

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of the implantation of accommodating intraocular lenses during cataract surgery

During cataract surgery the clouded natural lens of the eye is removed and clear vision is most commonly obtained with an implanted artificial lens. The standard intraocular lens has no focusing capability, whereas an accommodating intraocular lens allows focusing on near and distant objects.

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in August 2006

Procedure name

- Implantation of accommodating intraocular lenses during cataract surgery

Specialty societies

- Royal College of Ophthalmologists
- UK and Ireland Society for Cataract and Refractive Surgeons

Description

Indications

A cataract is the opacification of the eye's natural lens. It usually develops over a period of time, causing a gradual deterioration in eyesight and may eventually lead to blindness. Apart from increasing age, other risk factors for cataract include female sex, diabetes mellitus, exposure to sunlight, steroid

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treatment, nutrition and socio-economic status.¹ Cataract can also be the result of ocular injury. Cataracts can rarely occur in younger ages, either congenitally or in early life, usually related to inherent metabolic disorders.

A normal eye has the ability to focus between near and distant objects. At rest the eye is set for distance but as a result of contraction of the ciliary muscle the shape of the lens changes so increasing its power and allowing near objects to be seen. As part of the normal ageing process the human lens loses its ability to change shape and hence a spectacle lens is required to see near objects clearly.

In cataract surgery the human lens is replaced with an artificial lens which is of a fixed power and requires the use of reading spectacles for near vision. Multifocal and accommodative lenses are now being developed to obviate the use of reading glasses after cataract surgery.

Current treatment and alternatives

Cataract surgery is usually performed using local anaesthesia. In many countries phacoemulsification is the standard technique, but in less developed countries extracapsular surgery is still widely practised.

With phacoemulsification, after removal of the anterior lens capsule an ultrasound probe is used to break the lens into tiny pieces, which are removed through a small incision in the cornea. The posterior lens capsule is left in place to support the artificial lens. A flexible intraocular lens is then inserted through the incision and unfolds once in position inside the eye. The small corneal incision does not usually require sutures. Measurements of the eye are taken before surgery to enable selection of the correct lens power to achieve good sight for distance without spectacles.

With extracapsular surgery, a longer incision is required to allow manual removal of the natural lens nucleus in one piece. A rigid intraocular lens is then inserted and the incision requires sutures for closure.

What the procedure involves

Phacoemulsification is carried out in the same way as the conventional treatment but an accommodating intraocular lens is inserted rather than a standard intraocular lens. The aim of the procedure is to allow the eye to focus on near as well as distant objects.

Efficacy

The efficacy evidence in this overview relates to four randomised controlled trials.^{2,3,4,5,6}

Key efficacy outcomes listed by Specialist Advisers included uncorrected near and distance vision, near and distance vision corrected with spectacles, and the stability of uncorrected near and distance vision over time.

Amplitude of accommodation

This term refers to the ability of the eye to see both near and far objects without the need for spectacle lenses (which is normally lost around the fourth decade).

Two randomised controlled trials reported a statistically significantly larger degree of accommodation for accommodating lenses compared with monofocal lenses (1.9 D versus 0 D, $p < 0.05$ and 1.01 D versus 0.5 D, $p = 0.01$).^{2,5}

Near visual acuity

All four randomised controlled trials reported significantly better distance corrected near visual acuity for eyes with an accommodative lens than for eyes with a conventional intraocular lens. In one of these studies, the difference was statistically significant at 6 months (J9.3 versus J12.4, $p = 0.004$) but not 12 months (J11.5 versus J12.8, $p = 0.1$) (the larger the J number, the lesser the visual acuity).^{3,4} The 12-month follow-up, however, only included 67% (40/60) eyes. In another of these studies, 66% of eyes with accommodating lenses had distance corrected near visual acuity 20/40 or better at 6 months but this proportion went down to 49% of eyes at 12 months. No eyes with the conventional lens implant achieved distance corrected visual acuity of 20/40 or better at follow-up.⁶

Safety

The safety evidence in this overview relates to three randomised controlled trials, one non-randomised controlled trial and two case series.^{2,5,6,8,9,10}

Specialist Advisers listed potential adverse events to include decentration of the lens, posterior capsule opacification, buckling of the lens or haptics, capsular contraction syndrome and loss of quality of vision.

Posterior capsule opacification

A non-randomised comparative study reported that 12% (3/24) of eyes with an accommodating lens required capsulotomy for posterior capsule opacification, compared with 25% (8/32) of eyes with a multifocal lens and 29% (7/24) of eyes with a bifocal lens, after 12 months follow-up.⁸ Two case series reported capsulotomy for posterior capsule opacification in 14% (37/263) and 18% (12/65) of eyes after mean follow-ups of 12 and 23 months, respectively.^{9,10}

One randomised controlled trial of 42 eyes reported anterior and posterior capsule opacification in 86% of eyes with an accommodating lens implant at 12 months, compared with 25% (5/20) of eyes with a traditional lens implant.⁶ Another randomised controlled trial of 42 eyes reported mild posterior capsule opacification in 21% of eyes with an accommodating lens and 22% of eyes with a monofocal lens after 6 months follow-up.⁵

Anterior chamber haemorrhage

A randomised controlled trial reported one case of anterior chamber haemorrhage in 40 eyes with an accommodating lens implant (2.5%).²

Cystoid macular oedema

A large case series reported cystoid macular oedema in 3.7% (12/324) of eyes over a 12 month follow-up period. Persistent cystoid macular oedema was reported in 0.9% (3/304) of eyes.⁹

Quality of vision

A non-randomised controlled trial reported halos in 8% (2/24) and flare, flashes or glare each in 4% (1/24) of eyes with an accommodating lens. Higher rates of halos, flare and glare were reported by patients with either a multifocal or bifocal lens.⁸

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to implantation of accommodating intraocular lenses during cataract surgery. Searches were conducted via the following databases, covering the period from their commencement to 15th August 2006: MEDLINE, PreMedline, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches. (See appendix C for details of search strategy.)

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients undergoing cataract surgery.
Intervention/test	Implantation of accommodating intraocular lenses.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on four prospective randomised controlled trials, three non-randomised comparative studies and two case series.²⁻¹⁰ The randomised controlled trials all compare accommodating lenses with monofocal lenses; two included patients with the same lens implanted into both eyes,^{2,6} one included patients with either an accommodating or a conventional lens implanted into one eye only⁵ and one was a within-patient comparison study with a different lens implanted in each eye of one patient.^{3,4} One non-randomised comparative study used a sample of patients reported in a large case series and compared them to patients with a standard intraocular lens. The two studies were reported in the same article.⁹

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Existing reviews on this procedure

There were no published systematic reviews identified at the time of the literature search.

Related NICE guidance

There is no NICE guidance related to this procedure.

Table 2 Summary of key efficacy and safety findings on implantation of accommodating lenses during cataract surgery

Abbreviations used: D, dioptres; IOL, intraocular lens; VA, visual acuity.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Sauder G (2005)²</p> <p>Randomised controlled trial (prospective)</p> <p>Germany</p> <p>Study period: not stated</p> <p>n = 80 eyes</p> <p>Population: 40 patients with advanced cataract presenting for routine surgery</p> <ul style="list-style-type: none"> • 50% (40/80) accommodating IOL • 50% (40/80) monofocal IOL (controls) <p>Patients were randomised to receive either accommodating lens or monofocal lens in both eyes.</p> <p>Mean age:</p> <ul style="list-style-type: none"> • Accommodating lens = 73.3 years (range 62–82) • Monofocal lens = 72.7 years (range 59–80) <p>Exclusion criteria: age < 40 or > 80 years; diabetes mellitus; glaucoma; exudative age-related macular degeneration with large soft drusen; history of ocular trauma; previous ocular surgery.</p> <p>Technique: Accommodating lens = 1CU PCIOL (HumanOptics AG, Germany).</p> <p>Mean follow-up: 8 months</p> <p>Disclosure of interest: none of the authors declared an interest</p>	<p>Best corrected distance VA at follow-up (n = 76)</p> <ul style="list-style-type: none"> • Accommodating IOL = 0.94 • Monofocal IOL = 0.93 <p>p = 0.74</p> <p>Best corrected near VA at follow-up (n = 76)</p> <ul style="list-style-type: none"> • Accommodating IOL = 2.46 • Monofocal IOL = 2.01 <p>p = 0.34</p> <p>Near vision with distance correction at follow-up (n = 76)</p> <ul style="list-style-type: none"> • Accommodating IOL = 8.53J • Monofocal IOL = 11.61J <p>p = 0.03</p> <p>Range of accommodation at follow-up (n = 76)</p> <ul style="list-style-type: none"> • Accommodating IOL = 1.01 D • Monofocal IOL = 0.5 D <p>p = 0.01</p> <p>Change in anterior chamber depth from mydriasis (pupil dilation) to miosis (pupil constriction) at follow-up (n = 76)</p> <ul style="list-style-type: none"> • Accommodating IOL = 0.82 mm • Monofocal IOL = 0.40 mm <p>p = 0.01</p>	<p>Anterior chamber haemorrhage (intraoperative)</p> <ul style="list-style-type: none"> • Accommodating IOL = 2.5% (1/40) • Monofocal IOL = 0% (0/40) 	<p>Method of randomisation not described.</p> <p>One patient in each group (that is, four eyes in total) was lost to follow-up.</p> <p>The authors state that it is unclear how to measure the range of accommodation in pseudophakic eyes. The device used in this study to measure anterior chamber depth may give inaccurate results.</p>

Abbreviations used: D, dioptres; IOL, intraocular lens; VA, visual acuity.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Heatley C (2005)³, Hancox J (2006)⁴</p> <p>Randomised controlled trial (prospective)</p> <p>UK</p> <p>Study period: not stated</p> <p>n = 60 eyes</p> <p>Population: 30 patients with bilateral cataracts</p> <ul style="list-style-type: none"> • 50% (30/60) accommodating IOL • 50% (30/60) monofocal IOL (controls) <p>Patients were prospectively randomised to receive either the accommodative IOL in their first eye or a monofocal IOL. The alternate IOL was then implanted into the second eye within 4 to 6 weeks.</p> <p>Mean age (of 20 patients with complete follow-up): 71 years (range 31–89)</p> <p>Indications: all patients had uncomplicated cataracts and otherwise normal eyes.</p> <p>Technique: Accommodating lens = 1CU PCIOL (HumanOptics AG, Germany).</p> <p>Follow-up: 18 to 24 months.</p> <p>Disclosure of interest: no author has a financial or proprietary interest in any material or method mentioned.</p>	<p>Mean best corrected distance VA at 6 months:</p> <ul style="list-style-type: none"> • Accommodating IOL = -0.1 ± 0.74 D • Monofocal IOL = -0.1 ± 0.48 D, $p = 1.0$ <p>Mean best corrected distance VA at 12 months:</p> <ul style="list-style-type: none"> • Accommodating IOL = 0.05 ± 0.2 D • Monofocal IOL = -0.08 ± 0.1 D, $p = 0.03$ <p>Mean distance-corrected near VA at 6 months</p> <ul style="list-style-type: none"> • Accommodating IOL = $J9.3 \pm 0.71$ • Monofocal IOL = $J12.4 \pm 0.36$, $p = 0.004$ <p>Mean distance-corrected near VA at 12 months</p> <ul style="list-style-type: none"> • Accommodating IOL = $J11.47 \pm 0.7$ • Monofocal IOL = $J12.8 \pm 0.4$, $p = 0.1$ <p><i>Results at final follow-up (18 to 24 months)</i></p> <p>Mean distance corrected near VA</p> <ul style="list-style-type: none"> • Accommodating IOL = J10 • Monofocal IOL = J10 <p>Mean correction required to read J1</p> <ul style="list-style-type: none"> • Accommodating IOL = 2.31 ± 1.89 D • Monofocal IOL = 2.25 ± 0.53 D <p>Mean print size read at a speed > 80 words per minute on MNRead card</p> <ul style="list-style-type: none"> • Accommodating IOL = 0.46 ± 0.14 • Monofocal IOL = 0.48 ± 0.10, $p = 0.36$ <p>Mean near point (using accommodometer)</p> <ul style="list-style-type: none"> • Accommodating IOL = 43.26 ± 11.9 cm • Monofocal IOL = 47.4 ± 5.2 cm, $p = 0.11$ <p>A small anterior movement of the accommodating lens was seen with accommodation (0.01 ± 0.028 mm).</p> <p>There was a good correlation in distance corrected near acuity between fellow eyes ($r = 0.8318$, $p < 0.0001$).</p>	<p>'All surgery was uneventful'.</p> <p>Capsulotomy required during follow-up</p> <ul style="list-style-type: none"> • Accommodating IOL = 50% (10/20) • Monofocal IOL = 0% (0/20) <p>$p = 0.36$</p>	<p>The first paper reported results at 6 and 12 months. The second paper reported results from the same study 18 to 24 months after lens implantation.</p> <p>Both the patient and the examiner knew which eye had the accommodating lens in. There may, therefore, be an element of placebo effect.</p> <p>Of the 30 patients originally recruited, 3 were lost to follow-up, 2 were too frail to comply with the tests, and 1 had a tremor making measurement impossible. In 4 other patients, it was either not possible to get readings or the readings were unreliable due to errors induced by reflexes from the IOL. Complete data were therefore collected for only 67% (20/30) patients.</p> <p>The authors state that there was a decline in the mean near visual function over time. They note that the good correlation in distance corrected near acuity between fellow eyes suggests that improvement is related to non-IOL and psychological factors or improved cortical perception.</p>

Abbreviations used: D, dioptres; IOL, intraocular lens; VA, visual acuity.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Mastropasqua L (2003)^o</p> <p>Randomised controlled trial (prospective)</p> <p>Italy</p> <p>Study period: 2001</p> <p>n = 42 eyes</p> <p>Population: 42 patients with senile cataract</p> <ul style="list-style-type: none"> • 33% (14/42) accommodating IOL • 67% (28/42) monofocal IOL (controls) <p>Patients were randomised to receive either accommodating lens or monofocal lens in one eye.</p> <p>Mean age:</p> <ul style="list-style-type: none"> • Accommodating lens = 67 years (range 52–75) • Monofocal lens = 67 years (range 54–75) <p>Indications: Inclusion criteria: Senile cataract; candidates for phacoemulsification and in-the-bag IOL implantation; age between 50 and 75 years; axial length between 23 mm and 24 mm; corneal preoperative astigmatism < 1.00 D.</p> <p>Exclusion criteria: anterior segment pathology alterations such as chronic uveitis, zonular dialysis, pseudoexfoliation syndrome, glaucoma and diabetes; other ocular pathologies impairing visual function; previous anterior or posterior segment surgery; intraoperative or postoperative complications.</p> <p>Technique: Accommodating lens = 1 CU (Human Optics AG)</p> <p>Follow-up: 6 months</p> <p>Disclosure of interest: none of the authors has a financial or proprietary interest in any material or method mentioned.</p> <p>IP overview: implantation of accommodating intraocular lenses during cataract surgery</p>	<p>Mean uncorrected distance VA at 6 months</p> <ul style="list-style-type: none"> • Accommodating IOL = 0.76 ± 2.13 D • Monofocal IOL = 0.72 ± 1.30 D <p>Not significant (p value not stated)</p> <p>Mean best corrected distance VA at 6 months</p> <ul style="list-style-type: none"> • Accommodating IOL = 1.01 ± 0.74 D • Monofocal IOL = 1.01 ± 0.48 D <p>Not significant (p value not stated)</p> <p>Mean distance corrected near VA (Jaeger) at 6 months</p> <ul style="list-style-type: none"> • Accommodating IOL = 3.66 ± 2.12 • Monofocal IOL = 7.43 ± 0.50 <p>p < 0.001</p> <p>Amplitude of accommodation at 6 months</p> <ul style="list-style-type: none"> • Accommodating IOL = 1.90 ± 0.77 D • Monofocal IOL = 0 D <p>p < 0.05</p> <p>Mean spherical equivalent at 30 days</p> <ul style="list-style-type: none"> • Accommodating IOL = -0.16 ± 0.67 D • Monofocal IOL = -0.22 ± 0.69 D <p>Not significant (p value not stated)</p> <p>Mean astigmatism at 30 days</p> <ul style="list-style-type: none"> • Accommodating IOL = 0.73 ± 0.37 D • Monofocal IOL = 0.68 ± 0.41 D <p>Not significant (p value not stated)</p>	<p>Mild to moderate anterior capsule opacification at 1 month</p> <ul style="list-style-type: none"> • Accommodating IOL = 30% • Monofocal IOL = 33% <p>Mild posterior capsule opacification at 6 months</p> <ul style="list-style-type: none"> • Accommodating IOL = 21% • Monofocal IOL = 22% <p>No patient had capsule shrinkage.</p>	<p>Patients were blind to which group they were assigned. Method of randomisation was not described.</p> <p>Evaluation of visual parameters and accommodating amplitude was performed by a single examiner who was blind to which lens the patient had.</p> <p>No losses to follow-up were described.</p> <p>Results were reported as percentages with no denominators.</p>

Abbreviations used: D, dioptres; IOL, intraocular lens; VA, visual acuity.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Dogru M (2005)⁶</p> <p>Randomised controlled trial (prospective)</p> <p>Japan</p> <p>Study period: not stated</p> <p>n = 42 eyes</p> <p>Population: 26 patients with corticonuclear cataracts</p> <ul style="list-style-type: none"> • 52% (22/42) accommodating IOL • 48% (20/42) monofocal IOL (controls) <p>22 consecutive eyes of 16 patients had accommodating IOL and 20 eyes of 10 patients had monofocal IOL.</p> <p>Mean age:</p> <ul style="list-style-type: none"> • Accommodating lens = 64.7 years (range 49–71) • Controls = 67.7 years (range 61–73) <p>None of the patients had a history of any ocular disease other than cataracts or history of ocular surgery or contact lens use.</p> <p>Technique: Accommodating lens = 1CU PCIOL (HumanOptics AG, Germany).</p> <p>Follow-up: 12 months</p> <p>Disclosure of interest: none of the authors has a financial or proprietary interest in any material or method mentioned.</p>	<p>Uncorrected distance VA of 20/40 or above at 12 months</p> <ul style="list-style-type: none"> • Accommodating IOL = 77% (17/22) • Monofocal IOL = 80% (16/20) <p>The final best corrected distance visual acuity was above 20/25 in all eyes.</p> <p>Uncorrected near VA of 20/40 or above at 6 months</p> <ul style="list-style-type: none"> • Accommodating IOL = 67% • Monofocal IOL = 44% <p>Uncorrected near VA of 20/40 or above at 12 months</p> <ul style="list-style-type: none"> • Accommodating IOL = 53% • Monofocal IOL = 23% <p>Distance corrected near VA of 20/40 or above at 6 months</p> <ul style="list-style-type: none"> • Accommodating IOL = 66% • Monofocal IOL = 0% <p>Distance corrected near VA of 20/40 or above at 12 months</p> <ul style="list-style-type: none"> • Accommodating IOL = 49% • Monofocal IOL = 0% <p>Mean uncorrected near VA at 12 months</p> <ul style="list-style-type: none"> • Accommodating IOL = 20/63 • Monofocal IOL = 20/160 <p>p < 0.05</p> <p>Mean distance corrected near acuity was significantly higher in the eyes with an accommodating lens than the control group.</p> <p>The peak mean amplitude of accommodation in the accommodating lens group was observed at 3 months and was 0.5 ± 0.44 D. The amplitude decreased after 6 months.</p>	<p>There were no intraoperative or postoperative problems.</p> <p>The paper states that all eyes with the accommodating lens without an accommodative response except one had gradually increasing anterior and posterior capsular thickening and opacity at the 3-month, 6-month and 12-month examinations.</p> <p>Anterior and posterior capsule opacity rate in accommodating IOL group at 6 months = 34%</p> <p>Anterior and posterior capsule opacity rate in accommodating IOL group at 12 months = 86%</p> <p>25% (5/20) eyes in the control group had both anterior and posterior capsular opacity from 3 months onwards.</p>	<p>Control patients were age and sex matched. The method of randomisation was not described.</p> <p>No losses to follow-up were described.</p> <p>The authors state that prospective studies are needed to clarify whether capsule polishing affects the accommodative ability of the lens.</p> <p>The authors concluded that although the accommodating lens appeared to restore accommodation and provide additional near visual acuity postoperatively, the benefit seemed to disappear at 12 months.</p>

Abbreviations used: D, dioptres; IOL, intraocular lens; VA, visual acuity.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Macsai M (2006)⁷</p> <p>Non-randomised controlled study (retrospective)</p> <p>USA (multicentre)</p> <p>Study period: not stated</p> <p>n = 224 eyes</p> <p>Population: 112 patients with cataract</p> <ul style="list-style-type: none"> • 50% (112/224) accommodating IOL • 50% (112/224) monofocal IOL (controls) <p>Patients received either the accommodating lens or conventional lens in both eyes.</p> <p>Mean age (years):</p> <ul style="list-style-type: none"> • Accommodating lens = 65.5 ± 4.2 • Conventional lens = 60.1 ± 7.2 <p>Indications: Exclusion criteria: > 1.5 D keratometric cylinder; incomplete or damaged zonules; any anterior segment pathologic characteristics; uncontrolled glaucoma; characteristics or history of retinal detachment; macular degeneration; diabetic retinopathy; congenital bilateral cataract; marked microphthalmos or aniridia; blindness or prior ocular surgery in either eye.</p> <p>Technique: Accommodating lens = Crystalens IOL (Eyeonics); atropine was used for one day postoperatively.</p> <p>Follow-up (months):</p> <ul style="list-style-type: none"> • Accommodating lens = 5.9 ± 2.6 • Conventional lens = 7.1 ± 3.0 <p>Disclosure of interest: none of the authors has a financial or proprietary interest in any material or method mentioned.</p>	<p>Mean monocular uncorrected near VA</p> <ul style="list-style-type: none"> • Accommodating IOL = 0.69 ± 0.23 (J2) • Monofocal IOL = 0.35 ± 0.12 (J6) <p>p < 0.01</p> <p>Monocular uncorrected near VA J3 or better</p> <ul style="list-style-type: none"> • Accommodating IOL = 90% (101/112) • Monofocal IOL = 15% (17/112) <p>Mean binocular uncorrected near VA</p> <ul style="list-style-type: none"> • Accommodating IOL = 1.00 ± 0.00 (J1) • Monofocal IOL = 0.40 ± 0.13 (J6) <p>p < 0.01</p> <p>Binocular uncorrected near VA J3 or better</p> <ul style="list-style-type: none"> • Accommodating IOL = 100% (56/56) • Monofocal IOL = 29% (16/56) <p>Mean monocular uncorrected distance VA</p> <ul style="list-style-type: none"> • Accommodating IOL = 0.85 ± 0.30 (20/24) • Monofocal IOL = 0.70 ± 0.19 (20/29) <p>p < 0.01</p> <p>Mean binocular uncorrected distance VA</p> <ul style="list-style-type: none"> • Accommodating IOL = 1.16 ± 0.17 (20/17) • Monofocal IOL = 1.01 ± 0.14 (20/20) <p>p < 0.01</p> <p>Mean monocular best corrected near VA</p> <ul style="list-style-type: none"> • Accommodating IOL = 1.04 ± 0.19 (J1) • Monofocal IOL = 0.96 ± 0.10 (J1) <p>Mean binocular best corrected near VA</p> <ul style="list-style-type: none"> • Accommodating IOL = 1.00 ± 0.00 (J1) • Monofocal IOL = not measured <p>Mean monocular best corrected distance VA</p> <ul style="list-style-type: none"> • Accommodating IOL = 1.06 ± 0.17 (20/19) • Monofocal IOL = 0.98 ± 0.15 (20/20) <p>Mean binocular best corrected distance VA</p> <ul style="list-style-type: none"> • Accommodating IOL = 1.16 ± 0.17 (20/17) • Monofocal IOL = 1.01 ± 0.14 (20/20) <p>Focal point change through accommodation was significantly higher in accommodating lens group with all measurement methods used.</p>	<p>'At the time of examination, all lenses were well centred, with no reports of corneal oedema, inflammation, or posterior capsule opacification.'</p> <p>Postoperative examination was described as being masked and randomised, and was performed by a single observer. Randomisation process was not described.</p> <p>The reported results for mean binocular best corrected distance visual acuity for both lenses were exactly the same as for uncorrected distance visual acuity, although one result was described as being statistically significant and the other was not.</p> <p>Accommodation was measured using one objective and two subjective methods.</p>	<p>Patients chose which IOL to have implanted. Controls were age-matched patients receiving standard monofocal IOLs.</p>

Abbreviations used: D, dioptres; IOL, intraocular lens; VA, visual acuity.

Study details	Key efficacy findings	Key safety findings	Comments																																																																								
<p>Alió J (2004)⁸</p> <p>Non-randomised controlled trial</p> <p>Spain</p> <p>Study period: not stated</p> <p>n = 80 eyes</p> <p>Population: 40 patients with bilateral cataract</p> <ul style="list-style-type: none"> • 30% (24/80) accommodating IOL • 40% (32/80) multifocal IOL • 30% (24/80) diffractive bifocal IOL <p>Patients received the same lens in both eyes.</p> <p>Mean age (years):</p> <ul style="list-style-type: none"> • Accommodating IOL = 67.4 ± 9.8 • Multifocal IOL = 66.7 ± 14.1 • Bifocal IOL = 70.5 ± 8.8 <p>Indications: age between 30 and 80 years; bilateral cataract; in-the-bag IOL implantation.</p> <p>Exclusion criteria: astigmatism > 5.0 D; monocular vision; microphthalmos; aniridia; anterior segment congenital anomalies; macular diseases; retinal detachment; proliferative diabetic retinopathy; previous corneal or refractive surgery; other ocular diseases that may affect the visual outcome.</p> <p>Follow-up: 1 year</p> <p>Technique: Accommodating lens = Crystalens model AT-45; patients with accommodating lens were instructed to use atropine for 3 days postoperatively.</p> <p>Disclosure of interest: none of the authors has a financial or proprietary interest in any material or method mentioned.</p>	<p>Mean uncorrected near VA</p> <table border="1" data-bbox="663 245 1126 392"> <thead> <tr> <th>Type of IOL</th> <th>Preop</th> <th>1-year follow-up</th> </tr> </thead> <tbody> <tr> <td>Accommodating</td> <td>20/40</td> <td>20/32</td> </tr> <tr> <td>Multifocal</td> <td>20/32</td> <td>20/32</td> </tr> <tr> <td>Bifocal</td> <td>20/63</td> <td>20/25</td> </tr> </tbody> </table> <p>Mean best corrected near VA</p> <table border="1" data-bbox="663 448 1126 595"> <thead> <tr> <th>Type of IOL</th> <th>Preop</th> <th>1-year follow-up</th> </tr> </thead> <tbody> <tr> <td>Accommodating</td> <td>20/25</td> <td>20/20</td> </tr> <tr> <td>Multifocal</td> <td>20/25</td> <td>20/25</td> </tr> <tr> <td>Bifocal</td> <td>20/25</td> <td>20/25</td> </tr> </tbody> </table> <p>Mean uncorrected distance VA</p> <table border="1" data-bbox="663 651 1126 798"> <thead> <tr> <th>Type of IOL</th> <th>Preop</th> <th>1-year follow-up</th> </tr> </thead> <tbody> <tr> <td>Accommodating</td> <td>20/40</td> <td>20/25</td> </tr> <tr> <td>Multifocal</td> <td>20/63</td> <td>20/32</td> </tr> <tr> <td>Bifocal</td> <td>20/100</td> <td>20/32</td> </tr> </tbody> </table> <p>Mean best corrected distance VA</p> <table border="1" data-bbox="663 853 1126 1000"> <thead> <tr> <th>Type of IOL</th> <th>Preop</th> <th>1-year follow-up</th> </tr> </thead> <tbody> <tr> <td>Accommodating</td> <td>20/32</td> <td>20/25</td> </tr> <tr> <td>Multifocal</td> <td>20/40</td> <td>20/25</td> </tr> <tr> <td>Bifocal</td> <td>20/40</td> <td>20/25</td> </tr> </tbody> </table> <p>Mean add-plus for near vision at 1-year</p> <table border="1" data-bbox="663 1056 1151 1203"> <thead> <tr> <th>Type of IOL</th> <th>Preop</th> <th>1-year follow-up</th> </tr> </thead> <tbody> <tr> <td>Accommodating</td> <td>+2.5 ± 0.9</td> <td>+1.1 ± 0.5</td> </tr> <tr> <td>Multifocal</td> <td>+2.6 ± 0.8</td> <td>+1.0 ± 0.8</td> </tr> <tr> <td>Bifocal</td> <td>+2.8 ± 0.4</td> <td>+0.8 ± 0.7</td> </tr> </tbody> </table> <p>Best distance-corrected near VA</p> <table border="1" data-bbox="663 1259 1151 1406"> <thead> <tr> <th>Type of IOL</th> <th>Preop</th> <th>1-year follow-up</th> </tr> </thead> <tbody> <tr> <td>Accommodating</td> <td>20/32</td> <td>20/25</td> </tr> <tr> <td>Multifocal</td> <td>20/32</td> <td>20/25</td> </tr> <tr> <td>Bifocal</td> <td>20/50</td> <td>20/25</td> </tr> </tbody> </table>	Type of IOL	Preop	1-year follow-up	Accommodating	20/40	20/32	Multifocal	20/32	20/32	Bifocal	20/63	20/25	Type of IOL	Preop	1-year follow-up	Accommodating	20/25	20/20	Multifocal	20/25	20/25	Bifocal	20/25	20/25	Type of IOL	Preop	1-year follow-up	Accommodating	20/40	20/25	Multifocal	20/63	20/32	Bifocal	20/100	20/32	Type of IOL	Preop	1-year follow-up	Accommodating	20/32	20/25	Multifocal	20/40	20/25	Bifocal	20/40	20/25	Type of IOL	Preop	1-year follow-up	Accommodating	+2.5 ± 0.9	+1.1 ± 0.5	Multifocal	+2.6 ± 0.8	+1.0 ± 0.8	Bifocal	+2.8 ± 0.4	+0.8 ± 0.7	Type of IOL	Preop	1-year follow-up	Accommodating	20/32	20/25	Multifocal	20/32	20/25	Bifocal	20/50	20/25	<p>1 or 2 lines lost of best corrected near acuity</p> <ul style="list-style-type: none"> • Accommodating IOL = 0% (0/24) • Multifocal IOL = 12% (4/42) • Bifocal IOL = 4% (1/24) <p>1 or 2 lines lost of best corrected distance acuity</p> <ul style="list-style-type: none"> • Accommodating IOL = 0% (0/24) • Multifocal IOL = 0% (0/42) • Bifocal IOL = 4% (1/24) <p>Patient-reported halos at 1-year follow-up</p> <ul style="list-style-type: none"> • Accommodating IOL = 8% (2/24) • Multifocal IOL = 22% (7/32) • Bifocal IOL = 21% (5/24) <p>Patient-reported flare at 1-year follow-up</p> <ul style="list-style-type: none"> • Accommodating IOL = 4% (1/24) • Multifocal IOL = 6% (2/32) • Bifocal IOL = 8% (2/24) <p>Patient-reported flashes at 1-year follow-up</p> <ul style="list-style-type: none"> • Accommodating IOL = 4% (1/24) • Multifocal IOL = 3% (1/32) • Bifocal IOL = 4% (1/24) <p>Patient-reported glare at 1-year follow-up</p> <ul style="list-style-type: none"> • Accommodating IOL = 4% (1/24) • Multifocal IOL = 6% (2/32) • Bifocal IOL = 8% (2/24) <p>Laser capsulotomy for posterior capsule opacification at 1-year follow-up</p> <ul style="list-style-type: none"> • Accommodating IOL = 12% (3/24) • Multifocal IOL = 25% (8/32) • Bifocal IOL = 29% (7/24) <p>Secondary refractive surgery</p> <ul style="list-style-type: none"> • Accommodating IOL = 29% (7/24) • Multifocal IOL = 16% (5/32) • Bifocal IOL = 21% (5/24) 	<p>Patient selection was not described.</p> <p>There are differences in the preoperative mean uncorrected near and distance visual acuity between the three groups of patients. These differences are not discussed in the paper.</p> <p>In the paper, figures in the abstract and the table disagree with regard to the mean uncorrected near visual acuity for patients receiving the accommodating lens and for those receiving the multifocal lens. The figures presented here are the figures in the table and main body of text.</p> <p>Figures in the text and table of the paper disagree with regards to the percentage of patients undergoing capsulotomy. The figures described in the text rather than the table have been used for this overview.</p>
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IP overview: implantation of accommodating intraocular lenses during cataract surgery

Abbreviations used: D, dioptres; IOL, intraocular lens; VA, visual acuity.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Cumming JS (2006)⁹</p> <p>Case series</p> <p>USA (multicentre)</p> <p>Study period: 2000–2002</p> <p>n = 263 eyes (an additional 61 eyes were included in safety analysis)</p> <p>Population: 263 patients aged 50 years or older undergoing small-incision cataract extraction</p> <p>Unilateral implantation was followed by fellow-eye implantation (after a minimum of two weeks).</p> <p>Mean age = 70.0 years (range 49.5 to 87.8)</p> <p>Indications: Inclusion criteria: age 50 years or older; no ocular pathology; no more than 1.00 D of corneal astigmatism; potential for best corrected visual acuity of 20/32 or better in both eyes. Exclusion criteria: absence of intact capsule with an intact capsulorhexis; zonular rupture.</p> <p>Technique: Accommodating lens = Crystalens AT-45 (Eyeonics, Inc).</p> <p>Follow-up: 12 months</p> <p>Disclosure of interest: Study sponsored by Eyeonics, Inc. One author is an employee and stockholder in Eyeonics; one author is a stockholder and two other authors are consultants to Eyeonics.</p>	<p>One IOL could not be placed in capsular bag; this eye was included in safety data analysis only.</p> <p>Near VA through distance correction (unilateral)</p> <ul style="list-style-type: none"> • 20/25 (J1) or better = 24.8% (60/242) • 20/32 (J2) or better = 54.0% (130/242) • 20/40 (J3) or better = 90.1% (218/242) <p>Near VA through distance correction (bilateral)</p> <ul style="list-style-type: none"> • 20/25 (J1) or better = 51.6% (64/124) • 20/32 (J2) or better = 83.9% (104/124) • 20/40 (J3) or better = 100% (124/124) <p>Uncorrected near VA (unilateral)</p> <ul style="list-style-type: none"> • 20/25 (J1) or better = 43.2% (104/241) • 20/32 (J2) or better = 69.7% (168/241) • 20/40 (J3) or better = 88.4% (213/241) <p>Uncorrected near VA (bilateral)</p> <ul style="list-style-type: none"> • 20/25 (J1) or better = 72.6% (90/124) • 20/32 (J2) or better = 93.5% (116/124) • 20/40 (J3) or better = 98.4% (122/124) <p>100% (242/242) eyes were correctable to 20/40 (J3) or better near acuity through distance correction with add.</p> <p>Mean add power required to achieve best correct near acuity was reduced from +2.37 D at preoperative baseline to + 1.20 D at 12 months ($p < 0.0001$).</p> <p>Only 1 primary eye had intermediate VA worse than 20/40, which was attributable to macular degeneration and posterior capsule opacification.</p>	<p>'In no case was there a statistically significant difference between the incidence of adverse events reported in the study and the FDA Grid of Historical Controls.'</p> <p>12-month cumulative adverse events</p> <ul style="list-style-type: none"> • Endophthalmitis = 0.3% (1/324) • Hyphema = 0.3% (1/324) • Cystoid macular oedema = 3.7% (12/324) • Secondary surgical intervention = 0.6% (2/324) • Vitrectomy = 0.3% (1/324) • Repositioning of lens = 0.3% (1/324) • Hypopyon = 0% (0/324) • IOL dislocation = 0% (0/324) • Pupillary block = 0% (0/324) • Retinal detachment = 0% (0/324) • Iridectomy = 0% (0/324) • Lens removal = 0% (0/324) • Lens replacement = 0% (0/324) <p>12-month persistent adverse events (still present at 12-month follow-up)</p> <ul style="list-style-type: none"> • Iritis = 0.7% (2/298) • Cystoid macular oedema = 0.9% (3/304) • Corneal oedema = 0% (0/298) • Raised intraocular pressure requiring treatment = 0% (0/304) <p>A capsulotomy was performed in 14% (37/263) of primary eyes for posterior capsule opacification.</p>	<p>US FDA phase III clinical trial.</p> <p>324 eyes were included in the safety analysis. 263 eyes were included in efficacy and safety analysis. At the 12-month follow-up, 94% (246/263) eyes were available for analysis.</p> <p>A substudy to test contrast sensitivity under in a subset of patients and a control group receiving a standard IOL was also reported (see below).</p>

Abbreviations used: D, dioptres; IOL, intraocular lens; VA, visual acuity.			
Study details	Key efficacy findings	Key safety findings	Comments
Cumming JS (2006) <i>continued</i>	<p>Uncorrected distance VA (unilateral)</p> <ul style="list-style-type: none"> • 20/25 (J1) or better = 68.0% (166/244) • 20/32 (J2) or better = 80.7% (197/244) • 20/40 (J3) or better = 88.9% (217/244) <p>Uncorrected near VA (bilateral)</p> <ul style="list-style-type: none"> • 20/25 (J1) or better = 91.9% (113/123) • 20/32 (J2) or better = 97.6% (120/123) • 20/40 (J3) or better = 98.4% (121/123) <p>Best corrected distance VA (unilateral)</p> <ul style="list-style-type: none"> • 20/25 (J1) or better = 96.7% (235/243) • 20/40 (J3) or better = 99.2% (241/243) <p>Best corrected near VA (bilateral)</p> <ul style="list-style-type: none"> • 20/25 (J1) or better = 100% (123/123) <p>Patient reported improvement in quality of vision at 1 year = 95.4% (84/88)</p> <p>91.2% (115/126) patients implanted bilaterally were very satisfied, satisfied or somewhat satisfied with their visual outcome. 6.3% were somewhat dissatisfied with their outcome.</p> <p>128 patients with bilateral implants were asked to complete a survey. 25.8% patients reported that they did not wear glasses and 47.7% wore glasses 10 to 25% of the time. (The number of responses is not reported in the paper).</p>		

Abbreviations used: D, dioptres; IOL, intraocular lens; VA, visual acuity.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Cumming JS (2006)⁹</p> <p>Non randomised controlled trial</p> <p>USA</p> <p>Study period: 2000–2002</p> <p>n = 190 eyes</p> <p>Population: 190 patients with cataract</p> <ul style="list-style-type: none"> • 66% (126/190) accommodating IOL • 34% (64/190) standard IOL <p>Mean age (years):</p> <ul style="list-style-type: none"> • Accommodating IOL = 70.1 ± 8.0 (range 49.5 to 87.8) • Standard IOL = 73.8 ± 9.1 (range 52.1 to 89.1) <p>p = 0.004</p> <p>Indications: Inclusion criteria: age 50 years or older; no ocular pathology; no more than 1.00 D of corneal astigmatism; potential for best corrected visual acuity of 20/32 or better in both eyes. Exclusion criteria: absence of intact capsule with an intact capsulorhexis; zonular rupture.</p> <p>Technique: Accommodating lens = Crystalens AT-45 (Eyeonics, Inc); tests were done under extremely low light conditions.</p> <p>Follow-up: 3 to 6 months</p> <p>Disclosure of interest: Study sponsored by Eyeonics, Inc. One author is an employee and stockholder in Eyeonics; one author is a stockholder and two other authors are consultants to Eyeonics.</p>	<p>Monocular uncorrected near VA through distance correction J3 or better</p> <ul style="list-style-type: none"> • Accommodating IOL = 89.3% (108/121) • Standard IOL = 35.9% (23/64) <p>p ≤ 0.0001</p> <p>Monocular uncorrected intermediate VA through distance correction J3 or better</p> <ul style="list-style-type: none"> • Accommodating IOL = 99.2% (120/121) • Standard IOL = 93.8% (60/64) <p>p = 0.049</p> <p>Mean add power required to achieve best corrected near VA</p> <ul style="list-style-type: none"> • Accommodating IOL = +1.24 D (range 0.00 to +2.50 D) • Standard IOL = +2.32 D (range +1.00 to +3.00 D) <p>p < 0.0001</p> <p>Contrast sensitivity in accommodating lens group was no worse than that in the control group, in the presence or absence of glare.</p>	<p>No safety data were reported for this substudy (see main study above).</p>	<p>The accommodating lens group was composed of the first 126 eyes that met the inclusion criteria. The standard IOL group was composed of 64 consecutive eyes that met the inclusion criteria and were scheduled to reach the 3-month to 6-month postoperative period during the study period.</p> <p>Patients in the accommodating lens group were statistically significantly younger than those in the control group.</p>

Abbreviations used: D, dioptres; IOL, intraocular lens; VA, visual acuity.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Nguyen N (2005)¹⁰</p> <p>Case series (prospective)</p> <p>Germany</p> <p>Study period: 2000–2003</p> <p>n = 65 eyes</p> <p>Population: 65 patients undergoing phacoemulsification</p> <p>Mean age: 62 years (range 44–86)</p> <p>Indications and exclusion criteria identical to Kuchle M (2004), that is, inclusion criteria: Senile or presenile cataract treated with phacoemulsification</p> <p>Exclusion criteria: age < 40 years; diabetic retinopathy; prior intraocular surgery; previous ocular trauma; visible zonulolysis; phacodonesis; pseudoexfoliation syndrome; high myopia; high hypermetropia; complications occurring during cataract surgery.</p> <p>Technique: Accommodating lens = 1CU PCIOL (HumanOptics AG, Germany); no atropine was used.</p> <p>Mean follow-up: 23 months (range 4–40)</p> <p>Disclosure of interest: not stated</p>	<p>Mean best corrected distance VA at 12 months = 1.1 ± 0.1 D</p> <p>Mean best distance corrected near VA at 12 months = 0.4 ± 0.1 D</p> <p>Accommodative range determined by near point at 12 months = 2.0 ± 0.5 D</p> <p>Accommodative range determined by defocusing at 12 months = 1.8 ± 0.4 D</p> <p><i>Results in 12 patients after capsulotomy (12 eyes)</i></p> <p>Mean best corrected distance VA 6 weeks after laser capsulotomy (n = 12) = 1.0 ± 0.1 D</p> <p>Mean best distance corrected near VA 6 weeks after laser capsulotomy = 0.39 ± 0.08 D</p> <p>Accommodative range determined by near point 6 weeks after capsulotomy = 1.95 ± 0.6 D</p> <p>Accommodative range determined by defocusing 6 weeks after capsulotomy = 1.88 ± 0.47 D</p>	<p>Clinically relevant posterior capsule opacification with significant decrease of visual acuity (0.4 ± 0.2) requiring capsulotomy = 18% (12/65) (diagnosed between 15 and 22 months postoperatively, mean 20 months)</p> <p>The paper states that no PCIOL-related complications were seen in any of the patients during follow-up.</p>	<p>Pseudophakic accommodation was only measured subjectively. To minimise the learning effect of repeated measurement, the sequence of measurements were changed at each examination.</p> <p>It is not clear from the paper whether all patients had surgery on only one eye.</p>

Validity and generalisability of the studies

- Tests used to measure visual acuity are subjective; only one randomised controlled trial reported that both the patient and the examiner were blind to which lens had been implanted.⁵
- One study included patients with an accommodating lens implanted in one eye and a conventional lens in the other eye;^{3,4} however, in this study both the patient and the examiner knew which eye had the accommodating lens implant. Patients in the other studies either had the same lens implanted in both eyes or only one eye had an implant.
- The longest mean follow-up was 23 months, in a case series of 65 patients.¹⁰ Clinically relevant cases of posterior capsule opacification in this study were all diagnosed between 15 and 22 months postoperatively. Two studies also reported worsening efficacy results between 6 and 12 months follow-up.^{3,4,6}
- Inclusion criteria varied between studies with respect to age.
- The studies included two different types of accommodating lens.

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

Mr B James, Mr M Pande, Mr D Spalton

- Two advisers considered this procedure to be a minor variation of an existing procedure. One described it as first in a new class of procedure.
- The potential impact of this procedure on the NHS is moderate to major, in terms of numbers of patients eligible for treatment and use of resources.
- The main concerns regard efficacy rather than safety.
- This is a rapidly expanding field. One specialist adviser commented that it is premature that NICE consider this at the present time, as technology is in the early stages, and would be much more efficacious in future.
- The mechanism of action of accommodative lenses is unclear.

Issues for consideration by IPAC

There is more than one type of accommodating lens currently in use.

References

1. Royal College of Ophthalmologists (2004) Cataract surgery guidelines. Available from: www.rcophth.ac.uk/docs/publications/CataractSurgeryGuidelinesMarch2005Updated.pdf
2. Sauder G, Degenring RF, Kampeter B et al. (2005) Potential of the 1 CU accommodative intraocular lens. *British Journal of Ophthalmology* 89: 1289–92.
3. Heatley CJ, Spalton DJ, Hancox J et al. (2005) Fellow eye comparison between the 1CU accommodative intraocular lens and the Acrysof MA30 monofocal intraocular lens. *American Journal of Ophthalmology* 140: 207–13.
4. Hancox J, Spalton D, Heatley C, et al. (2006) Objective measurement of intraocular lens movement and dioptric change with a focus shift accommodating intraocular lens. *Journal of Cataract Refractive Surgery* 32: 1098–1103.
5. Mastropasqua L, Toto L, Nubile M et al. (2003) Clinical study of the 1CU accommodating intraocular lens. *Journal of Cataract Refractive Surgery* 29: 1307–12.
6. Dogru M, Honda R, Omoto M et al. (2005) Early visual results with the 1CU accommodating intraocular lens. *Journal of Cataract Refractive Surgery* 31: 895–902.
7. Macsai MS, Padnick-Silver L, Fontes BM (2006) Visual outcomes after accommodating intraocular lens implantation. *Journal of Cataract Refractive Surgery* 32: 628–33.
8. Alió JL, Tavalato M, De la Hoz F et al. (2004) Near vision restoration with refractive lens exchange and pseudoaccommodating and multifocal refractive and diffractive intraocular lenses. *Journal of Cataract Refractive Surgery* 30: 2494–503.
9. Cumming JS, Colvard DM, Dell SJ et al. (2006) Clinical evaluation of the Cystalens AT-45 accommodating intraocular lens. Results of the US Food and Drug Administration clinical trial. *Journal of Cataract Refractive Surgery* 32: 812–25.
10. Nguyen NX, Seitz B, Reese S et al. (2005) Accommodation after Nd: YAG capsulotomy in patients with accommodative posterior chamber lens 1CU. *Graefe's Archive for Clinical and Experimental Ophthalmology* 243: 120–6.

Appendix A: Additional papers on implantation of accommodating lenses during cataract surgery not included in summary table 2

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article title	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
Buratto L, Di Meglio G. Accommodative intraocular lenses: short-term visual results of two different lens types. <i>European Journal of Ophthalmology</i> 16: 33–9.	108 eyes of 75 patients. Mean follow-up = 15 months.	Comparison of two different types of accommodating lens. 92% and 84% of patients achieved uncorrected near VA of J3 or better.	A larger case series is included.
Claoue C (2004) Functional vision after cataract removal with multifocal and accommodating intraocular lens implantation: prospective comparative evaluation of Array multifocal and 1CU accommodating lenses. <i>Journal of Cataract Refractive Surgery</i> 30: 2088–91.	43 eyes (34 with multifocal IOL, 9 with accommodating IOL). Follow-up = 6 to 18 months.	Near uncorrected visual acuity 20/40 or better: Multifocal = 76% Accomm = 44% p = 0.007	Only 5 patients (9 eyes) had accommodating lens implant.
Cumming JS, Slade SG, Chayet A et al. (2001) Clinical evaluation of the Model AT-45 silicone accommodating intraocular lens. <i>Ophthalmology</i> 108: 2005–10.	76 eyes of 62 patients. Follow-up = 1 month.	No complications or adverse events. 97% uncorrected near visual acuity 20/30 or better.	Short-term follow-up.
Findl O, Kriechbaum K, Menapace R et al. (2004) Laserinterferometric assessment of pilocarpine-induced movement of an accommodating intraocular lens. <i>Ophthalmology</i> 111: 1515–21.	110 eyes of 55 patients. Follow-up = 3 months.	Pilocarpine induced a small but significant forward shift of the accommodating lens. Four eyes had haptic dislocations resulting in significant hyperopic shift; two lenses had to be explanted.	The main aim of the study was to measure pilocarpine-induced change in anterior chamber depth. Short term follow-up.
Jardim D, Soloway B, Starr C (2006) Asymmetric vault of an accommodating intraocular lens. <i>Journal of Cataract Refractive Surgery</i> 32: 347–50.	1 patient. Follow-up = 6 months.	Case report of late asymmetric vault caused by capsule fibrosis, occurring after 6 months. Resulted in reduced acuity at all distances.	Case report.

Article title	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
Kamppeter BA, Sauder G, Jonas JB (2005) Contrast and glare sensitivity after implantation of AcrySof® and Human Optics 1CU® intraocular lenses. <i>European Journal of Ophthalmology</i> 15: 458–61.	23 eyes (10 with accommodating lens, 13 with monofocal lens). Follow-up = 4 weeks.	The lenses did not vary significantly with regard to glare and contrast sensitivity.	Larger studies with longer follow-up have been included.
Küchle M, Seitz B, Langenbucher A et al. (2004) Comparison of 6-month results of implantation of the 1CU accommodative intraocular lens with conventional intraocular lenses. <i>Ophthalmology</i> 111: 318–24.	40 eyes of 40 (20 controls). Follow-up = 6 months.	Significantly higher accommodative range and better distance-corrected near visual acuity in accommodating lens group.	Larger studies have been included. Results from the same study centre are included in table 2 (ref 10).
Langenbucher A, Huber S, Nguyen N et al. (2003) Measurement of accommodation after implantation of an accommodating posterior chamber intraocular lens. <i>Journal of Cataract Refractive Surgery</i> 29: 677–85.	43 eyes of 43 patients (20 controls). Follow-up = 6 months.	Accommodation should be assessed with several techniques, including subjective and objective.	Results from the same study centre are included in table 2 (ref 10).
Nguyen N, Langenbucher A, Huber S et al. (2002) Short-term blood-aqueous barrier breakdown after implantation of the 1CU accommodative posterior chamber intraocular lens. <i>Journal of Cataract Refractive Surgery</i> 28: 1189–94.	20 eyes of 20 patients. Follow-up = 6 months.	No signs or persistent inflammation or pigment dispersion were seen.	Results from the same study centre are included in table 2 (ref 10).
Marchini G, Pedrotti E, Sartori P et al. (2004) Ultrasound biomicroscopic changes during accommodation in eyes with accommodating intraocular lenses. <i>Journal of Cataract Refractive Surgery</i> 30: 2476–82.	20 eyes of 14 patients. Follow-up = 6 months.	Anterior displacement of IOL occurred during near vision, proportional to accommodation capacity.	Larger studies have been included.
Schneider H, Stachs O, Katka Gobel et al. (2006) Changes of the accommodative amplitude and the anterior chamber depth after implantation of an accommodative intraocular lens. <i>Graefe's Archive for Clinical and Experimental Ophthalmology</i> 244: 322–9.	30 eyes of 30 patients (15 controls). Follow-up = 12 weeks.	There were no statistically significant differences in terms of change in anterior chamber depth or accommodative amplitude.	Larger studies with longer follow-up have been included
Wang CY, Ma B, Wang LL (2005) Clinical accommodative status study of the accommodative foldable intraocular lens. <i>International Journal of Ophthalmology</i> 5: 669–71.	20 eyes of 18 patients (10 controls). Follow-up = 3 months.	Uncorrected near visual acuity significantly better than control group.	Larger studies with longer follow-up have been included.

Appendix B: Related published NICE guidance for implantation of accommodating lenses during cataract surgery

Guidance	Recommendation
Interventional procedures	None applicable
Technology appraisals	None applicable
Clinical guidelines	None applicable
Public health	None applicable

Appendix C: Literature search for implantation of accommodating lenses during cataract surgery

IP: 363 Accommodating intraocular lenses for use in cataract surgery		
Database	Date searched	Version searched
Cochrane Library	11.4.06	Issue 1: 2006
CRD databases	“	-
Embase	“	1980 – week 14 2006
Medline	“	1966 – March week 5 2006
Premedline	“	- March week 5 2006
CINAHL	“	1982 – April week 1
British Library Inside Conferences	“	-
NRR	“	Issue 1: 2006
Controlled Trials Registry	“	-

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in other databases.

- 1 exp Lens Diseases/
- 2 cataract\$.tw.
- 3 aphakia.tw.
- 4 exp Cataract Extraction/
- 5 phakoemulsification.tw.
- 6 phacoemulsification.tw.
- 7 (cataract\$ adj3 (removal or extract\$)).tw.
- 8 or/4-7
- 9 Lenses, Intraocular/
- 10 Intraocular lens\$.tw.
- 11 IOL.tw.
- 12 or/9-11
- 13 crystalens.af.
- 14 human optics ICU.af.
- 15 Tetraflex.af.
- 16 (accommod\$ or accomod\$).tw.
- 17 or/13-16
- 18 Lens Implantation, Intraocular/
- 19 8 or 18
- 20 or/1-3
- 21 12 and 17 and 19 and 20
- 22 animal/
- 23 human/
- 24 22 not 23
- 25 21 not 24

NB: An updated search was performed on 15 August 2006.