Phakic posterior chamber lenses for high myopia: Functional and anatomical outcomes

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ABSTRACT

Purpose: To evaluate the functional and the anatomical outcomes after implantation of phakic posterior chamber intraocular lenses (IOLs) in highly myopic eyes.

Setting: Service d’Ophthalmologie, Hopital Purpan, Toulouse, France.

Methods: Fifty-eight eyes of 46 patients that had implantation of phakic posterior chamber lenses for high myopia were evaluated. Predictability, efficiency, safety, and subjective and objective quality of vision were evaluated preoperatively and at least 6 months postoperatively. The effect of the procedure on the cornea, aqueous humor, pupil, anterior chamber angle, crystalline lens, and retina were studied.

Results: Mean preoperative myopia was $-13.85 \pm 3.1$ diopters (D) (range $-8.00$ to $-19.25$ D). Mean postoperative spherical equivalent was $-1.22 \pm 0.83$ D (range $-0.75$ to $-3.50$ D); 56.9% of eyes were within $\pm 1.00$ D of the predicted result, and 77.6% gained 1 or more lines of best corrected visual acuity. All contact-lens-intolerant patients had improved quality of vision for day and night driving, distance vision, and vision under dim illumination. The mean postoperative level of contrast sensitivity without correction was higher than the mean preoperative level with correction. Adverse events were 2 cases of crystalline lens opacification 16 and 18 months after surgery and 2 cases of pigment deposits in the angle with increased intraocular pressure, which was controlled by beta-blockers.

Conclusion: Implantation of posterior chamber phakic IOLs is effective and predictable; however, long-term follow-up is needed.

Implantation of a phakic precrystalline lens is an emerging technique in the treatment of high myopia. It is now possible to evaluate the midterm effects of this procedure.

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Patients and Methods

Posterior chamber implantable contact lenses (ICLs) (Staar Surgical A.G.) were used to treat myopia in 58 eyes of 46 patients; 39 patients could not tolerate contact lenses for more than 2 hours a day. Postoperative follow-up was more than 2 years for 28 eyes and more than 9 months for 30 eyes.

Inclusion criteria were moderate to high myopia measured at the corneal plane (range $-8.00$ to $-20.00$ D).
diopters [D]); signed informed patient consent; age of at least 21 years at surgery. Exclusion criteria were an unstable refractive error; previous refractive surgery; a low endothelial cell count; keratoconus; glaucoma; history of iritis, synechias, pigment dispersion syndrome, or pseudoexfoliation; anterior chamber depth less than 2.8 mm.

Two weeks before surgery, laser iridotomies were performed. Two peripheral superior iridotomies were placed 80 degrees apart to avoid iridotomy occlusion by the ICL’s haptics. The size of the ICL was based on white-to-white length plus 0.5 mm, rounded to the nearest 0.5 mm.

A combination of topical medications (tropicamine 1% and phenylephrine 2.5%) was applied serially beginning 1 hour before surgery. The anesthesia method was based on patient and surgeon preference and included general anesthesia, peribulbar injection, or topical anesthesia by drops without intracameral injection.

A superior paracentesis was performed and the aqueous humor replaced by sodium hyaluronate 1%. A temporal corneal tunnel 3.2 mm wide and 1.75 to 2.00 mm long was created with a narrow diamond blade, allowing progressive opening of the anterior chamber.

After another injection of sodium hyaluronate, the ICL was implanted using 1 of 2 techniques. In the first 6 eyes, an injector was used but in 2 cases, the ICL settled upside-down in the anterior chamber and had to be removed. For subsequent procedures, insertion was done using a MacPherson forceps. The tip of the forceps was introduced in the entrance of the tunnel. Then, another MacPherson forceps was taken in the other hand, and the sides of the ICL were grabbed. The first forceps was opened and the ICL was regrasped and slowly pushed slightly farther. By alternating the forceps, the ICL was moved into the tunnel and unfolded in a controlled manner. The tip of the forceps never entered the anterior chamber, thus avoiding contact with the crystalline lens.

After the ICL unfolded, its proper orientation was checked. Then, each footplate in turn was placed beneath the iris with an unpolished flat manipulator without pressure being placed on the crystalline lens. Care was taken to avoid touching the thinnest part of the ICL (i.e., the middle).

The viscoelastic material was removed by gentle irrigation/aspiration, and acetylcholine chloride was injected. A combination steroid/antibiotic eyedrop was instilled, and 500 mg of intravenous acetazolamide was given at the conclusion of surgery and 4 hours later.

Quality of vision was evaluated preoperatively and 6 months postoperatively based on a questionnaire and contrast sensitivity testing. Patients were asked to evaluate subjectively their level of visual difficulty on a 5-point scale in 5 situations: distance vision when not driving, day driving, night driving, near vision, and distance vision under dim illumination. Response options were 1 = no trouble; 2 = a little trouble; 3 = moderate trouble; 4 = great deal of trouble; 5 = major trouble. The preoperative examination was done with the best possible correction using contact lenses or spectacles if the patient was contact-lens intolerant. The postoperative interview included additional questions about visual disturbances (halo and glare) and overall satisfaction with surgery, with the score ranging from 5 to 0.

A Colvard infrared pupillometer was used to measure pupil diameter in the last 15 cases in the series.

Contrast sensitivity testing was performed preoperatively with correction by contact lenses except when wearing lenses was impossible for a few minutes (2 cases). Two tests were used: the Vector Vision CSV 1000 and Gradual (Opsia), which provides a single global measure of contrast sensitivity. In all cases, the evaluation was performed at 3 levels of luminance (5, 85, and 700 candelas/m²) and at 3 spatial frequencies (3, 12, and 24 cycles per degree) for each level of luminance.

A detailed evaluation of 28 eyes was done 2 years after surgery to assess possible modifications of the anatomical structures of the eye induced by the ICL’s presence. A corneal endothelial cell count was performed preoperatively and 3, 6, 12, and 24 months postoperatively. Laser flare fluorophotometry was used to evaluate inflammation 6 months after surgery.

To evaluate possible effects of the contact between ICL and iris, the speed of iris contraction was measured with a Metrovision pupillometer. This device applies conventional techniques from real-time pattern recognition with feature analysis from standard video to monitor eye movement and pupil size.1 Corneal reflection
and the bright pupil images were evaluated using the same device.

**Results**

**Functional**

**Predictability.** Mean preoperative myopia was $-13.85 \pm 3.1$ (SD) (range $-8.00$ to $-19.25$ D). Postoperative mean sphherical equivalent was $-1.22 \pm 0.83$ (D) (range $+0.75$ to $-3.50$ D). Of all eyes, 56.9% had a residual refractive error within $\pm 1.00$ D of the predicted result and 68.9% within $\pm 2.00$ D; 15.5% had residual myopia of more than $-2.00$ D, and 3.4% had postoperative hyperopia less than $+1.00$ D.

**Visual acuity.** Mean preoperative best corrected visual acuity (BCVA) was 0.57 (range 0.1 to 1.0). Mean postoperative uncorrected visual acuity (UCVA) was 0.40 (range 0.1 to 0.9). Mean postoperative BCVA was 0.71 (range 0.4 to 1.0). Postoperative UCVA was higher than preoperative BCVA in 15.5% eyes, equal in 15.5%, and lower in 68.9%. Mean effectivity (i.e., the ratio of postoperative UCVA/preoperative BCVA) was 0.84 (Figure 1). After surgery, 20.6% of eyes retained the same BCVA as preoperatively, 77.6% gained 1 or more lines of BCVA, and 3.4% lost 2 lines of BCVA.

Safety (i.e., ratio between postoperative and preoperative BCVA) was 1.46 (Figure 2).

**Quality of vision.** The mean level of visual difficulties decreased significantly in all cases. In particular, the 39 contact-lens-intolerant patients reported marked improvement in the quality of vision. Of all patients, 54.3% reported halos with disturbances during night driving. However, 26.9% reported halos preoperatively regardless of the type of correction. The frequency of halo was higher when the ICL’s optical zone size was small. The rate of halos correlated to the difference between the scotopic pupil diameter and the optical zone size ($P < .01$) (Figure 3).

Regarding level of satisfaction, 56.5% of patients reported being very satisfied, 36.9% satisfied, and 6.5% moderately satisfied. No one reported being dissatisfied.

The mean contrast sensitivity without correction was higher postoperatively than preoperatively. The difference was statistically significant ($P < .05$) for each level of luminance at each spatial frequency (Table 1).

**Anatomical**

**Endothelial cell count.** Mean postoperative endothelial cell loss was 2.1% at 3 months, 2.3% at 6 months, 2.0% at 1 year, and 2.0% at 2 years. No eye had an endothelial cell loss greater than 3.8% at 1 year.

**Aqueous humor.** Flare was always less than 8.1 photons/mm, including in the 1 eye with a transient postoperative inflammatory reaction.

**Pupil.** There was a slight decrease in the speed of pupil contraction in most eyes 1 year after surgery. In all eyes, the relative position of corneal reflection and bright pupil images was normal.

| Table 1. Preoperative and postoperative contrast sensitivities evaluated by luminance levels (5, 85, 700 cd/m²) and spatial frequencies (3, 12, 24 c/d) (N = 58). |
|---|---|---|---|---|---|---|
| cd/m² | 5 | 12 | 24 c/d | 85 cd/m² | 3 | 12 | 24 c/d | 700 cd/m² | 3 | 12 | 24 c/d |
| Preop | 6.4 | 3.5 | 1.0 | 5.8 | 2.7 | 0.6 | 7.4 | 4.3 | 1.3 |
| Postop | 7.8 | 4.8 | 2.5 | 7.3 | 4.0 | 1.5 | 8.5 | 5.0 | 3.3 |
| cd = candelas; c/d = cycles per degree |

**Figure 1.** (Arne) Comparison of postoperative UCVA and preoperative BCVA (N = 58).

**Figure 2.** (Arne) Comparison of preoperative and postoperative BCVA (N = 58).
**Iridocorneal angle.** A pigmentary dispersion in the angle, not present preoperatively, was found in 9 eyes 18 months after surgery. In 2 cases, an increase in intraocular pressure (IOP) occurred that was well controlled by topical beta-blockers; no glaucomatous optic nerve damage was present. Pigment deposits on the periphery of the ICL optic were apparent in all eyes 1 year after surgery but caused no visual problems as the center of the ICL was not involved.

**Crystalline lens.** Anterior subcapsular opacities were seen in 2 cases. In 1, BCVA decreased to 20/200 and the ICL had to be removed; phacoemulsification was done with in-the-bag intraocular lens (IOL) implantation. Surgery via the initial corneal incision was uneventful. Postoperative restoration of vision was rapid.

**Retina.** Ocular coherence tomography revealed normal retinal structure and thickness in all eyes.

### Discussion

Several studies report that implantation of a posterior chamber phakic IOL can be an effective and safe method for correcting moderate to high myopia. Assetto and coauthors\(^2\) report the implantation of 15 ICLs and conclude that the preliminary results were promising, although the predictability of the prototype model they used was not totally satisfactory. Rosen and Gore\(^3\) studied 16 myopic eyes with an ICL and a 3 month follow-up. They concluded the method was predictable, safe, and effective for the correction of myopia.

Zaldivar and coauthors\(^4\) report the largest experience with phakic IOL implantation: 124 for myopia of \(-8.00\) to \(-19.00\) D. Mean spherical equivalent refraction was \(-13.38 \pm 2.23\) D preoperatively and \(-0.78 \pm 0.87\) D postoperatively. A gain of 2 or more lines of best spectacle-corrected visual acuity occurred in 36% of eyes. The authors emphasize their interest in secondary refractive procedures to correct unanticipated residual refractive errors. We believe that this 2-step procedure, biophtics, has an important place in the treatment of high and extreme myopia.

In 6 eyes outside the study we report, preoperative myopia was greater than \(-20.00\) D. We performed excimer laser treatment for residual myopia: photorefractive keratectomy in 2 cases; laser in situ keratomileusis (LASIK) in 4 cases. The time between the 2 procedures was at least 2 months so the intraocular procedure would be stable. The IOP increase during LASIK did not result in anatomical problems, and the postoperative refractive result was between 0 and \(-0.50\) D.

High-diopter ICLs have a small optical zone, resulting in night halos. Thus, we now prefer the combined procedure in cases of myopia greater than \(-16.00\) D. We implant an ICL with a large optical zone. This leaves

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<th>no trouble</th>
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<th>moderate</th>
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<td>Day driving</td>
<td>2.03</td>
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<tr>
<td>Night driving</td>
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an undercorrection that is treated by LASIK with a large optical zone. The corneal flap can be created in the operating room at the beginning of the implantation procedure and immediately replaced. Three weeks after surgery, refraction can be evaluated. The flap is lifted and excimer laser treatment is done in the stromal bed. This sequence allows better accuracy in the evaluation of the residual refractive error after ICL implantation.

Long-term safety of the presence of an ICL in the posterior chamber of a phakic eye must also be evaluated. Pigmentary dispersion was first reported by Assetto and coauthors. The pigment deposits on the ICL had no visual consequences as they were located at the optic–haptic junction rather than the central optic. Some pigment dispersion is probably surgically related; that is, the result of laser iridotomies and iris trauma during ICL implantation. Rubbing at the optic–haptic junction on the posterior side of the iris is the major mechanism, however. The ICL pushes the iris anteriorly, narrowing the angle.

In 2 of our cases, pigmentary deposits that were not present preoperatively were seen in the angle postoperatively, and IOP increased. Increased IOP after ICL implantation has been reported to be caused by pupillary block or secondary to postoperative corticosteroid treatment. To our knowledge, however, ours are the first reported cases of increased IOP likely caused by pigmentary dispersion. In both cases, a topical beta-blocker was effective and ICL removal was not necessary.

The potential for cataractogenesis is a crucial concern for the future of ICL implantation. However, if these highly myopic eyes develop cataract, removal of the ICL and phacoemulsification would be easy to perform and good vision restored, although accommodation would be lost.

Fechner and coauthors implanted a Chiron Adatomed silicone posterior chamber lens in 45 myopic eyes with a clear crystalline lens. Central subcapsular opacities developed in 8 eyes after 1 to 2 years. Trindade and Pereira reported a case of visually significant cataract formation 6 months after uneventful ICL implantation. In 1999, Fink and coauthors reported lens opacification in 3 eyes of 2 patients.

Several mechanisms have been put forward to explain cataractogenesis. Trauma to the crystalline lens during the implantation procedure is one. However, in our cases, the implantation was atraumatic and visual acuity remained good 1 year postoperatively.

There is also the possibility of metabolic disturbances caused by the ICL’s material. Even though the biocompatibility of HEMA collagen copolymer is reportedly excellent, it may disturb the metabolic exchanges.

In our 2 cases with cataract, biomicroscopy and examination by Scheimpflug photography showed that contact existed between the ICL and the center of the crystalline lens. The size of the ICL plays a crucial role in determining that the central vault is adequate to maintain space between the ICL and the crystalline lens.

In 30 eyes that received the same model of ICL used in this study, we checked the white-to-white measurements and compared them to the sizes of the implanted ICLs. When the size of the ICL was at least 0.6 mm greater than the white-to-white distance (20 cases), a space existed between the ICL and the crystalline lens. In contrast, when the ICL size exceeded the white-to-white distance by less than 0.4 mm (10 cases), contact occurred in half the cases.

Thus, choosing a large ICL appears to be mandatory to create a sufficient central vault but would be outweighed by the effect of contact between the ICL and the posterior iris surface. Excessive vaulting, however, can narrow the angle and cause contact between the haptic and the crystalline lens periphery.

The more recent model of ICLs (V4) is designed to avoid such contact. However, there are uncertainties about the long-term evolution with these lenses: (1) They are made of a soft material and the vaulting can flatten; (2) the curvature of the crystalline lens can change during accommodation and its thickness increase as the eye ages. This may lead to transient or permanent contact.

Conclusion

Implantation of a posterior chamber lens in a phakic eye appears to be a promising method for the treatment of high myopia. Functional results are good in terms of predictability, efficacy, and safety. The quality of vision is subjectively and objectively improved after implantation. Regarding the effects of implantation on the eye’s structure, the cornea is unaffected while in most studies of phakic anterior chamber lenses and phakic iris-claw
lenses,\textsuperscript{10} endothelial cell loss is higher. There is no inflammatory reaction when mild chronic uveitis is present when phakic eyes are fixated on the iris.\textsuperscript{11}

There is concern that contact between the ICL and crystalline lens may cause cataract formation. However, explantation of the ICL and phacoemulsification with in-the-bag IOL implantation can restore good UCVA in these highly myopic eyes. The anterior segment is not traumatized by the small incision. Moreover, contact can be avoided by enhancing the vault of the precrystalline lens.

The more worrisome problem is the potential glaucoma-inducing effect of pigment dispersion in the anterior chamber angle. Long-term evaluation is necessary to assess the exact incidence of this complication.

References


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