# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

## Interventional procedure overview of intraocular lens insertion for correction of refractive error, with preservation of the natural lens

Short-sightedness is the inability to see clearly at a distance. Eyesight can usually be corrected by wearing spectacles or contact lenses. Insertion of a clear plastic lens in front of the existing lens is a procedure that aims to improve vision in short-sightedness.

## 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 May 2008.

## Procedure name

- Intraocular lens insertion with preservation of the natural lens
- Phakic intraocular lens insertion.
- Implantable contact lens insertion.

## Specialty societies

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

# Description

## *Indications*

There are a number of forms of refractive error including myopia, hypermetropia, astigmatism and presbyopia. Myopia occurs when light from a distant object is brought into focus in front of the retina, rather than on it. This is usually because the eye is too long, but it may be due to the cornea being too steeply curved. Close objects are seen clearly but more distant ones are blurred. Hypermetropia occurs when light rays from distant objects entering the eye are focused behind the retina rather than on it. This is usually because the eye is too short, or the lens cannot be shaped by the eye muscles to be round enough. Distant objects are seen clearly but closer ones are blurred. Astigmatism occurs when light from objects is not focused sharply on the retina. This may be due to an irregular or toric curvature of the cornea or lens. Presbyopia is a condition where the crystalline (natural) lens becomes too rigid and is unable to change shape to focus light on the retina.

## *Current treatment and alternatives*

Focusing (refractive) errors are usually corrected by wearing either spectacles or contact lenses, both of which correct visual acuity and are acceptable solutions to the majority of people. In addition, surgical treatments that can be used to treat refractive error, including photorefractive keratectomy (PRK), laser in situ keratomileusis (LASIK), and insertion of peripheral clear crescent-shaped corneal implants.

## *What the procedure involves*

The procedure aims to implant an artificial intraocular lens with the eye's natural lens still in place (for brevity and consistency with the majority of the literature, the terms ‘phakic intraocular lens’ or ‘phakic lens’ are used to denote such lenses in the rest of the document).

The procedure is carried out under local anesthesia. A partial iridectomy is also usually preformed at the beginning of the procedure. With the pupil dilated using topical medication, the prosthetic intraocular lens (IOL) is inserted via a small corneal incision into either the anterior or the posterior chamber of the eye (depending on lens design). It is anchored to the iris, placed in the angle between the cornea and the iris, or positioned to float over the surface of the natural lens (again, depending on lens design). A nylon suture is sometimes used to close the incision. Postoperative care is with antiobiotic and steroid eye drops for a few weeks, and a bandage soft contact lens may be worn for a few days.

The advantage of this procedure over a conventional cataract operation with the insertion of a standard intra ocular lens is the retention of normal accommodation in younger patients.

Phakic intraocular lenses with a toric design (an asymmetric lens with different optical powers in different planes) have been developed to treat astigmatism.

## *Efficacy*

Mean manifest refraction spherical equivalent (MRSE) in a randomised controlled trial of 50 eyes (with the fellow eye as control) was –0.95 ± 0.45 D in eyes implanted with a phakic IOL and –0.74 ± 0.67 D in eyes treated with LASIK at 1-year follow-up (p not significant)[1]. In the same study mean uncorrected visual acuity (UCVA) of 20/40 or better was achieved in 60% (15/25) of phakic IOL-treated eyes and 80% (20/25) of LASIK-treated eyes at 1-year follow-up (p = 0.12). A non-randomised controlled trial of 9239 eyes reported that mean postprocedural MRSE was –1.78 ± 2.03 D in eyes implanted with a phakic IOL, 0.36 ± 1.30 D in LASIK-treated eyes, and –0.18 ± 0.5 D in PRK-treated eyes (significance not stated)[2].

A randomised controlled trial of 88 astigmatic eyes reported that mean best spectacle corrected visual acuity (BSCVA) of 20/12.5 or better at 1 year was achieved in 71% (27/38) of eyes implanted with a toric phakic IOL and in 14% (6/44) of eyes treated with PRK ($p < 0.001$)[3]. At 1-year follow-up predictability of refractive correction (within 0.5 D of that intended) was achieved in 76% (29/38) of toric phakic IOL-treated eyes, and 57% (25/44) of PRK-treated eyes ($p = 0.101$)[3]. In a non-randomised controlled trial of 769 eyes, correction to within 0.5 D of that intended was achieved in 69% (127/184) of phakic IOL-treated eyes and in 57% (57/100) of LASIK-treated eyes at 1-year follow-up[4].

A case series of 1140 eyes treated with phakic IOL implantation reported that at baseline 0% (0/622) of eyes had UCVA of 20/20 or better; at 3-year follow-up 27% (62/231) of eyes had UCVA of 20/20 or better (significance not stated)[5].

## *Safety*

In a non-randomised controlled trial of 9239 eyes retinal detachment was reported in 4% (12/294) of eyes implanted with a phakic IOL, <1% (11/3009) of eyes treated with LASIK, and <1% (9/5936) of eyes treated by PRK at a mean detachment time of 20.5, 24.6 and 53.6 months respectively[2].

A meta-analysis of 6338 eyes reported that new-onset cataracts developed in 1% (15/1161) of eyes receiving an angle-fixated anterior chamber IOL, less than 1% (20/2781) of eyes receiving an iris-fixated anterior chamber IOL, and 9% (223/2396) of eyes receiving a posterior chamber IOL; the length of follow-up varies between studies[6]. An anterior subcapsular cataract was reported in 2% (1/43) of eyes implanted with a toric phakic IOL in a randomised controlled trial at 2-year follow-up. The toric phakic IOL and cataracts were successfully removed and an alternative type of IOL was implanted[3].

A loss of 2 or more lines of BSCVA at 12-month follow-up was reported in 0% (0/38) of eyes having a toric phakic IOL implanted and 0% (0/44) of eyes treated with PRK (p = 1.00) in a randomised controlled trial of 88 eyes[3]. A randomised controlled trial of 50 fellow eyes reported loss of 2 or more lines of BSCVA in 0% (0/25) of eyes treated with a phakic IOL and 8% (2/25) of LASIK-treated eyes at 1-year follow-up (significance not stated)[1].

A case series of 1140 eyes implanted with a phakic IOL reported that 1% (10/1179) of eyes required the phakic IOL to be reattached to the iris. In 5 eyes this was due to poor fixation and in 5 eyes it was due to trauma[5]. In the same study raised intraocular pressure (IOP) of >30 mmHg was reported in 2% (18/1140) of eyes; however, this did not persist past 20 days in any patient.

A case series of 399 eyes reported that mean endothelial cell density decreased significantly from 2836 ± 398 cells/mm$^2$ at baseline to 2791 ± 246 cells/mm$^2$ at 4-year follow-up following insertion of one type of phakic IOL to treat myopia (p = 0.004), and from 2755 ± 362 cells/mm$^2$ to 2698 ± 576 cells/mm$^2$ at the same timepoint following insertion of a second type of phakic IOL (p = 0.002)[7]. In the same study explantation because of endothelial cell loss was necessary in 1% (3/399) of eyes.

A case series of 263 eyes implanted with a phakic IOL reported that there were halo and glare symptoms in 60% (157/263) of treated eyes at 1-year follow-up, and in 20% (54/263) of eyes this was recorded as a significant complaint[8].

A case report described vitreous heamorrhage following phakic IOL implantation in one eye at 1-day follow-up and in another eye at 18-day follow-up[9]. A second case report describes a zonular tear and partial dislocation of the phakic IOL into the vitreous cavity at 28-month follow-up[10], and a third case report records raised IOP of 54 mmHg at 3-day follow-up which persisted despite medical management[11]. All of these eyes required further surgical intervention.

# Literature review

## *Rapid review of literature*

The medical literature was searched to identify studies and reviews relevant to intraocular lens insertion with preservation of the natural lens. Searches were conducted via the following databases, covering the period from their commencement to 14 May 2008: 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.<br>Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study.<br>Conference abstracts were also excluded because of the difficulty of appraising methodology. |
| Patient | Patients with refractive error, myopia, astigmatism, hypermetropia, anisometropic amblyopia or presbyopia |
| Intervention/test | Intraocular lens insertion with preservation of the natural lens |
| 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 one meta analysis[6], two randomised controlled trials[3,1], two non-randomised controlled trials[2,4], three case series[5,8,7], and three case reports[9,10,11] totaling 8719 eyes treated with this procedure.

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 reviews identified at the time of the literature search.

## *Related NICE guidance*

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed below.

### Interventional procedures

- Implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery. NICE interventional procedures guidance IPG264 (2008).Available from www.nice.org.uk/IPG264
- Implantation of accommodating intraocular lenses for cataract. NICE interventional procedures guidance IPG209 (2007). Available from www.nice.org.uk/IPG209

- Corneal implants for the correction of refractive error. NICE interventional procedures guidance IPG225 (2007). Available from www.nice.org.uk/IPG225
- Photorefractive (laser) surgery for the correction of refractive errors. NICE interventional procedures guidance IPG164 (2006). Available from www.nice.org.uk/IPG164

### Technology appraisals

- None

### Clinical guidelines

- None

### Public health guidance

- None

## Table 2 Summary of key efficacy and safety findings on intraocular lens insertion for correction of refractive error, with preservation of the natural lens

Abbreviations used: BSCVA, best spectacle corrected visual acuity; IOL, intraocular lens; IOP, intraocular pressure; LASIK, laser in situ keratomileusis; MRSE, manifest refraction spherical equivalent; NS, not significant; PRK, photorefractive keratectomy; UCVA, uncorrected visual acuity

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| Chen L-J (2008) [6]<br><br>**Meta-analysis**<br><br>USA and Taiwan<br><br>**n = 6338 eyes (n = 1161 eyes angle-fixated anterior chamber, n = 2781 eyes iris-fixated anterior chamber, n = 2396 eyes posterior chamber)**<br><br>Study period: not stated.<br><br>Study aim: to study outcomes of phakic IOL surgery to determine the location, incidence, and outcomes of new onset and progressive cataracts.<br><br>Population: mean age = 36 years, male = 40%.<br><br>Intervention: insertion of various types of phakic IOLs. Description of technique not described for each.<br><br>**Median follow-up: 1 year**<br><br>Disclosure of interest: none | Efficacy outcomes were not reported on | **Complications**<br>Crude event rate summed across all studies<br><br>Halos/glare: Angle-fixated anterior chamber IOL 25% (294/1161); Iris-fixated anterior chamber IOL 9% (244/2781); Posterior chamber IOL 6% (142/2396)<br>Raised IOP: 11% (129/1161); 4% (118/2781); 5% (115/2396)<br>Uveitis: 4% (41/1161); 4% (125/2781); <1% (3/2396)<br>Cataracts: 1% (16/1161); 1% (41/2781); 11% (262/2396)<br>New onset cataracts: 1% (15/1161); <1% (20/2781); 9% (223/2396)<br><br>Of the new-onset cataracts the predominant type was nuclear sclerotic cataract in the angle-fixated (60%) and iris-fixated (50%) anterior chamber group, while in the posterior chamber group anterior subcapsular cataract was the most common type (91%).<br><br>Surgery was needed in 31% (63 eyes) of patients with anterior subcapsular cataract in the posterior chamber group. | Some of these patients are the same as reported in other case series described in this overview. However additional/new patients are described here.<br><br>Medline search only from 1966 to 2006.<br><br>Minimal study quality appraisal undertaken.<br><br>Not clear if duplicate study selection or data extraction was performed.<br><br>Not clear whether the definitions of outcomes was the same across all studies. |

Abbreviations used: BSCVA, best spectacle corrected visual acuity; IOL, intraocular lens; IOP, intraocular pressure; LASIK, laser in situ keratomileusis; MRSE, manifest refraction spherical equivalent; NS, not significant; PRK, photorefractive keratectomy; UCVA, uncorrected visual acuity

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| Schallhorn S (2007)[3]<br><br>**Randomised controlled trial**<br><br>USA<br><br>**n = 88 eyes (n = 43 eyes phakic IOL)**<br><br>Study period: not stated.<br><br>Study aim: to study outcomes of PRK and toric phakic IOL for the correction of moderate to high myopic astigmatism.<br><br>Population: mean age = 31 years, male = 60%. Patients with moderate to high myopia (–6 to –20 D) with astigmatism in the range 1 D to 4 D, and BSCVA of 20/40 or better in the best eye, with stable refraction for 12 months. No previous intraocular surgery.<br><br>Intervention: insertion of the Visian toric IOL following papillary dilatation with a cycloplegic agent, and local anesthetic, via a 3 mm horizontal corneal incision, posterior to the iris plane. Topical Ocuflux and systemic prednisolone given. Vs PRK with a traditional technique and mitomycin C adjunct followed by bandage soft contact lens topical antibiotics and artificial tears.<br><br>**Median follow-up: 1 year**<br><br>Disclosure of interest: one author is supported by manufacturer. | **Visual acuity**<br>Mean BSCVA (20/20) or better<br>Baseline / 1 year<br>Toric IOL: 93% (40/43) / 100% (38/38)<br>PRK: 89% (41/46) / 96% (42/44)<br>p: 0.715 / 0.497<br><br>Mean BSCVA (20/12.5) or better<br>Baseline / 1 year<br>Toric IOL: 2% (1/43) / 71% (27/38)<br>PRK: 2% (1/46) / 14% (6/44)<br>p: 1.0 / <0.001<br><br>Mean UCVA (20/20) or better 1-year follow-up<br>Toric IOL: 97% (37/38)<br>PRK: 82% (36/44)<br>p: 0.033<br><br>Mean UCVA (20/12.5) or better 1-year follow-up<br>Toric IOL: 47% (18/38)<br>PRK: 9% (4/44)<br>p: <0.001<br><br>Predictability of correction (achieved correction within 0.5 D of intended):<br>Up to 6 months follow-up:<br>Significantly better in the toric IOL group than the PRK group for all time points.<br>At 12-month follow-up:<br>Achieved in 76% (29/38) of the toric IOL group and 57% (25/44) of the PRK group (p = 0.101). | **Complications**<br><br>Procedure-related loss of acuity<br>Loss of 2 lines of BSCVA<br>Toric IOL / PRK / p<br>1 week: 0% (0/42) / 19% (8/43) / 0.006<br>1 month: 0% (0/42) / 4% (2/46) / 0.495<br>3 months: 0% (0/40) / 0% (0/44) / 1.000<br>6 months: 0% (0/33) / 0% (0/39) / 1.000<br>12 months: 0% (0/38) / 0% (0/44) / 1.000<br><br>Adverse events<br>A grade 2 anterior subcapsular cataract was noted in 2% (1/43) of eyes at 2-year follow-up. The patients underwent successful removal of the toric IOL and cataract, and a pseudo phakic IOL was implanted.<br><br>Visually insignificant anterior lens opacity was reported in 2% (1/43) of eyes at 1-month follow-up. This was not associated with loss of BSCVA (20/16) and UCVA was 20/20. Opacity did not change throughout the rest of the follow up-period.<br><br>There were no other adverse events reported in either group. | Toric IOLs were studied to correct astigmatism.<br><br>There were no differences between groups at baseline in terms of MRSE, astigmatism or demographic characteristics.<br><br>No details were provided of suturing of the incision post-toric IOL implantation.<br><br>Outcomes were collected from a standardised case report form. It was not stated whether collection was prospective or retrospective.<br><br>The proportion of patients available for evaluation at each follow-up time point varied from point to point. At 1-year follow-up 96% of the PRK group and 88% of the toric phakic IOL group were assessed.<br><br>UCVA was not evaluated at baseline for either group. |

Abbreviations used: BSCVA, best spectacle corrected visual acuity; IOL, intraocular lens; IOP, intraocular pressure; LASIK, laser in situ keratomileusis; MRSE, manifest refraction spherical equivalent; NS, not significant; PRK, photorefractive keratectomy; UCVA, uncorrected visual acuity

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| Schallhorn S (2007) cont. | **Refractive outcomes**<br><br>MRSE: Toric IOL: Baseline –8.04 ±1.28 D; 6 months 0.28 ±0.41 D; 1 year 0.27 ±0.36 D<br>PRK: Baseline –8.30 ±1.28 D; 6 months 0.76 ±0.86 D; 1 year 0.60 ±0.75 D<br>p: 0.640; 0.005; 0.541<br><br>Astigmatic cylinder: Toric IOL: Baseline 1.73 ±0.62 D; I week 0.52 ±0.39 D; 1 year 0.27 ±0.36<br>PRK: Baseline 1.73 ±0.73 D; I week 0.80 ±0.34 D; 1 year 0.52 ±0.34 D<br>p: 0.961; 0.020; 0.759<br><br>Stability of manifest refraction <0.5 D<br><br>Toric IOL / PRK / p<br>1 week–1 month: 93% (39/42) / 44% (19/43) / <0.001<br>1 month–3 months: 85% (34/40) / 57% (25/44) / 0.008<br>3 months–6 months: 91% (30/33) / 59% (23/39) / 0.003<br>6 months–12 months: 94% (31/33) / 85% (33/39) / 0.275 | Patients completed standardised subjective questionnaires. Symptoms were rated on a 1 to 10 scale from 'none' to 'extreme difficulty', except use of artificial tears which was rated on a 1 to 5 scale from 'no use' to '4 times a day or more'.<br><br>Results at 3 to 6 months' follow-up.<br><br>Median score / Toric IOL n = 22 / PRK n = 30 / p<br>Artificial tears use: 2 / 1 / 0.002<br>Vision fluctuation (not defined): 2 / 1 / 0.001<br>Glare symptoms at night: 3 / 2 / 0.33<br>Glare from oncoming car headlights: 3 / 2 / 0.014<br>Absolute figures not stated.<br><br>All other symptoms were not significantly different between groups at 3 to 6 months' follow-up. | Blinding of outcomes assessment is not stated.<br><br>The method of randomisation and allocation concealment is not stated.<br><br>No explanation is given for the numbers available for evaluation at each time point for any outcome. |

Abbreviations used: BSCVA, best spectacle corrected visual acuity; IOL, intraocular lens; IOP, intraocular pressure; LASIK, laser in situ keratomileusis; MRSE, manifest refraction spherical equivalent; NS, not significant; PRK, photorefractive keratectomy; UCVA, uncorrected visual acuity

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| Malecaze F J (2002)[1]<br>**Randomised controlled trial**<br>France and Spain<br>**n = 50 eyes (n = 25 eyes phakic IOL)**<br>Study period: not stated.<br>Study aim: to compare the refractive optical performance and safety of a phakic iris supported lens and LASIK for the treatment of –8 to –12 D of myopia.<br>Population: mean age = 38 years, male = 32%. Patients with moderate to high myopia (–8 to –12 D) with <1.5 D astigmatism, corneal thickness ≥530 µm. Myopia stable for 2 years, and no corneal disease or retinal detachment.<br>Intervention: target correction was emmetropia for both interventions. Insertion of the Artisan Phakic IOL following local anesthetic, via a 6.2 mm posterior corneal incision and attachment to the iris by claws on the lens. 5 or 6 nylon sutures used to close the incision. Topical cloramphenicol and prednisolone given. Vs LASIK microkeratome followed by topical antibiotics in fellow eye.<br>**Median follow-up: 1 year**<br>Disclosure of interest: one author is supported by manufacturer. | **Refractive outcomes**<br>Mean (standard deviation) MRSE<br>Baseline / 1 year<br>Phakic IOL: –10.19±1.56 D / –0.95±0.45 D<br>LASIK: –9.39 ±1.47 D / –0.74±0.67 D<br>p: NS / NS<br>Predictability of correction (achieved correction within 1.0 D of intended) was evident in 60% (15/25) of phakic IOL-treated eyes, and 64% (16/25) of LASIK-treated eyes at 1-year follow-up.<br>Mean (standard deviation) astigmatic cylinder (measure of astigmatism strength)<br>Baseline / 1 year<br>Phakic IOL: 0.73±0.34 D / 0.75±0.56 D<br>LASIK: 0.83±0.75 D / 0.42±0.55 D<br>p: NS / <0.01<br>**Visual acuity**<br>There were no statistically significant differences between the groups of eyes in efficacy at any time point up to 1 year.<br>Mean UCVA (20/25) or better 1-year follow-up<br>Phakic IOL: 20% (5/25)<br>LASIK: 24% (6/25)<br>p: 0.73<br>Mean UCVA (20/40) or better 1-year follow-up<br>Phakic IOL: 60% (15/25)<br>LASIK: 80% (20/25)<br>p: 0.12 | **Complications**<br>There were no significant adverse events reported in either group.<br>0% (0/25) of eyes in the phakic IOL group and 8% (2/25) of eyes in the LASIK group reported loss of 2 or more lines of BSCVA (significance not stated).<br>The safety index (mean postoperative BSCVA over the mean baseline BSCVA) was significantly higher with the phakic IOL (1.12±0.21) than following LASIK treatment (0.99±0.17) (p<0.02).<br>Mean (standard deviation) intraocular pressure (mmHg) at 1-year follow-up<br>Baseline / 1 year / p<br>Phakic IOL: 15.3 ±2.4 / 13.4 ±4.44 / NS<br>LASIK: 15.1 ±2.77 / 8.0 ±2.3 / <0.01<br>Mean endothelial cell loss at 1-year follow-up<br>Phakic IOL: 1.76±12.05%<br>LASIK: 0.42±11.95 %<br>p: 0.60<br>There were no statistically significant differences between the groups in terms of contrast sensitivity at 1-year follow-up.<br>There was no statistically significant difference in frequency of halos (p = 0.30) or glare (p = 0.20) between the groups. | Two clinicians undertook all the procedures; the same surgeon treated both eyes.<br>The order of treatment of the first eye with LASIK or phakic IOL was generated by random number tables.<br>Outcome evaluators did not take part in the surgical process and measurements were made double blind. Independent investigators undertook split lamp examination and corneal topography testing.<br>Power calculation at 70% was used to determine the sample size.<br>All patients completed the study at 1-year follow-up; 5 were unavailable at 6-month follow-up time point.<br>There were no differences at baseline in ophthalmic characteristics between the eyes.<br>Authors state that 1-year follow-up may be too short to evaluate the effect on the endothelium. |

Abbreviations used: BSCVA, best spectacle corrected visual acuity; IOL, intraocular lens; IOP, intraocular pressure; LASIK, laser in situ keratomileusis; MRSE, manifest refraction spherical equivalent; NS, not significant; PRK, photorefractive keratectomy; UCVA, uncorrected visual acuity

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| Ruiz-Moreno J M (2003)[2]<br><br>**Non-randomised controlled trial**<br><br>Spain<br><br>**n = 9239 eyes (n = 294 eyes phakic IOL, n = 5936 PRK, n = 3009 LASIK)**<br><br>Study period: April 1992 to Dec 2000.<br><br>Study aim: to analyse the incidence, characteristics and potential mechanisms of retinal disease in myopic patients following LASIK, PRK, or phakic IOLs.<br><br>Population: mean age = 31 years, male = 41%. Patients with stable myopia, unsuccessful attempt to wear contact lenses, BSCVA ≥0.05 (20/400) corneal thickness sufficient for LASIK or PRK. Patients who had previous radial keratotomy or cataract surgery were included; those with corneal disease, glaucoma or ocular trauma were excluded.<br><br>Intervention: insertion of the Baikoff, Morcher, Nuvita or Artisan phakic IOL into the anterior chamber (no further details stated). Vs LASIK Vs PRK using standard protocol.<br><br>**Mean follow-up: 67 months for PRK, 64 months for LASIK and 57 months for phakic IOLs**<br><br>Disclosure of interest: none. | **Refractive outcomes**<br>Mean (standard deviation) MRSE<br>Baseline / Postoperative<br>Phakic IOL: –18.50±5.00 D / –1.78±2.30 D<br>LASIK: –13.50±3.30 D / 0.36±1.30 D<br>PRK: –4.71±2.80 D / –0.18±0.50 D<br>Significance not stated. | **Complications**<br>Outcome / Phakic IOL / LASIK / PRK<br>Retinal detachment: 4% (12/294) / <1% (11/3009) / <1% (9/5936)<br>Mean time to detachment (months): 20.5± 17.4 / 24.6±20.4 / 53.6± 41.1<br>Successful reattach-ment first attempt: 92% (11/12) / 91% (10/11) / 89% (8/9)<br>Choroidal neo vascular-risation: 2% (7/294) / <1% (10/3009) / <1% (1/5936)<br>Epiretinal membrane: <1% (1/294) / 0% (0/3009) / 0% (0/5963)<br>Significance not stated.<br><br>In no patients with phakic IOL was it necessary to explant the lens during retinal surgery.<br><br>Regression analysis demonstrated a statistically significant correlation between retinal detachment and axial length (p = 0.039) (not stated whether short or long axis was safer). | All patients were treated at one site.<br><br>Operator experience was not stated.<br><br>The procedure was selected for each patient according to spherical equivalent, refraction, corneal thickness and biometry. It is likely therefore that there was clinical heterogeneity between the groups.<br><br>Some patients received more than one type of correction procedure. |

Abbreviations used: BSCVA, best spectacle corrected visual acuity; IOL, intraocular lens; IOP, intraocular pressure; LASIK, laser in situ keratomileusis; MRSE, manifest refraction spherical equivalent; NS, not significant; PRK, photorefractive keratectomy; UCVA, uncorrected visual acuity

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| Sanders D R (2003)[4]<br><br>**Non-randomised controlled trial**<br><br>USA<br><br>**n = 769 eyes (n = 210 eyes phakic IOL)**<br><br>Study period: Dec 1998 to Jun 2001.<br><br>Study aim: to compare the clinical outcomes following LASIK or phakic IOL insertion for correction of moderate to high myopic refractive errors.<br><br>Population: mean age = 38 years, male = 62%.<br><br>Intervention: insertion of the V4 implantable contact lens (STAAR) into the anterior chamber following dilating and cycloplegic agents, and local anesthetic, via a 3 mm corneal incision, lens footplates were tucked under the iris. Topical Ocuflux drops given. Vs LASIK using standard protocol.<br><br>**Mean follow-up: to 1 year**<br><br>Disclosure of interest: funded by manufacturer. | **Refractive outcomes**<br>BSCVA 20/20 or better %<br>Phakic IOL / LASIK / p<br>Baseline: 75% (157/210) / 82% (456/559) / 0.04<br>1 week: 82% (167/203) / 60% (240/401) / <0.001<br>6 months: 89% (175/196) / 82% (297/361) / 0.008<br>1 year: 90% (165/184) / 82% (77/94) / 0.09<br>Change in BSCVA lines (mean and SE)<br>Phakic IOL / LASIK / p<br>1 week: 0.26±0.064 / –0.40±0.052 / <0.001<br>6 months: 0.52±0.056 / 0.07±0.042 / <0.001<br>1 year: 0.48±0.054 / 0.20±0.067 / 0.001<br>UCVA 20/20 or better %<br>Phakic IOL / LASIK / p<br>1 day: 24% (51/210) / 16% (80/506) / 0.01<br>1 week: 38% (77/204) / 26% (108/420) / 0.002<br>6 months: 50% (98/197) / 35% (131/376) / <0.001<br>1 year: 52% (96/185) / 36% (36/100) / 0.01<br>Change in UCVA lines (mean)<br>Phakic IOL / LASIK / p<br>1 week: 10.25 / 9.91 / 0.004<br>6 months: 10.82 / 9.84 / <0.001<br>1 year: 10.91 / 10.15 / 0.002<br>Correction within 0.5 D of intended<br>Phakic IOL / LASIK / p<br>1 week: 68% (138/202) / 60% (250/420) / 0.03<br>6 months: 65% (127/196) / 53% (200/378) / 0.007<br>1 year: 69% (127/184) / 57% (57/100) / 0.05 | **Complications**<br>Loss of ≥2 lines BSCVA %<br>Phakic IOL / LASIK / p<br>1 week: 2% (5/203) / 11% (45/401) / <0.001<br>6 months: 0% (0/196) / 2% (8/361) / 0.008<br>1 year: 0% (0/184) / 0% (0/94) / 0.09<br><br>Phakic IOL / LASIK<br>Repeat surgery for enhancement: 0% (0/210) / 23% (128/559)<br>Repositioning of lens: <1% (1/210) / 0% (0/559)<br>Explant or replacement lens: 0% (0/210) / 0% (0/559)<br>Clinically significant lens opacity: 0% (0/210) / 0% (0/559)<br>Secondary LASIK procedure: 4% (9/210) / 0% (0/559)<br>Astigmatic keratotomy: 1% (2/210) / 0% (0/559)<br>Diffuse lamellar keratitis: 0% (0/210) / 3% (17/559)<br>Striae in corneal flap: 0% (0/210) / 3% (17/559)<br>Striae requiring surgery: 0% (0/210) / 2% (12/559)<br>Free cap – no loss of BSCVA: 0% (0/210) / <1% (1/559) | Phakic IOL insertion was undertaken at 14 sites participating in the FDA clinical trial. All LASIK procedures were undertaken by 11 surgeons at one centre.<br><br>Patients in the LASIK group were significantly older than those in the phakic IOL group by a mean of 1.5 years ($p = 0.001$), and were less myopic by 0.7 D ($p < 0.001$).<br><br>Follow-up in the LASIK group was 69% at 6 months, and 18% at 1 year; follow-up in the phakic IOL group was 97% and 88% respectively. Analysis reported that there was no significant difference between patients that were available for follow-up at 1 year and those that had shorter follow-up in terms of change in BSVA, UCVA or predictability of correction. |

Abbreviations used: BSCVA, best spectacle corrected visual acuity; IOL, intraocular lens; IOP, intraocular pressure; LASIK, laser in situ keratomileusis; MRSE, manifest refraction spherical equivalent; NS, not significant; PRK, photorefractive keratectomy; UCVA, uncorrected visual acuity

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| Stulting R D (2008)[5]<br><br>**Case series**<br><br>USA<br><br>**n = 1140 eyes**<br><br>Study period: Oct 1997 to Jul 2003.<br><br>Study aim: to determine safety and efficacy of a phakic IOL to treat axial myopia.<br><br>Population: age = 40 years, male = not stated. Patients with stable myopia no more than 0.5 D change in 1 month, unsatisfactory vision with contact lenses or spectacles. Patients with myopia (–4.5 to –22 D) with <2.0 D astigmatism, anterior chamber depth ≥3.2 mm, pupil size ≤4.5 mm, and endothelial cell count of ≥2000 cells/mm$^2$.<br><br>Intervention: insertion of a phakic IOL (Verisye) into the anterior chamber with a 5.2 to 6.2 mm corneal, limbal or scleral incision, and attachment to the midperipheral iris stroma. Postoperative medication at the discretion of the surgeon.<br><br>**Follow-up: to 3 years**<br><br>Disclosure of interest: study sponsored by a manufacturer. | **Refractive outcomes**<br>Accuracy of correction compared to intended<br>Within 1 D / Within 0.5 D<br>6 months: 65% / 72%<br>Absolute numbers not stated.<br><br>**Visual acuity**<br>UCVA: first eye<br>Baseline / 3 years<br>20/10: 0% (0/622) / 0% (0/231)<br>20/15: 0% (0/622) / 4% (10/231)<br>20/20: 0% (0/622) / 27% (62/231)<br>20/25: 0% (0/622) / 21% (48/231)<br>20/30: 0% (0/622) / 19% (44/231)<br>20/40: 0% (0/622) / 13% (30/231)<br>>20/40: 100% (622/622) / 16% (37/231)<br>Measurement of significance not reported. | **Complications**<br>Of the 622 first eyes treated, 98% (652/662) eyes had no surgical complications. Iris prolapse occurred in 1% (7/622) of eyes (no further details provided), and detached Descemet's membrane, reaction to anesthesia, and lens repositioning occurred in <1% (1/622) of eyes respectively.<br><br><1% (10/1179) of eyes required the lens to be reattached to the iris, in 5 eyes due to inadequate fixation and in 5 eyes due to trauma.<br><br>Retinal repair was required in <1% (6/1179) of eyes due to detachment in 4 eyes and macular hole in 2 eyes<br><br>2% (25/1179) of eyes had the phakic IOL explanted or replaced. Follow-up not stated.<br><br>Secondary refractive procedures were required in 7% (16/230) of eyes – acute keratotomy in 3 eyes, LASIK in 11 eyes, limbal relaxing surgery in 1 eye, and PRK in 1 eye. Time of follow-up to surgery not stated.<br><br>Loss of ≥2 lines BSCVA / Induced astigmatism >2 D<br>1 year: 1% (3/493) / 2% (12/492)<br>2 years: <1% (1/355) / 2% (7/355)<br>3 years: 1% (2/228) / 3.5% (8/226)<br><br>Contrast sensitivity data were obtained in 57 eyes of 31 patients. No sensitivity decrease was seen under photopic conditions (good light), photopic conditions with glare, and mesopic conditions. | Prospective open label trial.<br><br>Patients were selected from the patient population seeking refractive surgery.<br><br>Good description of subject accountability. 5% (59/1140) loss to follow-up.<br><br>Two different models of IOL were used in this series.<br><br>The number of eyes available for outcome analysis varied between the outcomes reported on.<br><br>Half of the adverse events occurred during the first 10 patients treated by each surgeon, most due to incorrect lens fixation. |

| Abbreviations used: BSCVA, best spectacle corrected visual acuity; IOL, intraocular lens; IOP, intraocular pressure; LASIK, laser in situ keratomileusis; MRSE, manifest refraction spherical equivalent; NS, not significant; PRK, photorefractive keratectomy; UCVA, uncorrected visual acuity | | | |
|---|---|---|---|
| **Study details** | **Key efficacy findings** | **Key safety findings** | **Comments** |
| Stulting R D (2008) cont. | | 2% (18/1140) of eyes treated had IOP >30 mmHg during follow-up. Most occurred on the first postoperative day and none persisted beyond 20 days' follow-up.<br><br>Iris pigment precipitates were seen in 9% (61/645) of eyes at 1 to 2 months' follow-up, but in no eyes at 3-year follow-up.<br><br>Corneal oedema was noted in 19% (128/660) of eyes at 1-day follow-up, and 2% (14/630) of eyes at 2-week follow-up. Most occurrences were described as mild.<br><br>Asymptomatic oval pupil was reported in 13% (86/660) of eyes at 1-day follow-up, 2% (10/581) at 4- to 6-month follow-up, and in 1 eye at 3-year follow-up. | |

Abbreviations used: BSCVA, best spectacle corrected visual acuity; IOL, intraocular lens; IOP, intraocular pressure; LASIK, laser in situ keratomileusis; MRSE, manifest refraction spherical equivalent; NS, not significant; PRK, photorefractive keratectomy; UCVA, uncorrected visual acuity

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| Guell J L (2008) [7]<br><br>**Case series**<br><br>Spain<br><br>**n = 205 (n = 399 eyes)**<br><br>Study period: Jan 1996 to Jan 2003<br><br>Study aim: to report the refractive, efficacy, and safety outcomes of patient implanted with a phakic IOL<br><br>Population: age = 33 years, male = 52%. Patients with myopia (n = 274 eyes), hyperopia (41 eyes) and/or astigmatism (84 eyes).<br><br>Intervention: insertion of a phakic IOL (Artisan iris claw) not otherwise described. Additional corneal refractive surgery was scheduled in some patients to adjust for residual refractive errors.<br><br>**Mean follow-up: 4 years**<br><br>Disclosure of interest: none | **Visual acuity**<br>Mean BSCVA<br>Group 1 – 5 mm IOL for myopia (n = 101)<br>Baseline: 20/50 ± 20/150<br>3 months postoperatively: 71% eyes (20/40)<br><br>Group 2 – 6 mm IOL for myopia (n = 173)<br>Baseline: 20/530 ± 20/90<br>3 months postoperatively: 17% (20/20 or better), 83% (20/40)<br><br>Group 3 – 5 mm IOL for hyperopia (n = 41)<br>Baseline: 20/35 ± 20/90<br>3 months postoperatively: 17% (20/20 or better), 76% (20/40)<br><br>Group 4 – toric IOL for astigmatism (n = 84)<br>Baseline: 20/30 ± 20/100<br>3 months postoperatively: 26% (20/20 or better), 86% (20/40) | **Complications**<br>Endothelial cell loss (mean scores) cell/mm$^2$<br><br>\| | Baseline | 1 year | 4 years \|<br>\| Group 1 \| 2836±398 \| 2598±350 \| 2791±246* \|<br>\| Group 2 \| 2755±362 \| 2643±414 \| 2698±576† \|<br>\| Group 3 \| 2735±355 \| 2600±442 \| 2560±335 \|<br>\| Group 4 \| 2632±543 \| 2673±439 \| Not available \|<br><br>* p = 0.004 vs baseline<br>† p = 0.002 vs baseline<br><br>Explantation because of endothelial cell loss was necessary in 1% (3/399) eyes; all these eyes were in group 1 in which a 5 mm lens was inserted for myopia. | Retrospective case series<br><br>Consecutive patients treated.<br><br>Loss to follow-up/patients available at each follow-up point is well described. |

Abbreviations used: BSCVA, best spectacle corrected visual acuity; IOL, intraocular lens; IOP, intraocular pressure; LASIK, laser in situ keratomileusis; MRSE, manifest refraction spherical equivalent; NS, not significant; PRK, photorefractive keratectomy; UCVA, uncorrected visual acuity

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| Alio J L (1999)[8]<br><br>**Case series**<br><br>Spain<br><br>**n = 160 (n = 263 eyes)**<br><br>Study period: Oct 1990 onwards.<br><br>Study aim: to report the outcomes for a group of patients implanted with a phakic IOL to ascertain the potential complications.<br><br>Population: age = not stated, male = not stated. Patients with stable myopia with BSCVA of 20/200 or better, anterior chamber depth ≥3.4 mm, and endothelial cell count of ≥2250 cells/mm$^2$. Exclusion criteria included cataract, glaucoma or IOP >20 mmHg, or personal or family history of retinal detachment.<br><br>Intervention: Insertion of a phakic IOL (ZB5M/F Chiron Domilens or ZSAL-4 Morcher) into the anterior chamber with a 6.0 mm limbal incision and peripheral iridotomy. Incision closed with a nylon suture with subtenon injection of gentamicin given. Postoperative medication: cyclopentolate, dexamethasone and neomycin.<br><br>**Mean follow-up: 4.9 years**<br><br>Disclosure of interest: none. | No efficacy outcomes are stated. | **Complications**<br>Halos and glare were reported in 60% (157/263) of eyes at 1 year, and these were considered 'significant' in 21% (54/263) eyes at this time point. At 7-year follow-up only 10% considered this significant (absolute numbers not stated).<br><br>Acute postoperative anterior uveitis was observed in 5% (12/263) of eyes, at a mean period of 3.2 days. None of these patients reported pain.<br><br>Elevated IOP of >21 mmHg requiring administration of antiglaucoma treatment was reported in 7% (19/263) of eyes. No eye required surgery to control IOP elevation. Kaplan-Meier survival analysis demonstrated that 86.54% of eyes were expected to have a normal IOP at 84-month follow-up.<br><br>Mean endothelial cell density — p<br>Baseline — 2715.44±393.68 cells/mm$^2$<br>3 months — 2690.13±395.08 cells/mm$^2$ — <0.05<br>1 year — 2640.67±414.19 cells/ mm$^2$ — <0.0001<br>(p value describes significance of change since last measurement time point)<br>Significant decreases in cell loss were recorded for all time points up to 7-year follow-up. Kaplan-Meier survival analysis demonstrated that 98.7% of eyes were expected to have a cell density higher than 1500 cells/mm$^2$ at 84-month follow-up.<br>Significant pupil ovalisation occurred in 6% (16/263) of eyes, and in 9 of these eyes the ovalisation occurred along the main axis of the phakic IOL. Ten eyes demonstrated areas of iris atrophy (length of follow-up not stated).<br>In 4% (11/263) of eyes the phakic IOL was explanted, in 9 eyes because of the development of cataracts, and in 2 because of unbearable night glare.<br>Retinal detachment was reported in 3% (8/263) of eyes. There was no significant correlation between detachment and gender, size, or type of phakic IOL. Survival analysis predicts that 95.43% of eyes will not experience retinal detachment at 84-month follow-up. | Prospective case series of consecutive patients treated by two surgeons.<br><br>Patients were selected for phakic IOL as being those that were not treatable by corneal refractive surgery available at the participating centre.<br><br>Patients with complications were examined more frequently than per protocol.<br><br>No eyes were lost to follow-up at 3 months; at 5 years 41 eyes were available for analysis and 17 were lost to follow-up. At 7 years 33 eyes were available for analysis and 25 were lost to follow-up. No reasons for loss to follow-up were given and no analysis was done to compare short-term outcomes between those that continued to attend and those that were lost to follow-up. |

Abbreviations used: BSCVA, best spectacle corrected visual acuity; IOL, intraocular lens; IOP, intraocular pressure; LASIK, laser in situ keratomileusis; MRSE, manifest refraction spherical equivalent; NS, not significant; PRK, photorefractive keratectomy; UCVA, uncorrected visual acuity

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| Nuzzi G (2002)[9]<br><br>**Case report**<br><br>Italy<br><br>**n = 2 (n = 4 eyes)**<br><br>Study period: not stated.<br><br>Study aim: to describe adverse outcomes.<br><br>Population: age = 35 years, male = 100%. Refraction –11.50 D to –16.00 D. BSCVA 20/25 to 20/40.<br><br>Intervention: bilateral insertion of the phakic myopic lens (Worst myopia iris claw lens) into the anterior chamber. No further details stated.<br><br>**Follow-up: to 2 years**<br><br>Disclosure of interest: not stated. | None stated. | **Case 1**<br>No intraoperative or immediate postoperative complications were reported.<br><br>Patient referred at 18-day follow-up with vitreous heamorrhage in the right eye. At 29-day follow-up examination found visual acuity was hand motion. The anterior segment was normal and the crystalline lens was clear. A massive vitreous heamorrhage precluded fundus examination. The retina was found to be attached on ultrasound examination. The left eye which had had a phakic lens implanted 14 months earlier was without complications.<br><br>The vitreous heamorrhage was unchanged at 3 months, so a pars plana vitrectomy was performed in order to clear it. Three days later pinhole vision was 20/200.<br><br>**Case 2**<br>No intraoperative complications were reported. Vitreous heamorrhage occurred in the left eye on the first day after lens implantation. Scan revealed a posterior vitreous detachment with thickening of the posterior hyaloids and attached retina.<br><br>At 69-day follow-up the patient had hand motion visual acuity with no anterior segment complications or lens opacity. Massive vitreous heamorrhage was present and the retina was not visible. Four days later pars plana vitrectomy was performed. The pupil size and the presence of the phakic lens and crystalline lens prevented full peripheral vitrectomy.<br><br>Total retinal detachment was found with grade C proliferative vitreoretinopathy, and an equatorial U-shaped retinal break at 10 o'clock. The retina was reattached, and 5 days later vision had improved to finger movement. The retina detached again in the lower quadrant by 6-week follow-up and a subcapsular cataract was present. A second procedure was undertaken to extract the phakic lens and crystalline lens; the retina was successfully reattached and at a further 2 years' follow-up BSCVA was 20/80. | Operator experience was not stated. The patients were initially implanted with phakic IOL at private clinics.<br><br>The total number of procedures undertaken of which these two cases are presented is not reported, so frequency of these complications is unknown.<br><br>Authors state that it is unclear whether the retinal tear developed due to intraoperative phakic IOL placement manoeuvres, or later, after retinal traction exerted by posterior vitreous detachment. |

Abbreviations used: BSCVA, best spectacle corrected visual acuity; IOL, intraocular lens; IOP, intraocular pressure; LASIK, laser in situ keratomileusis; MRSE, manifest refraction spherical equivalent; NS, not significant; PRK, photorefractive keratectomy; UCVA, uncorrected visual acuity

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| Hoyos J E (2005)[10]<br><br>**Case report**<br><br>Spain<br><br>**n = 1 (n = 2 eyes)**<br><br>Study period: 2001.<br><br>Study aim: to describe adverse outcomes.<br><br>Population: age = 31 years, male = not stated. Refraction –12.75 D in the right eye and –10.50 D in the left eye. BSCVA 20/30 and 20/50 respectively. Anterior chamber depth 3.79 mm and 3.68 mm respectively, and white-to-white distance 12 mm in both eyes. Otherwise, eyes were normal.<br><br>Intervention: bilateral insertion of the phakic refractive lens (Medennium) into the posterior chamber, –11.0 D in the right eye and –15.5 D in the left eye, following local anesthetic, via a self sealing 3.5 mm corneal incision. Surgical iridectomy was performed with scissors in the 12 o'clock position.<br><br>**Median follow-up: 28 months**<br><br>Disclosure of interest: none. | **Visual acuity**<br>At 3-, 6- and 12-month follow-up UCVA was 20/25 in the right eye and 20/30 in the left eye, with the phakic refractive lens well centered. | **Complications**<br>No complications occurred during surgery or early postoperative period.<br><br>At 18-month follow-up a slight oblique decentration was recorded in the left eye.<br><br>The patient complained of halos and blurred vision in the left eye at 28-month follow-up, however UCVA was 20/40 with plano refraction. Split lamp examination revealed a significant oblique decentration of the phakic lens. A zonular tear and partial dislocation of the lens into the vitreous cavity was suspected. The decision was made to explant the lens.<br><br>Explantation was performed with local anaesthesia, and a 4 mm self sealing corneal incision. Using viscoelastic and forceps the lens was picked up by the optic and explanted without difficulty. There were no breaks or deformity in the lens. A zonular dehiscence was noted between 2 and 3 o'clock. | It is not clear how many cases (the denominator) have been undertaken at this institution.<br><br>Long-term surgical treatment to resolve refractive error was not described.<br><br>Previous surgical treatment was not described or excluded.<br><br>Authors state that they have stopped implanting phakic lenses until the cause of the complication is elucidated.<br><br>A second case is also described in the report, however this patient also received cataract surgery during lens implant so was not extracted here. |

Abbreviations used: BSCVA, best spectacle corrected visual acuity; IOL, intraocular lens; IOP, intraocular pressure; LASIK, laser in situ keratomileusis; MRSE, manifest refraction spherical equivalent; NS, not significant; PRK, photorefractive keratectomy; UCVA, uncorrected visual acuity

| Study details | Key efficacy findings | Key safety findings | Comments |
|---|---|---|---|
| Kodjikian L (2002)[11]<br><br>**Case report**<br><br>France<br><br>**n = 1 eye**<br><br>Study period: not stated.<br><br>Study aim: to describe adverse outcomes.<br><br>Population: age = 23 years, male = 0%. Refraction –14.00 D in right eye and –10.00 D in the left eye. BSCVA 20/20 in both eyes. Right eye anterior chamber depth 3.54 mm, and white-to-white distance 12.75 mm, endothelial cell count was 3000 cells/mm$^2$. The patient tolerated contact lenses but presented for refractive surgery for medical reasons. No ocular or medical history.<br><br>Intervention: 5 days prior to surgery laser iridotomies were performed. Pupils were dilated to 8.0 mm with topic agents. Right eye insertion of the phakic IOL (PC, Staar surgical) into the posterior chamber 16.00 D following local anesthetic, via a 3.2 mm temporal corneal incision. The 4 corners of the lens were positioned beneath the iris. Miochol was used to constrict the pupil. A topical steroid/antibiotic was given.<br><br>**Follow-up: 43 months**<br><br>Disclosure of interest: none. | None stated. | **Complications**<br>A slit lamp examination and intraocular pressure measurement at 6-hour and 1-day follow-up were normal.<br><br>At 3-day follow-up the patient reported intense pain and blurred vision in the right eye. Ocular examination showed a shallow anterior chamber, corneal oedema, and IOP of 54 mmHg, and the pupil was not reactive. Visual acuity was hand motion. Gonioscopy was difficult but revealed a completely closed angle.<br><br>Initial diagnosis was secondary angle-closure glaucoma caused by papillary block. Intravenous acetazolamide, mannitol and pilocarpine were administered for 3 hours.<br><br>A further ocular examination revealed that the iris was flat and not bowed forward, iridotomies were patent, and the anterior chamber was narrow. IOP was 50 mmHg. Ultrasound examination revealed no abnormalities such as subchoroidal heamorrhage, or effusion. Malignant glaucoma was diagnosed, and atropine cycloplegia was prescribed.<br><br>Despite medical treatment IOP remained at 50 mmHg. At 5-day follow-up surgery was performed with general anesthesia and radial sclerotomy. 1.5 cc clear liquid vitreous was aspirated from the midvitreous cavity by a needle and the IOL removed uneventfully. The next day the IOP was 12 mmHg and the cornea and crystalline lens were clear, although iris atrophy and partial mydriasis were noted.<br><br>At 43-month follow-up the BSCVA was 20/25 with a rigid gas permeable contact lens, and IOP was 14 mmHg. | No details were given of corneal suturing. |

### *Validity and generalisability of the studies*

- There is considerable variation in the procedure between studies; some lenses are implanted in the anterior chamber and some in the posterior chamber.
- A number of studies describe the use of a toric phakic IOL to treat patients with astigmatism.
- Phakic IOLs have been studied for use in a range of conditions that result in refractive error, namely myopia, hypermetropia, astigmatism and amblyopia.
- The technology is continuing to develop, with long term follow-up only available on older lens designs.
- One non-randomised controlled trial compared phakic IOLs with clear lens extraction and IOL (Arne 2004)[12] which is listed in appendix A.

## Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Dr R Chaudhuri (Royal College of Ophthalmologists), Dr S Daya (United Kingdom and Ireland Society for Cataracts and Refractive Surgeons), Dr D Reinstein (Royal College of Ophthalmologists).

- All three Specialist Advisers considered this procedure to be established and no longer new.
- One Specialist Adviser commented that the title should be changed to 'phakic intraocular lens insertion..' while the other two considered the current title to be adequate.
- The following known/anecdotal adverse events relating to the procedure were listed: incorrect sizing of the lens leading to stress to the posterior chamber anatomy and requirement for replacement; lens power calculation error; iritis; and subluxation during implantation.
- Other theoretical adverse events listed included: endophthalmitis (and possible blindness); cataract formation; glaucoma; retinal detachment; dislocation; bio-incompatibility; endothelial cell loss; and pigment dispersion.
- The procedure is reserved for patients requiring a high degree of refractive correction in whom laser correction is unsuitable.
- The procedure is reversible.
- It should be performed by a trained intraocular surgeon with experience in anterior segment and refractive surgery who is performing this procedure regularly.
- Preoperative work-up is vital for fitting, as is correct lens calculation.
- A preoperative endothelial cell count should be undertaken, and because a foreign body is left in the eye patients should be followed up for life.
- There is likely to be a slow diffusion of this technique initially in the private sector, but with potential use in the NHS to treat astigmatism.

- The one Specialist Adviser who expressed an opinion though that the procedure will only be used in less than 10 specialist centers in the NHS.
- The key efficacy outcomes with this procedure include: improvements in UCVA and BSCVA, independence from optical aids and maintenance of quality of vision.
- The key safety outcomes with this procedure include: cataract; glaucoma; loss of lines of BSCVA; removal or correction of lens implant; requirement for additional refractive surgery; contrast sensitivity; and night vision disturbances.

## Issues for consideration by IPAC

- Non-English language study reports were excluded because significant data were available in English.
- Phakic IOLs may be more suitable for patients who are not suitable for laser refractive surgery owing to high myopia, or with a thin cornea.
- An atypically large number of relevant studies were identified for this procedure (>130 articles); the appendix A of this overview only describes the most significant studies that were not included in table 2.

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12 Arne JL. (2004) Phakic intraocular lens implantation versus clear lens extraction in highly myopic eyes of 30- to 50-year-old patients. Journal of Cataract & Refractive Surgery 30:2092-2096.

# Appendix A: Additional papers on intraocular lens insertion for correction of refractive error, with preservation of the natural lens

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.

For this procedure more than 130 relevant studies were identified from literature searching. In the interest of brevity only RCTs, non-randomised controlled trials reporting >200 eyes or comparing to a control intervention not otherwise described in the studies included in table 2, case series reporting >200 eyes, or case reports describing complications not otherwise described in the studies included in table 2 are listed below.

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Arne JL. Phakic intraocular lens implantation versus clear lens extraction in highly myopic eyes of 30- to 50-year-old patients. Journal of Cataract & Refractive Surgery 2004; 30(10):2092-2096 | NRCT<br><br>n = 77 eyes (n = 41 eyes phakic IOL)<br><br>Follow-up not stated | At 12-month follow-up, BSCVA had improved by 78.0% in the phakic IOL group and 83.3% in the clear lens extraction group. | Larger studies are included in table 2. |
| Budo C, Hessloehl JC, Izak M, et al. Multicenter study of the Artisan phakic intraocular lens. Journal of Cataract & Refractive Surgery 2000; 26(8):1163-1171 | Case series<br><br>n = 518 eyes<br><br>Follow-up to 3 years | A UCVA of 20/40 was achieved in 76.8% of eyes, and a BSCVA of 20/40 was observed in 93.9% of eyes. There were few persistent adverse events at 3-year follow-up. | Studies with longer follow-up are included in table 2. |
| Coullet J, Guell JL, Fournie P, et al. Iris-supported phakic lenses (rigid vs foldable version) for treating moderately high myopia: randomized paired eye comparison. American Journal of Ophthalmology 2006; 142(6):909-916 | RCT<br><br>n = 62 eyes (fellow eye comparison)<br><br>Follow-up 1 year | At 1-year follow-up UCVA was 20/40 or better in 51.6% (16/31) of eyes with an artisan phakic IOL and in 77.4% (24/31) of eyes with an artiflex phakic IOL (p = 0.033). No intraoperative complications were reported. | Comparison is between two phakic IOL designs, not with an alternative intervention as a control. |
| El Danasoury M A, El Maghraby A, Gamali T O. Comparison of the Iris-Fixed Artisan Lens Implnatation with Excimer Laser In Situ Keratomileusis in | RCT<br><br>n = 84 eyes (n = 43 phakic IOL)<br><br>Follow-up 1 year | UCVA was 20/20 or better in 21% of phakic IOL eyes and 12% of LASIK-treated eyes at 1-year follow-up. | Studies with longer follow-up are included in table 2. |

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Correcting Myopia between -9.00 and -19.50 diopters. Ophthalmology. 2002; 2002. 955-964. | | | |
| Guell JL, Morral M, Gris O, et al. Evaluation of Verisyse and Artiflex phakic intraocular lenses during accommodation using Visante optical coherence tomography. Journal of Cataract & Refractive Surgery 2007; 33(8):1398-1404 | RCT<br><br>n = 22 eyes (fellow eye comparison)<br><br>Follow-up not stated | There were no significant differences between the two phakic IOLs in any measurement. | Comparison is between two phakic IOL designs, not with an alternative intervention as a control. |
| Javaloy J, Alio JL, Iradier MT, et al. Outcomes of ZB5M angle-supported anterior chamber phakic intraocular lenses at 12 years. Journal of Refractive Surgery 2007; 23(2):147-158 | Case series<br><br>n = 225 eyes<br><br>Follow-up to 12 years | MRSE was –17.23 D at baseline and –1.80 D at 12-year follow-up. There was a mean annual decrease in endothelial cell density of 1.78%. | Larger studies are included in table 2. |
| Leccisotti A. Iridocyclitis associated with angle-supported phakic intraocular lenses. Journal of Cataract & Refractive Surgery 2006; 32(6):1007-1010 | Case series<br><br>n = 356 eyes<br><br>Follow-up not stated | Iridocyclitis was observed in 4.4% of hypermetropic eyes and 2.9% of myopic eyes treated with a phakic IOL. Mean time from surgery to iridocyclitis was 8.5 months. | Studies with longer follow-up are included in table 2. |
| Park, I. K., Lee, J. M., and Chun, Y. S. (2008)<br>Recurrent occlusion of laser iridotomy sites after posterior chamber phakic IOL implantation.<br>Korean Journal of Ophthalmology 22 (2) 130-132. | Case report<br><br>n=1<br><br>FU=26 months | Recurrent occlusion of laser iridotomy sites leading to clear lens extraction. | Larger studies are included in table 2. |
| Pop M, Payette Y. Initial results of endothelial cell counts after Artisan lens for phakic eyes: an evaluation of the United States Food and Drug Administration Ophtec Study. Ophthalmology 2004; 111(2):309-317 | Case series<br><br>n = 765 eyes<br><br>Follow-up to 2 years | No statistically significant postoperative endothelial cell loss was found. | No clinical outcomes are reported.<br>Potentially an overlap of patients with those reported in Stulting (2008) included in table 2. |

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non-inclusion in table 2 |
|---|---|---|---|
| Pop M, Payette Y. Refractive Lens Exchange Versus Iris-claw Artisan Phakic Intraocular Lens for Hyperopia. Journal of Refractive Surgery 2004; 20(1):20-24 | NRCT<br><br>n = 38 eyes (n = 19 eyes phakic IOL)<br><br>Follow-up not stated | At 1-month follow-up 84% of patients in the clear lens exchange/ psudophakic IOL group and 94% of the phakic IOL group had MRSE within 1 D of emmetropia. | Larger studies are included in table 2. |
| Sanders, D. R. (2008) Anterior subcapsular opacities and cataracts 5 years after surgery in the visian implantable collamer lens FDA trial. Journal of Refractive Surgery 24 (6) 566-570. | Case series<br><br>n=526<br><br>FU=4.7 years | Anterior subcapsular opacity occurred in 6% of patients, and cataracts in 1% | Larger studies are included in table 2. |
| Sanders DR, Vukich JA, ICL in Treatment of Myopia (ITM) Study Group. Incidence of lens opacities and clinically significant cataracts with the implantable contact lens: comparison of two lens designs. Journal of Refractive Surgery 2002; 18(6):673-682 | NRCT<br><br>n = 610 eyes (two different designs of phakic IOL)<br><br>Follow-up 17 to 31 months | Clinically significant cataract was observed more frequently with the V3 phakic IOL (9.2%) than the V4 phakic IOL (0.8%) ($p < 0.001$). | Comparison is between two phakic IOL designs, not with an alternative intervention as a control. |
| Saxena R, Boekhoorn SS, Mulder PG,. Long-term follow-up of endothelial cell change after Artisan phakic intraocular lens implantation. Ophthalmology 2008; 115(4):608-613 | Case series<br><br>n = 318 eyes<br><br>Follow-up to 5 years | At 5 years mean endothelial cell density loss was 8.3% (corrected to 5.3% for natural cell attrition). | No clinical outcomes are reported. |

# Appendix B: Related NICE guidance for intraocular lens insertion for correction of refractive error, with preservation of the natural lens

| Guidance | Recommendation |
|---|---|
| Interventional procedures | **Implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery. NICE interventional procedures guidance IPG264 (2008)**<br><br>1.1 The evidence on the implantation of multifocal (non-accommodative) intraocular lenses (IOLs) during cataract surgery raises no major safety concerns. Current evidence on the procedure's efficacy shows that it can provide good near and distance vision without the need for spectacles, but this is at the risk of a variety of potential visual disturbances. Clinicians wishing to use multifocal (non-accommodative) IOL implants during cataract surgery should therefore do so with normal arrangements for clinical governance and audit, but with special arrangements for consent<br><br>1.2 Clinicians wishing to undertake implantation of multifocal (non-accommodative) IOLs during cataract surgery should ensure that patients understand the risks of experiencing halos and glare, and the probability of reduced contrast sensitivity. Patients should also be made aware that lenses may be difficult to remove or replace. Patients should be provided with clear written information. In addition, the use of the Institute's information for patients ('Understanding NICE guidance') is recommended www.nice.org.uk/IPG264publicinfo).<br><br>1.3 Patient selection should take into account factors that may prevent patients from wearing spectacles, such as disabilities that interfere with spectacle use, because these may be additional indications for the use of multifocal lenses.<br><br>**Implantation of accommodating intraocular lenses for cataract. NICE interventional procedures guidance IPG209 (2007)**<br><br>1.1 Current evidence suggests that there are no major safety concerns associated with the implantation of accommodating lenses for cataract. There is evidence of short-term efficacy in correcting visual acuity but there is inadequate evidence that the procedure achieves accommodation. Therefore, the procedure should not be used without special arrangements for consent and for audit or research.<br><br>1.2 Clinicians wishing to undertake implantation of accommodating lenses should take the following actions. |

| | |
|---|---|
| | • Ensure that patients understand the uncertainty about the procedure's efficacy, and provide them with clear written information. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG209publicinfo).<br>• Audit and review clinical outcomes of all patients having implantation of accommodating lenses.<br><br>1.3 Publication of long-term efficacy outcomes of the procedure will be useful, particularly on the effects on accommodation. The Institute will review the procedure in due course.<br><br>**Corneal implants for the correction of refractive error. NICE interventional procedures guidance IPG225 (2007)**<br><br>1.1 Current evidence on the efficacy of corneal implants for the correction of refractive error shows limited and unpredictable benefit. In addition, there are concerns about the safety of the procedure for patients with refractive error which can be corrected by other means, such as spectacles, contact lenses, or laser refractive surgery. Therefore, corneal implants should not be used for the treatment of refractive error in the absence of other ocular pathology such as keratoconus.<br><br>**Photorefractive (laser) surgery for the correction of refractive errors. NICE Interventional procedures guidance IPG164 (2006)**<br><br>1.1 Current evidence suggests that photorefractive (laser) surgery for the correction of refractive errors is safe and efficacious for use in appropriately selected patients.<br><br>1.2 Clinicians undertaking photorefractive (laser) surgery for the correction of refractive errors should ensure that patients understand the benefits and potential risks of the procedure. Risks include failure to achieve the expected improvement in unaided vision, development of new visual disturbances, corneal infection and flap complications. These risks should be weighed against those of wearing spectacles or contact lenses.<br><br>1.3 Clinicians should audit and review clinical outcomes of all patients who have photorefractive (laser) surgery for the correction of refractive errors. Further research will be useful and clinicians are encouraged to collect longer-term follow-up data.<br><br>1.4 Clinicians should have adequate training before performing these procedures. The Royal College of Ophthalmologists has produced standards for laser refractive surgery (www.rcophth.ac.uk/docs/publications/RefractiveSurgeryStandardsDec2004.pdf ). |

# Appendix C: Literature search for intraocular lens insertion for correction of refractive error, with preservation of the natural lens

| Database | Date searched | Version/files | No. retrieved |
|---|---|---|---|
| Cochrane Database of Systematic Reviews – CDSR (Cochrane Library) | 13/05/2008 | 2008, Issue 2 | 3 |
| Database of Abstracts of Reviews of Effects – DARE (CRD website) | 12/05/2008 | - | 1 |
| HTA database (CRD website) | 12/05/2008 | - | 0 |
| Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library) | 13/05/2008 | 2008, Issue 2 | |
| MEDLINE (Ovid) | 12/05/2008 | 1950 to April Week 5 2008 | 411 |
| MEDLINE In-Process (Ovid) | 13/05/2008 | May 12, 2008 | 19 |
| EMBASE (Ovid) | 12/05/2008 | 1980 to 2008 Week 19 | 395 |
| CINAHL (Dialog DataStar) | 13/05/2008 | 1982 to date (Dialog version) | 23 |
| BLIC (Dialog DataStar) | 13/05/2008 | - | 3 |
| National Research Register (NRR) Archive | 12/05/2008 | - | 0 |
| UK Clinical Research Network (UKCRN) Portfolio Database | 12/05/2008 | - | 0 |
| Current Controlled Trials *meta*Register of Controlled Trials - *m*RCT | 12/05/2008 | - | 10 |
| Clinicaltrials.gov | 12/05/2008 | - | 0 |

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

| | |
|---|---|
| 1 | exp Myopia/ |
| 2 | myop$.tw. |
| 3 | nearsighted$.tw. |
| 4 | near sighted$.tw. |
| 5 | shortsighted$.tw. |
| 6 | short sighted$.tw. |
| 7 | Astigmatism/ |
| 8 | astigmat$.tw. |
| 9 | Refractive Errors/ |
| 10 | (refractive adj3 (error$ or defect$ or disorder$)).tw. |

| | |
|---|---|
| 11 | or/1-10 |
| 12 | Phakic Intraocular Lenses/ |
| 13 | pIOL$.tw. |
| 14 | Lenses, Intraocular/ |
| 15 | Lens Implantation, Intraocular/ |
| 16 | ((intraocular or intra-ocular or refractive) adj3 lens$).tw. |
| 17 | IOL$.tw. |
| 18 | phakic$.tw. |
| 19 | or/14-17 |
| 20 | 18 and 19 |
| 21 | 12 or 13 or 20 |
| 22 | 11 and 21 |
| 23 | (veriseye or veriflex or visian).tw. |
| 24 | 22 or 23 |
| 25 | Animals/ |
| 26 | Humans/ |
| 27 | 25 not (25 and 26) |
| 28 | 24 not 27 |