outcome data (attrition bias)	Unclear risk	There is no reporting of reporting of data attrition to permit judgment.
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry (trial was not registered).

Bias	Authors' judgement	Support for judgement
Other bias	High risk	Three of the study authors are consultants for the manufacturer of the LenSx platform evaluated in this study.

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Reference	Kránitz K, Miháltz K, Sándor GL, Takacs A, Knorz MC, Nagy ZZ. Intraocular lens tilt and decentration measured by Scheimpflug camera following manual or femtosecond laser-created continuous circular capsulotomy. Journal of Refractive Surgery 2012; 28(4):259-63.
Methods	Parallel-group RCT
Participants	Number of participants randomised: 45 (20 laser arm, 25 control arm) Number of eyes included: 45 (20 laser arm, 25 control arm) Country: Hungary Average age: 64 years laser arm, 68 years control arm Sex: 75% female laser arm, 92% female control arm Ethnic group: not described Inclusion criteria: only exclusion criteria are given. Exclusion criteria: "Patients with previous ocular surgery, trauma, active ocular disease, poorly dilated pupils, or known zonular weakness were excluded from the study."
Interventions	Surgical intervention: Laser assisted cataract surgery using the LenSx (Alcon Laboratories, Inc.) or manual phacoemulsification using the Accurus phacoemulsification machine (Alcon Laboratories, Inc.)
Outcomes	Intraocular lens decentration and tilt, Refraction, UDVA and CDVA.
Notes	Funding source: not reported. Declaration of interest: "Drs Knorz and Nagy are consultants to Alcon LenSx Inc. The remaining authors have no financial interest in the materials presented herein." Date study conducted; not reported Trial registration number: not reported

277 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization was done using computer-generated tables.
Allocation concealment (selection bias)	Unclear risk	Randomization was done using computer-generated tables.

Bias	Authors' judgement	Support for judgement
Blinding of participants and personnel (performance bias)	Unclear risk	Surgeon masking is not feasible for the study methodology described. No masking of participants is described.
Blinding of outcome assessment (detection bias)	Unclear risk	No masking of the outcome assessment is described.
Incomplete outcome data (attrition bias)	Unclear risk	There is no reporting of reporting of data attrition to permit judgment.
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry (trial was not registered).
Other bias	High risk	Two authors were consultants for the company that made the laser platform evaluated in this study.

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Reference	**Mastropasqua L, Toto L, Mastropasqua A, Vecchiarino L, Mastropasqua R, Pedrotti E, et al. Femtosecond laser versus manual clear corneal incision in cataract surgery. Journal of Refractive Surgery 2014; 30(1):27-33.**
Methods	Parallel-group RCT
Participants	Number of participants randomised: 60 Number of eyes included: 60 (right eyes) Country: Italy Average age: 70 years Sex: not described Ethnic group: not described Inclusion criteria: "age between 65 and 75 years, axial length between 23.0 and 24.0 mm, corneal astigmatism less than 2.00 diopters (D), nuclear cataract of grade 2 to 3 (nuclear opalescence 3/4) (Lens Opacities Classification System III), and corneal endothelial cell count greater than 1,200/mm " Exclusion criteria: "pathological alterations of the anterior segment (e.g. corneal opacities, keratoconus, chronic uveitis, zonular dialysis, pseudo-exfoliation syndrome, glaucoma, and diabetes mellitus), other ocular pathologies impairing visual function, previous anterior or posterior segment surgery, and intraoperative or postoperative complications "
Interventions	Surgical intervention: Laser assisted cataract surgery using the LenSx platform (Alcon Inc, Fort Worth, TX, USA) or manual phacoemulsification using the Alcon Constellation System (Alcon Laboratories, Inc.)
Outcomes	UDVA and CDVA (logMAR), keratometric astigmatism, corneal endothelial cell count, corneal thickness at the incision site and higher order corneal aberrations. Follow-up was 6 months.

Reference	Mastropasqua L, Toto L, Mastropasqua A, Vecchiarino L, Mastropasqua R, Pedrotti E, et al. Femtosecond laser versus manual clear corneal incision in cataract surgery. Journal of Refractive Surgery 2014; 30(1):27-33.
Notes	Funding source: not reported. Declaration of interest: "The authors have no financial or proprietary interest in the materials presented herein." Date study conducted; not reported Trial registration number: not reported

279 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The method of sequence generation is not described.
Allocation concealment (selection bias)	Unclear risk	The method of allocation concealment is not described.
Blinding of participants and personnel (performance bias)	Unclear risk	Surgeon masking is not feasible for the study methodology described. No masking of participants is described.
Blinding of outcome assessment (detection bias)	Unclear risk	No masking of the outcome assessment is described.
Incomplete outcome data (attrition bias)	Low risk	Based on the number of eyes reported in figure 1, there was no loss to follow up.
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry (trial was not registered).
Other bias	Low risk	Trial conflict of interest disclosure: "The authors have no financial or proprietary interest in the materials presented herein."

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Reference	Mastropasqua L, Toto L, Mattei PA, Vecchiarino L, Mastropasqua A, Navarra R, et al. Optical coherence tomography and 3-dimensional confocal structured imaging system-guided femtosecond laser capsulotomy versus manual continuous curvilinear capsulorhexis. Journal of Cataract and Refractive Surgery 2014; 40(12):2035-43.
Methods	Parallel-group RCT
Participants	Number of participants randomised: 90 Number of eyes included: 90 Country: Italy Average age: 69 years

Reference	**Mastropasqua L, Toto L, Mattei PA, Vecchiarino L, Mastropasqua A, Navarra R, et al. Optical coherence tomography and 3-dimensional confocal structured imaging system-guided femtosecond laser capsulotomy versus manual continuous curvilinear capsulorhexis. Journal of Cataract and Refractive Surgery 2014; 40(12):2035-43.**
	Sex: not described Ethnic origin: not described Inclusion criteria: The inclusion criteria were age between 65 years and 75 years, nuclear cataract grade 3 to 4 (nuclear opalescence [NO] 3/4 on Lens Opacities Classification System III), and a corneal endothelial cell count greater than 1200 cells/mm2. Exclusion criteria: poor pupil dilation, pathology that could alter the anterior segment (e.g. corneal opacities, keratoconus, chronic uveitis, zonular dialysis, pseudo-exfoliation syndrome, glaucoma, diabetes), other ocular pathology that can impair visual function, previous anterior or posterior segment surgery, and intraoperative or postoperative complications.
Interventions	Participants were randomised to one of 3 treatments with equal probability for each group: a) Laser assisted cataract surgery using a Lensx femtosecond laser (Alcon Laboratories Inc); the capsulotomy, lens fragmentation and corneal incisions were performed using the femtosecond laser. b) Laser assisted cataract surgery using a Lensar femtosecond laser (Lensar Inc); the capsulotomy and lens fragmentation were performed using the femtosecond laser. c) Manual phacoemulsification.
Outcomes	Difference in the distance between the IOL centroid and the pupil centroid 180 days after surgery, visual parameters, refractive parameters, circularity, capsulorhexis area, IOL centroid–pupil centroid distance, and capsulorhexis centroid–pupil centroid distance).
Notes	Funding source not reported. Declaration of interest: "No author has a financial or proprietary interest in any material or method mentioned." Date study conducted; not reported Trial registration number: not reported

281 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A computer-generated, 6-block, 15-patient randomisation list was generated using an in-house closed-source software developed in Matlab 2009b. Patients were assigned to 1 of the 3 treatments with an equal probability for each group.

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	The method of allocation concealment is not described.
Blinding of participants and personnel (performance bias)	Unclear risk	The trial methodology states: "The surgeon and the operating room staff were aware of group assignment. The patients were masked to group assignment until the study was completed." However it is unclear how the patients could remain masked unless sham laser was performed, and there is no description of this.
Blinding of outcome assessment (detection bias)	Low risk	"Examiners performing preoperative and postoperative assessments were masked to group assignment until the study was completed."
Incomplete outcome data (attrition bias)	Low risk	Based on the results ("Each group comprised 30 eyes (30 patients)"), it would appear that no patients were lost to follow up.
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry (trial was not registered).
Other bias	Low risk	"Financial Disclosure: No author has a financial or proprietary interest in any material or method mentioned."

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Reference	Nagy ZZ, Kránitz K, Takacs AI, Miháltz K, Kovács I, Knorz MC. Comparison of intraocular lens decentration parameters after femtosecond and manual capsulotomies. Journal of Refractive Surgery 2011; 27(8):564-9.
Methods	Parallel-group RCT
Participants	Number of participants randomised: 105 (53 laser arm, 52 control arm) Number of eyes included: 111 (54 laser arm, 57 control arm) Country: Hungary Average age: 65 years old laser group, 68 years old control group. Sex: 72% female laser group, 70% female control group Ethnic group: not described Inclusion criteria: only exclusion criteria are given. Exclusion criteria: "Patients with previous ocular surgery, trauma, active ocular disease, poorly dilated pupils, or known zonular weakness were excluded from the study."
Interventions	Surgical intervention: Laser assisted cataract surgery using the LenSx (Alcon Laboratories, Inc.) or manual phacoemulsification using the Accurus phacoemulsification machine (Alcon Laboratories, Inc.)
Outcomes	Circularity and area of capsulotomy and IOL decentration

Reference	Nagy ZZ, Kránitz K, Takacs AI, Miháltz K, Kovács I, Knorz MC. Comparison of intraocular lens decentration parameters after femtosecond and manual capsulotomies. Journal of Refractive Surgery 2011; 27(8):564-9.
Notes	Funding source: not reported Declaration of interest: "Drs Nagy and Knorz are consultants to LenSx Lasers Inc. The remaining authors have no proprietary interest in the materials presented herein." Date study conducted; not reported Trial registration number: not reported

283 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Using computer randomisation, patients and their right/left eyes were randomly selected for femtosecond and manual surgery.
Allocation concealment (selection bias)	Unclear risk	Using computer randomisation, patients and their right/left eyes were randomly selected for femtosecond and manual surgery.
Blinding of participants and personnel (performance bias)	Unclear risk	Surgeon masking is not feasible for the study methodology described. No masking of participants is described.
Blinding of outcome assessment (detection bias)	Unclear risk	No masking of the outcome assessment is described.
Incomplete outcome data (attrition bias)	Unclear risk	There is no reporting of reporting of data attrition to permit judgment.
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry (trial was not registered).
Other bias	High risk	Two authors were consultants for the company that made the laser platform evaluated in this study.

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Reference	Nagy ZZ, Dunai A, Kránitz K, Takács AI, Sándor GL, Hécz R, et al. Evaluation of femtosecond laser-assisted and manual clear corneal incisions and their effect on surgically induced astigmatism and higher-order aberrations. Journal of Refractive Surgery 2014; 30(8):522-5.
Methods	Parallel-group RCT
Participants	Number of participants randomised: 40 (20 laser arm, 20 control arm) Number of eyes included: 40 (20 laser arm, 20 control arm) Country: Hungary Average age: 70 years laser group versus 62 years control group.

Reference	Nagy ZZ, Dunai A, Kránitz K, Takács AI, Sándor GL, Hécz R, et al. Evaluation of femtosecond laser-assisted and manual clear corneal incisions and their effect on surgically induced astigmatism and higher-order aberrations. Journal of Refractive Surgery 2014; 30(8):522-5.
	Sex: not described Ethnic group: not described Inclusion criteria: only exclusion criteria are given. Exclusion criteria: "previous ocular surgery, trauma, active ocular disease, poorly dilated pupils, or known zonular weakness were excluded."
Interventions	Surgical intervention: Laser assisted cataract surgery using the LenSx platform (Alcon Laboratories Inc) or manual phacoemulsification (platform not described).
Outcomes	Surgically induced astigmatism and corneal higher order aberrations. Additional data reported: intra- and postoperative complications. Follow-up was 3 months.
Notes	Funding source: not reported. Declaration of interest: "Dr. Nagy is a consultant for Alcon Laboratories, Inc. The remaining authors have no financial or proprietary interest in the materials presented herein." Date study conducted; not reported Trial registration number: not reported

285 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Randomization was done using computer-generated tables (Microsoft Excel; Microsoft Corporation, Redmond, WA)."
Allocation concealment (selection bias)	Unclear risk	The method of allocation concealment is not described.
Blinding of participants and personnel (performance bias)	Unclear risk	Surgeon masking is not feasible for the study methodology described. No masking of participants is described.
Blinding of outcome assessment (detection bias)	Unclear risk	No masking of the outcome assessment is described.
Incomplete outcome data (attrition bias)	Unclear risk	There is no reporting of reporting of data attrition to permit judgment.
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry (trial was not registered).
Other bias	High risk	The corresponding author is a consultant to the manufacturer of the LenSx platform evaluated in this study

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Reference	**Reddy KP, Kandulla J, Auffarth GU. Effectiveness and safety of femtosecond laser-assisted lens fragmentation and anterior capsulotomy versus the manual technique in cataract surgery. Journal of Cataract and Refractive Surgery 2013; 39(9):1297-306.**
Methods	Parallel-group RCT
Participants	Number of participants randomised: 131 Number of eyes: 131 Country: India Average age: 59 years laser arm, 61 control arm. Sex: 46% female laser arm, 41% female control arm. Ethnic group: not described. Inclusion criteria: Eligible patients were at least 18 years old with clear corneal media and elected to have routine cataract surgery." Exclusion criteria: Exclusion criteria for all patients: Poorly dilating pupil or other pupil defect that prevents iris from adequate retraction peripherally. Lens/ zonule instability such as, but not restricted to, Marfan syndrome, pseudoexfoliation syndrome. Previous intraocular or corneal surgery of any kind, including any kind of surgery for refractive or therapeutic purposes in either eye. Known sensitivity to planned concomitant medications. Disorders of the ocular muscle, such as nystagmus or strabismus. Keratoconus. Wound-healing disorders, such as connective tissue disease, autoimmune illnesses, immunodeficiency illnesses, ocular herpes zoster or simplex, endocrine diseases, lupus, rheumatoid arthritis. Abnormal examination results from slitlamp, fundus, partial coherence interferometry. Autoimmune disease, collagenosis, or clinically significant atopy. Pregnancy or nursing. Additional exclusion criteria for those having laser-assisted procedures: Minimal and maximal K values in central 3.0mm zone that do not differ by more than 5.0 diopters (D) on a keratometric map of the cornea. Maximal K-value that does not exceed 60.0D and minimum value that is smaller than 37.0D. Corneal disease or pathology that precludes transmission of laser wavelength or distortion of laser light.

Reference	Reddy KP, Kandulla J, Auffarth GU. Effectiveness and safety of femtosecond laser-assisted lens fragmentation and anterior capsulotomy versus the manual technique in cataract surgery. Journal of Cataract and Refractive Surgery 2013; 39(9):1297-306.
	Abnormal examination results from scanning-slit corneal topography. Anterior chamber depth <2.4mm or >4.5mm measured by ultrasonic examination. The study enrolled 131 patients (laser group, 64; manual group, 67).
Interventions	Surgical intervention: Laser assisted cataract surgery using the Victus platform (Bausch & Lomb Technolas) or manual phacoemulsification using the Stellaris Vision Enhancement System (Bausch & Lomb).
Outcomes	Primary outcome measure: effective phacoemulsification time. Secondary outcome measures: mean phacoemulsification energy, mean phacoemulsification time, volume of balanced salt solution, subjective surgeon assessment of ease of phacoemulsification. Additional data reported: capsulotomy comparisons, intraocular lens decentration, safety data including posterior capsule tear and iris damage. Follow-up was limited to 1 day postoperatively.
Notes	-Selective analysis performed and reported: "During the clinical trial, it became evident that the P values of all phaco- emulsification parameters (EPT, mean phaco energy, mean phaco time, and balanced salt solution volume) were both surgeon dependent and cataract grade dependent. Evaluation by the Mann-Whitney U test showed that median cataract grade between the 2 treatment groups was equal except for those operated on by 1 surgeon. To ensure equal cataract grade distributions in the 2 study groups to guarantee correct data analysis and rule out preoperative bias, 7 eyes in the laser-assisted group and 4 in the manual group were excluded from further analysis. This resulted in 56 eyes in the laser-assisted group and 63 in the manual group that had subsequent analysis." Funding source: not reported Declaration of interest: "Dr. Reddy has received travel and research grants from Technolas Perfect Vision GmbH, Dr. Kandulla is an employee of Technolas Perfect Vision GmbH (a Bausch & Lomb company), and Dr. Auffarth has received travel and research grants as well as lecture fees from Technolas Perfect Vision GmbH/Bausch & Lomb." Date study conducted; not reported Trial registration number: not reported

287 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Different exclusion criteria for study arms at baseline.
Blinding of participants and personnel (performance bias)	High risk	Not described other than "open-label"
Blinding of outcome assessment (detection bias)	High risk	Not described other than "open-label"
Incomplete outcome data (attrition bias)	High risk	"During the clinical trial, it became evident that the P values of all phacoemulsification parameters (EPT, mean phaco energy, mean phaco time, and balanced salt solution volume) were both surgeon dependent and cataract grade dependent. Evaluation by the Mann-Whitney U test showed that median cataract grade between the 2 treatment groups was equal except for those operated on by 1 surgeon. To ensure equal cataract grade distributions in the 2 study groups to guarantee correct data analysis and rule out preoperative bias, 7 eyes in the laser-assisted group and 4 in the manual group were excluded from further analysis. This resulted in 56 eyes in the laser-assisted group and 63 in the manual group that had subsequent analysis."
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry (trial was not registered).
Other bias	High risk	Different exclusion criteria for groups at baseline. Several study authors report financial relationships with the manufacturers of the Victus platform evaluated in this study.

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Reference	**Schargus M, Suckert N, Schultz T, Kakkassery V, Dick BH. Femtosecond laser-assisted cataract surgery without OVD: A prospective intraindividual comparison. Journal of Refractive Surgery 2015; 31(3):146-52.**
Methods	Within-person (paired-eye) RCT
Participants	Number of participants randomised: 37 Number of eyes included: 74 Country: Germany Average age: 72 years Sex: 59% female Ethnic group: not described

Reference	Schargus M, Suckert N, Schultz T, Kakkassery V, Dick BH. Femtosecond laser-assisted cataract surgery without OVD: A prospective intraindividual comparison. Journal of Refractive Surgery 2015; 31(3):146-52.
	Inclusion criteria: had a visually significant cataract (NC2 to NC5 on the Lens Opacities Classification System III [LOCS III]), corrected distance visual acuity (CDVA) decreased 0.1logMAR in both eyes, dilated pupil width of 6.0 mm or greater, and were willing to volunteer for the trial after giving informed consent. Exclusion criteria: corneal scars, corneal diseases, corneal astigmatism of 1.5 diopters or greater, reduced endothelial cell count (ECC) (less than 1,500 cells/mm²), CCT less than 500 µm, glaucoma, pseudoexfoliation syndrome, zonular weakness, single eye, malformations, history of ocular surgery, intraocular tumours, active or past inflammations, age-related macular degeneration, diabetic retinopathy, axial length difference (greater than 0.5 mm) and axial length less than 21.5 mm or greater than 26 mm, pregnancy, reduced compliance, age younger than 22 years, or participation in another clinical study within 30 days of the preoperative visit.
Interventions	Laser assisted cataract surgery using the Catalys platform (Catalys Precision Laser System, AMO) or manual phacoemulsification using a Stellaris phaco machine (Bausch & Lomb).
Outcomes	Primary outcome measure: endothelial cell count before surgery and 3 and 6 months postoperatively. Secondary outcome measurements included evaluation of corneal thickness, IOP, CDVA, overall surgery time, and quantity of fluid passing through the eye during surgery.
Notes	Funding source: not reported. Declaration of interest: "Dr Dick is a paid consultant for Abbott Medical Optics. The remaining authors have no financial or proprietary interest in the materials presented." Date study conducted; October 2012 to May 2013 Trial registration number: not reported

289 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Both treatment group allocations were printed on a separate sheet, which were sealed in sequentially numbered identical envelopes according to the randomised allocation sequence.
Allocation concealment (selection bias)	Low risk	The enclosed assignments were inserted into sequentially numbered, opaque, well-sealed envelopes for allocation concealment, which were continuously monitored. Investigators ensured that the envelopes were opened sequentially and only after the participant's name and other details were written on the appropriate envelope.
Blinding of participants and personnel (performance bias)	Unclear risk	Surgeon masking is not feasible for the study methodology described. No masking of participants is described.

Bias	Authors' judgement	Support for judgement
Blinding of outcome assessment (detection bias)	Unclear risk	No masking of the outcome assessment is described.
Incomplete outcome data (attrition bias)	Unclear risk	There is no reporting of reporting of data attrition to permit judgment.
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry (trial was not registered).
Other bias	High risk	The contact author is a paid consultant for the company that makes the Catalys platform evaluated in this study.

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Reference	**Takács AI, Kovács, I, Miháltz K, Filkorn T, Knorz MC, Nagy ZZ. Central corneal volume and endothelial cell count following femtosecond laser-assisted refractive cataract surgery compared to conventional phacoemulsification. Journal of Refractive Surgery 2012; 28(6):387-91.**
Methods	Parallel-group RCT
Participants	Number of participants randomised: 76 Number of eyes: 76 Country: Hungry Average age: 67 years laser arm, 67 years control arm. Sex: 74% female laser arm, 61% female manual phacoemulsification arm. Ethnic group: not described. Inclusion criteria: Only exclusion criteria stated. Exclusion criteria: "Patients showing low cooperation, dense (grade 4) or white cataract, corneal scars or opacities, anterior segment abnormalities, floppy iris syndrome, and poor pupillary dilation were not included in the study."
Interventions	Laser assisted cataract surgery using the LenSx femtosecond laser (Alcon Laboratories Inc) or manual phacoemulsification using the Alcon Infinity phacoemulsification system (Alcon Laboratories Inc).
Outcomes	Postoperative central corneal edema, endothelial cell count, and endothelial cell function expressed by VSI (volume stress index).
Notes	Funding source: not reported. Declaration of interest: "Drs Nagy and Knorz are consultants to Alcon LenSx Inc. The remaining authors have no financial interest in the materials presented herein."

Reference	Takács AI, Kovács, I, Miháltz K, Filkorn T, Knorz MC, Nagy ZZ. Central corneal volume and endothelial cell count following femtosecond laser-assisted refractive cataract surgery compared to conventional phacoemulsification. Journal of Refractive Surgery 2012; 28(6):387-91.
	Date study conducted; February 2010 to February 2011 Trial registration number: not reported

291 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Patients were randomly assigned (using computer randomisation) to either group by the surgeon (ZZN).
Allocation concealment (selection bias)	Unclear risk	No further details other than above.
Blinding of participants and personnel (performance bias)	Unclear risk	Surgeon masking is not feasible for the study methodology described. No masking of participants is described.
Blinding of outcome assessment (detection bias)	Low risk	Examiners were not aware of which surgical procedure had been used when performing the postoperative examinations.
Incomplete outcome data (attrition bias)	Unclear risk	There is no reporting of reporting of data attrition to permit judgment.
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry (trial was not registered).
Other bias	High risk	Two authors were consultants for the company that made the laser platform evaluated in this study.

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Reference	Yu AY, Ni LY, Wang QM, Huang F, Zhu SQ, Zheng LY, et al. Preliminary clinical investigation of cataract surgery with a noncontact femtosecond laser system. Lasers in Surgery and Medicine 2015; 47(9):698-703.
Methods	Parallel-group RCT
Participants	Number of participants randomised: 36 Number of eyes: 44 Country: China Average age: 62 years laser arm, 57 years control arm. Sex: not described. Ethnic group: not described. Inclusion criteria: Normal and transparent cornea; Pupillary diameter of at least 6mm under dilation; Preoperative best corrected visual acuity worse than LogMAR 0.3

Reference	Yu AY, Ni LY, Wang QM, Huang F, Zhu SQ, Zheng LY, et al. Preliminary clinical investigation of cataract surgery with a noncontact femtosecond laser system. Lasers in Surgery and Medicine 2015; 47(9):698-703.
	Exclusion criteria: No local or systematic contraindications for cataract surgery.
Interventions	Laser assisted cataract surgery using the LENSAR femtosecond laser or manual phacoemulsification using the Bausch & Lomb Stellaris system.
Outcomes	Phacoemulsification time, energy, and complications during operation were recorded. Postoperative refraction at 1 day, 1 week, 1 and 3 months, the capsulorhexis size and corneal endothelial density at 1 and 3 months were also measured.
Notes	Funding source: funded by the International Cooperation Project of the Science and Technology Bureau of Zhejiang province, China (Grant No. 2013C14010). Declaration of interest: "All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported." Date study conducted; October 2013 to November 2013 Trial registration number: not reported

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Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias)	Unclear risk	Surgeon masking is not feasible for the study methodology described. No masking of participants is described.
Blinding of outcome assessment (detection bias)	Unclear risk	Corneal endothelial cell density and capsulorhexis size were measured by a masked examiner. No masking of other outcomes is described.
Incomplete outcome data (attrition bias)	Unclear risk	There is no reporting of reporting of data attrition to permit judgment.
Selective reporting (reporting bias)	Unclear risk	No access to study protocol or trials registry entry (trial was not registered).
Other bias	Low risk	

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E.6.2 Bilateral surgery

E.6.2.1 Bilateral simultaneous versus unilateral cataract surgery

Full citation	**Lundström M, Albrecht S, Nilsson M, et al. Benefit to patients of bilateral same-day cataract extraction. Journal of Cataract and Refractive Surgery 2006 32:826-30**
Study details	**Country/ies where the study was carried out:** Sweden **Study type:** Randomised controlled trial **Aim of the study:** To compare patients' self-assessed visual function after bilateral surgery performed on the same day with visual function after surgery in 1 eye at a time, with a 2-month interval between the first-eye surgery and the second-eye surgery. **Study dates:** Not reported **Sources of funding:** Study was supported by the County Council of Blekinge. No conflicts of interest are reported.
Participants	**Sample size:** 96 people **Inclusion criteria:** • Cataract with need for surgery in both eyes. • No other sight-threatening eye diseases in either eye. • An axial length of 21 to 27mm. • The ability to speak Swedish. **Exclusion criteria:** • Surgical complications during first-eye surgery (rupture of the posterior capsule, vitreous loss, very prolonged surgery because of surgical difficulties). • General diseases that could affect the immune system/actual infection. **Baseline characteristics:**

	Immediate sequential cataract surgery	Delayed sequential cataract surgery
Number	50	46
Mean age (y)	72.5	72.5
Women (%)	54.0	54.3

Methods	**Pre-surgical examination:** • Performed by 1 of 2 experiences registered ophthalmic nurses and 1 of 2 experiences cataract surgeons. Surgery and follow-up examinations were performed by the same surgeon and ophthalmic nurse. • Slit lamp examination and funduscopy.

Full citation	**Lundström M, Albrecht S, Nilsson M, et al. Benefit to patients of bilateral same-day cataract extraction. Journal of Cataract and Refractive Surgery 2006 32:826-30**
	• Measurement of visual acuity, refraction, near vision, applanation tonometry, keratometry and axial length, contrast sensitivity and stereoscopic vision. • Performed by 1 of 2 experiences registered ophthalmic nurses and 1 of 2 experiences cataract surgeons. Surgery and follow-up examinations were performed by the same surgeon and ophthalmic nurse. **Interventions:** • Immediate sequential cataract surgery – Both operations performed on the same day. • Delayed sequential cataract surgery – An interval of 2 months between the surgeries. **Measurement:** • Visual examination repeated 2 months after the first surgery (after first-eye surgery in the DSCS group and both-eye surgery in the ISCS group) and 4 months after the last surgery in both groups. **Surgery:** • The pupil was usually dilated with eye drops (cyclopentolate and phenylephrine) administered at home by the patient before the surgery, topical anaesthesia (oxybuprocaine drops), a 2.75mm corneal or corneoscleral tunnel incision plus a second paracentesis, phacoemulsification with implantation of a foldable hydrophobic acrylic intraocular lens using an injector, and 1mg cefuroxime instilled intracamerally at the end of surgery; no stitches and no shield were used. • Outpatient surgery was performed in all cases. Postoperatively, patients were given steroid drops (dexamethasone) 3 times a day for 1 week and twice a day for the following 2 weeks. • In the case of ISCS, the patient stayed on the operating table while the nurse prepared a separate new set of surgical instruments, irrigating lines, and fluids, but using the same phacomachine. • The nurse and surgeon prepared for the second operation by re-sterilising their hands and re-gowning. **Study outcomes:** • Visual acuity • Contrast sensitivity • Stereoscopic vision (TNO test) • Difference in refraction between left and right eye • Total disability • Satisfaction with vision • Cataract symptoms • Car driving **Group comparisons:** Parametric (t-test) and non-parametric (U-test) tests.
Results	**Visual acuity before surgery and 2 and 4 months after surgery:**

Full citation	Lundström M, Albrecht S, Nilsson M, et al. Benefit to patients of bilateral same-day cataract extraction. Journal of Cataract and Refractive Surgery 2006 32:826-30

Examination	Right Eye			Left Eye		
	ISCS	DSCS	p value*	ISCS	DSCS	p value*
Median VA – before surgery	0.6	0.6	0.847	0.6	0.6	0.608
Median VA – after 2 months	1.0	0.8	<0.001	1.0	0.8	<0.001
Median VA – after 4 months	1.0	1.0	0.551	1.0	1.0	0.489
VA ≥ 0.8, % eyes – before surgery	26	19.6		36	26.1	
VA ≥ 0.8, % eyes – after 2 months	91.5	51.2		85.1	55.8	
VA ≥ 0.8, % eyes – after 4 months	91.3	97.3		91.3	97.2	

*Mann-Whitney U test

Other outcome measures:

Parameter	Before surgery			After 2 months			After 4 months		
	ISCS	DSCS	p value	ISCS	DSCS	p value	ISCS	DSCS	p value
Median contrast sensitivity	1.65	1.65	0.416[1]	1.95	1.65	<0.01[1]	1.95	1.80	0.070[1]
Median stereoscopic vision	120	120	0.787[1]	60	60	0.772[1]	60	60	0.864[1]
Mean difference in refraction between left and right eyes				0.57	1.66	<0.01[2]	0.53	0.57	0.676[2]
Total disability sum score	13.5	13.0	0.966[1]	8.0	11.0	<0.001[1]	7.0	7.0	0.481[1]
Satisfaction with vision	3.0	3.0	0.662[1]	1.0	2.0	<0.001[1]	1.0	1.0	0.441[1]
Cataract symptoms	4.0	4.0	0.919[1]	3.0	4.0	<0.001[1]	2.0	3.0	0.179[1]
Car driving	3.0	3.0	0.711[1]	2.0	2.0	0.053[1]	2.0	2.0	0.254[1]

[1]Mann-Whitney U test. [2]Student t test

Comments	Risk of bias:

Full citation	**Lundström M, Albrecht S, Nilsson M, et al. Benefit to patients of bilateral same-day cataract extraction. Journal of Cataract and Refractive Surgery 2006 32:826-30**
	• Method of randomisation not reported ("Patients were randomly assigned to ISCS or DSCS"). • Not possible to blind patients or clinicians to group allocation. • Blinding of outcome assessment not reported. • No comparison of characteristics of those who did and did not complete the study (dropout rate of 8.3%).

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Full citation	**Sarikkola A, Uusitalo RJ, Hellstedt T, et al. Simultaneous bilateral versus sequential bilateral cataract surgery: Helsinki Bilateral Cataract Surgery Study Report 1. Journal of Cataract and Refractive Surgery 2011 32:826-30**
Study details	**Country/ies where the study was carried out:** Finland **Study type:** Randomised controlled trial **Aim of the study:** To evaluate the refractive outcomes, complication rates, and changes in patients' functional state and satisfaction with simultaneous compared with sequential bilateral cataract surgery. **Study dates:** 1st May 2002 – 28th February 2005 **Sources of funding:** Eye and Tissue Bank Foundation, Eye Foundation, Evald and Hilda Nissi Foundation, Finnish Medical Foundation, Helsinki University Central Hospital Research Fund. No conflicts of interest were reported.
Participants	**Sample size:** 520 people **Inclusion criteria:** • Age ≥18 years. • Visually significant bilateral cataract. • CDVA in better eye ≤20/40; or CDVA >20/40 but VF-7 <70; or predictive postoperative anisometropia ≥2.0D and CDVA in the second eye ≤20/25. • Axial length 21.5-26.0mm and difference between eyes ≤1.5mm. • Phacoemulsification under topical anaesthesia with sedation is feasible. • Patient has an escort available in case randomised to same-day surgery **Exclusion criteria:** • Immunosuppressive disease or medication/increased risk of infection. • Increased risk of corneal oedema. • Eye, adnexal or anatomical abnormality that would interfere with surgery. • Previous refractive surgery.

Full citation	Sarikkola A, Uusitalo RJ, Hellstedt T, et al. Simultaneous bilateral versus sequential bilateral cataract surgery: Helsinki Bilateral Cataract Surgery Study Report 1. Journal of Cataract and Refractive Surgery 2011 32:826-30

- Previous perforating or severe blunt eye injury.
- Lens luxation or iridodonesis.
- Glaucoma or intraocular pressure >24mm Hg.
- Uncontrolled systemic hypertension.
- Iodine allergy.

Baseline characteristics:

Characteristic	Intervention group	Control group	p value
Age (mean)	75.3	75.0	0.65[1]
Age (median)	75.8	75.9	0.68[1]
Sex (% female)	73.6	74.3	0.85[2]
Social setting: living alone (%)	50.4	53.1	0.54[2]
CDVA (median)	20/60	20/60	0.15[3]
VF-7 (mean)	65.5	65.6	0.95[1]
VF-7 (median)	66.70	68.75	0.67[1]
CS-5 (mean)	4.9	4.8	0.75[3]
Overall trouble with vision (mean)	3.0	2.9	0.56[1]
Overall satisfaction with vision (mean)	2.9	2.9	0.60[1]
Intraocular pressure (mm Hg – mean)	16.4	16.7	0.18[1]
Intraocular pressure (mm Hg – median)	16	17	0.10[3]
Axial length (mm – mean)	23.2	23.3	0.03[1]
Axial length (mm – median)	23.1	23.1	0.13[3]
Nuclear cataract (%)	45.6	51.0	0.03[2]
Immature cataract (%)	90.8	89.7	0.69[2]

[1]Student t-test. [2]Chi-squared test. [3]Mann-Whitney U-test.

Methods	**Presurgical examination:**

Full citation	Sarikkola A, Uusitalo RJ, Hellstedt T, et al. Simultaneous bilateral versus sequential bilateral cataract surgery: Helsinki Bilateral Cataract Surgery Study Report 1. Journal of Cataract and Refractive Surgery 2011 32:826-30
	• A complete ocular assessment was performed preoperatively. • Biometry was performed using a partial optical coherence interferometer or A-scan device. • Keratometry readings were obtained with automated keratometers. • The SRK/T formula was used to calculate the planned refraction and the posterior chamber IOL power. **Interventions:** • Immediate sequential cataract surgery – Both operations performed on the same day • Delayed sequential cataract surgery – An interval of 4-6 weeks between the surgeries **Measurement:** • A complete ocular assessment was performed preoperatively and 1 day and 1 month after each surgery. **Surgery:** • All surgeries were day case. One of 3 experienced surgeons performed each cataract extraction using as similar a technique as possible. • A prophylactic topical antibiotic protocol was combined with strict aseptic technique. Preoperatively, all patients received ofloxacin (Exocin) drops 4 times a day for 3 days. Aqueous povidone-iodine 5% solution was applied to the conjunctival sac, the lids were scrubbed mechanically, and a plastic drape that fully covered the lid margins and eyelashes was placed. • Topical anaesthesia was administered using lidocaine gel or oxybuprocaine drops (Obucain) according to surgeon preference and, when necessary, in combination with lidocaine 1% in the anterior chamber. All patients received intravenous fentanyl 0.8 mg/kg preoperatively. In cases of anxiety during surgery, 0.2 mg/kg intravenous propofol was given. All patients received continuous 30% oxygen supplementation. Their electrocardiogram, pulse oximetry, and end-tidal carbon dioxide concentrations were monitored continuously. Oscillometric blood pressure was monitored every 10 minutes. • In all cases, 3.5mm small incision clear corneal phacoemulsification was followed by implantation of an acrylic IOL. In eyes with a mature cataract, trypan blue staining was used to facilitate capsulorhexis creation. If there was doubt about whether the wound was leak proof at the end of the surgery after it was dehydrated, 1 to 2 radial sutures were placed to secure the wound. In case of vitreous loss, anterior vitrectomy was performed and a sulcus-fixated IOL was implanted. At the end of surgery, 1mg cefuroxime was injected into the anterior chamber and chloramphenicol drops were applied. The patient received a transparent eye shield to use at night for 1 week. Ofloxacin–prednisolone acetate eye drops were prescribed 4 times a day for 3 weeks postoperatively. • In the study group, the second-eye surgery was treated as a separate procedure. All staff rescrubbed and changed into fresh gloves and gowns before second-eye surgery. A different batch of instruments, balanced salt solution, and ophthalmic viscosurgical device was used in each surgery. If complications or unexpected difficulty occurred during first-eye surgery in the study group, the second-eye surgery was deferred. **Study outcomes:** • Intraoperative and postoperative complications

Full citation	**Sarikkola A, Uusitalo RJ, Hellstedt T, et al. Simultaneous bilateral versus sequential bilateral cataract surgery: Helsinki Bilateral Cataract Surgery Study Report 1. Journal of Cataract and Refractive Surgery 2011 32:826-30**
	• Patient satisfaction with surgery • Deviation from target refraction • Visual function • Cataract symptom score • Trouble with vision • Satisfaction with vision **Group comparisons:** Parametric (t-test) and non-parametric (U-test and chi-squared test) tests
Results	**Intraoperative and postoperative complications:**

Adverse event	All eyes			Second-eye surgery		
	Study group	Control group	p value*	Study group	Control group	p value*
Number of participants (Intraoperative)	493	506		243	246	
Anterior capsule tear	3	2	0.63	3	1	0.31
Posterior capsule tear	4	5	0.77	3	4	0.72
Zonular tear	1	2	0.59	0	1	0.32
Vitreous loss	2	3	0.75	2	2	0.51
Iridectomy	0	2	0.18	0	1	0.51
Sphincterotomy	4	1	0.18	2	1	0.51
Sutures in wound	12	22	0.05	0	1	0.32
Number of participants (24 hours postoperative)	492	504		243	245	
IOP > 30mm Hg	30	37	0.74	11	16	0.38
Would leak	1	1	0.56	0	1	0.41
IOL decentration	0	1	0.57	0	1	0.57
Out-of-bag IOL implantation	2	3	0.57	2	2	0.57
Central corneal oedema	16	15	0.98	2	7	0.36
Number of participants (1 month postoperative)	488	497		241	244	
IOL decentration	1	1	0.54	1	0	0.57

Full citation	Sarikkola A, Uusitalo RJ, Hellstedt T, et al. Simultaneous bilateral versus sequential bilateral cataract surgery: Helsinki Bilateral Cataract Surgery Study Report 1. Journal of Cataract and Refractive Surgery 2011 32:826-30

Central corneal oedema	7	6	0.64	5	4	0.65
Anterior chamber flare	5	2	0.42	3	2	0.60
Posterior capsule fibrosis	17	19	0.50	7	11	0.49
Cystoid macular oedema	1	2	0.57	0	1	0.57

*Chi-squared test

Patient satisfaction and deviation from target refraction:

Item	Category	Study group	Control group	p value*
Pain during surgery	**None**	364	390	0.03
	Mild	122	97	
	Moderate	4	14	
	Severe	0	2	
	No reply	3	3	
Difficulty lying on back	**None**	453	479	0.57
	A little	23	18	
	Moderate	2	2	
	A lot	0	2	
	No reply	2	3	
Overall satisfaction with surgery	**Very satisfied**	470	483	0.74
	Satisfied	16	19	
	Unsatisfied	0	1	
	No reply	6	3	
Absolute target refraction (dioptres)	**0.00 to 0.50**	328	342	0.92
	0.50 to 0.75	78	69	
	0.75 to 1.00	38	35	

Full citation	Sarikkola A, Uusitalo RJ, Hellstedt T, et al. Simultaneous bilateral versus sequential bilateral cataract surgery: Helsinki Bilateral Cataract Surgery Study Report 1. Journal of Cataract and Refractive Surgery 2011 32:826-30

	1.00 to 1.50	34	35	
	1.50 to 2.00	6	7	
	Over 2.00	4	6	

*Chi-squared test

Visual outcomes:

Measure	Study group				Control group				p value
	Mean (SD)	% improved	% same	% worse	Mean (SD)	% improved	% same	% worse	
VF-7	24.3 (21.0)	91.8	1.6	6.6	23.8 (19.2)	85.9	4.0	10.1	0.72
CS-5	3.4 (3.0)	85.6	5.8	8.6	3.5 (3.1)	85.1	9.3	5.6	0.99
Trouble with vision	1.6 (1.09)	86.4	11.9	1.6	1.5 (1.0)	85.5	12.9	1.6	0.95
Satisfaction with vision	1.5 (0.9)	87.2	11.9	0.8	1.6 (0.9)	87.2	9.7	1.2	0.95

Visual acuity:

One month postoperatively, the corrected distance visual acuity in the better eye was 20/25 or better in 376 eyes (77.1%) in the study group and in 336 eyes (68.0%) in the control group; and 20/40 or better in 478 eyes (98.0%) in the study group and in 474 eyes (96.0%) in the control group.

- In 4.7% of people in the control group, the initially calculated IOL power was changed before the second-eye surgery in an attempt to improve refractive outcomes.
- 6 patients in the intervention group had surgery on separate days (5 surgeon preference, 1 protocol error). 1 patient did not have second eye surgery (surgeon preference).
- 1 patient had same day surgery (protocol error). 2 patients no surgery (cancelled participation). 4 patients no second eye surgery (2 patient preference, 1 intercurrent disease, 1 social reasons).

Comments

Risk of bias:

- Not possible to blind patients or clinicians to group allocation.
- Blinding of outcome assessment not reported.

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<table>
<tr><td>Full citation</td><td>Serrano-Aguilar P, Ramallo-Fariña Y, Cabrera-Hernández JM, et al. Benefit to patients of bilateral same-day cataract extraction. Journal of Cataract and Refractive Surgery 2012 32:826-30</td></tr>
<tr><td>Study details</td><td>Country/ies where the study was carried out: Spain
Study type: Randomised controlled trial
Aim of the study: To assess the safety and effectiveness of immediately sequential (ISBCS) versus delayed sequential (DSBCS) bilateral cataract surgery.
Study dates: Patients recruited in 2008
Sources of funding: Spanish Ministry of Health and Consumer Affairs, Canary Islands Foundation for Health and Research. No conflicts of interest were reported.</td></tr>
<tr><td>Participants</td><td>Sample size: 845 people
Inclusion criteria:
Uncorrected distance visual acuity 20/40 or worse in each eye because of cataract.
Exclusion criteria:
Risk factors for endophthalmitis (chronic infections of the eyes or adnexa, immunosuppressive treatment).
Cataract nigran or Fuchs dystrophy.
Previous refractive surgery or myopia with possible staphylomas.
Severe concomitant eye conditions that could limit the degree of improvement achievable with surgery.
Complex cataracts of traumatic origin.
Marfan syndrome.
Uncontrolled ocular hypertension.
Diabetes with retinopathy and macular oedema.
Cognitive or behavioural impairments that could make surgery with topical anaesthetic problematic.
Baseline characteristics:
<table>
<tr><th>Characteristic</th><th>ISBCS (n=417)</th><th>DSBCS (n=390)</th><th>p value</th></tr>
<tr><td>Age – mean (SD)</td><td>72.9 (8.2)</td><td>71.7 (7.9)</td><td>0.066[1]</td></tr>
<tr><td>Age – median</td><td>74.0</td><td>73.0</td><td></td></tr>
<tr><td>Sex - % male</td><td>38.8</td><td>39.5</td><td>0.853[2]</td></tr>
<tr><td>VF-14 score - mean (SD)</td><td>66.6 (22.7)</td><td>66.0 (21.4)</td><td>0.695[3]</td></tr>
<tr><td>VF-14 score – median</td><td>68.2</td><td>65.9</td><td></td></tr>
<tr><td>UDVA – median</td><td>20/200</td><td>20/200</td><td>0.946[1]</td></tr>
</table></td></tr>
</table>

Full citation	**Serrano-Aguilar P, Ramallo-Fariña Y, Cabrera-Hernández JM, et al. Benefit to patients of bilateral same-day cataract extraction. Journal of Cataract and Refractive Surgery 2012 32:826-30**
	CDVA - median | 20/100 | 20/100 | 0.143[1] [1]Kolmogorov-Smirnov test. [2]Chi-squared test. [3]Student t-test
Methods	**Pre-surgical examination:** • A full ocular examination (adnexa, anterior pole, cataract graduation, tonometry, and funduscopy) was performed preoperatively. • Standard biometry was performed by an ophthalmologist or an optometrist using ultrasound bio-microscopy. • A partial optical coherence interferometer was used when potential biometric errors were suspected. **Interventions:** • Immediate sequential bilateral cataract surgery – Both operations performed in the same surgical operating room occupancy • Delayed sequential bilateral cataract surgery – An interval of 6 weeks between the surgeries. **Measurement:** • Every participating surgeon recorded information on intraoperative complications observed immediately after surgery and postoperative complications at the follow-up visits at 1 day, 5 days, and 1 month. • A researcher collected self- reported information from patients on potential postsurgical complications 1 month and 1 year after surgery. • The information systems of the NHSCI public hospitals were tracked during 2008 to 2009 to search for patients included in the study who received care for potentially relevant ophthalmologic complications associated with the cataract surgery. **Surgery:** • All patients received ambulatory surgery. One experienced surgeon at each participating clinic performed all operations assigned to each centre according to a predefined protocol. • To reduce the risk for infection during surgery, ofloxacin or ciprofloxacin were given prophylactically in combination with topical diclofenac sodium 2 hours before surgery. Aqueous povidone–iodine 5% was applied 3 to 5 minutes before surgery to the eyes and conjunctival sac. The surgical field was prepared by mechanically scrubbing the lids and fully covering the lid margins and eyelashes with a plastic drape. In the ISBCS group, this procedure was performed separately for each eye. • Surgery was performed in a routine manner by phacoemulsification with topical anaesthesia. • After hydrodissection and phacofragmentation, a flexible intraocular acrylic IOL was implanted. No sutures were used, and leaks were prevented by hydration with a saline solution. • For ISBCS, second-eye surgery was performed using the same procedure as for first-eye surgery after the surgeon changed gloves. A new surgical field was prepared with new gowns, surgical instruments, and ophthalmic viscosurgical devices. • Patients left the clinic with their eyes uncovered (i.e. no eye patch but wearing sunglasses) 1 hour after the end of surgery. **Study outcomes:** • Intraoperative and postoperative complications,

<table>
<tr><td>Full citation</td><td>Serrano-Aguilar P, Ramallo-Fariña Y, Cabrera-Hernández JM, et al. Benefit to patients of bilateral same-day cataract extraction. Journal of Cataract and Refractive Surgery 2012 32:826-30</td></tr>
<tr><td></td><td>• Visual acuity
• Visual function (VF-14)
Group comparisons: ANOVA, U-test and chi-squared tests.</td></tr>
<tr><td>Results</td><td>Intraoperative and postoperative complications:
<table>
<tr><th>Complication</th><th>ISBCS (n=834)</th><th>DSBCS (n=780)</th><th>p value*</th></tr>
<tr><td>Total intraoperative complications</td><td>2</td><td>1</td><td>>0.999</td></tr>
<tr><td>Iris herniation</td><td>2</td><td>0</td><td></td></tr>
<tr><td>Posterior capsule tear</td><td>0</td><td>1</td><td></td></tr>
<tr><td>Without intraoperative complications</td><td>832</td><td>779</td><td></td></tr>
<tr><td>Total postoperative complications</td><td>11</td><td>4</td><td>0.154</td></tr>
<tr><td>Immediate corneal oedema</td><td>10</td><td>3</td><td></td></tr>
<tr><td>Minor posterior capsule opacification</td><td>1</td><td>0</td><td></td></tr>
<tr><td>Foreign-body sensation</td><td>0</td><td>1</td><td></td></tr>
<tr><td>Without postoperative complications</td><td>823</td><td>776</td><td></td></tr>
</table>
*Chi-squared test
Additionally, 26 people in the ISBCS group and 54 people in the DSBCS group reported dry-eye sensation.

Visual acuity:
<table>
<tr><th>Parameter</th><th>ISBCS</th><th>DSBCS</th><th>p value</th></tr>
<tr><td>Preoperative UDVA (median)</td><td>20/200</td><td>20/200</td><td>0.946</td></tr>
<tr><td>Postoperative UDVA (median)</td><td>20/33</td><td>20/29</td><td>0.559</td></tr>
<tr><td>Preoperative CDVA (median)</td><td>20/100</td><td>20/100</td><td>0.143</td></tr>
</table></td></tr>
</table>

Full citation	**Serrano-Aguilar P, Ramallo-Fariña Y, Cabrera-Hernández JM, et al. Benefit to patients of bilateral same-day cataract extraction. Journal of Cataract and Refractive Surgery 2012 32:826-30**

Postoperative CDVA (median)	20/22	20/22	0.378

Visual function (self-reported VF-14):

Exam	ISBCS		DSBCS		p value[2]
	Mean (SD)	p value[1]	Mean (SD)	p value[1]	
M1: Preoperative	66.6 (22.7)	-	66.0 (21.4)	-	-
M2: 1 month after 1st surgery	93.3 (12.8)	-	81.3 (18.3)	-	-
M3: 1 month after 2nd surgery	-	-	95.8 (8.5)	-	-
M4: 1 year	95.3 (11.0)	-	96.9 (8.5)	-	-
M2-M1	26.7 (22.4)	<0.001[3]	15.3 (21.6)	<0.001[3]	<0.001[3]
M3-M1	-	-	29.8 (21.0)	<0.001[3]	-
M4-M1	28.7 (22.8)	<0.001[3]	30.9 (20.8)	<0.001[3]	0.07[3]
M4-M2	2.0 (13.2)	0.021[3]	15.5 (17.1)	<0.001[3]	<0.001[3]
M4-M3	-	-	1.1 (9.5)	0.204[3]	-

[1]ANOVA with repeated measures. [2]ANOVA with repeated measures to compare surgery types. [3]Multiple comparisons adjusted with Bonferroni correction

Comments	**Risk of bias:** • Not possible to blind patients or clinicians to group allocation. • Blinding of outcome assessment not reported.

296.2.2 Second-eye surgery versus no second-eye surgery

Full citation	**Castells V, Comas M, Alonso J, et al. In a randomized controlled trial, cataract surgery in both eyes increased benefits compared to surgery in one eye only. Journal of Clinical Epidemiology 2006 59:201-7**
Study details	**Country/ies where the study was carried out:** Spain **Study type:** Randomised controlled trial **Aim of the study:** To compare the benefits of cataract surgery in both eyes with those of surgery in one eye only.

<table>
<tr><td>Full citation</td><td>Castells V, Comas M, Alonso J, et al. In a randomized controlled trial, cataract surgery in both eyes increased benefits compared to surgery in one eye only. Journal of Clinical Epidemiology 2006 59:201-7</td></tr>
<tr><td></td><td>Study dates: July 1999-July 2000
Sources of funding: Catalan Agency for Health Technology Assessment and Research, Fondo de Investigacion Sanitaria. No conflicts of interest were reported.</td></tr>
<tr><td>Participants</td><td>Sample size: 296 people
Inclusion criteria:
• Scheduled for first-eye cataract surgery and presented bilateral indication for cataract surgery (visual acuity <0.3).
Exclusion criteria:
• Severe ocular comorbidity.
• Undergoing surgery combined with other ophthalmological procedure.
• Complications of first-eye surgery that would contraindicate surgery in the fellow eye.
Baseline characteristics:
<table>
<tr><th></th><th>Surgery in one eye</th><th>Surgery in both eyes</th></tr>
<tr><td>Number</td><td>148</td><td>148</td></tr>
<tr><td>Mean age (y)</td><td>72.0</td><td>71.7</td></tr>
<tr><td>Women</td><td>62.8%</td><td>61.5%</td></tr>
<tr><td>Binocular visual acuity (SD)</td><td>0.56</td><td>0.54</td></tr>
<tr><td>Ocular comorbidity</td><td>24.3%</td><td>23.0%</td></tr>
<tr><td>VF-14 (SD)</td><td>61.01 (22.28)</td><td>58.08 (20.59)</td></tr>
</table></td></tr>
<tr><td>Methods</td><td>Interventions:
• Surgery in both eyes (second eye surgery 2-4 months after first)
• Surgery in first eye only.
Measurement:
All patients assessed 1-2 before first-eye surgery and 4-6 months after the last surgery
Surgery:
Ambulatory surgery using a phacoemulsification technique with topical anaesthesia, 3-mm corneal incision and foldable lens without suture
Study outcomes:</td></tr>
</table>

Full citation	**Castells V, Comas M, Alonso J, et al. In a randomized controlled trial, cataract surgery in both eyes increased benefits compared to surgery in one eye only. Journal of Clinical Epidemiology 2006 59:201-7**
	• Visual acuity • Contrast sensitivity • Stereopsis • Visual function (VF-14) • Cataract symptoms score • Trouble and satisfaction with vision • General health status (SF-12)
Results	**Outcomes 4-6 months after final surgery:**

Outcome (SD)	Surgery in one eye	Surgery in both eyes	Difference (95% CI)
Sample size	135	139	N/A
Binocular best-corrected visual acuity, logMAR	0.18 (0.17)	0.11 (0.10)	0.07 (0.03, 0.12)
Change in visual acuity, logMAR	-0.38 (0.23)	-0.43 (0.18)	0.05 (-0.002, 0.09)
Binocular contrast sensitivity	1.57 (0.18)	1.61 (0.10)	0.04 (-0.002, 0.09)
Change in contrast sensitivity	0.44 (0.36)	0.46 (0.32)	0.02 (-0.09, 0.14)
Stereopsis	2.37 (0.69)	1.75 (0.24)	0.62 (0.45, 0.79)
Change in stereopsis	-0.51 (0.79)	-1.11 (0.69)	0.60 (0.36, 0.85)
VF-14	89.5 (15.9)	97.7 (7.1)	8.24 (4.35, 12.36)
Change in VF-14	28.3 (20.4)	39.9 (20.7)	11.57 (4.79, 18.12)
Trouble with vision	1.58 (0.86)	1.17 (0.48)	0.41 (0.17, 0.64)
Change in trouble with vision	-1.53 (1.30)	-1.96 (1.03)	0.43 (0.06, 0.81)
Satisfaction with vision	1.53 (0.81)	1.13 (0.38)	0.40 (0.20, 0.61)
Change in satisfaction with vision	-2.10 (1.02)	-2.61 (0.62)	0.51 (0.23, 0.79)
Cataract Symptoms Score	0.78 (1.90)	0.12 (0.45)	0.66 (0.21, 1.11)
Change in Cataract Symptoms Score	-3.17 (3.81)	-3.93 (3.13)	0.66 (-0.49, 1.86)
SF-12 – physical	46.2 (9.3)	47.5 (9.3)	1.30 (-1.85, 4.40)
Change in SF-12 – physical	1.40 (9.20)	1.76 (10.6)	-0.36 (-3.56, 3.04)

Full citation	**Castells V, Comas M, Alonso J, et al. In a randomized controlled trial, cataract surgery in both eyes increased benefits compared to surgery in one eye only. Journal of Clinical Epidemiology 2006 59:201-7**
	SF-12 – mental: 51.2 (6.6) | 53.1 (4.9) | 1.90 (0.03, 3.79) Change in SF-12 – mental: 2.96 (10.50) | 4.27 (10.20) | -1.31 (-4.71, 2.16)
Comments	**Risk of bias:** • Not possible to blind patients or clinicians to group allocation. • Blinding of outcome assessment not reported. • No comparison of characteristics of those who did and did not complete the study.

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Full citation	**Foss AJE, Harwood RH, Osborn F, et al. Falls and health status in elderly women following second eye cataract surgery: a randomised controlled trial. Age and Ageing 2006 35:66-71**
Study details	**Country/ies where the study was carried out:** UK **Study type:** Randomised controlled trial **Aim of the study:** To determine if second eye cataract surgery reduces the risk of falling and to measure associated health gain. **Study dates:** 2000-2004 **Sources of funding:** Health Foundation, Trent Regional Health Authority. No conflicts of interest were reported.
Participants	**Sample size:** 239 people **Inclusion criteria:** • Women aged over 70 • One successful cataract operation • Second operable cataract **Exclusion criteria:** • Complex cataracts (Fuchs corneal dystrophy, active intraocular inflammation, lens zonule dehiscence or lens instability) • Visual field defect • Severe co-morbid eye disease affecting visual acuity • Memory problems preventing the completion of questionnaires or reliable recall of falls **Baseline characteristics:**

	Surgery in one eye	Surgery in both eyes
Number	119	120
Median age	79.9	79.2

<table>
<tr><td>Full citation</td><td>Foss AJE, Harwood RH, Osborn F, et al. Falls and health status in elderly women following second eye cataract surgery: a randomised controlled trial. Age and Ageing 2006 35:66-71</td></tr>
<tr><td></td><td>
<table>
<tr><td>Women</td><td>62.8%</td><td>61.5%</td></tr>
<tr><td>Corrected visual acuity</td><td>0.08 (-0.20, 1.04)</td><td>0.06 (-0.40, 0.98)</td></tr>
<tr><td>Falls in last 12 months</td><td>48%</td><td>45%</td></tr>
</table>
</td></tr>
<tr><td>Methods</td><td>Interventions:
• Expedited surgery – target of second eye surgery within a month
• Routine surgery – surgery after 12 month follow-up point
Measurement:
All patients assessed at baseline and 1, 3, 6, 9 and 12 months
Surgery:
Small-incision cataract surgery and implantation of a folding silicone intraocular lens under local anaesthetic
Study outcomes:
• Falls
• Activity
• Confidence
• Hospital Anxiety and Depression Scale
• Barthel Index
• VF-14
• London Handicap Scale
• EQ-5D
• Visual acuity
• Contrast sensitivity
• Depth perception</td></tr>
<tr><td>Results</td><td>12 month outcomes:
<table>
<tr><th>Outcome (SD)</th><th>12 month mean (expedited)</th><th>12 month mean (control)</th><th>Adjusted difference</th></tr>
<tr><td>Sample size</td><td>116</td><td>113</td><td>N/A</td></tr>
<tr><td>Rate of falls (relative risk)</td><td>2.9 per 1000 patient-days</td><td>4.3 per 1000 patient-days</td><td>0.68 (0.39, 1.19)</td></tr>
</table>
</td></tr>
</table>

Full citation	**Foss AJE, Harwood RH, Osborn F, et al. Falls and health status in elderly women following second eye cataract surgery: a randomised controlled trial. Age and Ageing 2006 35:66-71**

Activity	7.6	7.8	0.4 (-0.8, 1.5)
Confidence	86.1	81.7	3.6 (0.9, 6.2)
HADS – anxiety	6.6	7.1	-0.2 (-1.0, 0.5)
HADS - depression	4.6	4.7	-0.5 (-0.7, 0.3)
Barthel Index	18.7	18.8	-0.1 (-0.2, 0.3)
VF-14	94.7	87.2	7.5 (5.1, 9.9)
LHS	85.2	80.8	4.4 (2.2, 6.5)
EQ-5D	0.73	0.69	0.02 (-0.03, 0.08)
Unaided visual acuity (logMAR)	0.15	0.23	-0.04 (-0.01, -0.08)
Spectacles visual acuity (logMAR)	0.04	0.09	-0.04 (-0.01, -0.06)
Pinhole visual acuity (logMAR)	0.04	0.09	-0.06 (-0.03, -0.09)
Contrast sensitivity	1.60	1.50	0.09 (0.06, 0.13)
Depth perception	1.36	1.93	-0.45 (-0.22, -0.69)

Comments	**Risk of bias:** • Study terminated early due to change in expected waiting time for routine surgery (it was felt to have become unethical to randomise people to waiting 1 year) • Not possible to blind patients or clinicians to group allocation. • Blinding of outcome assessment not reported. • No comparison of characteristics of those who did and did not complete the study.

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Full citation	**Laidlaw DAH, Harrad RA, Hopper CD, et al. Randomised trial of effectiveness of second eye cataract surgery. Lancet 1998 352:925-9**
Study details	**Country/ies where the study was carried out:** UK **Study type:** Randomised controlled trial **Aim of the study:** To examine the effects of second eye surgery in terms of patient perceptions as well as through visual acuity, contrast sensitivity and stereoacuity tests **Study dates:** February 1994-April 1995

<table>
<tr><td>Full citation</td><td>Laidlaw DAH, Harrad RA, Hopper CD, et al. Randomised trial of effectiveness of second eye cataract surgery. Lancet 1998 352:925-9</td></tr>
<tr><td></td><td>Sources of funding: Wellcome Trust</td></tr>
<tr><td>Participants</td><td>Sample size: 208 people
Inclusion criteria
Awaiting second eye cataract surgery at Bristol Eye Hospital
Unilateral cataract and uncomplicated contralateral pseudophakia with corrected Snellen visual acuity of at least 20/40 in the pseudophakic eye
Exclusion criteria:
Other visually significant ophthalmic pathology affecting either eye
Baseline characteristics:
<table>
<tr><th></th><th>Surgery in one eye</th><th>Surgery in both eyes</th></tr>
<tr><td>Number</td><td>103</td><td>105</td></tr>
<tr><td>Median age</td><td>76</td><td>76</td></tr>
<tr><td>Women</td><td>62.8%</td><td>61.5%</td></tr>
<tr><td>Binocular distance visual acuity (logMAR)</td><td>0.063 (0.127)</td><td>0.022 (0.101)</td></tr>
<tr><td>Binocular near reading visual acuity (logMAR)</td><td>0.29 (0.13)</td><td>0.28 (0.13)</td></tr>
</table></td></tr>
<tr><td>Methods</td><td>Interventions:
Expedited surgery – surgery planned to take place within 6 weeks
Routine surgery – 7-12 month wait for surgery
Measurement:
All patients assessed at baseline and 6 months later
Surgery:
Not stated
Study outcomes:
Patient reported visual difficulties
Visual acuity
Contrast sensitivity
Stereoacuity</td></tr>
</table>

Full citation	**Laidlaw DAH, Harrad RA, Hopper CD, et al. Randomised trial of effectiveness of second eye cataract surgery. Lancet 1998 352:925-9**

Results

6 month outcomes:

Outcome (SD)	6 month mean (expedited)	6 month mean (control)	Adjusted difference
Sample size	98	94	N/A
At least some difficulty reading normal print	6 (6%)	33 (36%)	30% (19, 41%)
Eyesight preventing activities most or all of the time	0	10 (11%)	11% (4%, 17%)
Below average overall vision	0	17 (18%)	18% (10%, 26%)
Eyesight interfering with life quite a lot or a great deal	1 (1%)	24 (26%)	25% (15%, 34%)
Uncorrected binocular mean distance (logMAR)	-0.027	0.052	0.063 (0.035, 0.090)
Corrected binocular mean near reading (logMAR)	0.23	0.27	0.047 (0.017, 0.077)
Binocular mean Pelli-Robson contrast sensitivity	1.76	1.54	-0.21 (-0.25, -0.17)
Stereoacuity 3000 or worse	12 (12%)	66 (70%)	58% (47%, 69%)

Comments

Risk of bias:

- Not possible to blind patients or clinicians to group allocation.
- Blinding of outcome assessment not reported.
- No comparison of characteristics of those who did and did not complete the study.

E.7 Anaesthesia

- What is the optimal type and administration of anaesthesia for cataract surgery?
- What is the effectiveness of sedation as an adjunct to local anaesthesia during cataract surgery?
- What is the effectiveness of hyaluronidase as an adjunct to local anaesthesia during cataract surgery?
- In what circumstances should general anaesthesia be considered in phacoemulsification cataract surgery?

E.7.1 Type and administration of anaesthesia

Full citation	Ezra D, Allan B. Topical anaesthesia alone versus topical anaesthesia with intracameral lidocaine for phacoemulsification. Cochrane Database of Systematic Reviews 2007
Study details	Country/ies where the study was carried out: UK Study type: Systematic Review Aim of the study: To compare Topical anaesthesia alone versus topical anaesthesia with intracameral lidocaine for phacoemulsification Study dates: Studies between 1980 and 8 June 2006 Sources of funding: Not reported
Participants	Sample size 1281 patients (8 RCTs) Data collection Primary Outcomes: Measures of pain or discomfort during surgery, measures of pain or discomfort after surgery, measures of patient satisfaction with anaesthesia. Inclusion criteria Randomized controlled trials (RCTs) comparing topical anaesthesia alone with topical anaesthesia and intracameral lidocaine, either in two eyes of the same patient or in different patients. Studies which used oral or intravenous sedation in addition to local anaesthesia. Exclusion criteria Studies which were biased by exclusion of more difficult operative cases, for example excluding patients with hard lens nuclei or with small pupils. Also studies assessing only patients with Fuch's endothelial dystrophy.
Methods	The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2006, Issue 2),MEDLINE (1966 To May 2006), EMBASE (1980 to May 2006) and LILACs (1982 to 3May 2006) were searched. They also searched the reference lists of the identified studies and the Science Citation Index. No language restriction was used. Intervention Administration of topical anaesthesia alone or topical anaesthesia combined with intracameral lidocaine for phacoemulsification.

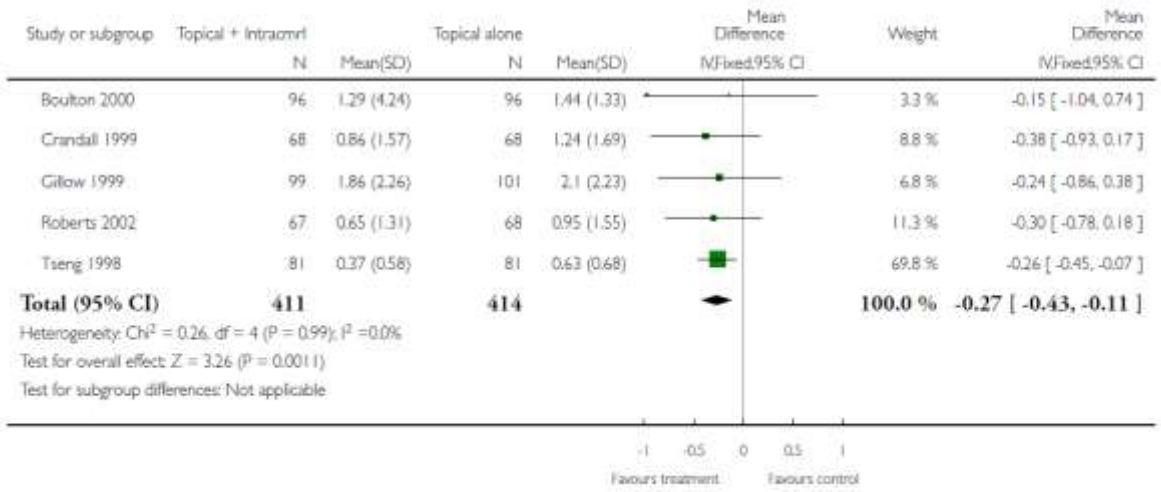
Full citation	Ezra D, Allan B. Topical anaesthesia alone versus topical anaesthesia with intracameral lidocaine for phacoemulsification. Cochrane Database of Systematic Reviews 2007
Results	

Analysis 1.1. Comparison 1 Topical plus intracameral versus topical only, Outcome 1 Pain score (Stevens) - intraoperative.

Review: Topical anaesthesia alone versus topical anaesthesia with intracameral lidocaine for phacoemulsification

Comparison: 1 Topical plus intracameral versus topical only

Outcome: 1 Pain score (Stevens) - intraoperative



Full citation	Ezra D, Allan B. Topical anaesthesia alone versus topical anaesthesia with intracameral lidocaine for phacoemulsification. Cochrane Database of Systematic Reviews 2007

Analysis 1.2. Comparison 1 Topical plus intracameral versus topical only, Outcome 2 Pain score - dichotomous.

Review: Topical anaesthesia alone versus topical anaesthesia with intracameral lidocaine for phacoemulsification

Comparison: 1 Topical plus intracameral versus topical only

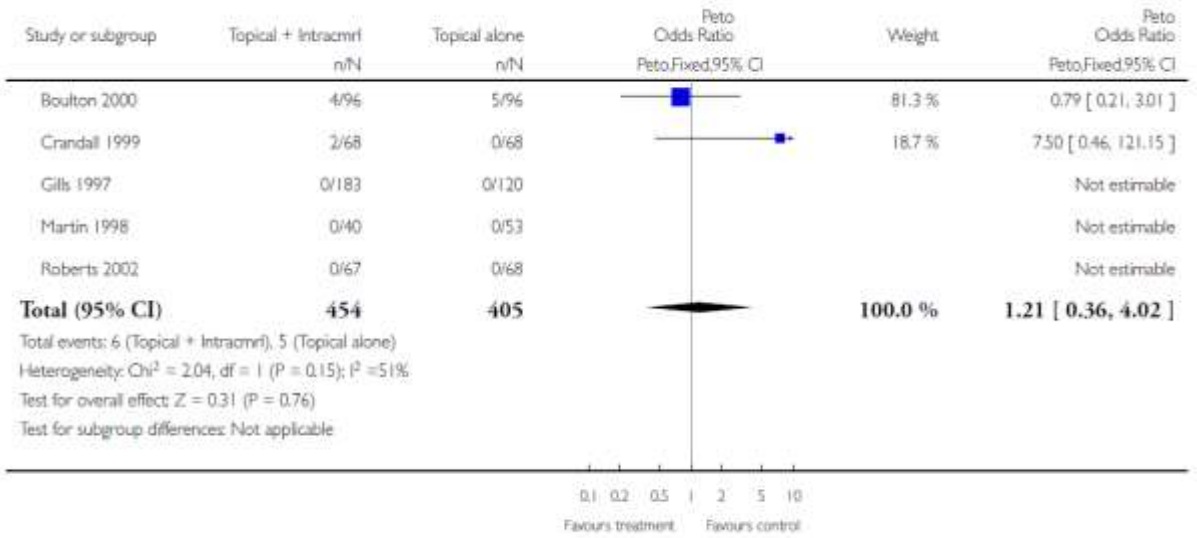
Outcome: 2 Pain score - dichotomous

Study or subgroup	Topical + Intracmrl n/N	Topical alone n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Carino 1998	7/30	15/30		14.9 %	0.30 [0.10, 0.92]
Gills 1997	60/183	62/120		65.2 %	0.46 [0.28, 0.73]
Martin 1998	9/40	23/53		19.9 %	0.38 [0.15, 0.95]
Total (95% CI)	**253**	**203**		**100.0 %**	**0.42 [0.28, 0.62]**

Total events: 76 (Topical + Intracmrl), 100 (Topical alone)

Heterogeneity: $Chi^2 = 0.49$, df = 2 ($P = 0.78$); $I^2 = 0.0\%$

Test for overall effect: Z = 4.36 ($P = 0.000013$)

Full citation	**Ezra D, Allan B. Topical anaesthesia alone versus topical anaesthesia with intracameral lidocaine for phacoemulsification. Cochrane Database of Systematic Reviews 2007**
	Analysis 3.1. Comparison 3 Topical plus intracameral versus topical only, Outcome 1 Adverse surgical event. Review: Topical anaesthesia alone versus topical anaesthesia with intracameral lidocaine for phacoemulsification Comparison: 3 Topical plus intracameral versus topical only Outcome: 1 Adverse surgical event 
Outcomes	Intracameral unpreserved 1% lidocaine is an effective adjunct to topical anaesthesia in phacoemulsification and significantly reduces intraoperative pain, although the effect is small. The use of topical anaesthesia alone was not found to lead to a higher chance of either intraoperative complications or need for intraoperative supplemental anaesthesia. The use of intracameral lidocaine did not subject the cornea to toxic injury.
Study Appraisal	1. Was an 'a priori' design provided? Yes 2. Was there duplicate study selection and data extraction? Yes 3. Was a comprehensive literature search performed? Yes

Full citation	Ezra D, Allan B. Topical anaesthesia alone versus topical anaesthesia with intracameral lidocaine for phacoemulsification. Cochrane Database of Systematic Reviews 2007
using AMSTAR (Assessing the Methodological Quality of Systematic Reviews)	4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes 5. Was a list of studies (included and excluded) provided? Yes 6. Were the characteristics of the included studies provided? Yes 7. Was the scientific quality of the included studies assessed and documented? Yes 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes 9. Were the methods used to combine the findings of studies appropriate? Yes 10. Was the likelihood of publication bias assessed? Yes 11. Was the conflict of interest included? Yes

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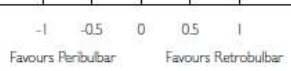
Full citation	Alhassan M, Kyari F, Ejere H. Peribulbar versus retrobulbar anaesthesia for cataract surgery. Cochrane Database of Systematic Reviews 2015
Study details	Country/ies where the study was carried out: UK Study type: Systematic Review Aim of the study: To compare Peribulbar versus retrobulbar anaesthesia for cataract surgery. Study dates: Studies between 1980 and 8 June 2006 Sources of funding: Not reported
Participants	Sample size 1438 patients (6 RCTs) Data collection Primary Outcomes: Pain experienced during surgery and measured using a visual analogue scale (VAS) (1 to 10) or any other method as described in the primary report. Acceptability of block to patients: the number of participants who reported that the blocks were acceptable to them. Inclusion criteria Randomized controlled clinical trials (RCTs) comparing retrobulbar block to peribulbar block for cataract surgery. Exclusion criteria Trials comparing peribulbar or retrobulbar anaesthesia with any others forms of anaesthesia for cataract surgery. Trials in which cataract surgery was combined with any other ocular surgery.
Methods	The Cochrane Central Register of Controlled Trials (CENTRAL) (March 2015); MEDLINE (1960 to March 2015); and EMBASE (1980 to March 2015). were searched. They also searched the Cochrane Anaesthesia Review Group Specialized Register. No language restriction was used.

Full citation	**Alhassan M, Kyari F, Ejere H. Peribulbar versus retrobulbar anaesthesia for cataract surgery. Cochrane Database of Systematic Reviews 2015**
	Intervention Trials comparing peribulbar block to retrobulbar block for cataract surgery. Peribulbar block included all its various modifications, as described by Ali-Melkkila 1993 and Davis 1989.
Results	**Analysis 1.1. Comparison 1 Peribulbar versus retrobulbar, Outcome 1 Pain score.** Review: Peribulbar versus retrobulbar anaesthesia for cataract surgery Comparison: 1 Peribulbar versus retrobulbar Outcome: 1 Pain score

Study or subgroup	Peribulbar N	Mean(SD)	Retrobulbar N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Athanikar 1991	71	3.71 (0.45)	71	3.76 (0.43)		90.5 %	-0.05 [-0.19, 0.09]
Weiss 1989	39	3.26 (1.04)	40	3.12 (0.98)		9.5 %	0.14 [-0.31, 0.59]
Total (95% CI)	**110**		**111**			**100.0 %**	**-0.03 [-0.17, 0.11]**

Heterogeneity: Chi² = 0.63, df = 1 (P = 0.43); I² =0.0%
Test for overall effect: Z = 0.45 (P = 0.65)
Test for subgroup differences: Not applicable



Full citation	Alhassan M, Kyari F, Ejere H. Peribulbar versus retrobulbar anaesthesia for cataract surgery. Cochrane Database of Systematic Reviews 2015

Analysis 1.4. Comparison 1 Peribulbar versus retrobulbar, Outcome 4 Local complications.

Review: Peribulbar versus retrobulbar anaesthesia for cataract surgery

Comparison: 1 Peribulbar versus retrobulbar

Outcome: 4 Local complications

Study or subgroup	Peribulbar n/N	Retrobubar n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Retrobular haemorrhage					
Athanikar 1991	0/71	1/71		100.0 %	0.33 [0.01, 8.05]
Subtotal (95% CI)	**71**	**71**		**100.0 %**	**0.33 [0.01, 8.05]**
Total events: 0 (Peribulbar), 1 (Retrobubar)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.68 (P = 0.50)					
2 Conjunctival chemosis					
Ali-Melkkila 1993	65/300	20/150		70.7 %	1.63 [1.02, 2.58]
Wong 1993	8/50	8/100		14.1 %	2.00 [0.80, 5.02]
Ali-Melkkila 1992	14/142	5/158		12.5 %	3.12 [1.15, 8.43]
Athanikar 1991	11/71	1/71		2.7 %	11.00 [1.46, 82.96]
Subtotal (95% CI)	**563**	**479**		**100.0 %**	**2.11 [1.46, 3.05]**
Total events: 98 (Peribulbar), 34 (Retrobubar)					
Heterogeneity: Chi² = 4.40, df = 3 (P = 0.22); I² =32%					
Test for overall effect: Z = 3.98 (P = 0.000068)					
3 Lid haematoma					
Ali-Melkkila 1993	8/300	11/150		100.0 %	0.36 [0.15, 0.88]
Subtotal (95% CI)	**300**	**150**		**100.0 %**	**0.36 [0.15, 0.88]**
Total events: 8 (Peribulbar), 11 (Retrobubar)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.23 (P = 0.026)					
4 Ptosis					
Feibel 1993	9/154	9/163		100.0 %	1.06 [0.43, 2.60]
Subtotal (95% CI)	**154**	**163**		**100.0 %**	**1.06 [0.43, 2.60]**
Total events: 9 (Peribulbar), 9 (Retrobubar)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.12 (P = 0.90)					

Full citation	Alhassan M, Kyari F, Ejere H. Peribulbar versus retrobulbar anaesthesia for cataract surgery. Cochrane Database of Systematic Reviews 2015
Outcomes	Little to choose between peribulbar and retrobulbar block in terms of anaesthesia and akinesia during surgery measuring acceptability to patients, need for additional injections and development of severe complications. Severe local or systemic complications were rare for both types of block.
Study Appraisal using AMSTAR (Assessing the Methodological Quality of Systematic Reviews)	1. Was an 'a priori' design provided? Yes 2. Was there duplicate study selection and data extraction? Yes 3. Was a comprehensive literature search performed? Yes 4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes 5. Was a list of studies (included and excluded) provided? Yes 6. Were the characteristics of the included studies provided? Yes 7. Was the scientific quality of the included studies assessed and documented? Yes 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes 9. Were the methods used to combine the findings of studies appropriate? Yes 10. Was the likelihood of publication bias assessed? Yes 11. Was the conflict of interest included? Yes

31E27.1.1 Topical vs sub-Tenon's anaesthesia

Full citation	Guay Y, Sales K. Sub-Tenon's anaesthesia versus topical anaesthesia for cataract surgery. Cochrane Database of Systematic Reviews 2015
Study details	Country/ies where the study was carried out: UK Study type: Systematic Review Aim of the study: To compare sub-Tenon's anaesthesia versus topical anaesthesia for cataract surgery. Study dates: Studies between 1990 and November 2014 Sources of funding: Not reported
Participants	Sample size 617 patients – 742 eyes (7 RCTs) Inclusion criteria Studies that compared sub-Tenon's anaesthesia versus topical anaesthesia (eye drops or gel) with or without intracameral injection. Data collection Primary Outcomes : Pain during surgery

Full citation	Guay Y, Sales K. Sub-Tenon's anaesthesia versus topical anaesthesia for cataract surgery. Cochrane Database of Systematic Reviews 2015
	Secondary Outcomes: Pain during administration of local anaesthetic, Patient satisfaction with analgesia provided. Complications that occurred as defined by study authors. Exclusion criteria Studies in which participants received intravenous sedation, as clinical experience has shown that intravenous sedation can mask pain perceived by the person.
Methods	MEDLINE (1990 to November 2014; Appendix 1), the Cochrane Central Register of Controlled Trials (CENTRAL) (2014, Issue 11; Appendix 2) and EMBASE (1990 to November 2014; Appendix 3) were searched. The search was first run in 2006 (Davison 2007) and was updated for 2006 to 2011 in May 2011, and for 2011 to 2014 in November 2014. No language restriction was used. Intervention Studies that compared sub-Tenon's anaesthesia versus topical anaesthesia (eye drops or gel) with or without intracameral injection.

Full citation	Guay Y, Sales K. Sub-Tenon's anaesthesia versus topical anaesthesia for cataract surgery. Cochrane Database of Systematic Reviews 2015
Results	

Analysis 1.1. Comparison 1 Topical anaesthesia versus sub-Tenon's anaesthesia, Outcome 1 Pain during surgery.

Review: Sub-Tenon's anaesthesia versus topical anaesthesia for cataract surgery

Comparison: 1 Topical anaesthesia versus sub-Tenon's anaesthesia

Outcome: 1 Pain during surgery

Study or subgroup	Topical N	Sub-Tenon N	Std. Mean Difference (SE)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
1 Low risk for outcome assessor blindness						
Sekundo 2004	50	50	0.679 (0.206)		16.7 %	0.68 [0.28, 1.08]
Zafirakis 2001	100	100	0.391 (0.143)		25.2 %	0.39 [0.11, 0.67]
Srinivasan 2004	65	136	0.457 (0.153)		23.6 %	0.46 [0.16, 0.76]
Subtotal (95% CI)	**215**	**286**			**65.4 %**	**0.47 [0.29, 0.66]**
Heterogeneity: Tau² = 0.0; Chi² = 1.34, df = 2 (P = 0.51); I² =0.0%						
Test for overall effect: Z = 5.09 (P < 0.00001)						
2 Unclear risk for outcome assessor blindness						
Vielpeau 1999	25	25	1.024 (0.301)		9.6 %	1.02 [0.43, 1.61]
Mathew 2003	46	73	0.81 (0.195)		17.9 %	0.81 [0.43, 1.19]
Chittenden 1997	16	19	1.05 (0.362)		7.1 %	1.05 [0.34, 1.76]
Subtotal (95% CI)	**87**	**117**			**34.6 %**	**0.90 [0.61, 1.20]**
Heterogeneity: Tau² = 0.0; Chi² = 0.55, df = 2 (P = 0.76); I² =0.0%						
Test for overall effect: Z = 6.06 (P < 0.00001)						
Total (95% CI)	**302**	**403**			**100.0 %**	**0.64 [0.43, 0.84]**
Heterogeneity: Tau² = 0.02; Chi² = 7.84, df = 5 (P = 0.17); I² =36%						
Test for overall effect: Z = 6.11 (P < 0.00001)						
Test for subgroup differences: Chi² = 5.95, df = 1 (P = 0.01), I² =83%						

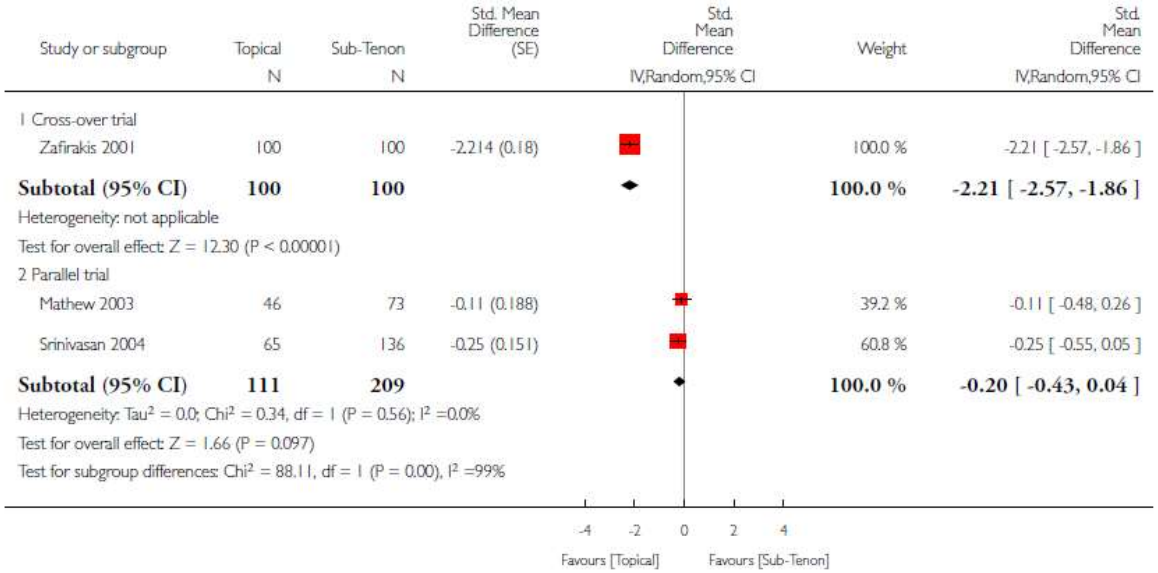
Full citation	Guay Y, Sales K. Sub-Tenon's anaesthesia versus topical anaesthesia for cataract surgery. Cochrane Database of Systematic Reviews 2015

Analysis 1.2. Comparison 1 Topical anaesthesia versus sub-Tenon's anaesthesia, Outcome 2 Pain during anaesthesia administration.

Review: Sub-Tenon's anaesthesia versus topical anaesthesia for cataract surgery

Comparison: 1 Topical anaesthesia versus sub-Tenon's anaesthesia

Outcome: 2 Pain during anaesthesia administration



Surgical Complications

Study ID	Subconjuctival haemorrhage (T vs ST)	Chemosis (T vs ST)	Posterior capsule tear (T vs ST)	Iris prolapse (T vs ST)	Iritis (T vs ST)

Full citation	Guay Y, Sales K. Sub-Tenon's anaesthesia versus topical anaesthesia for cataract surgery. Cochrane Database of Systematic Reviews 2015					
	Sekundo (2004)	-	-	-	-	1/50 vs 1/50
	Srinivasan (2004)	-	-	3/65 vs 2/136	0/65 vs 1/136	-
	Vielpeau (1999)	25/25 vs 25/25	0/25 vs 15/25	-	-	-
	T: Topical anaesthesia ST: sub-Tenon's anaesthesia					
Outcomes	Both topical anaesthesia and sub-Tenon's anaesthesia are accepted and safe methods of providing anaesthesia for cataract surgery. An acceptable degree of intraoperative discomfort has to be expected with either of these techniques.					
Study Appraisal using AMSTAR (Assessing the Methodological Quality of Systematic Reviews)	1. Was an 'a priori' design provided? Yes 2. Was there duplicate study selection and data extraction? Yes 3. Was a comprehensive literature search performed? Yes 4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes 5. Was a list of studies (included and excluded) provided? Yes 6. Were the characteristics of the included studies provided? Yes 7. Was the scientific quality of the included studies assessed and documented? Yes 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes 9. Were the methods used to combine the findings of studies appropriate? Yes 10. Was the likelihood of publication bias assessed? Yes 11. Was the conflict of interest included? Yes					

3E37.1.2 Retro/Peribulbar vs sub-Tenon's vs Topical

Full citation	Nielsen P, Allerod C. Evaluation of local anaesthesia techniques for small incision cataract surgery. J Cataract Refract Surg 1998;24:1136-1144
Study details	Country/ies where the study was carried out: Denmark Study type: RCT Aim of the study: To evaluate the surgical experiences and patient preference with 3 local anaesthesia techniques for small incision cataract surgery. Study dates: Not reported Sources of funding: Not reported
Participants	Sample size

<table>
<tr><th>Full citation</th><td>Nielsen P, Allerod C. Evaluation of local anaesthesia techniques for small incision cataract surgery. J Cataract Refract Surg 1998;24:1136-1144</td></tr>
<tr><td></td><td>66 patients (132 eyes)
Inclusion criteria
Patients scheduled to undergo simultaneous bilateral cataract surgery using only local anaesthesia in both eyes.
Exclusion criteria
Not reported</td></tr>
<tr><td>Methods</td><td>Patients randomised into 1 of 3 groups, each comprising 2 types of local anaesthesia:
Group 1: Retro/peribulbar (RBA) in 1 eye and topical (TA) in the other (n=22)
Group 2: Retro/peribulbar (RBA) in 1 eye and sub-Tenon’s (STA) in the other (n=22)
Group 3: Topical (TA) in 1 eye and sub-Tenon’s (STA) in the other (n=22)
In each group, half the patients had 1 type of anaesthesia in the first eye and the other half had the other type in the first eye.
Of the 130 eyes (2 excluded due to vasovagal attack whilst TA applied) 43 had RBA, 44 STA, and 43 TA
Data collection
Patients were interviewed on the evening of the surgery after both eyes had been unpatched and again the following morning. They were asked about the pain during anaesthetic application and during surgery using a visual analogue scale ranging from 0 to 100. Patients were also asked which local anaesthesia method they preferred.
Intervention
3 local anaesthetic procedures (Retro/peribulbar, Topical and sub-Tenon’s)
Analysis
t-test, Mann-Whitney U</td></tr>
<tr><td>Results</td><td>Visual analogue pain scores (Mean ±SD)
<table>
<tr><td>Anaesthetic procedure</td><td>Whole procedure (application and during surgery)</td></tr>
<tr><td>RBA</td><td>10.7 ± 12.2</td></tr>
<tr><td>TA</td><td>2.4 ± 4.6</td></tr>
<tr><td>STA</td><td>4.18 ± 8.3</td></tr>
</table>
P-value = <0.0001 (between RBA and TA), and 0.0008 (between RBA and STA). No significant differences between STA and TA

Patient satisfaction
<table>
<tr><td>Anaesthetic procedure</td><td>Preference for anaesthetic procedure (%)</td><td>Would not have anaesthetic procedure again (%)</td></tr>
</table></td></tr>
</table>

Full citation	Nielsen P, Allerod C. Evaluation of local anaesthesia techniques for small incision cataract surgery. J Cataract Refract Surg 1998;24:1136-1144		
	RBA	11/43 (26%)	17/43 (40%)
	TA	11/43 (26%)	8/43 (19%)
	STA	13/43 (30%)	7/44 (16%)
Outcomes	Significantly more pain was recorded for the whole procedure with RBA compared to the other 2 methods. More pain occurred with the application of RBA than with STA or TA.		
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Unsure 3 Were the patients, health workers and study personnel blinded? Unsure 4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A		

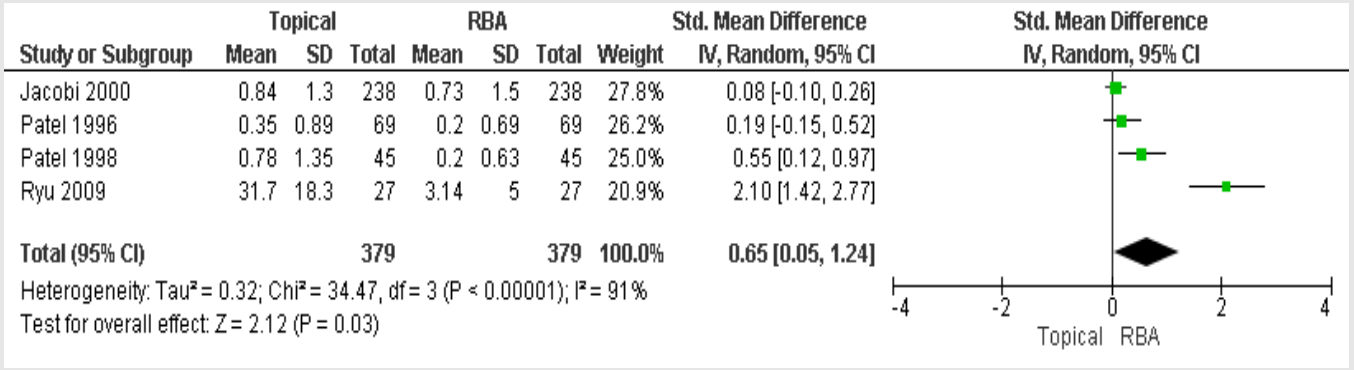
3147.1.3 Topical vs Peribulbar

Full citation	Naeem B, Raja A, Bashir R, et al. Comparison of peribulbar vs topical anaesthesia for phacoemulsification. Journal of Rawalpindi Medical College. 2007;11(2):79-82
Study details	Country/ies where the study was carried out: India Study type: RCT Aim of the study: To compare the efficacy of topical anaesthesia with peribulbar anaesthesia in phacoemulsification Study dates: February 2006 to February 2007 Sources of funding: Not reported
Participants	Sample size 200 patients Inclusion criteria Patients who underwent phacoemulsification with intraocular lens (IOL) implantation who have senile cataract Exclusion criteria Patients refusing informed consent, communication difficulties, suffering from dementia, nystagmus, unable to understand pain scales or those woth hazy cornea.
Methods	Patients were randomly assigned to 1 of 2 groups.

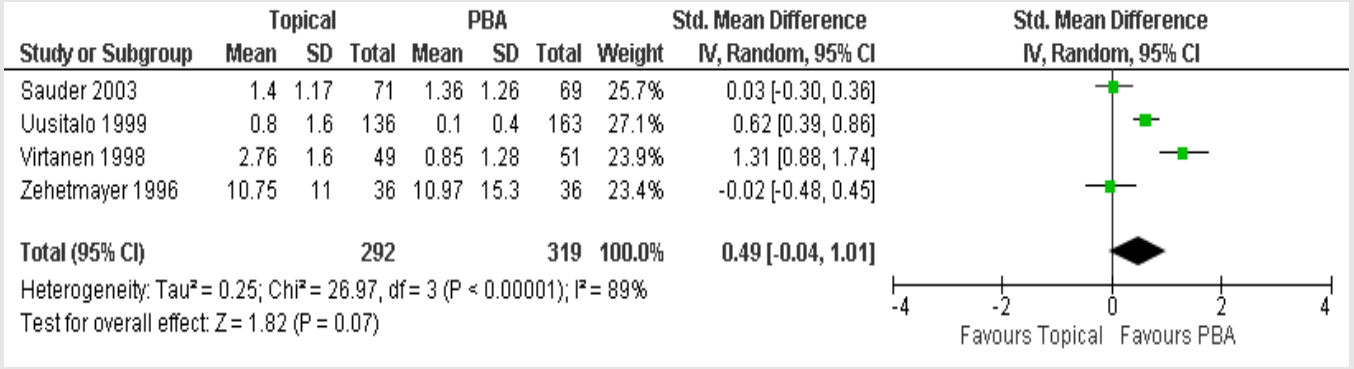
Full citation	**Naeem B, Raja A, Bashir R, et al. Comparison of peribulbar vs topical anaesthesia for phacoemulsification. Journal of Rawalpindi Medical College. 2007;11(2):79-82**
	Group 1: Peribulbar anaesthesia (4-5ml equal quantities of 2% xylocaine and 0.5% bupivacaine) n=100 Group 2: Topical anaesthesia (0.5% proparacaine) n=100 Data collection Patients were asked to grade the pain during surgery using a 4 point verbal pain scale Intervention Topical and peribulbar anaesthesia for cataract surgery Analysis Chi square test
Results	Mean subjective pain ratings Anaesthesia: Mean Pain score (SD) Peribulbar (Group 1): 0.56 (0.64) Topical (Group 2): 0.78 (0.85) Chi-square = 3.484, p value = 0.323
Outcomes	The difference between the two groups for pain scores during surgery was found to be statistically insignificant.
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Unsure 3 Were the patients, health workers and study personnel blinded? Unsure 4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

3157.1.4 Topical vs Regional anaesthesia (Retrobulbar/Peribulbar)

Full citation	**Zhao L, Zhu H, Zhao P, Wu Q, Hu Y. Topical anaesthesia versus Regional anaesthesia for cataract surgery: A Meta-analysis of Randomized Controlled Trials. Ophthalmology. 2012;119:659-667**
Study details	Country/ies where the study was carried out: China Study type: Systematic Review Aim of the study: To examine possible differences in the clinical outcomes of topical anaesthesia (TA) and regional anaesthesia including retrobulbar anaesthesia (RBA) and peribulbar anaesthesia (PBA) in phacoemulsification

Full citation	**Zhao L, Zhu H, Zhao P, Wu Q, Hu Y. Topical anaesthesia versus Regional anaesthesia for cataract surgery: A Meta-analysis of Randomized Controlled Trials. Ophthalmology. 2012;119:659-667**
	Study dates: Studies published up to July 6th 2010 Sources of funding: Not reported
Participants	Sample size 1369 eyes (8 RCTs) Inclusion criteria RCTs that included TA and RBA/PBA and assessed at least 1 of the primary and secondary objectives Data collection Primary Outcomes: Pain score during and after surgery, intraoperative difficulties, patient preference, inadvertent ocular movement, necessity to administer additional anaesthesia. Secondary Outcomes: Intraoperative complications, severe local or systemic complications, anaesthesia-related complications, postoperative visual acuity. Exclusion criteria TA in combination with other techniques, such as intracameral lidocaine regional nerve block, and sponge soaked with drugs inserted deeply into the conjunctival fornices.
Methods	PubMed, EMBASE and Cochrane Controlled Trials Register databases for publications were searched using the terms: topical anaesthesia or drop anaesthesia, retrobulbar anaesthesia or block, peribulbar anaesthesia or block, regional or local anaesthesia or block, periocular or periocular anaesthesia, cataract surgery, cataract extraction, and phacoemulsification.
Results	Mean pain score during surgery with TA and RBA  Mean pain score during surgery with TA and PBA

Full citation	**Zhao L, Zhu H, Zhao P, Wu Q, Hu Y. Topical anaesthesia versus Regional anaesthesia for cataract surgery: A Meta-analysis of Randomized Controlled Trials. Ophthalmology. 2012;119:659-667**



Intraoperative pain score (dichotomised data)

	Crude rate, n/N (%)			
	TA	RBA/PBA	Rate difference% (95% CI)	P for overall effect
Pain score	51/147	15/146	4.55 (2.58 – 8.05)	<0.00001

Intraoperative complications

	Crude rate, n/N (%)			
	TA	RBA/PBA	Rate difference% (95% CI)	P for overall effect
Capsule rupture	18/1022	20/1053	0.94 (0.50 – 1.79)	0.86
Zonule tear	12/358	7/360	1.72 (0.69 – 4.30)	0.24
Iris prolapse	5/471	1/471	3.83 (0.77 – 19.08)	0.10

Anaesthesia related complications

	Crude rate, n/N (%)			
	TA	RBA/PBA	Rate difference% (95% CI)	P for overall effect

<table>
<tr><th>Full citation</th><td colspan="5">Zhao L, Zhu H, Zhao P, Wu Q, Hu Y. Topical anaesthesia versus Regional anaesthesia for cataract surgery: A Meta-analysis of Randomized Controlled Trials. Ophthalmology. 2012;119:659-667</td></tr>
<tr><td></td><td colspan="5">
<table>
<tr><td>Chemosis</td><td>1/603</td><td>72/628</td><td>0.08 (0.0 - 0.13)</td><td><0.00001</td></tr>
<tr><td>Periorbital haematoma</td><td>0/667</td><td>51/692</td><td>0.10 (0.05 – 0.18)</td><td><0.00001</td></tr>
<tr><td>Subconjunctival haemorrhage</td><td>1/603</td><td>26/628</td><td>0.14 (0.07 – 0.31)</td><td><0.00001</td></tr>
</table>

Patient preference
<table>
<tr><td></td><td colspan="2">Crude rate, n/N (%)</td><td></td><td></td></tr>
<tr><td></td><td>TA</td><td>RBA/PBA</td><td>Rate difference% (95% CI)</td><td>P for overall effect</td></tr>
<tr><td>Patient preference</td><td>69/133 (52)</td><td>33/133 (25)</td><td>3.11 (1.90 – 5.09)</td><td><0.00001</td></tr>
</table>
</td></tr>
<tr><td>Outcomes</td><td colspan="5">Intraoperative pain perception was significantly higher in the TA group (p<0.05)
Patients significantly preferred TA (p<0.00001).
The RBA/PBA group had more frequent anaesthesia related complications, such as chemosis, periorbital haematoma and subconjunctival haemorrhage (p<0.05).
No statistically significant difference in surgery related complications (p<0.05)</td></tr>
<tr><td>Study Appraisal using AMSTAR (Assessing the Methodological Quality of Systematic Reviews)</td><td colspan="5">1. Was an 'a priori' design provided? Yes
2. Was there duplicate study selection and data extraction? Yes
3. Was a comprehensive literature search performed? Yes
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? Unsure
5. Was a list of studies (included and excluded) provided? Only inclusion list
6. Were the characteristics of the included studies provided? Yes
7. Was the scientific quality of the included studies assessed and documented? Unsure
8. Was the scientific quality of the included studies used appropriately in formulating conclusions? Unsure
9. Were the methods used to combine the findings of studies appropriate? Yes
10. Was the likelihood of publication bias assessed? Yes
11. Was the conflict of interest included? Yes</td></tr>
</table>

3167.1.5 Effect of warming the anaesthetic

Full citation	**Krause M, Weindler J, Ruprecht W. Does warming of anaesthetic solutions improve analgesia and akinesia in Retrobulbar anaesthesia? Ophthalmology 1997;104:429-432**
Study details	Country/ies where the study was carried out: Germany Study type: RCT Aim of the study: To investigate the effect of warming local anaesthetic solutions on pain of injection and on bulbar akinesia and analgesia of retrobulbar anaesthesia (RBA) Study dates: Not reported Sources of funding: Not reported
Participants	Sample size 70 patients Inclusion criteria Patients scheduled for elective cataract surgery under retrobulbar anaesthesia. Exclusion criteria Absence of informed consent, previous operations, retrobulbar and peribulbar injections, and history of severe injuries and infections. Orbital and bulbar malformations (e.g. microphthalmus) and an axial bulbar length greater than 26mm. Patients not able to cooperate with the demands of pain assessment due to language difficulties or limited physical or mental capabilities.
Methods	Patients were randomly allocated to receive 5ml either warm (37 ± 1oC) or cold (20 ± 1oC) anaesthetic solution (Bupivacaine 0.75%, Ultracaine 2% in a 2:1 ratio, Naphazoline nitrate (1:30000) and hyaluronidase (5 IU/ml)). Data collection Before and immediately after injection, subjective pain was assessed by patients choosing an integer between 0 and 10 on an ordinal analogue scale, where 0 = no pain and 10 = worst pain imaginable. Intervention Warm or cold anaesthetic for a retrobulbar block Analysis Mann-Whitney U test
Results	Mean injection pain Scores (± SD) | | Warm anaesthetic solution (n=35) | Cold anaesthetic solution (n=35) | | Average pain score (points) | 4.5 ± 2.3 | 5.2 ± 2.6 |
Outcomes	Injection pain was lower for the warm group in comparison to the cold group. No significant difference in bulbar analgesia after RBA between injections of warm and cold anaesthesia

Full citation	Krause M, Weindler J, Ruprecht W. Does warming of anaesthetic solutions improve analgesia and akinesia in Retrobulbar anaesthesia? Ophthalmology 1997;104:429-432
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Unsure 3 Were the patients, health workers and study personnel blinded? Yes (but not the investigator giving the injection) 4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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Full citation	Ursell P, Spalton D. The effect of solution temperature on the pain of peribulbar anaesthesia. Ophthalmology 1996;103:839-841
Study details	Country/ies where the study was carried out: UK Study type: RCT Aim of the study: To investigate the effect of warming local anaesthetic solutions on pain of injection for peribulbar anaesthesia Study dates: November 1994 to March 1995 Sources of funding: Dr Ursell was sponsored by the Iris fund for prevention of blindness.
Participants	Sample size 40 patients Inclusion criteria Patients scheduled for elective cataract surgery under peribulbar anaesthesia. Exclusion criteria Those unable to cooperate with the demands of filling out the pain analysis chart because of either language difficulties or memory impairment.
Methods	Patients were randomly allocated to receive either warm (37oC) or cool (20oC) anaesthetic solution (5ml Bupivacaine 0.5%, 5ml Lidocaine 2% and hyaluronidase (1550 IU)). Data collection After injection, patients were asked to assess the pain of the injection using the visual analogue scale (VAS). 'No pain' = 0 and 'worst pain ever' = 100. The centre of the scale at a score of 50 was marked with 'the pain of the needle'. Patients were asked to decide whether the injection pain was more or less than the pain of the needle. Intervention Warm or cold anaesthetic for a peribulbar block

<table>
<tr><th>Full citation</th><th>Ursell P, Spalton D. The effect of solution temperature on the pain of peribulbar anaesthesia. Ophthalmology 1996;103:839-841</th></tr>
<tr><td></td><td>Analysis
Student t test</td></tr>
<tr><td>Results</td><td>Mean injection pain Scores (± SD)
<table>
<tr><td></td><td>Warm anaesthetic solution (n=20)</td><td>Cool anaesthetic solution (n=20)</td></tr>
<tr><td>Average pain score</td><td>36.65 ± 24.7</td><td>53.35 ± 23.7</td></tr>
</table>
P = 0.026 (95% CI 22.1 – 33.2)</td></tr>
<tr><td>Outcomes</td><td>Pain sensation of local anaesthesia when injected was less when the solution is warmed to 37oC compared to 20oC (p=0.026)</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Unsure
3 Were the patients, health workers and study personnel blinded? Yes (but not the investigator giving the injection)
4 Were the groups similar at the start of the trial? Yes
5 Aside from the experimental intervention, were the groups treated equally? Yes
6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes
7 Can the results be applied to the local population? Yes
8 Were all clinically important outcomes considered? N/A</td></tr>
</table>

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Full citation	Jaichandran V, Vijaya L, George R, InderMohan B. Peribulbar anaesthesia for cataract surgery: Effect of lidocaine warming and alkalinisation on injection pain, motor and sensory nerve blockade. Indian Journal of Ophthalmology. 2010;58(2):105-108
Study details	Country/ies where the study was carried out: India Study type: RCT Aim of the study: To report pain and efficacy of warmed plain 2% lidocaine with plain 2% lidocaine at room temperature for peribulbar anaesthesia in cataract surgery Study dates: Not reported Sources of funding: Not reported
Participants	Sample size 200 patients Inclusion criteria Aged 40 or above scheduled for phacoemulsification cataract surgery under local anaesthesia Exclusion criteria

Full citation	**Jaichandran V, Vijaya L, George R, InderMohan B. Peribulbar anaesthesia for cataract surgery: Effect of lidocaine warming and alkalinisation on injection pain, motor and sensory nerve blockade. Indian Journal of Ophthalmology. 2010;58(2):105-108**
	Patients with a history of previous intraocular surgery under local anaesthetic, known allergy to lidocaine, mental retardation, one-eyed patients and those with inadequate vision to appreciate the visual analogue scale (less than 20/200 on Snellen visual acuity chart)
Methods	Patients were randomly allocated (based on a computer-generated random table) to receive either warm (37oC) or room temperature (18oC) anaesthetic solution (Lidocaine 2% with hyaluronidase 50 IU/ml)) Data collection Immediately after the injection of anaesthetic, the Visual analog scale (VAS) of 10cm was shown to the subjects to mark the pain perceived by them during the injection with zero cm representing no pain and 10cm representing the most severe pain. They were asked not to take into consideration the pain caused by the needle prick. Intervention Warm or room temperature anaesthetic for a peribulbar block Analysis Student t test
Results	Mean Pain Scores (± SD) on application of anaesthesia.

	Warm anaesthetic solution (n=50)	Room Temperature anaesthetic solution (n=50)
Mean pain score	1.68 ± 1.47	2.71 ± 1.93

Outcomes	Pain scores were lower in the warmed anaesthetic group compared to the room temperature group
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Yes 3 Were the patients, health workers and study personnel blinded? Yes (but not the investigator giving the injection) 4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

3197.1.6 Comparison of anaesthetic drugs

Full citation	**McLure H, Kumar C, Ahmed S, Patel A. A comparison of lidocaine 2% with levobupivacaine 0.75% for sub-Tenon's block. European Journal of Anaesthesiology. 2005;22:500-503**
Study details	Country/ies where the study was carried out: UK

<table>
<tr><th>Full citation</th><td>McLure H, Kumar C, Ahmed S, Patel A. A comparison of lidocaine 2% with levobupivacaine 0.75% for sub-Tenon’s block. European Journal of Anaesthesiology. 2005;22:500-503</td></tr>
<tr><td></td><td>Study type: RCT
Aim of the study: To compare the onset of action, and quality of block, of lidocaine 2% with levobupivacaine 0.75% for sub-Tenon’s block in patients undergoing cataract surgery.
Study dates: Not reported
Sources of funding: Not reported</td></tr>
<tr><td>Participants</td><td>Sample size
91 patients
Inclusion criteria
American Society of Anaesthesiologists physical status class I – III patients scheduled to undergo cataract surgery under a sub-Tenon’s block.
Exclusion criteria
Those unwilling to take part, communication or language problems, any history of allergy to amide local anaesthetic agents or pre-existing extra-ocular muscle palsy.</td></tr>
<tr><td>Methods</td><td>Patients were randomised by computer generated random order software to receive either lidocaine 2% or levobupivacaine 0.75%, both with hyaluronidase 15 IU/ml
Data collection
Immediately after surgery, patients were asked to score pain on injection and during surgery using a verbal analogue scale (VAS) from 0 = no pain to 10 = worst pain imaginable
Intervention
Sub-Tenon’s block with either lidocaine 2% or levobupivacaine 0.75%
Analysis
Fishers exact test, Student t test</td></tr>
<tr><td>Results</td><td>Mean injection Pain Scores (± SD)
<table>
<tr><td></td><td>Lidocaine (n=44)</td><td>Levobupivacaine (n=47)</td><td></td></tr>
<tr><td></td><td>Mean (SD)</td><td>Mean (SD)</td><td>p-value</td></tr>
<tr><td>Injection</td><td>0.63 (1.31)</td><td>0.98 (1.78)</td><td>0.24</td></tr>
<tr><td>Perioperative</td><td>0.53 (1.30)</td><td>0.13 (0.74)</td><td>0.07</td></tr>
</table>
Surgical complications
<table>
<tr><td>Group</td><td>Small conjunctival haemorrhage</td><td>P value</td><td>Chemosis</td><td>P value</td></tr>
<tr><td>Lidocaine 2%</td><td>26%</td><td></td><td>21%</td><td></td></tr>
</table></td></tr>
</table>

Full citation	McLure H, Kumar C, Ahmed S, Patel A. A comparison of lidocaine 2% with levobupivacaine 0.75% for sub-Tenon's block. European Journal of Anaesthesiology. 2005;22:500-503
	levobupivacaine 0.75% | 36% | 0.26 | 18% | 0.79
Outcomes	Non-significant trend towards increased perioperative pain in the lidocaine group. Pain scores were not significantly different for injection or perioperatively
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Yes 3 Were the patients, health workers and study personnel blinded? Yes 4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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Full citation	Soliman M, Macky T, Samir K. Comparative clinical trial of topical anaesthetic agents in cataract surgery. J Cataract Refract Surg 2004;30:1716-1720
Study details	Country/ies where the study was carried out: Egypt Study type: RCT Aim of the study: To assess the efficacy of lidocaine gel, bupivacaine drops and benoxinate drops as topical anaesthetic agents in cataract surgery. Study dates: Not reported Sources of funding: Not reported
Participants	Sample size 90 patients Inclusion criteria Patients scheduled to undergo planned routine cataract surgery (phacoemulsification). Exclusion criteria Nystagmus, deafness, anxiety, monocularity, unwillingness to have topical anaesthesia, reported allergy to topical anaesthetic agents, and inability to understand the 10-point verbal pain score (VPS) scale.
Methods	Patients randomised into 1 of 3 groups of 30 each based on the topical agent they were to receive: lidocaine 2% gel, bupivacaine 0.5% eye drops, or benoxinate 0.4% eye drops. Data collection

<table>
<tr><th>Full citation</th><td>Soliman M, Macky T, Samir K. Comparative clinical trial of topical anaesthetic agents in cataract surgery. J Cataract Refract Surg 2004;30:1716-1720</td></tr>
<tr><td></td><td>Patients were asked to score pain on application of the agent and intraoperatively using a 10 point verbal pain score (VPS) from 0 = no pain to 10 = unbearable pain.
Overall satisfaction with the surgical procedure was measured by asking whether they would be willing to have the same anaesthetic agent again.
Intervention
Topical anaesthetic (lidocaine 2% gel, bupivacaine 0.5% eye drops, or benoxinate 0.4% eye drops.)
Analysis
Chi-square test</td></tr>
<tr><td>Results</td><td>Verbal pain scores (Mean ±SD)
<table>
<tr><td>Anaesthetic</td><td>During application of anaesthetic</td><td>P-value</td><td>Intraoperatively</td><td>P-value</td></tr>
<tr><td>lidocaine 2% gel</td><td>2.97 ± 0.61</td><td><0.001</td><td>1.6 ± 1.9</td><td><0.001</td></tr>
<tr><td>bupivacaine 0.5% eye drops</td><td>1.53 ± 0.29</td><td></td><td>4.1 ± 2.2</td><td></td></tr>
<tr><td>benoxinate 0.4% eye drops</td><td>1.03 ± 0.26</td><td></td><td>7.1 ± 1.5</td><td></td></tr>
</table>
Patient satisfaction
<table>
<tr><td>Anaesthetic</td><td>Willing to have the same anaesthetic again</td><td>P-value</td></tr>
<tr><td>lidocaine 2% gel</td><td>93.3%</td><td><0.001</td></tr>
<tr><td>bupivacaine 0.5% eye drops</td><td>83.3%</td><td></td></tr>
<tr><td>benoxinate 0.4% eye drops</td><td>30.0%</td><td></td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>The mean VPS at application in the lidocaine group was statistically significantly higher than in the other 2 groups (p<0.001)
The mean VPS during surgery in the lidocaine group was statistically significantly lower than in the other 2 groups (p<0.001)
The patients overall satisfaction was statistically significantly higher in the lidocaine and bupivacaine groups than in the benoxinate group (p<0.001)</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Unsure
3 Were the patients, health workers and study personnel blinded? Unsure
4 Were the groups similar at the start of the trial? Yes
5 Aside from the experimental intervention, were the groups treated equally? Yes</td></tr>
</table>

Full citation	Soliman M, Macky T, Samir K. Comparative clinical trial of topical anaesthetic agents in cataract surgery. J Cataract Refract Surg 2004;30:1716-1720
skills programme)	6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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E.7.2 Sedation as an adjunct to local anaesthesia

Full citation	**Inan U, Sivaci R, Ermis S, Ozturk F. Effects of fentanyl on pain and haemodynamic response after retrobulbar block in patients having phacoemulsification. J Cataract Refract Surg 2003; 29:1137-1142**
Study details	Country/ies where the study was carried out: Turkey Study type: RCT Aim of the study: To determine the effects of systemic fentanyl analgesia in preventing the pain related to the administration of retrobulbar anaesthesia and cataract pain. Study dates: Not reported Sources of funding: Not reported
Participants	Sample size 120 patients Inclusion criteria Patients aged between 40 and 78 with American Society of Anaesthesiologists physical status I to III scheduled for cataract surgery. Exclusion criteria Patients with a history of hypertension, hyperthyroidism, or neurologic or psychiatric disorders.
Methods	Patients were prospectively randomised to receive local anaesthesia (control group) or local anaesthesia combined with fentanyl analgesia (fentanyl group). There were 60 patients in each group. Patients pain was evaluated by verbal pain scores (VPS) using a 4-point scale (0 = no pain, 1 = mild pain, 2 = moderate pain and 3 = severe pain) Intervention Cataract surgery by phacoemulsification with or without fentanyl given before a retrobulbar (RB) block administered Analysis Chi-square test
Results	Verbal Pain Scores

	Mean ± SD		
Scoring time	Fentanyl group	Control group	P value
During RB injection	0.06 ± 0.25	1.60 ± 0.52	0.000
During surgery	0.08 ± 0.27	1.06 ± 0.25	0.000

Outcomes	The VPS in the fentanyl group were lower than in the control group The fentanyl group had statistically significantly lower pain scores than the control group at all evaluations ($p<0.05$)

Full citation	Inan U, Sivaci R, Ermis S, Ozturk F. Effects of fentanyl on pain and haemodynamic response after retrobulbar block in patients having phacoemulsification. J Cataract Refract Surg 2003; 29:1137-1142
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Unsure 3 Were the patients, health workers and study personnel blinded? Unsure 4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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Full citation	Aydin O, Kir E, Ozkan S, Gursoy F. Patient controlled analgesia and sedation with fentanyl in phacoemulsification under topical anaesthesia. J Cataract Refract Surg 2002; 28:1968-1972
Study details	Country/ies where the study was carried out: Turkey Study type: RCT Aim of the study: To investigate the effects of IV patient-controlled sedation/analgesia with fentanyl during phacoemulsification surgery under topical anaesthesia Study dates: Not reported Sources of funding: Not reported
Participants	Sample size 68 patients Inclusion criteria Patients aged between 38 and 85 with American Society of Anaesthesiologists physical status I to III scheduled for cataract surgery. Exclusion criteria Patients with excessive blink reflex during intraocular pressure measurement by Goldmann applanation tonometry, insufficient pupil dilation, posterior synechias, hypermature cataract, previous glaucoma operation, nystagmus, fentanyl allergy, psychiatric disorders, low arterial blood pressure, and respiratory disorders.
Methods	Patients were prospectively randomised by creating a list from which the numbers 1 to 68 were used to randomly assign patients to 1 of 2 groups: fentanyl (n=34) or control (n=34). They were placed on the list in order of recruitment. In the fentanyl group, fentanyl was administered in 5µg doses by PCA equipment with a 5 minute lock out period after an initial IV dose of 0.7µg/kg in the control group, a balanced salt solution was given without an analgesic drug by PCA equipment. Data collection

<table>
<tr><th>Full citation</th><th>Aydin O, Kir E, Ozkan S, Gursoy F. Patient controlled analgesia and sedation with fentanyl in phacoemulsification under topical anaesthesia. J Cataract Refract Surg 2002; 28:1968-1972</th></tr>
<tr><td></td><td>Patients pain was evaluated by a verbal pain scale (VPS) (0 = no pain and 10 = worst pain imaginable) preoperatively and during the procedure (5, 10, 15, 20 and 30 minute intervals)
Patients were questioned postoperatively whether they would prefer to be operated on by the same method for a second procedure and for comfort (1 = poor, 2 = moderate, 3 = good and 4 = perfect)
Intervention
Cataract surgery with sedation by administration of fentanyl or balanced salt solution (control)
Analysis
Two tailed Student t-test</td></tr>
<tr><td>Results</td><td>Patient satisfaction
<table>
<tr><td>Group</td><td>Mean score ± SD</td></tr>
<tr><td>Fentanyl</td><td>3.79 ± 0.41</td></tr>
<tr><td>Control</td><td>3.44 ± 0.78</td></tr>
</table>
P=0.023</td></tr>
<tr><td>Outcomes</td><td>In both groups the VPS scores increased, in particular between 10 and 30 minutes intraoperatively
Patient satisfaction showed a significant difference between the 2 groups with the fentanyl group showing greater satisfaction.</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Yes
3 Were the patients, health workers and study personnel blinded? Yes
4 Were the groups similar at the start of the trial? Yes
5 Aside from the experimental intervention, were the groups treated equally? Yes
6 Were all of the patients who entered the trial properly accounted for sat its conclusion? Yes
7 Can the results be applied to the local population? Yes
8 Were all clinically important outcomes considered? N/A</td></tr>
</table>

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32E.7.3 Hyaluronidase as an adjunct to local anaesthesia

Full citation	Rowley S, Hale J, Finlay R. Sub-Tenon's local anaesthesia: the effect of hyaluronidase. British Journal of Ophthalmology 2000;84:435-436
Study details	Country/ies where the study was carried out: UK Study type: RCT Aim of the study: To investigate the effect of hyaluronidase on the quality of block achieved with sub-Tenon's local anaesthesia. Study dates: Not reported Sources of funding: Not reported
Participants	Sample size 150 patients Inclusion criteria Patients scheduled to undergo elective cataract surgery under local anaesthesia Exclusion criteria Patients with learning difficulties, profound deafness, dementia, high anxiety scores and those with a known adverse reaction to lignocaine or hyaluronidase
Methods	Patients were randomly allocated to one of two groups using random number tables. The control group received 3ml lignocaine 2% adrenaline 1:200 000 and the hyaluronidase group received 3ml the same but with the addition of 30 IU/ml of hyaluronidase. Data collection Patients pain was evaluated using a visual pain analogue 10cm in length (0 being no pain and 10 excruciating pain) Intervention Sun-Tenon's block with and without hyaluronidase Analysis Chi-square test, t-test and Mann-Whitney U test
Results	Mean Pain scores
Outcomes	The mean post-injection and perioperative pain scores were higher in the hyaluronidase group but these were not statistically significant.
Study Appraisal using CASP	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Yes 3 Were the patients, health workers and study personnel blinded? Yes

	Hyaluronidase (n=76)	No hyaluronidase (n=74)	Significance
Post-injection pain score	2.26	1.95	Not significant
Perioperative pain score	1.04	1.03	Not significant

Full citation	**Rowley S, Hale J, Finlay R. Sub-Tenon's local anaesthesia: the effect of hyaluronidase. British Journal of Ophthalmology 2000;84:435-436**
(Critical appraisal skills programme)	4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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Full citation	**Seghipour M, Mahdavifard A, Fouladi R et al. Hyaluronidase in sub-Tenon's anaesthesia for phacoemulsification, a double-blind randomised clinical trial. International Journal of Ophthalmology 2012;5(3):389-392**
Study details	Country/ies where the study was carried out: Iran Study type: RCT Aim of the study: To investigate the effect of hyaluronidase use on the quality of sub-Tenon's anaesthesia for phacoemulsification Study dates: February 2011 to July 2011 Sources of funding: Not reported
Participants	Sample size 42 patients Inclusion criteria Patients referred for elective cataract surgery under sub-Tenon's anaesthesia from the Nikookari Eye Hospital Exclusion criteria Patients with deafness or allergy to lidocaine or hyaluronidase.
Methods	Patients were assigned consecutive numbers on admission which were previously randomised to treatment groups. The control group n=21 (no hyaluronidase) received 2ml of lidocaine 2% solution, the hyaluronidase group n=21 received 2ml of a solution containing a 50:50 mixture of lidocaine 2% plus hyaluronidase 150 IU/ml. Data collection Patients intraoperative satisfaction Intervention Sub-Tenon's block with and without hyaluronidase Analysis Chi-squared
Results	Patient satisfaction

Full citation	**Seghipour M, Mahdavifard A, Fouladi R et al. Hyaluronidase in sub-Tenon's anaesthesia for phacoemulsification, a double-blind randomised clinical trial. International Journal of Ophthalmology 2012;5(3):389-392**
	<table><tr><th></th><th>Hyaluronidase (n=21)</th><th>Control (n=21)</th><th>P</th><th>Odds Ratio</th><th>95% CI</th></tr><tr><td>Yes</td><td>18 (85.7)</td><td>12 (57.1)</td><td></td><td></td><td></td></tr><tr><td>No</td><td>3 (14.3)</td><td>9 (42.9)</td><td>0.04</td><td>4.50</td><td>1.00 – 50.00</td></tr></table> Data presented as frequency (percentage)
Outcomes	85.7% of the patients in the Hyaluronidase group were satisfied with their operation, while this rate was 57.1% in the control group.
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Yes 3 Were the patients, health workers and study personnel blinded? Yes 4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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Full citation	**Guise P, Laurent S. Sub-Tenon's Block: The effect of hyaluronidase on speed of onset and block quality. Anaesth Intensive care 1999;27:179-181**
Study details	Country/ies where the study was carried out: New Zealand Study type: RCT Aim of the study: To investigate the effect of hyaluronidase on speed of onset and block quality in sub-Tenon's block Study dates: Not reported Sources of funding: Not reported
Participants	Sample size 120 patients Inclusion criteria Patients scheduled for elective cataract surgery under sub-Tenon's anaesthesia. Exclusion criteria Not reported

<table>
<tr><th>Full citation</th><th>Guise P, Laurent S. Sub-Tenon’s Block: The effect of hyaluronidase on speed of onset and block quality. Anaesth Intensive care 1999;27:179-181</th></tr>
<tr><td>Methods</td><td>Patients were randomised to receive either 2% plain lignocaine 3ml with 0.5% bupivacaine 2ml. The other consisted of 2% lignocaine 1ml containing 150 IU/ml of hyaluronidase and 2% plain lignocaine 2ml with 0.5% bupivacaine 2ml. The syringes were prepared at random and coded.
Data collection
Patient intraoperative pain and pain on injection of the block.
Intervention
Sub-Tenon’s block with and without hyaluronidase
Analysis
Chi-squared, t-test</td></tr>
<tr><td>Results</td><td>Patient comfort during procedure
<table>
<tr><td></td><td>Hyaluronidase (n=60)</td><td>No Hyaluronidase (n=60)</td><td>P</td></tr>
<tr><td>Pain on injection (Yes/No)</td><td>9/51</td><td>17/43</td><td>0.015</td></tr>
<tr><td>Intraoperative pain</td><td>0</td><td>2</td><td>Not significant</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>No significant differences in intraoperative pain
Patients in the no-hyaluronidase group experienced significantly more pain during block insertion</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Unsure
3 Were the patients, health workers and study personnel blinded? Yes
4 Were the groups similar at the start of the trial? Yes
5 Aside from the experimental intervention, were the groups treated equally? Yes
6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes
7 Can the results be applied to the local population? Yes
8 Were all clinically important outcomes considered? N/A</td></tr>
</table>

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<table>
<tr><th>Full citation</th><th>Schulenburg H, Sri-Chandana C, Lysons G, Columb M, McLure H. Hyaluronidase reduces local anaesthetic volumes for sub-Tenon’s anaesthesia. British Journal of Anaesthesia 2007;99(5):717-720</th></tr>
<tr><td>Study details</td><td>Country/ies where the study was carried out: UK</td></tr>
</table>

<table>
<tr><th>Full citation</th><td>Schulenburg H, Sri-Chandana C, Lysons G, Columb M, McLure H. Hyaluronidase reduces local anaesthetic volumes for sub-Tenon’s anaesthesia. British Journal of Anaesthesia 2007;99(5):717-720</td></tr>
<tr><td></td><td>Study type: RCT
Aim of the study: To examine the addition of hyaluronidase on the minimum local anaesthetic volume (MLAV required for a sub-Tenon’s block
Study dates: Not reported
Sources of funding: Not reported</td></tr>
<tr><td>Participants</td><td>Sample size
62 patients
Inclusion criteria
Patients scheduled for elective day case cataract surgery under local anaesthesia with an American Society of Anaesthesiologists physical status class I - III
Exclusion criteria
Patients with allergies to local anaesthetics or hyaluronidase, previous eye surgery, pre-existing extra-ocular muscle palsies, or communication difficulties.</td></tr>
<tr><td>Methods</td><td>Patients were randomised according to a computer-generated random number to receive either lidocaine 2% w/v with hyaluronidase 15 IU ml-1 or plain lidocaine 2% w/v.
Data collection
Using parallel up–down sequential allocation from a 4 ml starting volume, the volumes in both groups were changed using a testing interval of 1 ml according to the quality of globe akinesia. The median effective local anaesthetic volume (MLAV) was calculated for both groups using probit regression.
Intervention
Sub-Tenon’s block with and without hyaluronidase</td></tr>
<tr><td>Results</td><td>Median effective volumes, ratio and 95% confidence intervals (95% CI)
<table>
<tr><td></td><td>Estimate</td><td>95% CI</td></tr>
<tr><td>Control (ml)</td><td>6.4</td><td>5.1 – 8.1</td></tr>
<tr><td>Hyalrunonidase (ml)</td><td>2.6</td><td>2.1 – 3.3</td></tr>
<tr><td>Ratio</td><td>2.4</td><td>1.8 – 3.4</td></tr>
<tr><td>P-value</td><td>0.002</td><td></td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>Hyaluronidase permits a significant 2.4-fold (95% CI, 1.8–3.4) reduction in MLAV for sub-Tenon’s anaesthesia.
No adverse effects to hyaluronidase were noted.</td></tr>
</table>

Full citation	**Schulenburg H, Sri-Chandana C, Lysons G, Columb M, McLure H. Hyaluronidase reduces local anaesthetic volumes for sub-Tenon's anaesthesia. British Journal of Anaesthesia 2007;99(5):717-720**
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Yes 3 Were the patients, health workers and study personnel blinded? Yes 4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

E.7.4 General anaesthesia

No evidence was identified for this review question.

E.8 Preventing and managing complications

- What is the effectiveness of interventions (for example, prophylactic laser surgery) to prevent retinal detachment in people with myopia undergoing cataract surgery?
- What is the effectiveness of capsular tension rings applied during phacoemulsification cataract surgery?
- What is the effectiveness of interventions to increase pupil size to improve visual outcomes and reduce complications during phacoemulsification cataract surgery?
- What is the effectiveness of postoperative eye shields to prevent complications after cataract extraction?
- What is the effectiveness of prophylactic antiseptics (for example, topical iodine) and antibiotics to prevent endophthalmitis after cataract surgery?
- What is the effectiveness of prophylactic topical corticosteroids and/or NSAIDs to prevent inflammation and cystoid macular oedema after phacoemulsification cataract surgery?
- What is the effectiveness of interventions to reduce the impact of perioperative posterior capsule rupture?
- What is the effectiveness of interventions used to manage cystoid macular oedema following cataract surgery?

E.8.1 Interventions to prevent retinal detachment in people with myopia

No evidence was identified for this review question.

35E.8.2 Intra-operative pupil size management

Full citation	**Espindola R, Castro E, Santhiago M, Kara-Junior N. Aclinical comparison between DisCoVisc and 2% hydroxypropylmethylcellulose in phacoemulsification: a fellow eye study. Clinics 2012;67:1059-1062**
Study details	Country/ies where the study was carried out: Brazil Study type: RCT Aim of the study: To compare the effects and outcomes of two ophthalmic viscosurgical devices, 1.6% hyaluronic acid/4.0% chondroitin sulfate (DisCoVisc) and 2.0% hydroxypropylmethylcellulose (2% HPMC) during phacoemulsification. Study dates: Not reported Sources of funding: None reported
Participants	Sample size 39 patients (78 eyes) Inclusion criteria Bilateral age-related cataracts from grades 1 to 3 based on the lens opacities classification system (LOCS III), and no other ocular pathology or condition and pupil dilation that was greater than 7.0mm. Exclusion criteria Black, brunescent, traumatic or subluxated cataracts; coexisting corneal endothelial disease (endothelial cell count <2,000 cells/mm2); glaucoma; uveitis and pseudo-exfoliation, previous ocular surgery
Methods	An envelope system was used to randomly assign all enrolled patients to an OVD regimen. Sequenced and sealed envelopes containing the first type of OVD (2.0% HPMC or DisCoVisc) were prepared before surgery. An unscrubbed observer in the operating room opened the envelopes and assigned each patient to the prescribed option. The second eye was treated later and received the other viscoelastic agent for all steps of the phacoemulsification. Data collection Preoperative and postoperative examinations measured the best-corrected visual acuity (BCVA) Analysis Unpaired t-test, ANOVA, chi-square test, Fisher's exact test and the Mann-Whitney U-test.
Results	Postoperative BCVA (logMAR) – Mean ± SD | | DisCoVisc | 2% HPMC | P value | | 24 hours | 0.35 ± 0.28 | 0.53 ± 0.43 | <0.0001 | | 6 months | 0.02 ± 0.07 | 0.05 ± 0.10 | 0.104 |
Outcomes	There was a statistically significant difference between OVDs in terms of the postoperative mean BCVA at 24 hours post-surgery, but not at 6 months No adverse events (intraoperative or postoperative)

Full citation	**Espindola R, Castro E, Santhiago M, Kara-Junior N. Aclinical comparison between DisCoVisc and 2% hydroxypropylmethylcellulose in phacoemulsification: a fellow eye study. Clinics 2012;67:1059-1062**
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Yes 3 Were the patients, health workers and study personnel blinded? Unsure 4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for sat its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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Full citation	**Lorente R, Rojas V, Parga P, Moreno C, Varela J, Landaluce M, Mendez J, Lorente B. Intracameral phenylephrine 1.5% for prophylaxis against intraoperative floppy iris syndrome: Prospective, randomised fellow eye study. Ophthalmology 2012;119:2053-2058**
Study details	Country/ies where the study was carried out: Spain Study type: RCT Aim of the study: To evaluate the efficacy of intracameral phenylephrine (IPH) as prophylaxis against floppy iris syndrome (IFIS) Study dates: January 2011 to April 2011 Sources of funding: None reported
Participants	Sample size 42 patients (84 eyes) Inclusion criteria Patients receiving tamsulosin and scheduled to have routine phacoemulsification cataract surgery Exclusion criteria History of glaucoma, endothelial disease, media opacities, other than cataract, ocular trauma, zonular dialysis, iridocyclitis, iris neovascularisation, or prior iris surgery, preoperative pupil size less than 4.5mm after topical mydriatics, receiving treatment with any other alpha 1 antagonist or other drugs associated with IFIS.
Methods	One eye of each patient was randomised to receive 0.6ml of unpreserved bisulfite-free IPH 1.5% (Group 1) or balanced saline solution (BSS) (Group 2) Data collection Mean postoperative Best corrected visual acuity (BCVA) was recorded Analysis

<table>
<tr><th>Full citation</th><td>Lorente R, Rojas V, Parga P, Moreno C, Varela J, Landaluce M, Mendez J, Lorente B. Intracameral phenylephrine 1.5% for prophylaxis against intraoperative floppy iris syndrome: Prospective, randomised fellow eye study. Ophthalmology 2012;119:2053-2058</td></tr>
<tr><td></td><td>Mann-Whitney test</td></tr>
<tr><td>Results</td><td>Postoperative BCVA (Mean ± SD)
<table>
<tr><td></td><td>Group 1 (IPH)</td><td>Group 2 (BSS)</td><td>P value</td></tr>
<tr><td>BCVA (logMAR)</td><td>0.029 ± 0.07</td><td>0.042 ± 0.07</td><td>0.651</td></tr>
</table>
Mean pupil diameter
<table>
<tr><td></td><td colspan="3">Mean pupil diameter (mm)</td></tr>
<tr><td></td><td>Group 1 (IPH)</td><td>Group 2 (BSS)</td><td>P value</td></tr>
<tr><td>After hydrodissection</td><td>7.57 ± 1.04</td><td>6.46 ± 1.18</td><td>0.000</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>No statistically significant differences in BCVA (p=0.651) between the groups
Compared with before surgery, significant decrease in pupil size was detected after hydrodissection
No adverse events (intraoperative or postoperative)</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Unsure
3 Were the patients, health workers and study personnel blinded? Unsure
4 Were the groups similar at the start of the trial? Yes
5 Aside from the experimental intervention, were the groups treated equally? Yes
6 Were all of the patients who entered the trial properly accounted for sat its conclusion? Yes
7 Can the results be applied to the local population? Yes
8 Were all clinically important outcomes considered? N/A</td></tr>
</table>

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Full citation	**Moschos M, Chatziralli I, Sergentanis T. Viscoat versus Visthesia during phacoemulsification cataract surgery: corneal and foveal changes. BMC Ophthalmology 2011;11:9**
Study details	Country/ies where the study was carried out: Greece Study type: RCT Aim of the study: To compare the corneal and foveal changes of Viscoat and Visthesia in patients undergoing uneventful phacoemulsification cataract surgery. Study dates: Not reported

<table>
<tr><th>Full citation</th><td>Moschos M, Chatziralli I, Sergentanis T. Viscoat versus Visthesia during phacoemulsification cataract surgery: corneal and foveal changes. BMC Ophthalmology 2011;11:9</td></tr>
<tr><td></td><td>Sources of funding: None reported</td></tr>
<tr><td>Participants</td><td>Sample size
77 patients
Inclusion criteria
Patients undergoing cataract surgery recruited from the 1st Department of Ophthalmology, University of Athens, Athens, Greece
Exclusion criteria
Corneal abnormalities, history of intraocular surgery, preoperative endothelial cell count less than 1500 cells/mm2, history of uveitis, diabetes, age-related macular degeneration and intraoperative complications, such as posterior capsule rupture, vitreous loss, lost nucleus, zonule dehiscence and wound leak.</td></tr>
<tr><td>Methods</td><td>Patients were randomized into two groups based on type of OVD used during phacoemulsification: Viscoat or Visthesia.
Data collection
Best corrected visual acuity (BCVA) was measured pre and postoperatively
Analysis
Mann-Whitney-Wilcoxon test</td></tr>
<tr><td>Results</td><td>Postoperative BCVA (logMAR) – mean ± SD
<table>
<tr><td></td><td>Viscoat (n=41)</td><td>Visthesia (n=36)</td><td>P value</td></tr>
<tr><td>3 days</td><td>0.24 ± 0.24</td><td>0.26 ± 0.37</td><td>0.238</td></tr>
<tr><td>15 days</td><td>0.07 ± 0.09</td><td>0.05 ± 0.08</td><td>0.041</td></tr>
<tr><td>28 days</td><td>0.0014 ± 0.0078</td><td>0.001 ± 0.0083</td><td>0.926</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>Postoperative BCVA (logMAR) did not differ between the two groups.</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Unsure
3 Were the patients, health workers and study personnel blinded? Unsure
4 Were the groups similar at the start of the trial? Yes
5 Aside from the experimental intervention, were the groups treated equally? Yes
6 Were all of the patients who entered the trial properly accounted for sat its conclusion? Yes
7 Can the results be applied to the local population? Yes
8 Were all clinically important outcomes considered? N/A</td></tr>
</table>

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<table>
<tr><th>Full citation</th><th>Papaconstantinou D, Karmiris T, Diagourtas A, Koutsandrea C, Georgalas I. Clinical trial evaluating Viscoat and Visthesia ophthalmic viscosurgical devices in corneal endothelial loss after cataract extraction and intraocular lens implantation. Cutaneous and ocular toxicology. 2014;33:173-180</th></tr>
<tr><td>Study details</td><td>Country/ies where the study was carried out: Greece
Study type: RCT
Aim of the study: To assess and compare the safety and the efficacy of VisThesia and Viscoat in cataract surgery
Study dates: Not reported
Sources of funding: None reported</td></tr>
<tr><td>Participants</td><td>Sample size
44 patients (44 eyes)
Inclusion criteria
Aged over 50, senile cataract, not having any evidence of subluxation or pseudoexfoliation or any other associated ocular pathology
Exclusion criteria
Preoperative diagnosed glaucoma and/or IOP greater than 20mmHg, intraoperative events such as manual dilation of pupil, posterior capsular rent and placement of a sulcus IOL.</td></tr>
<tr><td>Methods</td><td>The operating surgeon was told on the operation table to use single OVD allocated for the patients for the entire procedure as per the randomisation
Data collection
Mean pre and postoperative Best corrected visual acuity (BCVA)
Analysis
Student t-test, Chi-Squared</td></tr>
<tr><td>Results</td><td>Postoperative BCVA (logMAR) – mean ± SD
<table><tr><td>Visthesia (n=22)</td><td>Viscoat (n=22)</td></tr><tr><td>0.83 ± 1.4</td><td>0.85 ± 1.2</td></tr></table></td></tr>
<tr><td>Outcomes</td><td>Postoperative BCVA statistically improved in both groups but there was no difference between them
No adverse events (intraoperative or postoperative)</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Unsure
3 Were the patients, health workers and study personnel blinded? Yes
4 Were the groups similar at the start of the trial? Yes
5 Aside from the experimental intervention, were the groups treated equally? Yes
6 Were all of the patients who entered the trial properly accounted for sat its conclusion? Yes</td></tr>
</table>

Full citation	**Papaconstantinou D, Karmiris T, Diagourtas A, Koutsandrea C, Georgalas I. Clinical trial evaluating Viscoat and Visthesia ophthalmic viscosurgical devices in corneal endothelial loss after cataract extraction and intraocular lens implantation. Cutaneous and ocular toxicology. 2014;33:173-180**
	7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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Full citation	**Shingleton B, Mitrev P. Anterior chamber maintainer versus viscoelastic material for intraocular lens implantation: Case control study. J Cataract Refract Surg 2001;27:711-714**
Study details	Country/ies where the study was carried out: USA Study type: Case Control Aim of the study: To compare best corrected visual acuity (BCVA) and IOP in eyes that had a foldable IOL implanted with the use of an anterior chamber maintainer (ACM) in 1 eye and hyaluronate 3% (Vitrax) viscoelastic material in the other Study dates: Not reported Sources of funding: Private funds of the Ophthalmic consultants of Boston
Participants	Sample size 33 patients (66 eyes) Inclusion criteria Patients having bilateral cataract extraction Exclusion criteria Ocular conditions that could affect the measured postoperative outcomes (e.g. glaucoma, age related macular degeneration, amblyopia), monocular patients, those receiving dissimilar IOL models.
Methods	The operating surgeon arbitrarily assigned patients to the ACM or viscoelastic group for the first eye. For the second, a technician ascertained which technique was used in the first eye before opening the appropriate amount of viscoelastic material for surgery. Data collection Mean pre and postoperative Best corrected visual acuity (BCVA) Analysis Student t-test
Results	Postoperative BCVA

	Mean BCVA (Decimal) ± SD		
Examination	ACM Group (n=33)	Vitrax Group (n=33)	P value
1 Day	0.60 ± 0.18	0.68 ± 0.22	0.11
3-6 weeks	0.82 ± 0.19	0.77 ± 0.22	0.40

Full citation	**Shingleton B, Mitrev P. Anterior chamber maintainer versus viscoelastic material for intraocular lens implantation: Case control study. J Cataract Refract Surg 2001;27:711-714**
Outcomes	No significant difference in postoperative BCVA between the groups No adverse events (intraoperative or postoperative)
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Did the authors use an appropriate method to answer their question? Yes 3 Were the cases recruited in an acceptable way? Unclear 4 Were the controls selected in an acceptable way? Unclear 5 Was the exposure accurately measured to minimise bias? Unclear 6 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unclear 7 Do you believe the results? Yes 8 Can the results be applied to the local population? Yes 9 Do the results of this study fit with other available evidence? N/A

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Full citation	**Shingleton B, Campbell C, O'Donoghue M. Effects of pupil stretch techniques during phacoemulsification on postoperative vision, intraocular pressure and inflammation. J Refract Surg 2006;32:1142-1145**
Study details	Country/ies where the study was carried out: USA Study type: Retrospective case control Aim of the study: To determine whether pupil stretching during phacoemulsification affects postoperative best corrected visual acuity (BCVA), intraocular pressure (IOP) and inflammation compared with results in patients without pupil stretch Study dates: 1995 to 2004 Sources of funding: None reported
Participants	Group characteristics Group 1 (Pupil stretch) : 57 eyes had glaucoma, of those 10 had pseudoexfoliation, 12 had previous glaucoma filters and 19 were on a glaucoma regime (including pilocarpine), 1 was on Flomax Group 2 (Control) : 15 eyes had had glaucoma, of those 2 had pseudoexfoliation, 1 had previous glaucoma filters and 4 were on pilocarpine, 0 patients on Flomax Sample size 240 eyes (115 with pupil stretch, 125 eyes without) Inclusion criteria Patients who underwent cataract surgery in which a pupil stretch technique was performed and a control group who did not undergo pupil stretching (matched population for preoperative characteristics)

<table>
<tr><th>Full citation</th><td colspan="7">Shingleton B, Campbell C, O'Donoghue M. Effects of pupil stretch techniques during phacoemulsification on postoperative vision, intraocular pressure and inflammation. J Refract Surg 2006;32:1142-1145</td></tr>
<tr><td></td><td colspan="7">Exclusion criteria
None reported</td></tr>
<tr><td>Methods</td><td colspan="7">Data collection
Mean pre and postoperative (1 day, 1 month and 1 year) Best corrected visual acuity (BCVA)
Analysis
Student t-test</td></tr>
<tr><td>Results</td><td colspan="7">Postoperative results
<table>
<tr><td></td><td colspan="3">Group 1 (pupil stretching)</td><td colspan="3">Group 2 (Control)</td></tr>
<tr><td>Parameter</td><td>1 Day</td><td>1 Month</td><td>1 Year</td><td>1 Day</td><td>1 Month</td><td>1 Year</td></tr>
<tr><td>BCVA (logMAR)
Mean ± SD</td><td>0.31 ± 0.27</td><td>0.21 ± 0.21</td><td>0.23 ± 0.23</td><td>0.52 ± 0.34</td><td>0.15 ± 0.26</td><td>0.18 ± 0.21</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td colspan="7">Postoperative BCVA at 1 year, improved in both groups but there was no significant difference between them
Postoperative ocular inflammation was mild in both groups and absent at 1 year</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td colspan="7">1 Did the study address a clearly focused issue? Yes
2 Did the authors use an appropriate method to answer their question? Yes
3 Were the cases recruited in an acceptable way? Unclear
4 Were the controls selected in an acceptable way? Unclear
5 Was the exposure accurately measured to minimise bias? Unclear
6 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unclear
7 Do you believe the results? Yes
8 Can the results be applied to the local population? Unsure
9 Do the results of this study fit with other available evidence? N/A</td></tr>
</table>

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Full citation	**Wilczynski M, Wierzchowski T, Synder A, Omulecki W. Results of phacoemulsification with Malyugin Ring in comparison with manual iris stretching with hooks in eyes with narrow pupils. Eur J Ophthalmology 2013;23:196-201**
Study details	Country/ies where the study was carried out: Poland Study type: RCT Aim of the study: To evaluate the results of phacoemulsification in eyes with a narrow pupil dilated with Malyugin Ring in comparison with manual pupillary stretching hooks.

<table>
<tr><th>Full citation</th><th>Wilczynski M, Wierzchowski T, Synder A, Omulecki W. Results of phacoemulsification with Malyugin Ring in comparison with manual iris stretching with hooks in eyes with narrow pupils. Eur J Ophthalmology 2013;23:196-201</th></tr>
<tr><td></td><td>Study dates: Not reported
Sources of funding: None reported</td></tr>
<tr><td>Participants</td><td>Sample size
40 patients (40 eyes)
Inclusion criteria
Patients undergoing phacoemulsification and IOL implantation
Exclusion criteria
Not reported</td></tr>
<tr><td>Methods</td><td>Patients were randomly assigned to one of 2 groups using the RANDBETWEEN function in MS Excel to generate random numbers to assign consecutive patients. Group 1: Malyugin Ring (n=23), Group 2: Manual stretching (n=17)
Group characteristics – all patients had posterior synechiae present, the causes outlined below:-
Group 1: 3 eyes with previous uveitis, 2 eyes had previous YAG iridotomy, 9 eyes had previous trabeculectomy, 3 eyes previous pilocarpine use, 2 eyes previous pseudoexfoliation.
Group 2: 1 eye with previous uveitis, 3 eyes had previous YAG iridotomy, 13 eyes had previous trabeculectomy, 4 eyes previous pilocarpine use, 0 eyes previous pseudoexfoliation.
Data collection
Mean pre and postoperative (1 day and 1 month) Best corrected visual acuity (BCVA)
Analysis
Mann-Whitney U</td></tr>
<tr><td>Results</td><td>Postoperative BCVA (Decimal) – mean ± SD
<table>
<tr><td>Malyugin Ring (n=23)</td><td>Manual stretching (n=17)</td></tr>
<tr><td>0.75 ± 0.30</td><td>0.56 ± 0.56</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>Postoperative BCVA statistically improved in both groups.
Postoperative BCVA in eyes where Malyugin Ring was used was significantly better than in the group where the pupil was stretched with 2 hooks.
No serious complications were reported.</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Yes
3 Were the patients, health workers and study personnel blinded? Unsure
4 Were the groups similar at the start of the trial? Yes</td></tr>
</table>

Full citation	Wilczynski M, Wierzchowski T, Synder A, Omulecki W. Results of phacoemulsification with Malyugin Ring in comparison with manual iris stretching with hooks in eyes with narrow pupils. Eur J Ophthalmology 2013;23:196-201
skills programme)	5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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E.8.3 Interventions to reduce the impact of perioperative posterior capsule rupture

No evidence was identified for this review question.

E.8.4 Capsular tension rings

Full citation	**Alio J, Plaza-Puche A, Pinero D. Rotationally asymmetric multifocal IOL implantation with and without capsular tension ring: Refractive and visual outcomes and intraocular optical performance. J Cataract Refract Surg. 2012;28:253-258**
Study details	Country/ies where the study was carried out: Spain Study type: RCT Aim of the study: To ascertain whether the refractive, visual and intraocular optical quality outcomes of an IOL are enhanced by the use of a capsular tension ring Study dates: Not reported Sources of funding: Grant from the Spanish Ministry of Health (RD07/0062). Dr Alio is a clinical investigator for Oculentis GmbH
Participants	Sample size 53 patients (90 eyes) Inclusion criteria Patients with visually significant cataract or presbyopic suitable for refractive lens exchange with refractive astigmatism ≤ 3.00 diopters. Exclusion criteria Any other ocular comorbidities, amblyopia, neuro-ophthalmic disease and previous refractive corneal surgery
Methods	Patients were assigned randomly using a random number sequence to one of the following 2 groups: No ring group: IOL implantation with no capsular tension ring (n=43 eyes) Ring group: IOL implantation with capsular tension ring (n=47 eyes) Data collection Visual acuity was measured pre and postoperatively, refractive measurements were undertaken postoperatively Intervention Implantation of a Lentis Mplus LS-312 IOL with or without a capsular tension ring Analysis Student t-test, Mann-Whitney test
Results	3 month postoperative outcomes

	Mean ± Standard deviation		
Outcome	No ring group	Ring group	P value
UDVA (logMAR)	0.15 ± 0.21	0.19 ± 0.28	0.26
CDVA (logMAR)	0.05 ± 0.10	0.02 ± 0.06	0.08
UNVA (logRAD)	0.21 ± 0.17	0.22 ± 0.16	0.73
CDNVA(logRAD)	0.23 ± 0.21	0.15 ± 0.12	0.14

Full citation	**Alio J, Plaza-Puche A, Pinero D. Rotationally asymmetric multifocal IOL implantation with and without capsular tension ring: Refractive and visual outcomes and intraocular optical performance. J Cataract Refract Surg. 2012;28:253-258**
	CNVA (logRAD) | 0.09 ± 0.13 | 0.10 ± 0.10 | 0.57 UDVA = uncorrected distance visual acuity, CDVA = corrected distance visual acuity, UNVA = uncorrected near visual acuity CDNVA = distance-corrected near visual acuity, CNVA = corrected near visual acuity
Outcomes	Intermediate visual outcomes were significantly improved when the IOL was implanted with a capsular tension ring
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Yes 3 Were the patients, health workers and study personnel blinded? Unsure 4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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Full citation	**Bayraktar S, Altan T, Kucuksumer Y, Yilmaz O. Capsular tension ring implantation after capsulorhexis in phacoemulsification of cataracts associated with pseudoexfoliation syndrome. J Cataract Refract Surg. 2001;27:1620-1628**
Study details	Country/ies where the study was carried out: Turkey Study type: RCT Aim of the study: To evaluate the effect of a capsular tension ring (CTR) in preventing zonular complications Study dates: August 1998 to January 2000 Sources of funding: Not reported
Participants	Sample size 78 eyes Inclusion criteria Patients diagnosed as having cataract associated with pseudoexfoliation syndrome Exclusion criteria Advanced glaucoma with compromised optic discs, exudative age-related macular degeneration, diabetic retinopathy, or other disease that would result in low postoperative BCVA (best corrected visual acuity)
Methods	Patients were randomly assigned to 1 of 2 groups: CTR implanted (after capsulorhexis and hydro-dissection) before phacoemulsification (n=39 eyes) No CTR implanted (n=39 eyes) acting as the control

<table>
<tr><th>Full citation</th><td colspan="4">Bayraktar S, Altan T, Kucuksumer Y, Yilmaz O. Capsular tension ring implantation after capsulorhexis in phacoemulsification of cataracts associated with pseudoexfoliation syndrome. J Cataract Refract Surg. 2001;27:1620-1628</td></tr>
<tr><td></td><td colspan="4">Data collection
Postoperative complications and visual acuity
Intervention
Implantation of an IOL with and without a capsular tension ring</td></tr>
<tr><td>Results</td><td colspan="4">Postoperative findings
<table>
<tr><td></td><td colspan="2">Group</td><td></td></tr>
<tr><td>Finding</td><td>CTR (n=39)</td><td>Control (n=39)</td><td>P value</td></tr>
<tr><td>Corneal oedema n (%)</td><td></td><td></td><td>0.77</td></tr>
<tr><td>Grade 0</td><td>12 (30.8)</td><td>13 (33.3)</td><td>-</td></tr>
<tr><td>Grade 1</td><td>13 (33.3)</td><td>14 35.9)</td><td>-</td></tr>
<tr><td>Grade 2</td><td>10 (25.6)</td><td>9 (23.1)</td><td>-</td></tr>
<tr><td>Grade 3</td><td>4 (10.3)</td><td>2 (5.1)</td><td>-</td></tr>
<tr><td>Grade 4</td><td>0</td><td>1 (2.6)</td><td>-</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td colspan="4">Difference in postoperative corneal oedema was not statistically significant</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td colspan="4">1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Unsure
3 Were the patients, health workers and study personnel blinded? Unsure
4 Were the groups similar at the start of the trial? Yes
5 Aside from the experimental intervention, were the groups treated equally? Yes
6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes
7 Can the results be applied to the local population? Yes
8 Were all clinically important outcomes considered? N/A</td></tr>
</table>

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Full citation	**Kocabora M, Gulkilik G, Yilmazli C. The preventative effect of capsular tension ring in phacoemulsification of senile cataracts with pseudoexfoliation. Annals of Ophthalmology. 2007;39:37-40**
Study details	Country/ies where the study was carried out: Turkey Study type: RCT

<table>
<tr><th>Full citation</th><td>Kocabora M, Gulkilik G, Yilmazli C. The preventative effect of capsular tension ring in phacoemulsification of senile cataracts with pseudoexfoliation. Annals of Ophthalmology. 2007;39:37-40</td></tr>
<tr><td></td><td>Aim of the study: To evaluate the preventative effect of capsular tension ring in phacoemulsification
Study dates: 2002 to 2004
Sources of funding: Not reported</td></tr>
<tr><td>Participants</td><td>Sample size
84 eyes
Inclusion criteria
Senile cataract with pseudoexfoliation
Exclusion criteria
Apparent zonular dialysis, uncontrolled glaucoma, previous ocular surgery and ocular conditions causing low visual acuity.</td></tr>
<tr><td>Methods</td><td>Patients were chosen randomly into 2 groups:
Group A (with CTR) n=41 eyes
Group B (without CTR) n=43 eyes
Data collection
Best corrected visual acuity (BCVA) was measured postoperatively.
Intervention
IOL implantation with or without capsular tension ring
Analysis
Chi-square and student’s t test</td></tr>
<tr><td>Results</td><td>Postoperative outcomes (3 months)
<table>
<tr><td></td><td>Group A – with CTR
(n=41)</td><td>Group B – without CTR
(n=43)</td><td>
P value</td></tr>
<tr><td>Post-op BCVA</td><td>0.75 ± 0.24</td><td>0.65 ± 0.23</td><td>0.24</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>No statistically significant difference in the postoperative BCVA of both groups</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Unsure
3 Were the patients, health workers and study personnel blinded? Unsure
4 Were the groups similar at the start of the trial? Yes
5 Aside from the experimental intervention, were the groups treated equally? Yes
6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes
7 Can the results be applied to the local population? Yes</td></tr>
</table>

Full citation	**Kocabora M, Gulkilik G, Yilmazli C. The preventative effect of capsular tension ring in phacoemulsification of senile cataracts with pseudoexfoliation. Annals of Ophthalmology. 2007;39:37-40**
	8 Were all clinically important outcomes considered? N/A

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Full citation	**Lee D, Shin S, Joo C. Effect of a capsular tension ring on intraocular lens decentration and tilting after cataract surgery. J Cataract Refract Surg. 2002;28:843-846**
Study details	Country/ies where the study was carried out: South Korea Study type: RCT Aim of the study: To evaluate the effect of a capsular tension ring (CTR) on the tilting and decentration of IOLs after cataract surgery Study dates: Not reported Sources of funding: Supported by the 2000 Inje University research grant
Participants	Sample size 20 patients (40 eyes) Inclusion criteria Patients who had phacoemulsification and posterior IOL implantation Exclusion criteria History of systemic disease (e.g. hypertension, thyroid disease, diabetes mellitus), ocular surgery, presence of ocular disease (e.g. glaucoma, uveitis, retinal)
Methods	One eye in each patient randomly received an IOL alone and in the fellow eye, an IOL and capsular tension ring Data collection IOL decentration was measured at 7, 30 and 60 days post cataract surgery Intervention Implantation of an IOL with or without a CTR Analysis Paired t test
Results	Postoperative IOL decentration

	Mean IOL decentration (mm) ± SD		
Group	7 Days	30 Days	60 Days
CTR / IOL	0.38 ± 0.16	0.43 ± 0.15	0.42 ± 0.17
IOL only	0.49 ± 0.11	0.53 ± 0.14	0.57 ± 0.16
P value	0.017	0.037	0.013

Full citation	**Lee D, Shin S, Joo C. Effect of a capsular tension ring on intraocular lens decentration and tilting after cataract surgery. J Cataract Refract Surg. 2002;28:843-846**
Outcomes	The extent of IOL decentration was statistically significantly less in eyes with both an IOL and CTR than in those with an IOL only Capsular tension ring reduces undesirable postsurgical IOL movement for at least 60 days
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Unsure 3 Were the patients, health workers and study personnel blinded? Unsure 4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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Full citation	**Mastropasqua R, Toto L, Vecchiarino L, Falconio G, Nicola M, Mastropasqua A. Multifocal IOL implant with or without capsular tension ring: study of wavefront error and visual performance. Eur J Ophthalmol 2013;23:510-517**
Study details	Country/ies where the study was carried out: Italy Study type: RCT Aim of the study: To evaluate visual performance and wavefront error after multifocal IOL implant with or without capsular tension ring (CTR) Study dates: June 2011 to August 2011 Sources of funding: none reported
Participants	Sample size 60 patients (60 eyes) Inclusion criteria Aged between 50 and 75 years, axial length between 23.0 and 24.0 mm, and corneal preoperative astigmatism less than 1.00 D Exclusion criteria Anterior segment pathologic alterations, such as chronic uveitis, zonular dialysis, pseudoexfoliation syndrome, glaucoma and diabetes; other ocular pathologies impairing visual function; previous anterior or posterior segment surgery; and intraoperative or postoperative complications
Methods	Patients were randomised (using a computer generated randomisation list) to one of 2 groups: Group 1 – multifocal IOL and CTR (n=30) Group 2 – multifocal IOL without CTR (n=30) Data collection Patients were examined 20 days and 360 days after surgery for IOL decentration in both x-axis and y-axis

<table>
<tr><th>Full citation</th><td colspan="6">Mastropasqua R, Toto L, Vecchiarino L, Falconio G, Nicola M, Mastropasqua A. Multifocal IOL implant with or without capsular tension ring: study of wavefront error and visual performance. Eur J Ophthalmol 2013;23:510-517</td></tr>
<tr><td></td><td colspan="6">Intervention
Implantation of a multifocal IOL with and without a capsular tension ring
Analysis
Wilcoxon U test</td></tr>
<tr><td>Results</td><td colspan="6">Decentration values (Mean ± Standard Deviation)
<table>
<tr><td>Variable</td><td colspan="2">IOL without CTR</td><td>P value</td><td colspan="2">IOL with CTR</td><td>P value</td></tr>
<tr><td></td><td>20 days</td><td>360 days</td><td></td><td>20 days</td><td>360 days</td><td></td></tr>
<tr><td>Decentration in x (mm)</td><td>-0.13 ± 0.44</td><td>-0.12 ± 0.43</td><td>0.978</td><td>0.08 ± 0.58</td><td>0.05 ± 0.48</td><td>0.978</td></tr>
<tr><td>Decentration in y (mm)</td><td>-0.10 ± 0.03</td><td>-0.08 ± 0.01</td><td>0.461</td><td>0.02 ± 0.15</td><td>0.02 ± 0.12</td><td>0.679</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td colspan="6">IOL decentration was higher in group 1 (IOL with CTR) compared to group 2 (IOL without CTR)</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td colspan="6">1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Yes
3 Were the patients, health workers and study personnel blinded? Unsure
4 Were the groups similar at the start of the trial? Unsure
5 Aside from the experimental intervention, were the groups treated equally? Yes
6 Were all of the patients who entered the trial properly accounted for sat its conclusion? Yes
7 Can the results be applied to the local population? Yes
8 Were all clinically important outcomes considered? N/A</td></tr>
</table>

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Full citation	**Park H, Lee H, Kim D, Kim E, Seo K, Kim T. Effcet of co-implantation of a capsular tension ring on clinical outcomes after cataract surgery with monofocal intraocular lens implantation. Yonsei Med J 2016;57:1236-1242**
Study details	Country/ies where the study was carried out: South Korea Study type: RCT Aim of the study: To evaluate the effect of co-implantation of a capsular tension ring (CTR) and IOL on clinical outcomes and visual quality after cataract surgery Study dates: Sources of funding: None reported
Participants	Sample size 39 patients (52 eyes) Inclusion criteria

<table>
<tr><th>Full citation</th><td>Park H, Lee H, Kim D, Kim E, Seo K, Kim T. Effcet of co-implantation of a capsular tension ring on clinical outcomes after cataract surgery with monofocal intraocular lens implantation. Yonsei Med J 2016;57:1236-1242</td></tr>
<tr><td></td><td>Patients scheduled for cataract surgery and aged between 40 and 85 years
Exclusion criteria
Previous ocular or intraocular surgery, evidence of trauma, acute or chronic corneal infection, inflammatory conditions of the cornea on slit-lamp examination, and intraoperative or postoperative complications. Previous history of any other ocular disease that might affect visual outcomes (colour vision disturbance and chronic uveitis) or contrast sensitivity (glaucoma, maculopathy and high myopia).</td></tr>
<tr><td>Methods</td><td>Patients were randomly assigned to 1 of 2 groups using a randomisation sequence created in Excel with a 1:1 allocation using random block sizes of 2, 4 and 6.
Group 1 – IOL insertion with a CTR (n=26 eyes)
Group 2 – IOL insertion without a CTR (26 eyes)
Data collection
All patients were examined preoperatively and postoperatively (1 and 3 months) for uncorrected distance visual acuity (UCDVA) and corrected distance visual acuity (CDVA)
Intervention
IOL insertion with and without a capsular tension ring</td></tr>
<tr><td>Results</td><td>Visual outcomes (Mean ± Standard Deviation)
<table>
<tr><th>Outcome</th><th>Group 1 (IOL with CTR)</th><th>Group 2 (IOL without CTR)</th><th>P value</th></tr>
<tr><td>UCDVA (logMAR)</td><td></td><td></td><td></td></tr>
<tr><td>1 month postoperatively</td><td>0.11 ± 0.02</td><td>0.10 ± 0.02</td><td>0.750</td></tr>
<tr><td>3 months postoperatively</td><td>0.09 ± 0.02</td><td>0.10 ± 0.02</td><td>0.604</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>CDVA (logMAR)</td><td></td><td></td><td></td></tr>
<tr><td>1 month postoperatively</td><td>0.05 ± 0.01</td><td>0.03 ± 0.01</td><td>0.381</td></tr>
<tr><td>3 months postoperatively</td><td>0.03 ± 0.01</td><td>0.02 ± 0.01</td><td>0.654</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>Cylindrical error (D)</td><td></td><td></td><td></td></tr>
<tr><td>1 month postoperatively</td><td>-0.45 ± 0.11</td><td>-0.40 ± 0.11</td><td>0.779</td></tr>
<tr><td>3 months postoperatively</td><td>-0.48 ± 0.10</td><td>-0.42 ± 0.10</td><td>0.679</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>The preoperative logMAR UCDVA and CDVA of both groups were improved at 1 and 3 months after surgery</td></tr>
</table>

Full citation	Park H, Lee H, Kim D, Kim E, Seo K, Kim T. Effcet of co-implantation of a capsular tension ring on clinical outcomes after cataract surgery with monofocal intraocular lens implantation. Yonsei Med J 2016;57:1236-1242
	No significant difference between the groups in cylindrical error at any time point
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Yes 3 Were the patients, health workers and study personnel blinded? Unsure 4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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Full citation	Rohart C, Gatinel D. Influence of a capsular tension ring on ocular aberrations after cataract surgery: A comparative study. J Refract Surg 2009;25:116-121
Study details	Country/ies where the study was carried out: France Study type: RCT Aim of the study: To evaluate the effects of a capsular tension ring on ocular and corneal aberrations after cataract surgery Study dates: Not reported Sources of funding: None reported
Participants	Sample size 20 patients (40 eyes) Inclusion criteria At least 50 years old with a diagnosis of cataract in both eyes that was non traumatic in origin and a difference of less than 2.00 diopters (D) of predicted IOL power between both eyes Exclusion criteria Ocular pathology other than cataract, inflammation, previous ocular surgery, pseudoexfoliation syndrome, intraoperative posterior rupture, pupil diameter smaller than 6 mm after pharmacologic dilation, more than 1.50 D of corneal cylinder using simulated keratometry values, abnormal corneal topographic patterns, poor enantiomorphism, eyes with extreme axial length (< 22.5 mm and >24.5 mm)
Methods	The eye that received the CTR was randomly assigned using a randomisation schedule and the fellow eye received the IOL without a CTR Data collection Mean Best spectacle-corrected visual acuity was measured 3 months postoperatively Intervention

<table>
<tr><th>Full citation</th><th>Rohart C, Gatinel D. Influence of a capsular tension ring on ocular aberrations after cataract surgery: A comparative study. J Refract Surg 2009;25:116-121</th></tr>
<tr><td></td><td>IOL implantation with and without CTR</td></tr>
<tr><td>Results</td><td>Visual acuity – 3 months postoperatively (Mean ± Standard Deviation)
<table>
<tr><td>Group</td><td>BSCVA (logMAR)</td></tr>
<tr><td>IOL with CTR (n=20)</td><td>0.92 ± 0.11</td></tr>
<tr><td>IOL without CTR (n=20)</td><td>0.94 ± 0.09</td></tr>
<tr><td>P value</td><td>0.86</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>No statistically significant differences were noted between the groups in mean postoperative BSCVA</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Yes
3 Were the patients, health workers and study personnel blinded? Unsure
4 Were the groups similar at the start of the trial? Unsure
5 Aside from the experimental intervention, were the groups treated equally? Yes
6 Were all of the patients who entered the trial properly accounted for sat its conclusion? Yes
7 Can the results be applied to the local population? Yes
8 Were all clinically important outcomes considered? N/A</td></tr>
</table>

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E.8.5 Interventions to prevent endophthalmitis

Study	ESCRS 2007
Methods	Study design: randomized controlled trial Exclusions and loss to follow-up: 324 (2%) participants were lost to follow-up; 68 participants were excluded because they did not undergo the planned surgery or they withdrew consent Study follow-up: six weeks
Participants	Setting: 24 ophthalmology units in Austria, Belgium, Germany, Italy, Poland, Portugal, Spain, Turkey, and the United Kingdom Enrolment: 16,603 patients undergoing phacoemulsification cataract surgery Age: median for men was 73 years; for women was 75 years Gender: 42% men and 58% women Inclusion criteria: participants having routine cataract surgery at any study unit Exclusion criteria: participants allergic to penicillins and cephalosporins, those in long-term nursing homes, pregnant, or younger than 18 years; groups severely at risk of infection (i.e., atopic keratoconjunctivitis or active blepharitis)
Interventions	Intervention #1: intracameral cefuroxime 0.9% (injected into the anterior chamber at the end of surgery) Intervention #2: topical levofloxacin 0.5% (instilled one drop one hour before surgery, one drop half an hour before surgery, and three more drops at 5-minute intervals immediately after surgery) Intervention #3: combined intracameral cefuroxime and topical levofloxacin Intervention #4: placebo drops (no sham injection was given) General: All study centers used povidone iodine 5% for antisepsis. Some centers additionally performed skin cleansing procedures; no detergents were used. Postoperative treatment: All participants were given topical levofloxacin 0.5% starting the morning after surgery (approximately 18 hours after surgery) and four times daily for six days.
Outcomes	Primary outcomes (at six weeks post-surgery): 1. Overall number of participants with presumed infectious postoperative endophthalmitis 2. Number of participants with infectious endophthalmitis as proven by at least one of Gram stain, culture or polymerase chain reaction (PCR) Secondary outcomes: other risk factors for increased susceptibility, such as clear corneal incision or surgery during summer months, or decreased risk, such as foldable intraocular lenses (IOLs) inserted with sterile injector, etc Unit of analysis: the participant (one eye per person)
Notes	Study dates: September 2003 to January 2006 Full study name: European Society of Cataract and Refractive Surgeons Study on the Antibiotic Prophylaxis of Post-operative Endophthalmitis Funding source: European Society of Cataract and Refractive Surgeons (ESCRS) and Santen GmbH, Germany Publication language: English

372 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Twelve-block computerized randomization stratified by study center was used.
Allocation concealment (selection bias)	Low risk	An electronic database was used to conceal the treatment assignments for each participant. Droppers were labeled with sequential subject IDs, which were entered into the database at the time of surgery to determine whether or not an injection should be given. Treatment allocation codes were held in a central randomization file.
Masking of participants (performance bias)	Low risk	Partial masking of participants was done with use of placebo drops. No sham injection was performed.
Masking of physicians and clinical care providers (performance bias)	Low risk	Partial masking of physicians was done by using identically labeled droppers. No sham injection was performed.
Masking of outcome assessment (detection bias)	Low risk	Physicians were partially masked and it was reported that clinical partners were masked throughout the study.
Incomplete outcome data (attrition bias)	Low risk	324 (2%) participants who were lost to follow-up and 68 (0.4%) participants who did not undergo the planned surgery or withdrew consent were excluded from the intention-to-treat analyses.
Selective reporting (reporting bias)	Low risk	Study outcomes were published in study protocols, trial registrations and methods papers prior to the study beginning. Results were reported for these primary and secondary outcomes.
Other bias	Low risk	Performed power calculations to enroll a study size to detect a four-fold reduction in risk at 5% significance level. The study chairman, coordinator, clinical partners and data monitoring committee were masked while the study was running.

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Study	Sobaci et al. 2003
Methods	Study design: randomized controlled trial Exclusions and loss to follow-up: eyes for which the surgical procedure was modified due to physician discretion at time of surgery were excluded from the study Study follow-up: six weeks
Participants	Setting: Gülhane Military Medical Academy and Medical School Hospital, Ankara, Turkey Enrolment: 644 eyes of 640 participants undergoing phacoemulsification cataract surgery

Study	Sobaci et al. 2003
	Age: Group 1: 64.2 ± 14.3 (range 43 to 87) years; Group 2: 61.2 ± 14.2 (range 40 to 81) years Gender: not reported Inclusion criteria: people scheduled to undergo phacoemulsification surgery Exclusion criteria: participants with previous history of immunosuppressive treatment, diabetes mellitus, ocular surgery, recent infection or inflammation
Interventions	Intervention #1: balanced salt solution (BSS)-only irrigating infusion fluid (n = 322 eyes) Intervention #2: BSS with antibiotics (20 mg/mL vancomycin and 8 mg/mL gentamicin; n = 322 eyes) General: Interventions were given intraoperatively. Preoperative treatment, postoperative treatment and follow-up were identical for both groups Preoperative treatment: One-day course of topical ofloxacin (0.3%) and diclofenac sodium (1 mg/mL) four times a day; conjunctival smears were obtained just before povidone iodine instillation at time of surgery Surgical technique: Phacoemulsification with a standard 3.2 mm clear corneal incision, circular capsulotomy, and stop-chop technique followed by foldable hydrophobic acrylic IOL implantation; no sutures, subconjunctival antibiotics or steroid injections were used Postoperative treatment: Eyes were treated with ofloxacin (0.3%), dexamethasone (1 mg/mL) and indomethasine (0.1%) drops with a four-week tapering dose; participants were discharged the day after surgery
Outcomes	Primary outcomes: 1. Risk of postoperative endophthalmitis 2. Aqueous humor contamination during phacoemulsification Participants were seen on days 2, 5, 10, 15, 30 and 45 Unit of analysis: the eye (both eyes of four participants were included separately in the analysis)
Notes	Study dates: May 2000 to June 2002 Funding source: not reported Publication language: English The study authors reported the rate of postoperative endophthalmitis at their institution was 0.109%, but only 644 eyes were included in the study

374 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Patients were randomly allocated to irrigating infusion fluid containing either balanced salt solution (BSS)-only (group 1; 322 eyes of 320 patients) or BSS with antibiotics (20 mg/ml vancomycin and 8 mg/ml gentamicin) (group 2; 322 eyes of 320 patients), according to the scheduled day of surgery, which was performed one after another. (1:1)."

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	Method of allocation concealment not reported.
Masking of participants (performance bias)	Unclear risk	Masking of participants was not reported.
Masking of physicians and clinical care providers (performance bias)	Unclear risk	Masking of physicians was not reported.
Masking of outcome assessment (detection bias)	Unclear risk	Masking of outcome assessors was not reported.
Incomplete outcome data (attrition bias)	High risk	Eyes for which the surgical procedure was modified due to physician discretion at time of surgery were excluded from the study. The number of excluded participants was not reported.
Selective reporting (reporting bias)	Low risk	Results were reported for both primary outcomes.
Other bias	Low risk	No other potential sources of bias identified.

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E.8.6 Intervention to prevent cystoid macular oedema

The evidence tables in this section were produced by the Cochrane Eyes and Vision Group, as part of a collaboration with the NICE Internal Clinical Guidelines Team.

Study	Almeida 2008
Methods	Study design: Parallel group RCT Open Label
Participants	Country: Canada Setting: Eye hospital Intervention: NSAIDS plus steroids Number of people (eyes) randomised: NR (53) Number (%) of people followed up: 38 (72%) eyes Average age in years: 71 Age range in years: 45-92 Percentage women: 51% Ethnic group: NR Percentage with diabetes: 19% Percentage with uveitis: 2% Comparator: Steroids alone Number of people (eyes) randomised: NR (53) Number (%) of people followed up: 42 (79%) eyes Average age in years: 72 Age range in years: 45-92 Percentage women: 70% Ethnic group: NR Percentage with diabetes: 23% Percentage with uveitis: 0% Inclusion criteria: clinic patient having phacoemulsification with intraocular lens (IOL) implantation in their first eye;agreed to participate Exclusion criteria: hypersensitivity to the NSAID drug class; aspirin/NSAID-induced asthma; pregnancy in the third trimester

Study	Almeida 2008
	Pretreatment: More women in control group (70%) versus ketorolac group (51%) but unclear of importance of this difference. Eyes:106 eyes of 98 patients enrolled but clinical trials registry specifies first eye surgery only.
Interventions	Intervention: NSAIDS plus steroids ketorolac tromethamine 0.5% (Acular) Times per day: QDS Duration pre-op: 2 days Duration post-op: 28 days prednisolone acetate 1% (brand name not reported) Times per day: QDS for 7d, BDS for 7d Duration pre-op: days: 0 Duration post-op: days: 14 Comparator: Steroids alone prednisolone acetate 1% (brand name not reported) Times per day: QDS for 7d, BDS for 7d Duration pre-op: days: 0 Duration post-op: days: 14 All participants also received gatifloxacin 0.3% (Zymar) 4 times a day for 1 week. Type of surgery: phacoemulsification
Outcomes	Follow-up: 1 month Adverse effects CMO (not defined but OCT used) Change in total macular volume
Contact details	Authors name: Sherif El-Defrawy Institution: Queen's University, Ontario, Canada Email: eldefras@hdh.kari.net Address: Department of Ophthalmology, Queen's University, Hotel Dieu Hospital, Brock Wing 230A, 166 Brock Street, Kingston, Ontario K7L 5G2, Canada.
Notes	Funding sources: "Funded by a Queen's University grant, Kingston, Ontario, Canada" Declaration of interest: "No author has a financial or proprietary interest in any material or method mentioned."

Study	Almeida 2008
	Date study conducted: June 2006 to May 2007 (from clinical trials registry entry) Trial registration number: NCT00335439 Contacting study investigators: not contacted

381 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement Comment: Not reported how list was generated.
Allocation concealment (selection bias)	High risk	Quote: "open-label nonmasked" Judgement Comment: High risk of bias given open-label nature of trial.
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: Open label study
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: Open label study
Incomplete outcome data (attrition bias)	Unclear risk	Quote: "98 were assessed at 1 week and 80 at 1 month;" Judgement Comment: 38/53 (72%) in ketorolac group seen at 1 month vs 42/53 (79%) of non treated group. I case of CMO excluded in non treated group; 3 ketorolac-related AE excluded.
Selective reporting (reporting bias)	Low risk	Judgement Comment: Only one outcome specified on clinical trials registry and this outcome was the main focus of the published report.

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Study	Almeida 2012
Methods	Study design: Parallel group RCT
Participants	Country: Canada Setting: Eye hospital Intervention: NSAIDS plus steroids Number of people (eyes) randomised: NR Number (%) of people followed up: 54 (NR but overall 84% fup) Average age in years: NR (but overall average age was 72 years) Age range in years: NR (but overall range was 50 to 88 years) Percentage women: NR (but overall 54% were women)

Study	Almeida 2012
	Ethnic group: NR Percentage with diabetes: NR (but "low risk" population) Percentage with uveitis: NR (but "low risk" population) Intervention: NSAIDS plus steroids Number of people (eyes) randomised: NR Number (%) of people followed up: 54 (NR but overall 84% fup) Average age in years: NR (but overall average age was 72 years) Age range in years: NR (but overall range was 50 to 88 years) Percentage women: NR (but overall 54% were women) Ethnic group: NR Percentage with diabetes: NR (but "low risk" population) Percentage with uveitis: NR (but "low risk" population) Comparator: Steroids plus placebo Number of people (eyes) randomised: NR Number (%) of people followed up: 54 (NR but overall 84% fup) Average age in years: NR (but overall average age was 72 years) Age range in years: NR (but overall range was 50 to 88 years) Percentage women: NR (but overall 54% were women) Ethnic group: NR Percentage with diabetes: NR (but "low risk" population) Percentage with uveitis: NR (but "low risk" population) Inclusion criteria: 18 years of age or older; cataract and were expected to have phacoemulsification with implantation of a posterior chamber intraocular lens (IOL) Exclusion criteria: preexisting retinal disease (eg, diabetic retinopathy, vein occlusion, exudative macular degeneration);previous uveitis, previous intraocular surgery;allergy or hypersensitivity to NSAIDs. "Enrolled patients who had complicated cataract surgery (eg, significant corneal edema, posterior capsule rupture, vitreous loss, dropped nuclear material, retained cortical material, or an IOL not placed in the capsular bag) were subsequently excluded." Pretreatment: "There were no differences in age, sex, or operative eye between the 3 groups" Eyes: Probably one eye only included in the trial but not clearly reported and unclear how selected.
Interventions	Intervention 1: NSAIDS plus steroids ketorolac 0.5% (brand name not reported)

Study	Almeida 2012
	Times per day: QDS Duration pre-op: days: 1 Duration post-op: days: 28 prednisolone 1% (brand name not reported) Times per day: QDS for 7d, TDS for 7d, BDS for 7d, ODS for 7d Duration pre-op: days: 0 Duration post-op: days: 28 Intervention 2: NSAIDS plus steroids nepafenac 0.1% (brand name not reported) Times per day: QDS Duration pre-op: days: 1 Duration post-op: days: 28 prednisolone 1% (brand name not reported) Times per day: QDS for 7d, TDS for 7d, BDS for 7d, ODS for 7d Duration pre-op: days: 0 Duration post-op: days: 28 Comparator: Steroids plus placebo sterile saline drops Times per day: QDS Duration pre-op: days: 1 Duration post-op: days: 28 prednisolone 1% (brand name not reported) Times per day: QDS for 7d, TDS for 7d, BDS for 7d, ODS for 7d Duration pre-op: days: 0 Duration post-op: days: 28 All participants received gatifloxacin 0.3% drops 4 times a day starting 3 days before surgery and continued for 1 week after surgery. Type of surgery: phacoemulsification
Outcomes	Follow-up: 1 month Quality of life (COMTOL questionnaire) Change in CRT (not used in the analysis because no SD reported)

Study	Almeida 2012
	Change in BCVA logMAR Change in total macular volume Change in average macular cube thickness
Contact details	Authors name: David RP Almeida Institution: Queen's University, Ontario, Canada Email: dalmeida@evolation-medical.com Address: Department of Ophthalmology, Queen's University, Hotel Dieu Hospital, 166 Brock Street, Eye Centre (Johnson 6), Kingston, Ontario K7L 5G2, Canada.
Notes	Funding sources: "Funded by an unrestricted Queen's University educational research grant." Declaration of interest: "No author has a financial or proprietary interest in any material or method mentioned." Date study conducted: March 2010 to May 2011 Trial registration number: NCT01395069 Contacting study investigators: trial authors not contacted

383 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Patients were randomly assigned to receive a placebo (sterile saline drops), nepafenac 0.1%, or ketorolac 0.5%." Judgement Comment: Not reported how list was generated.
Allocation concealment (selection bias)	Unclear risk	Quote: "The placebo, nepafenac, and ketorolac suspensions were supplied in identical generic drop bottles that were individually made by the Kingston General Hospital Investigational Pharmacy division. Bottles concealed medicatio n information and were labeled with study identification number, patient identification number, expiration date, and emergency contact information only." Judgement Comment: Unclear if investigators involved in the treatment allocation were masked
Blinding of participants and personnel (performance bias)	Low risk	Quote: "The placebo, nepafenac, and ketorolac suspensions were supplied in identical generic drop bottles that were individually made by the Kingston

Bias	Authors' judgement	Support for judgement
		General Hospital Investigational Pharmacy division. Bottles concealed medication information and were labeled with study identification number, patient identification number, expiration date, and emergency contact information only." Judgement Comment: Placebo-controlled study
Blinding of outcome assessment (detection bias)	Low risk	Quote: "The placebo, nepafenac, and ketorolac suspensions were supplied in identical generic drop bottles that were individually made by the Kingston General Hospital Investigational Pharmacy division. Bottles concealed medication information and were labeled with study identification number, patient identification number, expiration date, and emergency contact information only." Judgement Comment: Placebo-controlled study which probably means that the outcome assessors were masked.
Incomplete outcome data (attrition bias)	Unclear risk	Quote: "One hundred sixty-two patients, 54 in each arm, made up the intent-to-treat data set." Quote: "Ninety-seven patients (35 placebo, 32 ketorolac, 30 nepafenac) completed the COMTOL interview questionnaire (60.0% response rate)." Judgement Comment: 84% follow-up. Not clearly reported but no evidence for any differential drop out by intervention group. 31 patients out of 193 lost to follow-up (16%). However, only 97 patients (60%) completed the COMTOL interview questionnaire and no further breakdown of losses to follow-up in each group provided.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: Outcomes on clinical trial registry entry (NCT01395069) were reported but the trial was retrospectively registered. .

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Study	Asano 2008
Methods	Study design: Parallel group RCT
Participants	Country: Japan Setting: 5 Eye hospitals Intervention: NSAIDS alone Number of people (eyes) randomised: 75 (75) Number (%) of people followed up: 71 (95%)

Study	Asano 2008
	Average age in years: 66 Age range in years: NR Percentage women: 56% Ethnic group: NR Percentage with diabetes: 0 (excluded) Percentage with uveitis: 0 (excluded) Comparator: Steroids alone Number of people (eyes) randomised: 75 (75) Number (%) of people followed up: 71 (95%) Average age in years: 66 Age range in years: NR Percentage women: 55% Ethnic group: NR Percentage with diabetes: 0 (excluded) Percentage with uveitis: 0 (excluded) Inclusion criteria: age 55 to 75 years of age;nuclear hardness of Emery-Little grade IV or less;surgery in 1 eye only Exclusion criteria: acute infection or inflammation within 1 month after initiation of the study; allergy to NSAIDs, steroids, or fluorescein; history of eye trauma or intraocular disease other than cataract; pseudoexfoliation syndrome; uveitis;glaucoma; diabetes and related complications; kidney disease;asthma or chronic airway disease; uncontrolled hypertension;severe heart failure; myocardial infarction or cerebrovascular disorders; intraoperative complications such as posterior capsule rupture, vitreous loss, retained lens nucleus, or lens fragments in the vitreous Pretreatment: None noted. Compared age, gender, duration of surgery, ultrasound time, irrigating solution and hardness of crystalline lens. Eyes: One eye, unclear how selected
Interventions	Intervention: NSAIDS alone diclofenac sodium 0.1% (brand name not reported) Times per day: QDS on day of surgery; TDS post-op Duration pre-op: days: 3 hours, 2 hours, 1 hour, and 30 minutes before surgery Duration post-op: days: 56 Comparator: Steroids alone

Study	Asano 2008
	betamethasone sodium 0.1% (brand name not reported) Times per day: QDS on day of surgery; TDS post-op Duration pre-op: days: 3 hours, 2 hours, 1 hour, and 30 minutes before surgery Duration post-op: days: 56 Concomitant mydriatic and antibiotic agents were permitted. Type of surgery: phacoemulsification
Outcomes	Follow-up: 8 weeks. Adverse effects CMO reported at 5 weeks only (fluorescein angiography using Miyake 1977 classification, grades I-III taken as CMO) Laser flare-cell photometry (mean value of anterior-chamber flare reported) BCVA logMAR (final value)
Contact details	Authors name: Kensaku Miyake Institution: Shohzankai Medical Foundation, Miyake Eye Hospital Email: miyake@spice.or.jp Address: Shohzankai Medical Foundation, Miyake Eye Hospital, 3-15-68, Ozone, Kita-ku, Nagoya, 462-0825, Japan
Notes	Funding sources: NR Declaration of interest: "No author has a financial or proprietary interest in any material or method mentioned." Date study conducted: April 2004 to September 2005 Trial registration number: NR Contacting study investigators: trial authors not contacted

385 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The test drugs were assigned to patients at random after the controller validated that the assigned therapy was indistinguishable from the alternative therapy." Judgement Comment: Not reported how list was generated.

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	Quote: "The controller kept the assignment code until completion of the study." Judgement Comment: This probably means that the allocation was concealed from the investigators although it was not clearly reported who the controller was exactly.
Blinding of participants and personnel (performance bias)	Low risk	Quote: "The test drugs were assigned to patients at random after the controller validated that the assigned therapy was indistinguishable from the alternative therapy. The controller kept the assignment code until completion of the study. The controller created an emergency code, which was given to the principal investigator in an envelope. The investigator could open the envelope if severe adverse effects developed. The test drugs were administered to each patient 3 hours, 2 hours, 1 hour, and 30 minutes before surgery and 3 times a day for 8 weeks after surgery." Judgement Comment: Although not clearly stated that participants and personnel were unaware of which treatment received the study was placebo controlled and efforts made to keep the allocation away from investigators so we assume that masking was done.
Blinding of outcome assessment (detection bias)	Low risk	Quote: "The test drugs were assigned to patients at random after the controller validated that the assigned therapy was indistinguishable from the alternative therapy. The controller kept the assignment code until completion of the study. The controller created an emergency code, which was given to the principal investigator in an envelope. The investigator could open the envelope if severe adverse effects developed. The test drugs were administered to each patient 3 hours, 2 hours, 1 hour, and 30 minutes before surgery and 3 times a day for 8 weeks after surgery." Judgement Comment: Although not clearly stated that outcome assessors were unaware of which treatment received the study was placebo controlled and efforts made to keep the allocation away from investigators so we assume that masking was done.
Incomplete outcome data (attrition bias)	High risk	Quote: "Of the 150 eyes initially included in this study, 75 were assigned to the diclofenac group and 75 to the betamethasone group. Four patients in each group dropped out of the study: 1 in each group due to complications; 3 in the diclofenac group and 2 in the betamethasone group due to a discontinuation proposal (there were patients who withdrew their consent during the course of

Bias	Authors' judgement	Support for judgement
		this study); 1 in the betamethasone group for not returning to the hospital 2 weeks after surgery. Seventy- one eyes in each group completed the study." Judgement Comment: In the results text quoted follow-up appeared to be high (95%) and equal between groups but in table 3 visual acuity results follow-up was lower 58/75 (77%) versus 52/75 (69%) and unclear why. Judgement Comment: Some of the exclusion criteria may have lead to bias if they occurred differently between two treatment groups: "acute infection or inflammation within 1 month after initiation of the study" and "intraoperative complications such as posterior capsule rupture, vitreous loss, retained lens nucleus, or lens fragments in the vitreous" however these exclusions were not reported.
Selective reporting (reporting bias)	High risk	Judgement Comment: No access to protocol or trials registry entry but noted that data on CMO were reported only at 5 weeks but other data available at 8 weeks follow-up.

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Study	Cervantes Coste 2009
Methods	Study design: Parallel group RCT
Participants	Country: Mexico Setting: Eye hospital Intervention: NSAIDS plus steroids Number of people (eyes) randomised: 30 (30) Number (%) of people followed up: 30 (100%) Average age in years: 73 Age range in years: 52 to 88 Percentage women: 67% Ethnic group: NR Percentage with diabetes: 17% Percentage with uveitis: 0 (excluded) Comparator: Steroids alone Number of people (eyes) randomised: 30 (30) Number (%) of people followed up: 30 (100%)

Study	Cervantes Coste 2009
	Average age in years: 71 Age range in years: 51 to 85 Percentage women: 60% Ethnic group: NR Percentage with diabetes: 23% Percentage with uveitis: 0 (excluded) Inclusion criteria: adult patients 40 years of age or older; diagnosed with senile and/or metabolic cataract (according to the Lens Opacities Classification System LOCS III, with classification NO and NC 2–3); scheduled for surgery by phacoemulsification and IOL implantation inside the capsular bag; normal fundoscopy exam (if observance was possible) Exclusion criteria: pregnancy or breastfeeding; history of ocular inflammatory or infectious eye disease; treatment for eye infection within 30 days prior to inclusion in the study;alterations on the eye surface (including dry eye); history of ocular surgery and/or trauma; knowledge or suspicion of allergy or hypersensitivity to the preservatives, steroids, topical NSAIDs, or any other component of the study medication; use of eye medications, including PG analogs; use of topical or systemic steroids within 30 days prior to inclusion in the study; use of topical or systemic NSAIDs within 14 days prior to inclusion in the studynon-controlled diabetes mellitus (DM), based on clinical history and blood glucose level (126 mg); proliferative diabetic retinopathy, and/or macular edema;preoperative mydriasis less than 6 mm prior to the study; synechiae; ocular alteration preventing adequate mydriasis such as iris atrophy; macular alteration documented by optical coherence tomography (OCT), including macular edema of any etiology, macularholes, epiretinal membrane, macular degeneration related to age, and central serous chorioretinopathy; the use of contact lens in the eye involved during the study Pretreatment: No differences noted; compared age, gender, operated eye, ocular and systemic pathology. Eyes: One eye, unclear how selected.
Interventions	Intervention: NSAIDS plus steroids nepafenac 0.1% (brand name not reported) Times per day: 1 drop every 15 minutes(4 doses) 1 hour prior to surgery; TDS otherwise Duration pre-op: days: 1 Duration post-op: days: 42 dexamethasone (combined with tobramycin) (brand name not reported) Times per day: QDS Duration pre-op: days: 0

Study	Cervantes Coste 2009
	Duration post-op: days: 10 Comparator: Steroids alone dexamethasone (combined with tobramycin) (brand name not reported) Times per day: QDS Duration pre-op: days: 0 Duration post-op: days: 10 Type of surgery: phacoemulsification
Outcomes	Follow-up: 6 weeks Poor vision outcome due to MO ("None of the patients developed clinically significant macular oedema associated with vision loss") CRT at follow-up (final value) Adverse effects Inflammation ("inflammatory cells greater than 1+ during first week of postoperative visits") Total macular volume Subgroup analysis by diabetes reported
Contact details	Authors name: Guadalupe Cervantes-Coste Institution: Asociación Para Evitar la Ceguera en México I.A.P. Hospital Email: gpecervantes@hotmail.com Address: Av. México 85-5, México City, 06100 México
Notes	Funding sources: NR Declaration of interest: The authors have no conflicts of interest to disclose. Date study conducted: NR Trial registration number: NR Contacting study investigators: trial authors not contacted

387 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "This was a prospective, randomized, single-masked, single- center, longitudinal, experimental and comparative study in patients undergoing phacoemulsification cataract surgery"

Bias	Authors' judgement	Support for judgement
		Judgement Comment: Not reported how list was generated. Trial described as “randomised” but with no further details.
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Not reported how allocation administered.
Blinding of participants and personnel (performance bias)	Unclear risk	Quote: "The identity of patients receiving preoperative mydriatic or preoperative mydriatic and nepafenac was concealed from the surgeons." Judgement Comment: Only the surgeons appeared to be masked.
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: The study compared nepafenac versus no treatment so is essentially open label. No information was provided on masking. We assume that in absence of reporting on this outcome assessors were not masked.
Incomplete outcome data (attrition bias)	Low risk	Quote: "All patients completed the follow-up visits over a 6-week period". Judgement Comment: No patients appeared to have been excluded or lost to follow-up
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No access to protocol or trials registry entry.

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Study	Chatziralli 2011
Methods	Study design: Parallel group RCT
Participants	Country: Greece Setting: Eye hospital Intervention: NSAIDS plus steroids Number of people (eyes) randomised: 73 (NR) Number (%) of people followed up: 70 (96%) Average age in years: 74 Age range in years: NR Percentage women: 39% Ethnic group: NR Percentage with diabetes: 9% Percentage with uveitis: 0 (excluded) Comparator: Steroids alone Number of people (eyes) randomised: 72 (NR)

Study	Chatziralli 2011
	Number (%) of people followed up: 68 (94%) Average age in years: 74 Age range in years: NR Percentage women: 41% Ethnic group: NR Percentage with diabetes: 10% Percentage with uveitis: 0 (excluded) Inclusion criteria: NR Exclusion criteria: history of intraocular surgery on the eye to be operated; any previous episode of uveitis in the eye to be operated; severe systemic disease (heart failure of the New York Heart Association stage III of IV, endstage renal failure, pulmonary failure, receiving chemotherapy); regular, systemic use of steroid or nonsteroid antiinflammatory drugs (NSAID) during the last 3 months Pretreatment: None noted; compared age, gender, baseline visual acuity, education, marital status, smoking,and various systemic ocular factors. Eyes: Probably one eye only included in the trial but not clearly reported and unclear how selected
Interventions	Intervention: NSAIDS plus steroids ketorolac tromethamine 0.5% (Acular, Allergan) Times per day: TDS Duration pre-op: days: 3 Duration post-op: days: 28 dexamethasone 0.1% (in combination with tobramycin 0.3%) (Tobradex, Alcon) Times per day: 5xdaily preop, QDS postop Duration pre-op: days: 3 Duration post-op: days: 28 Comparator: Steroids alone dexamethasone 0.1% (in combination with tobramycin 0.3%) (Tobradex, Alcon) Times per day: 5xdaily preop, QDS postop Duration pre-op: days: 3 Duration post-op: days: 28 Type of surgery: phacoemulsification
Outcomes	Follow-up: 6 weeks

Study	Chatziralli 2011
	Poor vision outcome due to MO Adverse effects, pain and ocular discomfort (itching or foreign-body sensation) on a 0–10 visual analog scaleCMO (fundoscopy plus Amsler grid) Inflammation (presence of corneal oedema, Tyndall reaction or conjunctival hyperemia) BCVA logMAR (final value)
Contact details	Authors name: Irini Chatziralli Institution: Department of Ophthalmology, Veroia General Hospital Email: eirchat@yahoo.gr Address: Department of Ophthalmology, Veroia General Hospital, 28, Papanastasiou Street, GR–17342 Athens (Greece)
Notes	Funding sources: NR Declaration of interest: NR Date study conducted: October 2009, to January 2010 Trial registration number: NR Contacting study investigators: trial authors not contacted

389 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The patients were randomized to 1 of the 2 postoperative treatment arms:" Judgement Comment: Not reported how list was generated.
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Not reported how allocation administered
Blinding of participants and personnel (performance bias)	Low risk	Quote: "The study was masked to the patients, i.e. they received unmarked bottles so as to be unaware of which treatment they received."
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: No information on masking of outcome assessors. We assume that in absence of reporting on this outcome assessors were not masked.
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: Follow-up high and reasonable equal between groups: 70/73 (96%) in NSAIDS group versus 68/72 (94%) in steroid group.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No access to protocol or trials registry entry.

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Study	Donnenfeld 2006
Methods	Study design: Parallel group RCT
Participants	Country: USA Setting: Eye hospital Intervention: NSAIDS plus steroids Number of people (eyes) randomised: 25 (NR) Number (%) of people followed up: NR Average age in years: NR (age overall was 73 years) Age range in years: NR Percentage women: NR (overall 55% women) Ethnic group: NR Percentage with diabetes: 0 (excluded) Percentage with uveitis: 0 (excluded) Intervention: NSAIDS plus steroids Number of people (eyes) randomised: 25 (NR) Number (%) of people followed up: NR Average age in years: NR (age overall was 73 years) Age range in years: NR Percentage women: NR (overall 55% women) Ethnic group: NR Percentage with diabetes: 0 (excluded) Percentage with uveitis: 0 (excluded) Intervention: NSAIDS plus steroids Number of people (eyes) randomised: 25 (NR) Number (%) of people followed up: NR Average age in years: NR (age overall was 73 years) Age range in years: NR Percentage women: NR (overall 55% women) Ethnic group: NR Percentage with diabetes: 0 (excluded) Percentage with uveitis: 0 (excluded)

Study	Donnenfeld 2006
	Comparator: Steroids plus placebo Number of people (eyes) randomised: 25 (NR) Number (%) of people followed up: NR Average age in years: NR (age overall was 73 years) Age range in years: NR Percentage women: NR (overall 55% women) Ethnic group: NR Percentage with diabetes: 0 (excluded) Percentage with uveitis: 0 (excluded) Inclusion criteria: scheduled for phacoemulsification Exclusion criteria: known sensitivity to any ingredient in the study medications; monocular status; a history of previous intraocular surgery;diabetes mellitus; a history of uveitis, iritis, or intraocular inflammation; use of a systemic NSAID during the study or the week before surgery; or pupils that did not dilate to more than 5.0 mm before surgery or requiring mechanical pupil stretching; pregnant, nursing an infant, or planning a pregnancy . Pretreatment: "There were no significant between-group differences in any demographic variable or baseline value" Eyes: Unclear if one or both eyes included
Interventions	Intervention: NSAIDS plus steroids ketorolac tromethamine 0.4% (brand name not reported) Times per day: QDS for 3d pre-op; TDS every 15 minutes before surgery; QDS for 21d post-op Duration pre-op: days: 3 Duration post-op: days: 21 prednisolone acetate 1% (brand name not reported) Times per day: QDS for 14d; BDS for 7d Duration pre-op: days: 0 Duration post-op: days: 21 Intervention: NSAIDS plus steroids ketorolac tromethamine 0.4% (brand name not reported) Times per day: QDS for 1d pre-op; every 15m in hr before surgery; QDS for 21d post-op Duration pre-op: days: 1 Duration post-op: days: 21

Study	Donnenfeld 2006
	prednisolone acetate 1% (brand name not reported) Times per day: QDS for 14d; BDS for 7d Duration pre-op: days: 0 Duration post-op: days: 21 Intervention: NSAIDS plus steroids ketorolac tromethamine 0.4% (brand name not reported) Times per day: every 15m in hr before surgery; QDS for 21d post-op Duration pre-op: days: 0 Duration post-op: days: 21 prednisolone acetate 1% (brand name not reported) Times per day: QDS for 14d; BDS for 7d Duration pre-op: days: 0 Duration post-op: days: 21 Comparator: Steroids plus placebo prednisolone acetate 1% (brand name not reported) Times per day: QDS for 14d; BDS for 7d Duration pre-op: days: 0 Duration post-op: days: 21 placebo (vehicle) Times per day: q15 min in the hour before surgery. QDS postoperatively Duration pre-op: days: 0 Duration post-op: days: 21 All participants received topical gatifloxacin 0.3% 4 times a day for 3 days before cataract surgery and for 1 week after surgery. Type of surgery: phacoemulsification
Outcomes	Follow-up: 3 months Adverse effects (patient discomfort on a 1 to 5 scale and need for analgesia) CMO (at 2 weeks only, "clinically significant CME" but otherwise not defined, no OCT) Inflammation ("Mean inflammation score" but was not possible to calculate SD) BCVA logMAR (final value)
Contact details	Authors name: Eric D. Donnenfeld

Study	Donnenfeld 2006
	Institution: Ophthalmic Consultants of Long Island Email: eddoph@aol.com Address: Ophthalmic Consultants of Long Island, Ryan Medical Arts Building, 2000 North Village Avenue, Suite 402, Rockville Centre, New York 11570, USA
Notes	Funding sources: "Supported in part by an unrestricted grant from Allergan Inc., Irvine, California, and the Lions Eye Bank for Long Island, Long Island, New York, USA" Declaration of interest: "Drs. Donnenfeld, Perry, and Wittpenn are consultants to Allergan Pharmaceuticals. No other author has a financial or proprietary interest in any material or method mentioned." Date study conducted: NR Trial registration number: NR Contacting study investigators: trial authors not contacted

391 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Group assignment was based on a random-number-generated protocol that was created before initiation of the study." Quote: "Group assignment was based on a random-number-generated protocol that was created before initiation of the study."
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Not reported how allocation administered.
Blinding of participants and personnel (performance bias)	Unclear risk	Judgement Comment: Placebo controlled but not clear if masking was successful - some of the groups had different schedules.
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: Placebo controlled but not clear if masking was successful - some of the groups had different schedules. Corneal endothelial cell counts and OCT scans were evaluated by masked specialists. It was unclear whether assessors of other outcomes were aware of the treatment allocation, or if only the specialists were affected.
Incomplete outcome data (attrition bias)	Unclear risk	Judgement Comment: Follow-up not reported
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No access to protocol or trials registry entry.

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Study	Endo 2010
Methods	Study design: Parallel group RCT Open label
Participants	Country: Japan Setting: Eye hospital Intervention: NSAIDS alone Number of people (eyes) randomised: 40 (40) Number (%) of people followed up: 31 (78%) Average age in years: 68 Age range in years: NR (overall age range 37-84 years) Percentage women: 48% Ethnic group: NR Percentage with diabetes: 100% Percentage with uveitis: 0 (excluded) Comparator: Steroids alone Number of people (eyes) randomised: 35 (35) Number (%) of people followed up: 31 (89%) Average age in years: 69 Age range in years: NR Percentage women: 42% Ethnic group: NR Percentage with diabetes: 100% Percentage with uveitis: 0 (excluded) Inclusion criteria: patients with diabetes undergoing small incision phacoemulsification with intraocular lens implantation Exclusion criteria: foveal thickness of 250 microns or more; severe diabetic retinopathy for which ocular surgery (including photocoagulation) indicated;use of topical medications for glaucoma, uveitis and other diseases that cause CMO; ocular allergies to bromfenac or steroids (ST group); use of systemic steroids or non-steroidal anti-inflammatory drugs;serious cardiac, cerebral or renal disease Pretreatment: No major imbalances; compared age, gender, hypertension, blood urea nitrogen. HbA1c slightly higher in NSAIDs group. Eyes: One eye, unclear how selected.
Interventions	Intervention: NSAIDS alone

Study	Endo 2010
	bromfenac sodium (Bronuck, Senju,Pharmaceutical Company Ltd, Osaka,Japan) Times per day: BDS Duration pre-op: days: 0 Duration post-op: days: 42 Comparator: Steroids alone betamethasone sodium phosphate (with fradiomycin sulfate) followed by fluorometholone 0.1%(Rinderon-A, Shionogi, Osaka, Japan and Flumetholon 0.1%, Santen) Times per day: QDS for 7d (betamethasone); QDS for 35 d (fluorometholone) Duration pre-op: days: 0 Duration post-op: days: 42 Preoperatively, all participants received gatifloxacin (four times daily for 1 day preoperatively; on the day of surgery, they received 0.5% tropicamide, 0.5% phenylephrine hydrochloride every 30 min 2 hr preoperatively. Postoperatively, gatifloxacin four times daily until week 6, and 0.5% tropicamide and 0.5% phenylephrine hydrochloride once daily for 1 week Type of surgery: phacoemulsification
Outcomes	Follow-up: 6 weeks CRT at follow-up (final value) Adverse effects Inflammation (anterior chamber flare values, photon count per millisecond) BCVA logMAR (final value)
Contact details	Authors name: Naoko Endo Institution: Tokyo Women's Medical University Diabetes Centre Email: 51026745@mail.goo.ne.jp Address: Tokyo Women's Medical University Diabetes Centre, 8-1 Kawada-cho, Shinjuku-ku, Tokyo 162-0054, Japan
Notes	Funding sources: NR Declaration of interest: "The authors have no financial interest in any aspect of this article." Date study conducted: March 2005 to May 2007 Trial registration number: NR Contacting study investigators: trial authors not contacted

393 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "A prospective open-label trial was con ducted using the envelope method." Judgement Comment: Not reported how list was generated.
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Although mentioned "envelope method" not enough information on how the allocation was administered.
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: Open label study.
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: Open label study.
Incomplete outcome data (attrition bias)	High risk	Judgement Comment: 17% (13/75) of patients were excluded. Vague reasons were provided. Three were excluded because of difficulty with the OCT measurement. Ten patients (10 eyes) dropped out of the study because of poor health (eight patients), posterior capsular rupture (one patient) and epidemic keratoconjunctivitis (one patient). No details were provided about the 'difficulties with OCT measurements' and 'poor health'" 31/40 (78%) in NSAIDs group and 31/35 (89%) in steroids group were followed-up but reasons for dropout by group were not clearly reported.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No access to protocol or trials registry entry.

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Study	Jung 2015
Methods	Study design: Parallel group RCT
Participants	Country: South Korea Setting: Eye hospital Intervention: NSAIDS plus steroids Number of people (eyes) randomised: 28 (28) Number (%) of people followed up: NR Average age in years: 67 Age range in years: NR Percentage women: 54% Ethnic group: NR

Study	Jung 2015
	Percentage with diabetes: 25% Percentage with uveitis: NR Intervention: NSAIDS plus steroids Number of people (eyes) randomised: 32 (32) Number (%) of people followed up: NR Average age in years: 68 Age range in years: NR Percentage women: 53% Ethnic group: NR Percentage with diabetes: 28% Percentage with uveitis: NR Comparator: Steroids Number of people (eyes) randomised: 31 (31) Number (%) of people followed up: NR Average age in years: 67 Age range in years: NR Percentage women: 58% Ethnic group: NR Percentage with diabetes: 26% Percentage with uveitis: NR Inclusion criteria: males or non-pregnant females aged between 20- to 80-years-old. Exclusion criteria: poor general condition, including high blood pressure, poor blood glucose control, or renal failure; history of ocular trauma or disease; history of intraocular surgery; systemic or topical NSAIDs or corticosteroids use within 4 weeks of enrollment; known hypersensitivity to salicylates or other NSAIDs; and use of alpha-1 adrenergic antagonist or other analogous systemic medications that may increase the tendency for miosis during the operation (intraoperative floppy iris syndrome). Pretreatment: no major imbalances, age, sex, hypertension, diabetes, macular thickness and volume and ocular surface status compared. Eyes: One eye, unclear how selected
Interventions	Intervention: NSAIDS plus steroids bromfenac sodium 0.1% (Bronuck, Senju Pharmaceutical co Ltd, Osaka, Japan)

Study	Jung 2015
	Times per day: BDS plus 2 drops at 20m intervals 2 hrs before surgery. Duration pre-op: days: 3 Duration post-op: days: 28 prednisolone acetate 1% (brand name not reported) Times per day: QDS Duration pre-op: days: 0 Duration post-op: days: 28 Intervention: NSAIDS plus steroids ketorolac 0.45% (Acuvail, Allergan Inc, CA, USA) Times per day: BDS plus 2 drops at 20m intervals 2 hrs before surgery. Duration pre-op: days: 1 Duration post-op: days: 14 prednisolone acetate 1% (brand name not reported) Times per day: QDS Duration pre-op: days: 0 Duration post-op: days: 28 Comparator: Steroids alone prednisolone acetate 1% (brand name not reported) Times per day: QDS Duration pre-op: days: 0 Duration post-op: days: 28 All patients received topical gatifloxacin 0.3% QDS for 28 days. Type of surgery: phacoemulsification
Outcomes	Follow-up: 1 month Change in macular thickness Change in macular volume Adverse effects Inflammation (flare)
Contact details	Authors name: Dr. Tae-im Kim Institution: Yonsei University College of Medicine Email: tikim@yuhs.ac

Study	Jung 2015
	Address: Department of Ophthalmology, Yonsei University College of Medicine, 50-1 Yonsei-ro, Seodaemun-gu, Seoul 03722, Korea.
Notes	Funding sources: "This research was supported by Basic Science Research Program through the National Research Foundation of Korea (NRF) funded by the Ministry of Education, Science and Technology 2013R1A1A2058907)." Declaration of interest: "The authors have no financial conflicts of interest" Date study conducted: November 2013 to June 2014 Trial registration number: NR Contacting study investigators: trial authors not contacted

395 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement Comment: Not reported how list was generated. Trial was described as “randomised” but with no further details.
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Not reported how allocation administered. Trial was described as “randomised” but with no further details.
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment:No information on masking. We assume that in absence of reporting on this patients and personnel were not masked.
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: Open label or no information on masking. We assume that in absence of reporting on this outcome assessors were not masked.
Incomplete outcome data (attrition bias)	Unclear risk	Judgement Comment: Follow-up not reported.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No access to protocol or trials registry entry.

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Study	Mathys 2010
Methods	Study design: Parallel group RCT
Participants	Country: USA Setting: Eye hospital Intervention: NSAIDS plus steroids Number of people (eyes) randomised: 42 (42)

Study	Mathys 2010
	Number (%) of people followed up: 39 (93%) Average age in years: 74 Age range in years: 51-90 Percentage women: 54% Ethnic group: NR Percentage with diabetes: 0 (excluded) Percentage with uveitis: 0 (excluded) Comparator: Steroids alone Number of people (eyes) randomised: 42 (42) Number (%) of people followed up: 40 (95%) Average age in years: 70 Age range in years: 44-88 Percentage women: 53% Ethnic group: NR Percentage with diabetes: 0 (excluded) Percentage with uveitis: 0 (excluded) Inclusion criteria: planning to have cataract surgery by KLC at the Ambulatory Care Center, the University of NorthCarolina Hospitals. Exclusion criteria: medically treated diabetes mellitus; history of uveitis;use of topical prostaglandin analogues for glaucoma; history of earlier intraocular surgery in the same eye; retinal vascular disease; macular degeneration;abnormal preoperative OCT measurements Pretreatment: Nepafenac group were slightly older, similar gender, pre-op VA, follow-up time, slightly longer phaco time, Eyes: One eye, unclear how selected.
Interventions	Intervention: NSAIDS plus steroids nepafenac 0.1% (brand name not reported) Times per day: TDS Duration pre-op: days: 0 Duration post-op: days: 28 prednisolone acetate 1% (brand name not reported) Times per day: QDS Duration pre-op: days: 0

Study	Mathys 2010
	Duration post-op: days: 28 Comparator: Steroids alone prednisolone acetate 1% (brand name not reported) Times per day: QDS Duration pre-op: days: 0 Duration post-op: days: 28 All participants received nepafenac 0.01% drops in the operated eye thrice, 5 min apart, immediately before surgery to maintain pupillary dilation and postoperatively, moxifloxacin 0.5% four times a day for 10 days. Type of surgery: phacoemulsification
Outcomes	Follow-up: 2 months Change in CRT Adverse effects BCVA logMAR (final value)
Contact details	Authors name: KL Cohen Institution: School of Medicine, University of North Carolina Email: klc@med.unc.edu Address: Department of Ophthalmology, School of Medicine, University of North Carolina at Chapel Hill, 5100 Bioinformatics Building, 130 Mason Farm Road, CB no. 7040, Chapel Hill, NC 27599–7040, USA
Notes	Funding sources: "This work was supported in part by Research to Prevent Blindness, Inc., New York, NY" Declaration of interest: "Kenneth C Mathys and Kenneth L Cohen have no financial interest." Date study conducted: June 2007 to April 2008 Trial registration number: NCT00494494 Contacting study investigators: trial authors not contacted

397 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Subjects were randomised according to the even/odd subject identification number, using computer-generated random numbers, to the

Bias	Authors' judgement	Support for judgement
		control group (standard of care only) or the treatment group (standard of care plus nepafenac)."
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Not reported how allocation administered.
Blinding of participants and personnel (performance bias)	High risk	Quote: "were consecutively enrolled in this randomised, non-masked, parallel-group clinical trial." Judgement Comment: Participants were not masked
Blinding of outcome assessment (detection bias)	Low risk	Quote: "At the 2 months visit, technicians, who were masked to treatment, measured ETDRS BCVA, and OCT scans were performed." Judgement Comment: Experienced ophthalmic photographers, who were masked to treatment, obtained Stratus OCT (Carl Zeiss Meditec, Inc., San Francisco, CA, USA) scans using the fast macular thickness protocol.
Incomplete outcome data (attrition bias)	Low risk	Quote: "The mean time to follow-up was 73.31 days (± 21.58 SD, range 55–146) in the treatment group and 68.98 days (± 13.98, range 50–120) in the standard-of- care group." Judgement Comment: 39/42 (93%) of intervention group and 40/42 (95%) of comparator group followed-up. Missing data less than 20% (i.e. more than 80% follow-up) and equal follow-up in both groups and no obvious reason why loss to follow-up should be related to outcome
Selective reporting (reporting bias)	Low risk	Judgement Comment: Outcomes on trial registry entry were reported.

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Study	Miyake 2007
Methods	Study design: Randomised control trial
Participants	Country: Japan Setting: Eye hospital Intervention; NSAIDS alone Number of people (eyes) randomised: 31 (31) Number (%) of people followed up: 25 (81%) Average age in years: 65 Age range in years: NR Percentage women: 48%

Study	Miyake 2007
	Ethnic group: NR Percentage with diabetes: 0 (excluded) Percentage with uveitis: 0 (excluded) Comparator: Steroids alone Number of people (eyes) randomised: 31 (31) Number (%) of people followed up: 25 (81%) Average age in years: 66 Age range in years: NR Percentage women: 60% Ethnic group: NR Percentage with diabetes: 0 (excluded) Percentage with uveitis: 0 (excluded) Inclusion criteria: age 50 to 70 years; subjected for unilateral surgery or to have 6 months' span between surgeries in patients with bilateral cataract Exclusion criteria: eyes encountering acute ocular infection or inflammation during the first month of the study; eyes showing sensitivity to diclofenac or fluorometholone; eyes showing sensitivity to fluorescein sodium; eyes with insufficient dilation, (pupil diameter 4 mm) and with hazy media affecting laser Doppler flowmetry (LDF); eyes with history of other ocular surgeries; eyes with pseudoexfoliation syndrome; history of trauma; uveitis, glaucoma or other disorders; complication of diabetes and kidney disorders; heart failure, cardiac infarction, and cerebrovascular disease; uncontrollable hypertension; rupture of the posterior capsule, vitreous loss, and other complications during a cataract/IOL implantation procedure. Pretreatment: No major imbalances; compared age and sex. Eyes: One eye, unclear how selected.
Interventions	Intervention; NSAIDS alone diclofenac 0.1% (Diclod, Wakamoto, Tokyo, Japan) Times per day: QDS on day of surgery (3,2,1,0.5 hrs before surgery); TDS post-op Duration pre-op: days: 0 Duration post-op: days: 35 Comparator: Steroids alone fluorometholone 0.1% (Flumethrone, Santen, Osaka, Japan) Times per day: QDS on day of surgery (3,2,1,0.5 hrs before surgery); TDS post-op

Study	Miyake 2007
	Duration pre-op: days: on day of surgery Duration post-op: days: 35 mydriatics and antibiotics Type of surgery: phacoemulsification
Outcomes	Follow-up: 5 weeks CMO (fluorescein angiography using Miyake 1977 classification) Inflammation (mean aqueous flare, ?units) Snellen acuity only, not included in the analysis
Contact details	Authors name: Kensaku Miyake Institution: Shohzankai Medical Foundation, Miyake Eye Hospital Email: miyake@spice.or.jp Address: Miyake Eye Hospital, 3-15-68, Ozone, Kita-ku, Nagoya 462-0825, Japan
Notes	Funding sources: NR Declaration of interest: Reported none for all authors. Date study conducted: NR Trial registration number: NR Contacting study investigators: trial authors not contacted

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Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Each patient was randomly assigned to one of the two groups by one of the authors (SA), using the envelope method,.." Judgement Comment: Not reported how list was generated.
Allocation concealment (selection bias)	Unclear risk	Quote: "sEach patient was randomly assigned to one of the two groups by one of the authors (SA), using the envelope method, ..." Judgement Comment: Reported that envelopes used but unclear if they were sequentially numbered, sealed, opaque envelopes.
Blinding of participants and personnel (performance bias)	Unclear risk	Judgement Comment: Study described as being "conducted in a prospective, double-masked, randomized manner" Patients probably masked not clearly described.

Bias	Authors' judgement	Support for judgement
Blinding of outcome assessment (detection bias)	Low risk	Judgement Comment: Fluorescein angiography and laser flarimetry assessed by masked observers and analysis was masked. .
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: 25/31 (80%) of eyes in both groups were followed up and reasons for loss to follow-up did not appear to be related to outcome.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No access to protocol or trials registry entry.

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Study	Miyake 2011
Methods	Study design: Parallel group RCT
Participants	Country: Japan Setting: Eye hospital Intervention; NSAIDS alone Number of people (eyes) randomised: 30 (30) Number (%) of people followed up: 28 (93%) Average age in years: 64 Age range in years: 48-82 Percentage women: 47% Ethnic group: NR Percentage with diabetes: 7% Percentage with uveitis: 0% (excluded) Comparator: Steroids alone Number of people (eyes) randomised: 30 (30) Number (%) of people followed up: 27 (90%) Average age in years: 66 Age range in years: 37-83 Percentage women: 45% Ethnic group: NR Percentage with diabetes: 10% Percentage with uveitis: 0% (excluded) Inclusion criteria: aged over 20 years; phacoemulsification cataract extraction and IOL implantation between October 2007 and April 2008 at Shohzankai Medical Foundation, Miyake Eye Hospital.

Study	Miyake 2011
	Exclusion criteria: systemic, topical, or ointment steroidal agents within 14 days of surgery; had had an intraocular or periocular injection of steroidal agents within 90 days of surgery; had taken systemic or topical NSAIDs within 7 days of surgery; had a history of ophthalmic surgery (including laser surgery) or of ocular trauma that could affect the study results; had pseudoexfoliation syndrome; had a history of chronic or recurring ocular inflammation (eg, uveitis or scleritis); had diabetic retinopathy; hadan ocular anomaly (eg, aniridia, congenital cataract); had iris atrophy; had disorders that would preclude improvementin visual function; had macular edema; had severe corneal epithelial disorder (eg, corneal ulcer); had no visual function in the contralateral eye; were scheduled to have other ocular surgery from baseline to 5 weeks after cataract surgery; had secondary IOL implantation, were allergic to or might have been sensitive to NSAIDs, amfenac, or fluorometholone; had a positiveskin reaction to fluorescein; had a tendency to bleed or were currently on anticoagulants; had had prostaglandin-type treatment for glaucoma within 4 days of surgery; had been included in a previous study of prostaglandin type antiglaucoma drugs; had joined another clinical study within 30 days of the study; had ocular infection, had uncontrollable diabetes mellitus; hadsevere liver, kidney, or heart disorder; might have been pregnant or were currently breast feeding; had otherfactors determined to be unsuitable for the study. Pretreatment: No major imbalances. Eyes: One eye, unclear how selected.
Interventions	Intervention; NSAIDS alone nepafenac 0.1% (Nevanec) Times per day: TDS except for day of surgery QDS Duration pre-op: days: 1 Duration post-op: days: 35 Comparator: Steroids alone fluorometholone 0.1% (Flucon) Times per day: TDS except for day of surgery QDS Duration pre-op: days: 1 Duration post-op: days: 35 Levofloxacin ophthalmic solution 0.5% (Cravit) was applied to each eye 5 times before surgery and 3 times a day after surgery for 2 weeks." Type of surgery: phacoemulsification
Outcomes	Follow-up: 5 weeks Change in CRT Adverse effects

Study	Miyake 2011
	CMO (fluorescein angiography using Miyake 1977 classification) Inflammation (mean flare, photons/millisecond)
Contact details	Authors name: K Miyake Institution: Shohzankai Medical Foundation, Miyake Eye Hospital (K.Miyake, Ota, G.Miyake), Nagoya, and TokyoMetropolitan Geriatric Hospital (Numaga), Tokyo, Japan Email: miyake@spice.or.jp Address: Shohzankai Medical Foundation, Miyake Eye Hospital, 3-15-68, Ozone, Kita-ku, Nagoya, 462-0825, Japan
Notes	Funding sources: NR Declaration of interest: "Drs. Miyake and Numaga are consultants to Alcon Japan Ltd." Date study conducted: October 2007 to April 2008 Trial registration number: NR Contacting study investigators: PI emailed to confirm how patients allocated

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Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement Comment: Not reported how list was generated. Trial was described as “randomised” but with no further details.
Allocation concealment (selection bias)	Unclear risk	Quote: "The 2 drugs had identical outer appearances and could not be differentiated. The same physician (J.N.) served as the medical monitor and assigned 1 of the drugs to each patient." Judgement Comment: Unclear if allocation concealed from person recruiting participants.
Blinding of participants and personnel (performance bias)	Unclear risk	Judgement Comment: Described as “double blind” with no information on who was masked.
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: Described as “double blind” with no information on who was masked.
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: Missing data less than 20% (i.e. more than 80% follow-up) and equal follow-up in both groups and no obvious reason why loss to follow-up should be related to outcome: 28/30 (93%) in nepafenac group and 27/30 (90%) in the fluorometholone group

Bias	Authors' judgement	Support for judgement
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No access to protocol or trials registry entry.

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Study	Miyanaga 2009
Methods	Study design: Parallel group RCT
Participants	Country: Japan Setting: Eye hospital Intervention: NSAIDS plus steroids Number of people (eyes) randomised: 24 (NR) Number (%) of people followed up: NR Average age in years: 71 Age range in years: 46-86 Percentage women: 71% Ethnic group: NR Percentage with diabetes: 0 (excluded) Percentage with uveitis: 0 (excluded) Intervention; NSAIDS alone Number of people (eyes) randomised: 25 (NR) Number (%) of people followed up: NR Average age in years: 74 Age range in years: 48-86 Percentage women: 68% Ethnic group: NR Percentage with diabetes: 0 (excluded) Percentage with uveitis: 0 (excluded) Comparator: Steroids alone Number of people (eyes) randomised: 23 (NR) Number (%) of people followed up: NR Average age in years: 70 Age range in years: 41-83

Study	Miyanaga 2009
	Percentage women: 74% Ethnic group: NR Percentage with diabetes: 0 (excluded) Percentage with uveitis: 0 (excluded) Inclusion criteria: scheduled to undergo routine phacoemulsification combined with IOL Exclusion criteria: corneal disease; glaucoma; uveitis; pseudoexfoliation syndrome; diabetes; other pathologies that might affect treatmentresponses or evaluations; systemic or topical anti-inflammatory therapy within 1 month prior to surgery. Pretreatment: Quote "There were no significant differences between groups in gender or age." Eyes: Probably one eye only included in the trial but not clearly reported and unclear how selected
Interventions	Intervention: NSAIDS plus steroids bromfenac 0.1% (Bronuck; Senju Pharmaceutical Co.,Osaka, Japan) Times per day: BDS Duration pre-op: days: 0 Duration post-op: days: 56 betamethasone 0.1% for 28 days and fluorometholone for 28 days (Rinderon, Shionogi Pharmaceutical, Japan, and Flumetholon, Santen Pharmaceutical co) Times per day: QDS Duration pre-op: days: 0 Duration post-op: days: 56 Intervention; NSAIDS alone bromfenac 0.1% (Bronuck; Senju Pharmaceutical Co.,Osaka, Japan) Times per day: BDS Duration pre-op: days: 0 Duration post-op: days: 56 Comparator: Steroids alone betamethasone 0.1% for 28 days and fluorometholone for 28 days (Rinderon, Shionogi Pharmaceutical Co., Osaka, Japan, and Flumetholon, Santen Pharmaceutical Co) Times per day: QDS Duration pre-op: days: 0 Duration post-op: days: 56

Study	Miyanaga 2009
	All participants received 0.5% levofloxacin eyedrops four times daily until 2 months after surgery, and 0.5%tropicamide and 0.5% phenylephrinehydrochloride once daily for 2 weeks. The pupils were dilated with a combination of 0.5% tropicamide and 0.5% phenylephrine hydrochloride eyedrops (Mydrin-P; Santen Pharmaceutical Co., Osaka, Japan) and 5% phenylephrine hydrochloride eyedrops (Neosynesin; Kowa Co., Nagoya, Japan). Preoperative treatment consisted of 0.5% levofloxacin eyedrops (Cravit; Santen Pharmaceutical Co.), given four times daily for 1 week. All groups additionally received 0.5% levofloxacin eyedrops four times daily until 2 months after surgery, and 0.5% tropicamide and 0.5% phenylephrine hydrochloride once daily for 2 weeks Type of surgery: phacoemulsification
Outcomes	Follow-up: 2 months Adverse effects CMO ("obvious CMO confirmed by OCT") Inflammation (aqueous flare, photons/millisecond)
Contact details	Authors name: Masaru Miyanaga Institution: Miyata Eye Hospital Email: miyanaga@miyata-med.ne.jp Address: Miyata Eye Hospital, 6-3 Kurahara, Miyakonojo, Miyazaki 885-0051, Japan
Notes	Funding sources: NR Declaration of interest: NR Date study conducted: February 2006 to August 2006 Trial registration number: NR Contacting study investigators: trial authors not contacted

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Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement Comment: Not reported how list was generated. Trial was described as “randomised” but with no further details.
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Not reported how list was generated. Trial was described as “randomised” but with no further details.

Bias	Authors' judgement	Support for judgement
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No information on masking. We assume that in absence of reporting on this patients and personnel were not masked.
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: No information on masking. We assume that in absence of reporting on this outcome assessors were not masked
Incomplete outcome data (attrition bias)	Unclear risk	Judgement Comment: Only 1 patient was withdrawn from the study from the steroid only group due to CMO 1 month postop. Otherwise follow-up not reported.
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No access to protocol or trials registry entry.

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Study	Moschos 2012
Methods	Study design: Parallel group RCT
Participants	Country: Greece Setting: Eye hospital Intervention: NSAIDS plus steroids Number of people (eyes) randomised: 38 (38) Number (%) of people followed up: NR Average age in years: 77 Age range in years: NR Percentage women: 68% Ethnic group: NR Percentage with diabetes: 0 (excluded) Percentage with uveitis: 0 (excluded) Comparator: Steroids alone Number of people (eyes) randomised: 41 (41) Number (%) of people followed up: NR Average age in years: 77 Age range in years: NR Percentage women: 63% Ethnic group: NR Percentage with diabetes: 0 (excluded)

Study	Moschos 2012
	Percentage with uveitis: 0 (excluded) Inclusion criteria: Patients requiring phacoemulsification cataract surgery Exclusion criteria: presence of corneal abnormalities; history of intraocular surgery; preoperative ECC < 1,500 cells/mm2; history of uveitis, diabetes, and age-related macular degeneration; regular, systemic use of steroid or NSAIDs during the previous 3 months; and intraoperative complications, such as posterior capsule rupture, vitreous loss, lost nucleus, zonule dehiscence, and wound leak. Pretreatment: No major imbalances noted. Eyes: One eye, unclear how selected.
Interventions	Intervention: NSAIDS plus steroids diclofenac sodium 0.1% (Denaclof, Novartis Hellas, Athens, Greece) Times per day: TDS Duration pre-op: days: 3 Duration post-op: days: 28 dexamethasone sodium phosphate 0.1% (combined with chloramphenicol 0.5%) (Dispersadron (Novartis Hellas, Athens, Greece) Times per day: QDS Duration pre-op: days: 0 Duration post-op: days: 28 Comparator: Steroids alone dexamethasone sodium phosphate 0.1% (combined with chloramphenicol 0.5%) (Dispersadron, Novartis Hellas, Athens, Greece) Times per day: QDS Duration pre-op: days: 0 Duration post-op: days: 28 Type of surgery: phacoemulsification
Outcomes	Follow-up: 1 month CRT at follow-up (final value) BCVA logMAR (final value)
Contact details	Authors name: Irini P. Chatziralli Institution: Department of Ophthalmology University of Athens Email: eirchat@yahoo.gr

Study	Moschos 2012
	Address: Department of Ophthalmology, University of Athens, 28 Papanastasiou street 17342 Athens, Greece
Notes	Funding sources: NR Declaration of interest: "No competing financial interests exist." Date study conducted: NR Trial registration number: NR Contacting study investigators: trial authors not contacted

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Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomized (through random number gen eration) to 1 of the 2 postoperative treatment arms:"
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Not reported how allocation administered. Trial described as “randomised” but with no further details.
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No information on masking. We assume that in absence of reporting on this patients and personnel were not masked.
Blinding of outcome assessment (detection bias)	High risk	Judgement Comment: No information on masking. We assume that in absence of reporting on this patients and personnel were not masked.
Incomplete outcome data (attrition bias)	Unclear risk	Judgement Comment: Follow-up not reported
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No access to protocol or trials registry entry.

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Study	Wittpenn 2008
Methods	Study design: Parallel group RCT
Participants	Country: USA Setting: Eye hospital Intervention: NSAIDS plus steroids Number of people (eyes) randomised: 268 (268) Number (%) of people followed up: 227 (85%) given OCT at 4 weeks; 35 (13%) at 6 weeks Average age in years: 70

Study	Wittpenn 2008
	Age range in years: NR Percentage women: 53% (only reported for whole cohort) Ethnic group: 82% white (only reported for whole cohort) Percentage with diabetes: NR Percentage with uveitis: NR Comparator: Steroids plus placebo Number of people (eyes) randomised: 278 (278) Number (%) of people followed up: 251 (90%) given OCT at 4 weeks; 42 (15%) at 6 weeks Average age in years: 70 Age range in years: NR Percentage women: 53% (only reported for whole cohort) Ethnic group: 82% white (only reported for whole cohort) Percentage with diabetes: NR Percentage with uveitis: NR Inclusion criteria: scheduled to undergo cataract surgery; 20/20 BCVA potential without any evidence of macular abnormality, including age-related macular changes, epiretinal membranes, or other retinal-vascular anomalies. Exclusion criteria: systemic diseases with ocular manifestations of the disease (eg, diabetic patientswith normal retinal exams were not excluded); vitreous loss or capsular disruption/rupture occurred duringsurger; postoperative day 1, the surgeon felt the amount of inflammation was greater than expected and, in his bestclinical judgment, more aggressive anti-inflammatory treatment was indicated. Pretreatment: Quote "There were no statistically significant between-group differences in any demographic variable." but no data reported. Eyes: One eye, unclear how selected.
Interventions	Intervention: NSAIDS plus steroids ketorolac 0.4% (Acular LS, Allergan Inc, Irvine, California, USA) Times per day: QDS, 4 doses every 15 minutes one hour pre-op Duration pre-op: days: 3 Duration post-op: days: 28 to 42 prednisolone acetate 1% (Pred Forte, Allergan Inc) Times per day: QDS

Study	Wittpenn 2008
	Duration pre-op: days: 0 Duration post-op: days: "until one 5-ml bottle was empty" Comparator: Steroids plus placebo prednisolone acetate 1% (Pred Forte, Allergan Inc) Times per day: QDS Duration pre-op: days: 0 Duration post-op: days: "until they exited the study" placebo (artificial tears) Brand name: NR Times per day: QDS Duration pre-op: days: 3 Duration post-op: days: "until one 5-ml bottle was empty" The comparator group: "...also received four drops of ketorolac 0.4% one hour prior to cataract surgery." Type of surgery: phacoemulsification
Outcomes	Follow-up: 4 weeks Poor vision outcome due to MO (OCT confirmed CMO with visual acuity <6/9.) Adverse effects CMO (Quote "Definite CME: Presence of cystoid changes associatedwith substantial (>40µm) retinal thickening evident on OCT 2. Probable CME: Presence of changes in retinal contour and increased macular thickness relative to preoperative baseline, but without definite cystoid changes.3. Possible CME: Mild to moderate changes in retinal thickness or contour without cystoid changes.")
Contact details	Authors name: John R. Wittpenn Institution: State University of New York at Stony Brook Email: jrwittpenn@aol.com Address: State University of New York at Stony Brook, 2500 Route 347, Building 24, Stony Brook, NY 11790
Notes	Funding sources: "This study was supported by an unrestricted education grant from Allergan Inc, Irvine, Calfiornia" Declaration of interest: "The authors indicate no financial conflict of interest" Date study conducted: June 2005 to August 2006 Trial registration number: NCT00348244

Study	Wittpenn 2008
	Contacting study investigators: trial authors not contacted

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomized in a 1:1 ratio using a randomly generated list of patient identifica- tion numbers"
Allocation concealment (selection bias)	Low risk	Quote: "A central coordination center (IMEDS Inc, Riverside, California, USA; [M.E.]) generated the allocation se- quence, enrolled participants, and assigned participants to their treatment groups."
Blinding of participants and personnel (performance bias)	High risk	Quote: "The patients and technical staff were unmasked because regulations prevented the medications from being repackaged into similar, unmarked bottles. The labels were covered but the technicians were capable of recognizing the bottle color and shape. Patients, however, would only have been unmasked if they researched the type and shape of the different bottles."
Blinding of outcome assessment (detection bias)	Low risk	Quote: "All investigators were masked with regard to treatment group."
Incomplete outcome data (attrition bias)	High risk	Judgement Comment: Very low follow-up at 6 weeks. "Of the 546 patients who entered the study, 77 patients also returned for the week-6 visit, 35 in the ketorolac/steroid group and 42 in thesteroid group."
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No access to protocol and trials registry entry did not include outcomes.

Study	Yavas 2007
Methods	Study design: Parallel group RCT
Participants	Country: Turkey Setting: Eye hospital Intervention: NSAIDS plus steroids Number of people (eyes) randomised: 126 (126) Number (%) of people followed up: 121 (96%) Average age in years: 64 Age range in years: NR

Study	Yavas 2007
	Percentage women: 43% Ethnic group: NR Percentage with diabetes: 0 (excluded) Percentage with uveitis: 0 (excluded) Comparator: Steroids alone Number of people (eyes) randomised: 63 (63) Number (%) of people followed up: 58 (92%) Average age in years: 65 Age range in years: NR Percentage women: 36% Ethnic group: NR Percentage with diabetes: 0 (excluded) Percentage with uveitis: 0 (excluded) Inclusion criteria: NR Exclusion criteria: history of intraocular surgery; any complication during cataract surgery; glaucoma; uveitis; vitreoretinalpathology; history of diabetes mellitus, hypertension, or cardiac disease; or topical or systemic drug use Pretreatment: Some imbalances in age and sex but unclear if important. Eyes: Right eye only included.
Interventions	Intervention: NSAIDS plus steroids indomethacin 0.1% (brand name not reported) Times per day: QDS pre-op; TDS postop. Half received post-op only. Duration pre-op: days: 3 Duration post-op: days: 30 prednisolone acetate 1% (brand name not reported) Times per day: QDS Duration pre-op: days: 0 Duration post-op: days: 30 Comparator: Steroids alone prednisolone acetate 1% (brand name not reported) Times per day: QDS Duration pre-op: days: 0

Study	Yavas 2007
	Duration post-op: days: 30 All participants received 1 drop of topical antibiotic (ofloxacin 0.3%) 4 times daily for 1 week. Type of surgery: phacoemulsification
Outcomes	Follow-up: 3 months CMO (Quote "Slight fluorescein leakage into the cystic space without enclosing the entire central fovea or complete fluorescein accumulation in the cystic space was diagnosed as angiographic CME." BCVA (final value)
Contact details	Authors name: Guliz Yavas Institution: Afyon Kocatepe University Email: gkumbar@ttnet.net.tr Address: P.K. 25, 06502 Bahcelievler, Ankara, Turkey
Notes	Funding sources: NR Declaration of interest: "No author has a financial or proprietary interest in any material or method mentioned." Date study conducted: NR Trial registration number: NR Contacting study investigators: trial authors not contacted

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Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Patients were randomized into 3 groups." Judgement Comment: Not reported how list was generated. Trial was described as “randomised” but with no further details.
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Not reported how allocation administered. Trial was described as “randomised” but with no further details.
Blinding of participants and personnel (performance bias)	High risk	Judgement Comment: No information on masking. We assume that in absence of reporting on this patients and personnel were not masked.
Blinding of outcome assessment (detection bias)	Unclear risk	Quote: "Fluorescein angiography was performed in all patients, and fluorescein leakage to diagnose angiographic CME was evaluated by a masked observer."

Bias	Authors' judgement	Support for judgement
		Judgement Comment: Unclear if other outcomes were masked.
Incomplete outcome data (attrition bias)	Unclear risk	Judgement Comment: Follow-up not reported
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No access to protocol or trials registry entry.

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Study	Zaczek 2014
Methods	Study design: Parallel group RCT
Participants	Country: Sweden Setting: Eye Hospital Intervention: NSAIDS plus steroids Number of people (eyes) randomised: 80 (80) Number (%) of people followed up: 75 (94%) Average age in years: 70 Age range in years: NR Percentage women: 64% Ethnic group: NR Percentage with diabetes: NR Percentage with uveitis: NR Comparator: Steroids plus placebo Number of people (eyes) randomised: 80 (80) Number (%) of people followed up: 77 (96%) Average age in years: 68 Age range in years: NR Percentage women: 65% Ethnic group: NR Percentage with diabetes: NR Percentage with uveitis: NR Inclusion criteria: 45 and 85 years of age; cataract surgery under local anesthesia; translucent cataract for good-quality OCT scans of the macular at baseline Exclusion criteria: small pupils (<5.0 mm after pharmacologic dilation); dark brown irides; exfoliation syndrome, history of uveitis; glaucoma; macular degeneration; vision impairing eye disorder except

Study	Zaczek 2014
	cataract; diabetic patients; pregnant women; patients using topical or systemic anti-inflammatory treatment; hypersensitivity to any of the given study treatments; intraoperative difficulties (eg.loose zonularfibers, extended operating time, residual cortical material); intraoperative complications (eg. posterior capsule rupture and vitreous loss) Pretreatment: no major imbalances, age, gener and operated eye compared. Eyes: One eye, unclear how selected.
Interventions	Intervention: NSAIDS plus steroids nepafenac 0.1% (brand name not reported) Times per day: TDS Duration pre-op: days: 2 Duration post-op: days: 21 dexamethasone 0.1% (Isopto-Maxidex) Times per day: TDS Duration pre-op: days: 0 Duration post-op: days: 21 Comparator: Steroids plus placebo dexamethasone 0.1% (Isopto-Maxidex) Times per day: TDS Duration pre-op: days: 0 Duration post-op: days: 21 placebo (Tears Naturale II Polyquad) Times per day: thrice before surgery 5 minutes apart/TDS Duration pre-op: days: 2 Duration post-op: days: 21 Type of surgery: phacoemulsification
Outcomes	Follow-up: 6 weeks Adverse effects CMO (OCT verified but not defined) Inflammation (mean naterior chamber reported in figure but no SD could be calculated) BCVA logMAR (final value) Change in total macular volume
Contact details	Authors name: Anna Zaczek

Study	Zaczek 2014
	Institution: Scanloc Healthcare AB Email: anna. zaczek@scanloc.se Address: Scanloc Healthcare AB, Lilla Bommen 6, 411 04 Gothenburg, Sweden
Notes	Funding sources: Supported by Alcon Research Ltd, Fort Worth, Texas, USA, and S.A.Alcon-Couvreur N.V., Puurs, Belgium, which produced and provided the masked eyedrop bottles. Partially supported by Alcon, Inc., Sweden. Financial support was also provided through the regional agreement on Medical training and Clinical research (ALF) between Stockholm County Council and Karolinska Institutet (20120623). Declaration of interest: "No author has a financial or proprietary interest in any material or method mentioned." Date study conducted: NR Trial registration number: NR Contacting study investigators: trial authors not contacted

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Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement Comment: Not reported how list was generated. Trial described as “randomised” but with no further details.
Allocation concealment (selection bias)	Low risk	Quote: "All products used in this clinical trial were produced, labeled, packaged, and released by S.A. Alcon-Couvreur N.V. Puurs, Belgium. Nepafenac and placebosuspensions were supplied in identical bottles labeled witha protocol and a patient number so neither the investigators nor the patients were able to identify their contents."
Blinding of participants and personnel (performance bias)	Low risk	Quote: "All products used in this clinical trial were produced, labeled, packaged, and released by S.A. Alcon-Couvreur N.V. Puurs, Belgium. Nepafenac and placebo suspensions were supplied in identical bottles labeled witha protocol and a patient number so neither the investigators nor the patients were able to identify their contents."
Blinding of outcome assessment (detection bias)	Low risk	Quote: "All products used in this clinical trial were produced, labeled, packaged, and released by S.A. Alcon-Couvreur N.V. Puurs, Belgium. Nepafenac and placebo suspensions were supplied in identical bottles labeled

Bias	Authors' judgement	Support for judgement
		witha protocol and a patient number so neither the investigators nor the patients were able to identify their contents".
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: Missing data less than 20% (i.e. more than 80% follow-up) and equal follow-up in both groups and no obvious reason why loss to follow-up should be related to outcome
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: No access to protocol or trials registry entry.

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Study	Pollack 2016
Methods	Study design: Parallel group RCT
Participants	Country: Europe, India, Israel, New Zealand and the USA Setting: Eye Hospital Intervention: NSAIDS plus steroids Number of people (eyes) randomised: 87 Number (%) of people followed up: 80 Average age in years: 68.1 Age range in years: NR Percentage women: 36.3% Ethnic group: Asian, Black or African-American, Native Hawaiian or Other, Pacific Islander, White and Other Percentage with diabetes: 100 Percentage with uveitis: NR Comparator: Steroids Number of people (eyes) randomised: 88 Number (%) of people followed up: 80 Average age in years: 69.4 Age range in years: NR Percentage women: 45% Ethnic group: Asian, Black or African-American, Native Hawaiian or Other, Pacific Islander, White and Other Percentage with diabetes: 100

Study	Pollack 2016
	Percentage with uveitis: NR Inclusion criteria: Planned cataract extraction by phacoemulsification with the implantation of a posterior chamber intraocular lens (IOL) into the lens capsule; History of Type 1 or Type 2 diabetes; History of non-proliferative diabetic retinopathy (NPDR), mild, moderate, or severe, in the study eye as defined by the International Clinical Diabetic Retinopathy Disease Severity Scale; Able to understand and sign an informed consent approved by an IRB/IEC; Central subfield macular thickness less than or equal to 320 µm in the study eye prior to cataract surgery; Absence of clinically significant macular oedema in the study eye as detected by clinical exam. Exclusion criteria: Signs of vitreomacular traction or epiretinal membrane in the study eye as detected by the reading center or Investigator; Current or previous ocular disease other than diabetic retinopathy in the study eye that, in the opinion of the Investigator, would have confounded the assessments of the macula, the retina, or central vision; Planned multiple procedures for the study eye during the cataract/IOL implantation surgery (eg, trabeculoplasty, corneal transplant); Corneal transplant in study eye; Baseline cumulative corneal fluorescein staining score (ie, sum of scores for all 5 corneal regions) for the study eye greater than or equal to 5, or baseline corneal fluorescein staining score in any single region for the study eye greater than or equal to 3. Pretreatment: no major imbalances, age, gender and operated eye compared. Eyes: NR
Interventions	Intervention: NSAIDS plus steroids nepafenac 0.1% (NEVANAC, Alcon Research, Fort Worth, Texas, USA) Times per day: Three times daily Duration pre-op: days: 1 Duration post-op: days: 90 dexamethasone 0.1% (Brand not reported) Times per day: Four times daily Duration pre-op: days: 0 Duration post-op: days: 14 Comparator: Steroids dexamethasone 0.1% (Brand not reported) Times per day: Four times daily Duration pre-op: days: 0 Duration post-op: days: 14 Type of surgery: phacoemulsification

Study	Pollack 2016
Outcomes	Follow-up: 90 days Adverse effects CMO BCVA Change in total macular volume
Contact details	Authors name: Ayala Pollack Institution: Department of Ophthalmology, Kaplan Medical Centre Email: Correspondence to drrishisingh@gmail.com Address: Department of Ophthalmology, Kaplan Medical Center, Rehovot, Israel
Notes	Funding sources: Alcon Research Declaration of interest: " GS reports personal fees from Alcon, during the conduct of the study. DS reports others from Alcon Research Ltd, outside the submitted work. HR reports personal fees from Alcon, during the conduct of the study. RPS reports grants and personal fees from Alcon, grants and personal fees from Genentech, grants and personal fees from Regeneron, personal fees from Shire, during the conduct of the study". Date study conducted: Between August 2009 and August 2011 Trial registration number: NR Contacting study investigators: trial authors not contacted

413 **Risk of bias table**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement Comment: Not reported how list was generated. Trial described as "randomised" but with no further details.
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Trial described as "double-masked" but with no further details.
Blinding of participants and personnel (performance bias)	Unclear risk	Judgement Comment: No details provided.
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: No details provided
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: ITT analysis was performed

Bias	Authors' judgement	Support for judgement
Selective reporting (reporting bias)	Low risk	Judgement Comment: The study reported all outcomes that were measured in the study

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Study	Singh 2012
Methods	Study design: Parallel group RCT
Participants	Country: USA Setting: Eye Hospital Intervention: NSAIDS plus steroids Number of people (eyes) randomised: 133 Number (%) of people followed up: 125 Average age in years: 66.6 Age range in years: NR Percentage women: 66.4% Ethnic group: American Indian, Alaska Native, Asian, Black or African, American, White, and other. Percentage with diabetes: 100% Percentage with uveitis: NR Comparator: Steroids plus placebo Number of people (eyes) randomised: 130 Number (%) of people followed up: 126 Average age in years: 66.4 Age range in years: NR Percentage women: 59.5% Ethnic group: American Indian, Alaska Native, Asian, Black or African, American, White, and other. Percentage with diabetes: 100% Percentage with uveitis: NR Inclusion criteria: Diabetic (type 1 or type 2); 18 years and older; existing diagnosis of non-proliferative diabetic retinopathy that required cataract extraction with planned implantation of a posterior chamber intraocular lens; at least 50% of all enrolled patients were required to have moderate to severe non-proliferative diabetic retinopathy, as defined by the International Clinical Diabetic Retinopathy Disease Severity Scale

Study	Singh 2012
	Exclusion criteria: Significant corneal staining scores at baseline; history of dry eye syndrome; other conditions that may have caused macular oedema, including pre-existing histories of retinal vein occlusions, ocular surgeries, inflammatory eye diseases, ocular infections, congenital ocular anomalies, and ocular traumas; central subfield macular thickness 250 microns or more; baseline cysts, and the presence of macular traction and epiretinal membranes; use of concomitant medications such as topical or systemic NSAIDs and steroids Pretreatment: no major imbalances, age, gener and operated eye compared. Eyes: One eye, unclear how selected.
Interventions	Intervention: NSAIDS plus steroids nepafenac 0.1% Times per day: Three times daily Duration pre-op: days: 1 Duration post-op: days: 90 Prednisolone acetate (Omnipred; Alcon Research Ltd) Times per day: Four times daily Duration pre-op: days: 0 Duration post-op: days: at least 14 Comparator: Steroids plus placebo Prednisolone acetate (Omnipred; Alcon Research Ltd) Times per day: Four times daily Duration pre-op: days: 0 Duration post-op: days: at least 14 placebo (vehicle) Times per day: Three times daily Duration pre-op: days: 1 Duration post-op: days: 90 Type of surgery: NR
Outcomes	Follow-up: 90 days Adverse effects CMO BCVA using standardised Early Treatment Diabetic Retinopathy Study chart at 4m or 1m in both eyes

Study	Singh 2012
	Change in total macular thickness and volume
Contact details	Authors name: Rishi Singh Institution: Cole Eye Institute, Cleveland Clinical Foundation Email: drrishisingh@gmail.com Address: Cole Eye Institute, Cleveland CLinica Foundation, 9500 Euclid Avenue, i-32 Cleveland, OH 44195, USA
Notes	Funding sources: NR Declaration of interest: NR Date study conducted: Between November 2008 and July 2010 Trial registration number: NCT00782717 Contacting study investigators: trial authors not contacted

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement Comment: Not reported how list was generated. Trial described as “randomised” but with no further details.
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: Trial described as “double-masked” but with no further details.
Blinding of participants and personnel (performance bias)	Unclear risk	Judgement Comment: No details provided.
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: No details provided
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: ITT analysis was performed
Selective reporting (reporting bias)	Low risk	Judgement Comment: The study reported all outcomes that were measured in the study

4.16.8.6.1 Adverse events

Study	Follow-up	Number of people followed up	Adverse effects
Almeida 2008	1 month	74	Quote "There were 3 dropouts in the treatment group related to ketorolac corneal toxicity, most notably pain attributed to the drops"
Almeida 2012	1 month	162	Quote “One patient in the ketorolac group was hospitalized with a cardiovascular event and could not complete the follow-up. Finally, 1 patient on nepafenac had side effects of ocular redness and irritation and could not continue with the study.”
Asano 2008	8 weeks	142	2 "complications" not specified
Cervantes-Costa 2009	6 weeks	60	Quote "There were no serious treatment-related adverse events or toxicity related to the use of nepafenac 0.1%."
Chatziralli 2011	6 weeks	138	Quote "All patients reported pain and ocular discomfort lower than 1/10 on the visual analog scale at all time points."
Donnenfeld 2006	2 weeks	100	Quote "Use of ketorolac 0.4% for 1 or 3 days provided decreased levels of patient discomfort intraoperatively and postoperatively. Intraoperatively, 3 days of ketorolac 0.4% provided significantly lower discomfort scores than with 1-hour and placebo dosing (P<.001). One day of ketorolac 0.4% also provided significantly reduced intraoperative discomfort scores than with 1-hour dosing (P= .001) and placebo dosing (P<.001). Postoperatively, 3 days of ketorolac 0.4% provided significantly lower discomfort scores than 1-hour dosing or control dosing (P<.001) (Figure 5). In addition, patients randomized to 1 or 3 days of ketorolac 0.4% were significantly less likely to require additional intravenous anesthesia (8% in each group) than patients in the control group (40%) (P=.008). Twenty percent of patients in the 1-hour group required additional anesthesia for pain control."
Endo 2010	6 weeks	62	Quote "No adverse events were noted in either group.""
Jung 2015	1 month	91	Quote "There were no adverse events except for a mild burning sensation in one patient in the ketorolac group; the symptom was tolerable and did not lead to discontinuation of the medication."
Mathys 2010	2 months	79	Quote "There were no adverse events reported by patients using nepafenac"
Miyake 2007	5 weeks	50	Adverse effects not reported
Miyake 2011	5 weeks	55	NSAIDS: 6 AEs. decreased lacrimation, conjunctivitis allergic, abnormal sensation in eye, vomiting (2), constipation Steroid group: 9 AEs. decreased lacrimation, conjunctivitis allergic, retinal hemorrhage, keratoconjuncitivtis sicca, chorioretinopathy, influenza, insomnia, diarrhea, humeral fracture

Study	Follow-up	Number of people followed up	Adverse effects
Miyanaga 2009	2 months	72	Adverse effects not reported
Moschos 2012	1 month	79	Adverse effects not reported
Wittpenn 2008	4 weeks	478	Quote "The most commonly reported adverse events (investigator self-report) in the ketorolac/steroid group were burning/stinging/tearing (4/268). Transient elevations in intraocular pressure (IOP) were the most commonly reported adverse event in the steroid group (3/278). There were two serious adverse events, both in the steroid group: one patient developed endophthalmitis and one patient died (cause determined to be unrelated to the study medication)."
Yavas 2007	3 months	179	Adverse effects not reported
Zaczek 2014	6 weeks	152	Quote "Mild to moderate punctuate epithelial defects of the cornea were found in both groups 3 weeks after treatment.Statistically significantly more patients in the nepafenac group than in the control group had corneal fluorescein staining (20 [26.7%] versus 8 [10.4%]) (PZ.0119). Headache was reported by 3 patients (4.0%) in the nepafenac group and 2 patients (2.6%) in the control group (PZ.9750). No other systemic or local untoward effects were recorded during 3 weeks of treatment in either study group."

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E.8.7 Managing cystoid macular oedema

Full citation	Heier J, Topping T, Baumann W , Dirks M and Chern S. Ketorolac vs Prednisolone vs Combination therapy in the treatment of acute pseudophakic cystoid macular oedema. American academy of ophthalmology. 2000;107:2034-2039
Study details	Country/ies where the study was carried out: USA Study type: RCT Aim of the study: To evaluate the efficiency of ketorolac tromethamine, prednisolone acetate and ketorolac and prednisolone combination therapy in the treatment of acute cystoid macular oedema occurring after cataract surgery. Study dates: Not reported Sources of funding: Unrestricted research grant from Allergan Pharmaceuticals
Participants	Sample size 26 patients Inclusion criteria Patients diagnosed with acute clinical CME with visual acuity of 20/40 or worse 21 to 90 days after uncomplicated cataract extraction and intraocular lens implantation. Exclusion criteria Snellen VA better than 20/40, Fluorescein angiogram not consistent with CME, Use of any NSAID or anti-inflammatory agent other than topical prednisolone within 7 days preceding surgery, use of more than 325 mg/day of aspirin within 7 days of study starting (no other systemic anti-inflammatory allowed), use of systemic corticosteroids within 7 days preceding study, ocular disease preventing adequate examination of the fundus or preventing a clear fluorescein angiogram, any ocular disease that could be responsible for the decreased VA, diabetic retinopathy, unstable systemic disease including hypertension, previous eye disease resulting in a history of macular oedema (other than pseudophakic CME in fellow eye), any ocular surgery other than cataract extraction and IOL implantation, complicated cataract surgery (such as rupture of the posterior capsule or obvious iris damage).
Methods	Patients were randomised to one of three treatment arms: Group P – Prednisolone acetate (1.0%) Group K – Ketorolac tromethamine (0.5%) Group C – Ketorolac and Prednisolone Groups P and K also received a second medication consisting of artificial tears (so that each patient was taking 2 different drops – 1 drop, 4 times a day) Medications were randomised by the pharmacy and pre-masked to both patients and examiners Patients were examined preoperatively and at monthly intervals postoperatively with final examination occurring 1 month after discontinuation of the medication. Intervention Ketorolac tromethamine (0.5%), Prednisolone acetate (1.0%) or combination therapy to treat CME
Results	Results of drug therapy

<table>
<tr><th>Full citation</th><th>Heier J, Topping T, Baumann W , Dirks M and Chern S. Ketorolac vs Prednisolone vs Combination therapy in the treatment of acute pseudophakic cystoid macular oedema. American academy of ophthalmology. 2000;107:2034-2039</th></tr>
<tr><td></td><td>
<table>
<tr><td>Variable</td><td>Group P (n=8)</td><td>Group K (n=9)</td><td>Group C (n=9)</td></tr>
<tr><td>Av. Final visual acuity
Range</td><td>20/40+
20/25 to 20/70</td><td>20/40
20/20 to 20/100</td><td>20/30+
20/20 to 20/40</td></tr>
<tr><td>Av improvement in lines of acuity
Range</td><td>1.1
-2 to +2</td><td>1.9
-1 to +4</td><td>3.8
+1 to +6</td></tr>
<tr><td>≥ two-line improvement</td><td>50% (4/8)</td><td>67% (6/9)</td><td>89% (8/9)</td></tr>
<tr><td>≥ two-line decline</td><td>12% (1/8)</td><td>0%</td><td>0%</td></tr>
<tr><td>Patients with final VA ≥ 20/40</td><td>62% (5/8)</td><td>67% (6/9)</td><td>100% (9/9)</td></tr>
</table>
</td></tr>
<tr><td>Outcomes</td><td>Significant difference in visual acuity was detected between group P and group C at visits 4 (p=0.006) and 5 (p=0.042)
No significant difference noted between group K and group C with respect to visual acuity
At no time during the study was a significant difference detected between group P and group K with regard to visual acuity
Combination therapy offers benefits over monotherapy with either agent alone.</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Unsure
3 Were the patients, health workers and study personnel blinded? Yes
4 Were the groups similar at the start of the trial? Yes
5 Aside from the experimental intervention, were the groups treated equally? Yes
6 Were all of the patients who entered the trial properly accounted for at its conclusion? Yes
7 Can the results be applied to the local population? Yes
8 Were all clinically important outcomes considered? N/A</td></tr>
</table>

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Full citation	Rho D. Treatment of acute pseudophakic cystoid macular oedema: Diclofenac versus ketorolac. Journal of Cataract Refract Surg. 2003;29:2378-2384
Study details	Country/ies where the study was carried out: USA Study type: RCT

<table>
<tr><th>Full citation</th><td>Rho D. Treatment of acute pseudophakic cystoid macular oedema: Diclofenac versus ketorolac. Journal of Cataract Refract Surg. 2003;29:2378-2384</td></tr>
<tr><td></td><td>Aim of the study: To compare diclofenac sodium solution and ketorolac tromethamine solution in the treatment of cystoid macular oedema after cataract surgery.
Study dates: Between 1995 and 1999
Sources of funding: Not reported</td></tr>
<tr><td>Participants</td><td>Sample size
34 patients
Inclusion criteria
Patients with clinical CME after uneventful phacoemulsification cataract removal.
Exclusion criteria
Patients with a history of intraocular surgery before cataract surgery, vitreous loss during cataract surgery, CME, uveitis, or vitreoretinal pathology</td></tr>
<tr><td>Methods</td><td>Patients were randomised to receive 1 drop, 4 times a day of diclofenac sodium (0.1% solution, n=18) or ketorolac tromethamine (0.5% solution, n=16) in the eye with CME.
As most patients received some form of perioperative or postoperative corticosteroid or NSAID, all patients completed a washout period of at least 14 days before beginning treatment.
Data collection
Patients were examined preoperatively and every 2-3 weeks postoperatively for 26 weeks for Visual acuity, reduction and elimination of CME.
Intervention
Diclofenac sodium (0.1% solution) or ketorolac tromethamine (0.5% solution) after uneventful cataract surgery to treat CME
Analysis
Two sided statistical test</td></tr>
<tr><td>Results</td><td>Results
<table>
<tr><td>Parameter</td><td>Ketorolac</td><td>Diclofenac</td><td>P value</td></tr>
<tr><td>Mean final VA (all patients)</td><td>20/58 ± 94.1</td><td>20/49 ± 56.8</td><td>0.74</td></tr>
<tr><td>Mean VA (CME eliminated)</td><td>20/25 ± 3.7</td><td>20/25 ± 3.9</td><td>1.0</td></tr>
<tr><td>Mean time to elimination (weeks)</td><td>12.8 ± 2.5</td><td>13.6 ± 2.8</td><td>0.49</td></tr>
<tr><td>Patients with CME elimination (%)</td><td>75</td><td>78</td><td>0.86</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>Within 26 weeks Diclofenac eliminated CME in 14 patients (78%), Ketorolac in 12 patients (75%)</td></tr>
</table>

Full citation	**Rho D. Treatment of acute pseudophakic cystoid macular oedema: Diclofenac versus ketorolac. Journal of Cataract Refract Surg. 2003;29:2378-2384**
	Mean time to CME resolution was 13.6 weeks with diclofenac and 12.8 weeks for ketorolac Both treatments methods resulted in a significant reduction in CME and a significant improvement in visual acuity
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Was the assignment of patients to treatments randomised? Unsure 3 Were the patients, health workers and study personnel blinded? Unsure 4 Were the groups similar at the start of the trial? Yes 5 Aside from the experimental intervention, were the groups treated equally? Yes 6 Were all of the patients who entered the trial properly accounted for sat its conclusion? Yes 7 Can the results be applied to the local population? Yes 8 Were all clinically important outcomes considered? N/A

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Full citation	**Singal N, Hopkins J. Pseudophakic cystoid macular oedema: ketorolac alone vs ketorolac plus prednisolone. Can J Ophthalmol. 2004;39:245-50**
Study details	Country/ies where the study was carried out: Canada Study type: RCT Aim of the study: To evaluate the use of NSAIDs and steroids in the management of cystoid macular oedema. Study dates: December 1999 to February 2001 Sources of funding: Authors supported by the department of ophthalmology and vision sciences, University of Toronto
Participants	Sample size 10 patients Inclusion criteria Patients diagnosed with CME occurring at least 6 weeks after cataract surgery – CME defined as an Early Treatment Diabetic Retinopathy Study (ETDRS) for this publication Exclusion criteria Patients with best corrected ETDRS vision better than 20/40, Snellen equivalent, no CME within the previous 4 weeks, use of steroids, pre-existing macular disease or diabetic maculopathy detected on fluorescein angiography
Methods	Patients were randomly assigned to one of two treatment arms by the hospital pharmacy: 0.5% ketorolac tromethamine plus placebo, or 0.5% ketorolac tromethamine plus 1% prednisolone acetate. Each drop administered 4 times daily. Both patients and examiner were masked.

<table>
<tr><th>Full citation</th><td>Singal N, Hopkins J. Pseudophakic cystoid macular oedema: ketorolac alone vs ketorolac plus prednisolone. Can J Ophthalmol. 2004;39:245-50</td></tr>
<tr><td></td><td>Data collection
Each patient was examined at baseline and 30, 60 and 90 days following randomisation for best corrected ETDRS vision
Intervention
Treatment for CME with ketorolac or ketorolac + prednisolone
Analysis
ANOVA</td></tr>
<tr><td>Results</td><td>Outcome measures
<table>
<tr><td></td><td colspan="3">Group</td></tr>
<tr><td>Variable</td><td>Ketorolac (n=4)</td><td>Ketorolac + prednisolone (n=6)</td><td>P value</td></tr>
<tr><td>Mean ETDRS Snellen equivalent vision (± SD)</td><td></td><td></td><td></td></tr>
<tr><td>30 days</td><td>48.5 (± 9.7)</td><td>55.2</td><td>0.24</td></tr>
<tr><td>60 days</td><td>52.6 (± 20.2</td><td>53.0</td><td>0.10</td></tr>
<tr><td>90 days</td><td>50.0 (± 29.0)</td><td>54.7 (± 7.25)</td><td>0.36</td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>There was no significant change in vision within either group over time.
No significant difference in vision was noted between the two groups at any visit</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Was the assignment of patients to treatments randomised? Unsure
3 Were the patients, health workers and study personnel blinded? Yes
4 Were the groups similar at the start of the trial? Yes
5 Aside from the experimental intervention, were the groups treated equally? Yes
6 Were all of the patients who entered the trial properly accounted for sat its conclusion? Yes
7 Can the results be applied to the local population? Yes
8 Were all clinically important outcomes considered? N/A</td></tr>
</table>

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E.8.8 Postoperative eye shields

No evidence was identified for this review question.

E.9 Postoperative assessment

- What are the early and late complications of cataract surgery?
- What should the postoperative assessment include?
- Who and in what setting should carry out the postoperative assessment?
- What issues should be considered when organising postoperative care?
- What is the appropriate time to assess outcomes in the postoperative period?
- If the postoperative assessment and care are undertaken outside of the hospital, how should outcomes between surgical units and these providers be effectively communicated?

E.9.1 Complications of surgery

Full citation	Bjerrum S, Mikkelsen K, La Cour M. Risk of psuedophakic retinal detatchment in 202,226 patients using fellow eye non-operated eye as reference. Ophthalmology 2013;120:2573-2579
Study details	Country/ies where the study was carried out: Denmark Study type: Retrospective cohort Aim of the study: To study the risk of pseudophakic retinal detachment (PRD) after first eye phacoemulsification cataract surgery. Study dates: 2000 through 2010 Sources of funding: Bjerrum and La Court sponsored by Alcon
Participants	Sample size 202,226 Inclusion criteria Underwent surgery during study period and 40 years of age or older at the time of surgery. Coded with KCJE20- phacoemulsification with implantation of an artificial lens in the posterior chamber in the Danish National Patient Register (NPR) Exclusion criteria Individuals with additional codes other than KCJE20. Those with recorded cataract, trauma, vitreoretinal surgery (including tumours), globe removal in either eye, bilateral cataract surgery, missing information detailing which eye operated on.
Methods	The NPR was used to identify individuals who underwent uncomplicated phacoemulsification surgery in their first eye. They were followed up until entries were found in the NPR for surgery for RD in either eye. Analysis Cox regression
Results	465 PRDs in the cataract operated eye were identified 110 PRDs in the fellow non-operated eye identified

Full citation	**Bjerrum S, Mikkelsen K, La Cour M. Risk of psuedophakic retinal detatchment in 202,226 patients using fellow eye non-operated eye as reference. Ophthalmology 2013;120:2573-2579**
Outcomes	0.23% incidence rate of PRD Relative risk of PRD was 4.23 when compared to PRD in the fellow non-operated eye
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Did the authors use an appropriate method to answer their question? Yes 3 Were the cases recruited in an acceptable way? Yes 4 Was the exposure accurately measured to minimise bias? Unclear 5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unclear 6 Do you believe the results? Yes 7 Can the results be applied to the local population? Yes 8 Do the results of this study fit with other available evidence? N/A

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Full citation	**Boberg-Ans G, Henning V, Villumsen J, LaCour M. Long-term incidence of rhegmatogenous retinal detachment and survival in a defined population undergoing standardized phacoemulsification surgery. Acta Ophthalmol Scand. 2006;84:613-618**
Study details	Country/ies where the study was carried out: Denmark Study type: Retrospective cohort Aim of the study: To determine the long-term risk of pseudophakic retinal detachment (PRD) in a defined population Study dates: 1996 through 1998 Sources of funding: Dandy foundation
Participants	Sample size 6352 patients Inclusion criteria Patients on the registry in the Eye department, Copenhagen University Hospital undergoing phacoemulsification surgery for cataract surgery. Exclusion criteria Where phacoemulsification was part of a posterior segment procedure and eyes with a prior record of RD
Methods	Cataract operated eyes were identified from the registry. Eyes that subsequently underwent surgery for PRD were identified by a search in the Danish Patients Registry (LPR) with the end-point of the study being surgery rhegmatogenous retinal detachment
Results	Cumulated incidence rate

Year	Cumulated incidence rate of RD per eye (95% CI)	Cumulated incidence rate of RD per patient (95% CI)

Full citation	**Boberg-Ans G, Henning V, Villumsen J, LaCour M. Long-term incidence of rhegmatogenous retinal detachment and survival in a defined population undergoing standardized phacoemulsification surgery. Acta Ophthalmol Scand. 2006;84:613-618**
	1 year: 0.16 (0.09 to 0.30); 0.18 (0.09 to 0.35) 8 years: 0.93 (0.65 to 1.33); 1.13 (0.80 to 1.59)
Outcomes	The 8 year cumulated incidence of PRD after phacoemulsification was 0.93 per eye (95% CI 0.65 – 1.33). 8.77 (95% CI 7.12 – 10.72) times higher than expected in eyes that do not undergo cataract surgery.
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Did the authors use an appropriate method to answer their question? Yes 3 Were the cases recruited in an acceptable way? Yes 4 Was the exposure accurately measured to minimise bias? Unclear 5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unclear 6 Do you believe the results? Yes 7 Can the results be applied to the local population? Yes 8 Do the results of this study fit with other available evidence? N/A

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Full citation	**Chu C, Johnston R, Buscombe C, Sallam A, Mohamed Q, Yang Y. Risk factors and incidence of macular edema after cataract surgery. Ophthalmology 2016;123:316-323**
Study details	Country/ies where the study was carried out: UK Study type: Retrospective case series Aim of the study: To define the incidence of pseudophakic macular edema (PME) after cataract surgery and to identify contributory risk factors Study dates: Between December 2010 and December 2014 Sources of funding: National institute for Health research and Alcon
Participants	Sample size 81,984 eyes Inclusion criteria Patients recorded on the database to have had any phacoemulsification and intraocular lens implantation procedure. Exclusion criteria Patients receiving prophylactic topical NSAIDs, confounding pathologic features, no recording of diabetes or retinopathy status before and after surgery.
Methods	Patients captured from the same EMR system who had phacoemulsification cataract surgery were analysed. Those who underwent sequential surgery in the second eye during the study period had both eyes included, and data on individual eyes were treated as independent units for the purpose of the analysis.

Full citation	Chu C, Johnston R, Buscombe C, Sallam A, Mohamed Q, Yang Y. Risk factors and incidence of macular edema after cataract surgery. Ophthalmology 2016;123:316-323
	Outcomes Diagnosis of cystoid macular oedema or new-onset macular oedema in patients with diabetes, recorded within 90 days of surgery Analysis Multiple t-tests using the Holm-Sidak method
Results	Baseline incidence of PME in eyes without operative complications, diabetes or risk factors was 1.17%
Outcomes	Pseudophakic macular oedema occurs commonly after phacoemulsification cataract surgery even in the absence of complications and risk factors
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Did the authors use an appropriate method to answer their question? Yes 3 Were the cases recruited in an acceptable way? Yes 4 Was the exposure accurately measured to minimise bias? Unclear 5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Yes 6 Do you believe the results? Yes 7 Can the results be applied to the local population? Yes 8 Do the results of this study fit with other available evidence? N/A

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Full citation	Clark A, Morlet N, Ng J, Preen D, Semmens J. Risk for retinal detachment after phacoemulsification. Arch ophthalmol. 2012;130:882-888
Study details	Country/ies where the study was carried out: Australia Study type: Retrospective longitudinal study Aim of the study: To estimate the long term cumulative incidence and risk factors for retinal detachment (RD) after phacoemulsification. Study dates: January 1989 to December 2001 Sources of funding: This study was supported by grants 110250 and 303114 from the Australian National Health and Medical Research Council Project.
Participants	Sample size 65,055 phacoemulsification procedures on 46,258 patients Inclusion criteria All patients who underwent phacoemulsification cataract surgery during the study period Exclusion criteria Cases where an RD occurred before the first-ever cataract extraction operation, where eye trauma was involved or where vitreoretinal surgery

<table>
<tr><th>Full citation</th><td>Clark A, Morlet N, Ng J, Preen D, Semmens J. Risk for retinal detachment after phacoemulsification. Arch ophthalmol. 2012;130:882-888</td></tr>
<tr><td></td><td>was performed concurrently.</td></tr>
<tr><td>Methods</td><td>Data from all Western Australia hospitals (public and private) obtained from the Hospital Morbidity Data Collection, one of the core data sets of the Western
Australian Data Linkage System. Phacoemulsification procedures were identified using the International Classification of Diseases, 9th Revision, Australian Clinical Modification (ICD-9-CM)25 codes for procedures 13.41 through 13.43 and the International Classification of Diseases, 10th Revision,
Australian Modification (ICD-10-AM) 26 codes 42698-02, 42698-03, 42702-04, 42702-05, 42702-06, and 42702-07.
All surgically treated RD cases were identified using specific ICD procedure codes associated with RD repair (ICD-9-CM codes 14.3 through 14.59 and 14.9 and ICD-10-AM codes 42773-00, 42773-01, 42776-00, 42809-01, and 90079-00). Only RD associated procedures that occurred after the associated phacoemulsification procedure were considered.
Analysis
Kaplan-Meier analysis</td></tr>
<tr><td>Results</td><td>Outcomes
<table>
<tr><th>Year of surgery</th><th>Phacoemulsification procedure. No. (%)
(n=65 055)</th><th>Retinal detachment, No. (%)
(n=237)</th><th>5-Year cumulative incidence % (95% CI)</th></tr>
<tr><td>1989 - 1993</td><td>3974 (6.1)</td><td>49 (20.7)</td><td>0.96 (0.70 – 1.32)</td></tr>
<tr><td>1994 - 1998</td><td>28 345 (43.6)</td><td>123 (51.9)</td><td>0.43 (0.36 – 0.51)</td></tr>
<tr><td>1999 - 2001</td><td>32 736 (50.3)</td><td>65 (27.4)</td><td>0.25 (0.19 – 0.33)*</td></tr>
</table>
*3 year incidence rate</td></tr>
<tr><td>Outcomes</td><td>Overall crude incidence rate (10 years) of RD was 0.4%
The crude incidence of RD after phacoemulsification declined by a mean of 19% for each year after 1989 (incidence rate ratio, 0.81; 95% CI, 0.77-0.84)
The median time to RD after phacoemulsification was 11 months(range,0-8.4 years), with the cumulative incidence increasing almost linearly from 0.47% (95%CI,0.41%-0.54%) by 5 years after surgery to 0.68% (0.56%-0.83%) by 10 years after surgery</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal</td><td>1 Did the study address a clearly focused issue? Yes
2 Did the authors use an appropriate method to answer their question? Yes
3 Were the cases recruited in an acceptable way? Yes
4 Was the exposure accurately measured to minimise bias? Unclear
5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unsure
6 Do you believe the results? Yes</td></tr>
</table>

Full citation	Clark A, Morlet N, Ng J, Preen D, Semmens J. Risk for retinal detachment after phacoemulsification. Arch ophthalmol. 2012;130:882-888
skills programme)	7 Can the results be applied to the local population? Yes 8 Do the results of this study fit with other available evidence? N/A

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Full citation	Colleaux K, Hamilton K. Effect of prophylactic antibiotics and incision type on the incidence of endophthalmitis after cataract surgery. Can J ophthalmol 2000;35:373-378
Study details	Country/ies where the study was carried out: Canada Study type: Retrospective chart review Aim of the study: To determine the effect of prophylactic antibiotics and incision type on endopthalmitis incidence. Study dates: Sept 1st 1994 to Jan 31st 1998 Sources of funding: none reported
Participants	Sample size 13 886 cataract operations Inclusion criteria Patients undergoing cataract surgery during the study period Exclusion criteria Not reported
Methods	Hospital medical records were searched to identify phacoemulsification surgeries undertaken. All cases of endophthalmitis within the study period were also searched for. All cases arising following cataract surgery at the study centre were included. Surgeons were asked to respond to a survey asking for incision method used and use of antibiotics. Operative reports were also reviewed to verify the antibiotic regimes used. Intervention Subconjunctival antibiotic injections (gentamicin or a combination of gentamicin and cefazolin) vs none Pre-operative antibiotic drops vs none – the antibiotics used included tobramycin, hentamicin, ofloxacin and polymyxin-trimethoprim Clear-corneal vs Scleral tunnel incisions Analysis Poisson regression analysis
Results	Frequency of post-operative endophthalmitis

Number of procedures	Number (%) of cases of endophthalmitis

Full citation	**Colleaux K, Hamilton K. Effect of prophylactic antibiotics and incision type on the incidence of endophthalmitis after cataract surgery. Can J ophthalmol 2000;35:373-378**
	13 886 | 10 (0.072) Incidences of postoperative endophthalmitis with subconjunctival antibiotic injections than without (0.011% vs 0.179%) p = 0.009, OR 16.23 (1.92 – 137.14)
Outcomes	Incidences of postoperative endophthalmitis significantly lower with subconjunctival antibiotic injections than without The difference in the incidence with preoperative antibiotic drops and none was not significant The difference in the incidence with clear-corneal and scleral tunnel incisions was not significant
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Did the authors use an appropriate method to answer their question? Yes 3 Were the cases recruited in an acceptable way? Yes 4 Was the exposure accurately measured to minimise bias? Unclear 5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unsure 6 Do you believe the results? Yes 7 Can the results be applied to the local population? Yes 8 Do the results of this study fit with other available evidence? N/A

439

Full citation	**Creuzot-Garcher C, Benzenine E, Mariet A, Lazzer A, Chiquet C, Bron A, Quantin C. Incidence of acute postoperative endophthalmitis after cataract surgery. Ophthalmology 2016;123:1414-1420**
Study details	Country/ies where the study was carried out: France Study type: Retrospective cohort Aim of the study: To report the incidence of acute postoperative endophthalmitis (POE) after cataract surgery in France (2005-2014) Study dates: January 2005 to December 2014 Sources of funding: Not reported but Creuzot-Garcher C obtains personal fees from Alcon, Allergan, Bausch & Lomb, Bayer, Novartis, Horus and Théa
Participants	Sample size 3 983 525 patients (6 371 242 eyes) Inclusion criteria Patients admitted to healthcare facilities undergoing cataract surgery by phacoemulsification and presenting acute POE. Combined procedures (i.e. cataract extraction concomitant with glaucoma, corneal surgery or vitreoretinal procedures) were included

<table>
<tr><th>Full citation</th><th>Creuzot-Garcher C, Benzenine E, Mariet A, Lazzer A, Chiquet C, Bron A, Quantin C. Incidence of acute postoperative endophthalmitis after cataract surgery. Ophthalmology 2016;123:1414-1420</th></tr>
<tr><td></td><td>Exclusion criteria
Modalities of cataract extraction other than phacoemulsification</td></tr>
<tr><td>Methods</td><td>The national administrative database (PMSI) was searched for patients who had cataract surgery identified by the CCAM code BFGA004 corresponding to ‘cataract extraction performed by phacoemulsification with intraocular lens implantation in a capsular bag’. All hospitalisations within 42 days of cataract surgery with a code for endophthalmitis H440 or H441 were also selected.
Analysis
Poisson regression analysis</td></tr>
<tr><td>Results</td><td>Incidence of POE
<table>
<tr><td>Year</td><td>No. of cataract surgeries</td><td>No. of acute POE cases</td><td>Overall incidence of acute POE (%)</td></tr>
<tr><td>2005</td><td>495 765</td><td>719</td><td>0.145</td></tr>
<tr><td>2014</td><td>757 993</td><td>405</td><td>0.053</td></tr>
<tr><td>Total (2005 – 2014)</td><td>6 371 242</td><td>6668</td><td></td></tr>
</table></td></tr>
<tr><td>Outcomes</td><td>The incidence of acute POE decreased from 0.145% to 0.053% during this 10 year period
Mean incidence of acute POE from 2005 to 2014 was 0.105%</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Did the authors use an appropriate method to answer their question? Yes
3 Were the cases recruited in an acceptable way? Yes
4 Was the exposure accurately measured to minimise bias? Unclear
5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unsure
6 Do you believe the results? Yes
7 Can the results be applied to the local population? Yes
8 Do the results of this study fit with other available evidence? N/A</td></tr>
</table>

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Full citation	Day A, Donachie P, Sparrow J, Johnston R. The royal college of Ophthalmologists’ National Ophthalmology database study of cataract surgery: report 1, visual outcomes and complications. Eye 2015;29:552-560
Study details	Country/ies where the study was carried out: UK Study type: Retrospective cohort Aim of the study: To describe the outcomes of cataract surgery in the UK Study dates: August 2006 and November 2010

<table>
<tr><th>Full citation</th><td>Day A, Donachie P, Sparrow J, Johnston R. The royal college of Ophthalmologists' National Ophthalmology database study of cataract surgery: report 1, visual outcomes and complications. Eye 2015;29:552-560</td></tr>
<tr><td></td><td>Sources of funding: The Special Trustees of Moorfield's Eye Hospital provided an unrestricted grant to fund the analysis (grant number ST1307A). ACD was supported by the National Institute for Health Research (NIHR) Biomedical Research Centre based at Moorfields Eye Hospital NHS Foundation Trust and UCL Institute of Ophthalmology.</td></tr>
<tr><td>Participants</td><td>Sample size
127 685 patients (180 114 eyes)
Inclusion criteria
Patients aged 18 years or older undergoing cataract surgery using phacoemulsification where the primary intention was cataract surgery.
Exclusion criteria
Patients undergoing combined cataract surgery (cataract + other operations) where the cataract component may not have been the primary reason for surgery.</td></tr>
<tr><td>Methods</td><td>Data was extracted from 31 UK NHS Trusts of which 28 had recorded data for cataract surgery,
All data were recorded using a single EMR system. The lead clinician and Caldicott Guardian (responsible nominee for data protection) at each NHS Trust gave written approval for anonymised data extraction.
In all centres the EMR software mandated the collection of the presence or absence of surgical complications. If the surgeon indicated that a complication occurred, then they had to select from a pre-populated list of complications specific to that operation, or select 'other' and record the complication using free text.
Results for post cataract retinal detachment surgery and endophthalmitis treatment were confined to centres where this could be cross-checked with other RCOphth NOD treatment data
Analysis
Fishers exact test and Pearson's Chi squared test</td></tr>
<tr><td>Results</td><td>Intraoperative complications in the operated eye
<table>
<tr><td>Reported intraoperative complications, n (column %)</td><td>Total
(n=180 114)</td></tr>
<tr><td>No intraoperative complication</td><td>172 614 (95.8)</td></tr>
<tr><td>One or more intraoperative complications</td><td>7500 (4.2)</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td>Posterior capsule rupture and / or vitreous loss (PCR)</td><td>3514 (2.0)</td></tr>
<tr><td>Other</td><td>1218 (0.7)</td></tr>
<tr><td>Iris trauma / prolapse</td><td>901 (0.5)</td></tr>
<tr><td>Zonule dialysis</td><td>870 (0.5)</td></tr>
</table></td></tr>
</table>

<table>
<tr><th>Full citation</th><td>Day A, Donachie P, Sparrow J, Johnston R. The royal college of Ophthalmologists' National Ophthalmology database study of cataract surgery: report 1, visual outcomes and complications. Eye 2015;29:552-560</td></tr>
<tr><td></td><td>
<table>
<tr><td>Corneal epithelial abrasion</td><td>500 (0.3)</td></tr>
<tr><td>Endothelial damage / descemet's tear</td><td>404 (0.2)</td></tr>
<tr><td>Nuclear / epinuclear fragment into vitreous*</td><td>316 (0.2)</td></tr>
<tr><td>Corneal oedema</td><td>254 (0.1)</td></tr>
<tr><td>Lens exchange required / other IOL problems</td><td>212 (0.1)</td></tr>
<tr><td>Phaco burn / wound problems</td><td>151 (<0.1)</td></tr>
<tr><td>Hyphaema</td><td>99 (<0.1)</td></tr>
<tr><td>Choroidal / suprachoroidal haemorrhage</td><td>89 (<0.1)</td></tr>
</table>
*This complication is reported separately and as part of the PCR results

Visual loss
<table>
<tr><td>Visual loss in all eyes</td><td>Overall, n (%)</td></tr>
<tr><td>Number</td><td>94 106</td></tr>
<tr><td>Visual loss</td><td>1455 (1.5)</td></tr>
</table>
</td></tr>
<tr><td>Outcomes</td><td>Rate of PCR = 1.95% (95% CI: 1.89 – 2.02%). The rate was 1.63% in eyes without co-pathology (1847/113 610) and 2.51% (1667/66 504) in those eyes with a co-pathology.

The rate of retinal detachment surgery within 3 months of cataract surgery was 0.03% (45/139 537 cases, 95% CI: 0.02%–0.04%).

The rate of endophthalmitis within 3 months of cataract surgery was 0.03% (43/145,868 cases, 95% CI: 0.02–0.04%).

Significant visual loss occurred in 1455 (1.5%) eyes.</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal skills programme)</td><td>1 Did the study address a clearly focused issue? Yes
2 Did the authors use an appropriate method to answer their question? Yes
3 Were the cases recruited in an acceptable way? Yes
4 Was the exposure accurately measured to minimise bias? Unclear
5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Yes
6 Do you believe the results? Yes
7 Can the results be applied to the local population? Yes</td></tr>
</table>

Full citation	Day A, Donachie P, Sparrow J, Johnston R. The royal college of Ophthalmologists' National Ophthalmology database study of cataract surgery: report 1, visual outcomes and complications. Eye 2015;29:552-560
	8 Do the results of this study fit with other available evidence? N/A

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Full citation	Day A, Donachie P, Sparrow J, Johnston R. United Kingdom National ophthalmology database study of cataract surgery: Report 3: Pseudophakic retinal detachment. Ophthalmology 2016;123:1711-1715
Study details	Country/ies where the study was carried out: UK Study type: Retrospective case series Aim of the study: To investigate time to pseudophakic retinal detachment (RD) after cataract surgery. Study dates: August 2006 and November 2010 Sources of funding: Not reported but RLJ is an equity owner of Medisoft Limited, Leeds, UK
Participants	Sample size 46 824 patients (61 907 eyes) Inclusion criteria Patients aged 18 years or older undergoing cataract surgery using phacoemulsification where the primary intention was cataract surgery. Exclusion criteria Patients undergoing combined cataract surgery (cataract + other operations) where the cataract component may not have been the primary reason for surgery.
Methods	Data was extracted from 31 UK NHS Trusts of which 13 had recorded data for both cataract surgery and vitreoretinal surgery on the same electronic medical record. Analysis was restricted to eligible cataract operations performed up to 3 months before the data extraction and from within each centre from the date of the first record of an RD operation recorded on the EMR. Analysis Kaplan-Meier
Results	Pseudophakic Retinal detachment surgery was performed on 131 eyes of 129 patients during the study period For eyes that progressed to RD surgery, the median time to pseudophakic RD surgery was 6.3 months
Outcomes	Retinal detachment rate was 0.21% (95% CI 0.18% - 0.25%)
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Did the authors use an appropriate method to answer their question? Yes 3 Were the cases recruited in an acceptable way? Yes 4 Was the exposure accurately measured to minimise bias? Unclear 5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Yes 6 Do you believe the results? Yes

Full citation	**Day A, Donachie P, Sparrow J, Johnston R. United Kingdom National ophthalmology database study of cataract surgery: Report 3: Pseudophakic retinal detachment. Ophthalmology 2016;123:1711-1715**
	7 Can the results be applied to the local population? Yes 8 Do the results of this study fit with other available evidence? N/A

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Full citation	**Du D, Wagoner A, Barone S, Zinderman C, Kelman J, MaCurdy T, Forshee R, Worrall C, Izurieta H. Incidence of endophthalmitis after corneal transplant or cataract surgery in a medicare population. Ophthalmology 2014;121:290-298**
Study details	Country/ies where the study was carried out: USA Study type: Retrospective cohort Aim of the study: To estimate the incidence of infectious endophthalmitis after corneal transplant or cataract surgery and the trend of endophthalmitis during the study period Study dates: 2006 to 2011 Sources of funding: None reported
Participants	Sample size 2 261 779 cataract surgeries Inclusion criteria Medicare patients who underwent cataract surgery in a hospital or outpatient setting using ICD-9-CM procedure codes and CPT-4/HCPCS codes Exclusion criteria Patients younger than 65 years, those with a diagnosis of endophthalmitis or with other eye surgeries within 180 days before or on the day of the index surgery.
Methods	Medicare database was searched for patients undergoing cataract operations using the procedure code ICD-9-CM Endophthalmitis was searched for using 3 code sets 1. ICD-9-CM codes, 2. Combining ICD-9-CM codes with current procedural terminology (CPT-4) or 3. Combining ICD-9-CM codes with antifungal prescriptions for endophthalmitis caused by fungal infection. Analysis Multivariate Cox
Results	Incidence of postoperative endophthalmitis after cataract surgery

Endophthalmitis	Postoperative interval	Cataract surgery (n = 2 261 779)	
		Cases	Incidence
Sensitive definition (ICD-9-CM codes only)	6 weeks 6 months	2874 4416	0.127% 0.195%

Full citation	**Du D, Wagoner A, Barone S, Zinderman C, Kelman J, MaCurdy T, Forshee R, Worrall C, Izurieta H. Incidence of endophthalmitis after corneal transplant or cataract surgery in a medicare population. Ophthalmology 2014;121:290-298**

Specific definition (ICD-9-CM codes and CPT/HCPCS codes)	6 weeks 6 months	1417 1991	0.063% 0.088%
Fungal endophthalmitis (ICD-9-CM codes and antifungal medication claim)	6 weeks 6 months	52 121	0.002% 0.005%

CPT-4 = current procedural terminology, Fourth edition; HCPCS = Healthcare common procedure coding system; ICD-9-CM = International classification of diseases, Ninth revision, clinical modification.

Outcomes	The infectious endophthalmitis incidence rates ranged from 0.06% to 0.20% in the cataract surgery cohort Limitations The authors reported that the ICD-9-CM code had not been validated among Medicare patients and therefore they may have overestimated the rates based on only this diagnosis code set. Only Medicare patients with fee-for-service insurance were included in the study Patients may receive their prescriptions for antifungals via an alternative method not coded for in the database
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Did the authors use an appropriate method to answer their question? Yes 3 Were the cases recruited in an acceptable way? Yes 4 Was the exposure accurately measured to minimise bias? Unclear 5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unsure 6 Do you believe the results? Yes 7 Can the results be applied to the local population? Yes 8 Do the results of this study fit with other available evidence? N/A

443

Full citation	**Freeman E, Roy-Gagnon M, Fortin E, Gauthier D, Popescu M, Boisjoly. Rate of endophthalmitis after cataract surgery in Quebec, Canada, 1996-2005. Arch Ophthalmol 2010;128:230-234**
Study details	Country/ies where the study was carried out: Canada Study type: Retrospective chart review Aim of the study: To estimate annual incidence of endophthalmitis after cataract surgery Study dates: January 1st 1996 through December 31st 2005 Sources of funding: Fund for ophthalmology research of the University of Montreal
Participants	Sample size

<table>
<tr><th>Full citation</th><td>Freeman E, Roy-Gagnon M, Fortin E, Gauthier D, Popescu M, Boisjoly. Rate of endophthalmitis after cataract surgery in Quebec, Canada, 1996-2005. Arch Ophthalmol 2010;128:230-234</td></tr>
<tr><td></td><td>490 690 cataract surgical procedures
Inclusion criteria
Patients who had a Quebec State Control for Health Insurance (RAMQ) procedural code that indicated cataract extraction with an intraocular lens implantation (ICD-9 code 360.0)
Exclusion criteria
Patients who underwent trabeculectomy or corneal transplantation on or within 90 days of their cataract surgery</td></tr>
<tr><td>Methods</td><td>For each cataract surgery record, they obtained data from the RAMQ, they also requested information with regard to endophthalmitis diagnoses and other selected ocular procedures for the time of cataract surgery until December 31, 2005. Specifically, they obtained information with regard to the presence and date of an endophthalmitis diagnosis code, indication that a trabeculectomy was performed, indication that a corneal transplantation was performed. In addition, because some cases of endophthalmitis were treated on an inpatient basis, they also requested data with regard to the presence of an International Classification of Diseases, Ninth Revision (ICD-9)15 code for endophthalmitis as the primary reason for hospital admission from the Maintenance and Exploitation of Data for the Study of Hospitalized Patients (MED-ECHO) hospital discharge summary database and the date of this diagnostic code.
Analysis
Cochrane-Armitage test</td></tr>
<tr><td>Results</td><td>Annual rate of reported endophthalmitis within 90 days of cataract surgery
<table>
<tr><th>Year</th><th>Number of patients</th><th>Number of cataract surgical procedures</th><th>Rate per 1000 surgical procedures*
(95% Confidence Interval)</th></tr>
<tr><td>1996</td><td>70</td><td>33 165</td><td>2.1 (1.6 – 2.7)</td></tr>
<tr><td>2005</td><td>43</td><td>51 539**</td><td>0.8 (0.6 – 1.1)</td></tr>
<tr><td>Total</td><td>754</td><td>490 690</td><td>1.5 (1.4 – 1.7)</td></tr>
</table>
*Cochrane-Armitage test for linear trend P<0.001
**Cataract surgical procedures occurring after September 30, 2005, were excluded to allow for 90 days follow-up for endophthalmitis</td></tr>
<tr><td>Outcomes</td><td>Overall incidence rate was 1.5 per 1000 surgical procedures (95% CI 1.4 – 1.7)</td></tr>
<tr><td>Study Appraisal using CASP (Critical appraisal</td><td>1 Did the study address a clearly focused issue? Yes
2 Did the authors use an appropriate method to answer their question? Yes
3 Were the cases recruited in an acceptable way? Yes
4 Was the exposure accurately measured to minimise bias? Unclear
5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unsure
6 Do you believe the results? Yes</td></tr>
</table>

Full citation	**Freeman E, Roy-Gagnon M, Fortin E, Gauthier D, Popescu M, Boisjoly. Rate of endophthalmitis after cataract surgery in Quebec, Canada, 1996-2005. Arch Ophthalmol 2010;128:230-234**
skills programme)	7 Can the results be applied to the local population? Yes 8 Do the results of this study fit with other available evidence? N/A

444

Full citation	**Ianchulev T, Litoff D, Ellinger D, Stiverson K, Packer M. Population health outcomes study of more than 21,000 cases in the United States. Ophthalmitis 2016;123:723-728**
Study details	Country/ies where the study was carried out: USA Study type: Retrospective case series Aim of the study: To identify safety and effectiveness outcomes of office-based cataract surgery Study dates: January 1st 2011 to December 30th 2014 Sources of funding: None reported although DL, DE and KS are employees of Kaiser Permanante (health plan company)
Participants	Sample size 21,501 eyes undergoing cataract surgery in total: 21,484 (99.9%) eyes by phacoemulsification surgery, 16 (0.01%) eyes by ECCE surgery Inclusion criteria Patients undergoing elective office-based cataract surgery Exclusion criteria Not reported
Methods	An institutional database of cataract surgery performed in Minor procedure room (MPRs) at 3 Kaiser Permanente Colorado (KPCO) facilities with the codes 66984/66982 was searched. Records were analysed for the incidence of intraoperative and postoperative adverse events.
Results	Ocular adverse events from 21,484 eyes which underwent cataract surgery

Ocular Adverse Event parameter	Eyes, n (% of eyes)
Posterior capsule rupture	119 (0.55%)
Vitreous loss	73 (0.34%)
Endophthalmitis within 30 days	0 (0.00%)
Hyphema within 30 days	5 (0.02%)
Retinal detachment/tear within 90 days	30 (0.14%)
Cystoid macular oedema within 90 days	6 (0.03%)
Corneal oedema between 1-3 months	110 (0.51%)
Iritis/uveitis between 1-5 months	330 (1.53%)

Full citation	Ianchulev T, Litoff D, Ellinger D, Stiverson K, Packer M. Population health outcomes study of more than 21,000 cases in the United States. Ophthalmitis 2016;123:723-728
	Surgical re-intervention within 3 months: 131 (0.61%) Surgical re-intervention within 6 months: 150 (0.70%)
Outcomes	Intraoperative adverse event incidence rate: capsular tear (0.55%), vitreous loss (0.34%) Postoperative adverse event incidence rate: iritis (1.53%), corneal oedema (0.53%), retinal tear or detachment (0.14%) No endophthalmitis was reported
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Did the authors use an appropriate method to answer their question? Yes 3 Were the cases recruited in an acceptable way? Yes 4 Was the exposure accurately measured to minimise bias? Unclear 5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unsure 6 Do you believe the results? Yes 7 Can the results be applied to the local population? Yes 8 Do the results of this study fit with other available evidence? N/A

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Full citation	Olsen T, Jeppesen P. The incidence of retinal detachment after cataract surgery. The open ophthalmology journal 2012;6:79-82
Study details	Country/ies where the study was carried out: Denmark Study type: Retrospective cohort Aim of the study: To estimate the cumulative risk of retinal detachment (RD) after routine cataract surgery by phacoemulsification Study dates: 2000 to 2005 Sources of funding: Danish eye health society grant
Participants	Sample size 7,856 patients (12,222 consecutive cataract surgeries) Inclusion criteria Adult cataract surgeries performed from year 2000 to 2005 Exclusion criteria Not reported
Methods	Based on our electronic case record system we extracted a consecutive list of all adult cataract surgeries performed from year 2000 to 2005 Cases with a diagnosis of RD were identified through the procedure-coding database at the Medical Registry of Aarhus University Hospital, which is based on Diagnosis Related Groups (DRG) and used to report to the Danish Patients Registry (LPR).

Full citation	Olsen T, Jeppesen P. The incidence of retinal detachment after cataract surgery. The open ophthalmology journal 2012;6:79-82
	Analysis Unpaired t-test and Chi square test
Results	Forty-eight (48) cases of RD were identified making an overall cumulative risk of 0.39%. The time interval between cataract surgery and RD varied from 0.03 to 77.8 months (mean 26.5 months)
Outcomes	The cumulative risk of RD after lens surgery was about 2.3 times the natural incidence
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Did the authors use an appropriate method to answer their question? Yes 3 Were the cases recruited in an acceptable way? Yes 4 Was the exposure accurately measured to minimise bias? Unclear 5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unsure 6 Do you believe the results? Yes 7 Can the results be applied to the local population? Yes 8 Do the results of this study fit with other available evidence? N/A

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Full citation	Petousis V, Sallam A et al. Risk factors for retinal detachment following cataract surgery: the impact of posterior capsular rupture. British journal of ophthalmology 2016;100:1461-1465
Study details	**Country/ies where the study was carried out:** UK **Study type:** Retrospective cohort **Aim of the study:** To determine the risk factors for retinal detachment following cataract surgery **Study dates:** 2005 to 2014 **Sources of funding:** Non reported but RJL is a director and shareholder in Medisoft
Participants	**Sample size** 18,065 consecutive first eye cataract surgeries **Inclusion criteria** All phacoemulsification cataract surgeries performed from November 2005 to January 2014 **Exclusion criteria** Combined procedures, vitrectomised eyes and eyes with a history of trauma
Methods	Analysis of Medisoft software for incidences of RD in all phacoemulsification cataract operations **Analysis** Unpaired t-test and Chi square test
Results	The Retinal detachment rate at 7 years was 0.30% Median time to RD was 15 months (mean:18 months, range 0-84 months)

Full citation	**Petousis V, Sallam A et al. Risk factors for retinal detachment following cataract surgery: the impact of posterior capsular rupture. British journal of ophthalmology 2016;100:1461-1465**
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Did the authors use an appropriate method to answer their question? Yes 3 Were the cases recruited in an acceptable way? Yes 4 Was the exposure accurately measured to minimise bias? Unclear 5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unsure 6 Do you believe the results? Yes 7 Can the results be applied to the local population? Yes 8 Do the results of this study fit with other available evidence? N/A

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Full citation	**Venter J, Pelouskova M, Collins B, Schallhorn S, Hannan S. Visual outcomes and patient satisfaction in 9366 eyes using refractive segmented multifocal intraocular lenses. J Cataract Refarct Surg 2013;39:1477-1484**
Study details	Country/ies where the study was carried out: UK Study type: Retrospective case series Aim of the study: To report the effectiveness, patient satisfaction and complication rate with a zonal refractive intraocular lens in a high volume of patients Study dates: January 2010 and January 2012 Sources of funding: None reported
Participants	Sample size 4683 patients (9366 eyes) Inclusion criteria Patients who underwent bilateral phacoemulsification followed by implantation of a Lentis MPlus IOL. Amblyopic patients were restricted to those with a corrected distance visual acuity of 6/9 or better in the amblyopic eye and 6/6 or better in the fellow eye. Exclusion criteria History of glaucoma or retinal detachment, corneal disease, corneal surgery, ocular inflammation, neuro-ophthalmic disease, macular degeneration or retinopathy; and keratometric cylinder greater than 1.50 diopters.
Methods	Retrospective data of patients with binocular Lentis MPlus IOLs were analysed. The main outcome measures were visual outcomes, patient satisfaction and complications.
Results	Adverse events

Adverse Event	Percentage of cohort
Cumulative hyphema	0.01
Cumulative macular oedema	1.1

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	Cumulative retinal detachment: 0.04 Cumulative pupillary block: 0.0 Cumulative endophthalmitis: 0.01 Cumulative hypopyon: 0.0 Cumulative surgical re-intervention: 0.5 Persistent macular oedema: 0.02 Persistent corneal oedema: 0.05 Persistent iritis: 0.0 Persistent raised intraocular pressure requiring treatment: 0.01 Cumulative = adverse events that occurred at any time during postoperative care Persistent = adverse events that persisted 1 year postoperatively
Outcomes	Postoperative complication rate was clinically acceptable
Study Appraisal using CASP (Critical appraisal skills programme)	1 Did the study address a clearly focused issue? Yes 2 Did the authors use an appropriate method to answer their question? Yes 3 Were the cases recruited in an acceptable way? Yes 4 Was the exposure accurately measured to minimise bias? Unclear 5 Have the authors taken account of the potential confounding factors in the design and/or in their analysis? Unsure 6 Do you believe the results? Yes 7 Can the results be applied to the local population? Yes 8 Do the results of this study fit with other available evidence? N/A

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E.9.2 Details of postoperative assessment

Study	Kessel L, Andresen J, Erngaard D, Flesner P, Tendal B, and Hjortdal J. (2015). Safety of deferring review after uneventful cataract surgery until 2 weeks postoperatively. J Cataract Refract Surg 2015; 41:2755–2764
Study type	Systematic review and meta-analysis
Aim/ objective of the study	To examine whether first-day postoperative examination after uneventful cataract surgery in low-risk patients can be omitted without compromising patient safety.
Source of funding	Danish Health and Medicines Authorities, Copenhagen, Denmark
Study duration	Study duration: 2 trials had a trial duration of 2 weeks and 1 trial had 4 weeks.
Sample size	Total (n): • 3 trials with a total of 886 participants were included. First postoperative day review group: n=435 Deferred-review group: n=451
Inclusion/ exclusion criteria	Randomised controlled trials comparing no first-day postoperative review (intervention) versus regular first-day postoperative review (comparison)
Comparison	No first-day postoperative review (Intervention) vs regular first-day postoperative review (comparison)
Outcomes	• Postoperative complications at or prior to the 2-week postoperative review • The corrected distance visual acuity at the 2-week postoperative visits • Number of unscheduled visits between discharge and the 2-week postoperative visit.
Risk of bias	• The review addresses an appropriate and clearly focused question that is relevant to the review question? Yes • The review collects the type of studies you consider relevant to the guidance review question? Yes • The literature search is sufficiently rigorous to identify all the relevant studies? Yes • Study quality is assessed and reported? Yes • An adequate description of the methodology is used in included and the methods used are appropriate to the question? No • Overall assessment of internal validity? High validity • Overall assessment of external validity? High validity Overall quality: Moderate