ABSTRACT

PURPOSE: To examine the efficacy, predictability, stability, and safety of posterior chamber phakic intraocular lens (IOL) implantation in patients with extreme myopia.

METHODS: We analyzed the results of 124 eyes that received a posterior chamber hydrogel collagen plate phakic IOL (Staar Collamer Implantable Contact Lens, ICL) for the correction of their myopia. The target postoperative spherical equivalent refraction was emmetropia. Mean follow-up was 11 months (range 1 to 36 mo).

RESULTS: The mean preoperative spherical equivalent refraction was -13.38 ± 2.23 D (range, -8.50 to -18.63 D). Mean postoperative spherical equivalent refraction at last examination was -0.78 ± 0.87 D (range, -1.63 to -3.50 D), with 69% (86 eyes) within ±1.00 D and 44% (55 eyes) within ±0.50 D of emmetropia. The refraction remained stable with a statistically insignificant change (p > 0.05 at each interval) during follow-up. A gain of two or more lines of spectacle-corrected visual acuity was seen in 36% (45 eyes) at last examination. One eye (0.8%) lost two or more lines of spectacle-corrected visual acuity from a retinal detachment.

CONCLUSION: Posterior chamber phakic IOL implantation with the Staar Collamer plate lens is an effective and safe method for reducing or correcting myopia between -8 and -19 D. Gains in spectacle-corrected visual acuity were common, and results suggested good refractive stability. Improvements in phakic IOL power calculation formulas are needed to improve the predictability of refractive outcome. [J Refract Surg 1998;14:294-305]

The surgical correction of ametropias has progressed in the past several years. Refractive keratotomy, excimer laser photorefractive keratectomy (PRK), and laser in situ keratomileusis (LASIK) have demonstrated good results for the treatment of myopia and astigmatism.\(^1\) Scanning excimer laser systems with software to treat hyperopia and perform asymmetric ablations have made it possible to offer LASIK to patients with a wide range of refractive errors.

The treatment of higher amounts of myopia and hyperopia using corneal surgery is more controversial, with LASIK showing the greatest promise.\(^3\)\(^,\)\(^8\)\(^,\)\(^15\) However, large ablation depths, smaller diameter ablation zones, increased optical aberrations, and poorer predictability have raised doubts that the cornea is the appropriate site for correction of high to extreme refractive errors.\(^2\)\(^,\)\(^7\)

Several non-corneal refractive procedures to treat extreme myopia, such as Salgado's scleral resection procedure, are now of historical interest only.\(^16\) In contrast, clear lens extraction for extreme myopia, based on the work of early 18th century eye surgeons, is still being done, and has been used for hyperopia as well.\(^16\)\(^,\)\(^18\) Lens extraction in cataract patients exposes patients to the risks of retinal detachment and cystoid macular edema.\(^19\) Younger patients undergoing elective clear lens extraction for myopia are exposed to the same risks. However, clear lens extraction faces the problems of loss of accommodation and difficulties of intraocular lens (IOL) power calculations.\(^20\)\(^,\)\(^21\)

In the 1950s, after witnessing the early successes of the IOLs for correction of aphakia, Strampelli designed a minus power IOL for phakic patients with extreme myopia.\(^22\) Barraquer was the first to report a long-term study of these one piece, polymethylmethacrylate (PMMA) plate anterior chamber
angle fixated phakic IOLs. Without the benefit of the operating microscope, nylon sutures, viscoelastics, refined IOL manufacturing, and knowledge of corneal endothelial function, approximately 60% of the lenses had to be removed because of corneal edema or the uveitis-glaucoma-hyphema syndrome.²³

Phakic IOL surgery was abandoned until renewed interest began with Fechner’s modification of the Worst iris claw lens and Baikoff’s modification of the Kelman multiflex anterior chamber IOL in the middle 1980s.²⁴⁻²⁶ Both of these anterior chamber phakic IOLs have undergone a series of design improvements and have demonstrated reasonable performance regarding efficacy, predictability, and stability of the refractive result for high myopia. Earlier models produced endothelial cell loss; later models showed minimal loss.²⁷⁻³¹

We began implanting the Baikoff lens (first the ZB model, then the ZBMF model) in 1989. Although we also obtained reasonable efficacy and predictability of the refractive result over a 6 year period, concerns about the small optic zone size of 4.0 mm that caused patients’ complaints of halos and glare, progressive iris retraction with oval pupils, and large incision size of 6.0 mm, led us to search for a lens with a better design for myopia and one that could also treat hyperopia.

In December 1993, we began implanting the Staar plate posterior chamber phakic IOL, (Implantable Contact Lens (ICL); Staar Surgical AG Nidau, Switzerland). Fyodorov originated this lens style in 1986, using a one-piece silicone collar button phakic IOL with a 500 to 600 nm teflon coat.³² Problems with cataract formation and uveitis lead to refinements in lens design, including the incorporation of collagen into the lens material to improve biocompatibility (Neumann AC. “Update on three IOLs for myopia” by Schonfeld AR, Ocular Surgery News, Dec 1, 1993. Presented at the ESCRs Annual Symposium, Innsbruck, Austria, September 1993; Fechner PU. “Phakic PCL is promising for high myopia” by Schonfeld AR, Ocular Surgery News, Intl. Ed., 4:12, Dec 1993. Presented at the ESCRs Annual Symposium, Innsbruck, Austria, September 1993). As the lens has evolved through approximately six design changes, investigators have achieved encouraging initial results.³²⁻³³

Following is the results of our initial 124 myopic eyes that received posterior chamber phakic IOLs in which the target postoperative spherical equivalent refraction was emmetropia.
PATIENTS AND METHODS

Intraocular Lens Design

The current Staar Surgical-AG IOL (ICL) is made of a porcine collagen/HEMA copolymer (< 0.1% collagen) with a refractive index of 1.45 at 35° C. The plate haptic design is shown in Figure 1. It is a foldable lens that may be implanted through a 3.2 mm or smaller corneal incision, at times under topical anesthesia. The central concave/convex optic comes in sizes ranging from 4.5 to 5.5 mm in diameter, depending on the lens power. Available powers are, for myopic lenses, -3 to -20 diopters (D) and, for hyperopic lenses, +3 to +17 D. Other lens powers are sometimes available. Five lens lengths are manufactured, ranging from 10.8 to 13.0 mm, to accommodate different eye sizes. Several distinct lens designs were implanted during the study. The predominant designs were the IC2020 (61 eyes), the IC2020-N3 (34 eyes), and the IC2M-120 to ICM-130 series (19 eyes had either the ICM-120 V2, ICM-125 V1, ICM-125 V2, ICM-130 V1, or the ICM-130 V2 phakic IOL implanted.) The IC2020-N3 and ICM series lenses differ in labeling only; the lenses are otherwise identical.

Patient Selection

From March 1993 to December 1996 we implanted posterior chamber phakic IOLs into 124 eyes of 85 patients with high to extreme myopia (-8 to -19 D) in whom the target postoperative spherical equivalent refraction was emmetropia. Mean preoperative spherical equivalent refraction was -13.38 ± 2.23 D (range, -8.50 to -18.63 D). Mean age at the time of surgery was 34 years (range, 22 to 51 yr).

Exclusion criteria included previous intraocular surgery, visually significant cataract, glaucoma, proliferative diabetic retinopathy, and retinal breaks. Patients with advanced systemic disease were also excluded from the study.

Preoperative examination included uncorrected visual acuity, spectacle-corrected visual acuity with manifest and cycloplegic refractions, keratometry, corneal topography (EyeSys, Houston, TX), pachymetry, specular microscopy (We used the Konan Keeler Pocklington contact specular microscope until July 1995; thereafter, the Konan Noncon Robo-CA noncontact specular microscope was used.), A-scan ultrasonography, slit-lamp microscopy, application tonometry, and dilated fundoscopy.

Lens power calculations were performed with formulas developed by Staar. The independent variables in the formula are preoperative spherical equivalent spectacle refraction, vertex distance, average keratometric power, corneal thickness, and central anterior chamber depth. Early experience demonstrated a tendency of the formula to lead to undercorrections. The final choice of lens power was therefore determined following adjustments based on target postoperative refraction, lens availability, and the surgeon’s experience. The length of phakic IOL implanted was determined based on the patient’s horizontal corneal diameter (white-to-white). The size of the phakic IOL chosen was horizontal corneal diameter plus 0.5 mm, rounded to the nearest 0.5 mm increment. Corneal diameter was measured with the computerized calipers on the videokeratoscope (EyeSys). The goal was to implant a phakic IOL of slightly larger size than the ciliary
sulcus in order to promote anterior IOL vaulting and secure fixation.

Intraoperative arcuate transverse keratotomies for astigmatism were performed on 33 eyes. A second refractive procedure to correct residual refractive error was performed in 28 eyes.

Surgical Technique

In order to decrease the incidence of postoperative pupillary block, we began (in June 1994) placing peripheral laser iridotomies at least 4 days before surgery. Until August 1995, patients received a single superior iridotomy; subsequently, we began placing two superior iridotomies positioned between 60° to 90° apart in order to decrease the likelihood of iridotomy occlusion by the phakic IOL haptics. Iridotomies were 250 to 500 µm in diameter and located superiorly (covered by the upper eyelid) in the peripheral iris. From June 1994 until July 1996, only the Nd:YAG laser was used (single burst, 3 to 10 mJ). Subsequently, we began using the argon-green laser prior to applying the Nd:YAG spots in order to decrease iris bleeding and pigment deposition on the phakic IOL (Argon settings: 50 µm spot size, 650 to 1000mW power, and 0.2 to 0.5 second duration).

All phakic IOL implantations were performed by author, Roberto Zaldívar (RZ), according to the following technique. Tropicamide 1%, phenylephrine 2.5%, diclofenac, and gentamicin were applied serially beginning 1 hour preoperatively. Anesthesia was achieved with peribulbar injection (105 eyes) or topical lidocaine (19 eyes). When good pupillary dilation and ocular anesthesia were obtained, patients were taken to the operating room, and a lid speculum was placed. A superior paracentesis and a 3.2 mm temporal clear corneal incision were made with a diamond knife. Sodium hyaluronate (OcuCoat, Storz, St. Louis, MO) was injected into the anterior chamber.

The Staar Collamer posterior chamber phakic IOL was used in all eyes. Because of modifications relating to optic size, posterior radius of curvature of the IOL, and positioning markings, not all lenses were identical. Under direct visualization with the operating microscope, the phakic IOL was positioned in the lens insertion cartridge. A 1.0-mm diameter piece of microsurgical sponge was cut and placed behind the cartridge within the lens injector to protect the phakic IOL from the injector arm.

The injector tip was then placed within the wound (but not into the anterior chamber), and the lens was slowly injected into the anterior chamber, anterior to the iris plane, ensuring proper orienta-

tion. With two separate maneuvers, an intraocular hook (Sinsky hook) was used to place the two corners of the temporal haptic beneath the iris, with gentle posterior pressure. The two corners of the nasal haptic were then positioned in a similar fashion. A rotational technique (dialing-in the temporal haptic) was abandoned early in the surgery because it produced increased postoperative pigment dispersion. Verification of proper lens orientation was aided by the positioning holes, which are only open on the haptics’ anterior surface—in the event a phakic IOL is inverted, the surgeon is unable to place the intraocular hook into the positioning holes. Acetylcholine was injected into the anterior chamber. Remaining viscoelastic was removed with gentle irrigation and aspiration with the AMO Prestige phacoemulsification system (AMO Prestige, Allergan, Irvine, Calif). Topical tobramycin-dexamethasone and gentamicin in addition to 500 mg of intravenous acetazolamide were given at the conclusion of the surgery. Eyes that had received peribulbar anesthesia were patched.

Secondary Refractive Procedures

Residual refractive errors were treated with radial or arcuate transverse keratotomy in 23 eyes and LASIK in five eyes, according to previously described techniques. The secondary refractive procedures were performed no sooner than 4 weeks following phakic IOL implantation. Six eyes underwent removal of their initial phakic IOL (Table 1). The refractive outcomes reported here are those before any secondary surgical procedure.

Follow-up

Routine postoperative examinations were scheduled at 1 day, 1 month, 3 to 6 months, 12 months, 18 to 24 months, then every year after surgery. The mean follow-up was 11.0 ± 4.2 months (range, 1 to 36 mo). The follow-up rate was 100% at 1 day and 1 month (124 eyes), 89% at 6 months (80 of the 90 eyes that had surgery at least 6 months prior), 65% at 12 months (51 of 78 eyes that were 12 months postoperative), 50% at 18 to 24 months (33 of an available 66 eyes), and 100% at 36 months (three of three eyes).

All follow-up examinations included questioning the patient about subjective complaints. Uncorrected visual acuity, spectacle-corrected visual acuity, automated keratometry, applanation tonometry, and slit-lamp biomicroscopy were performed at each examination. IOL vaulting, pigment dispersion, and crystalline lens clarity were particularly observed. Lens clarity and pigment on the phakic
IOL surface was graded from 0 to 4+ by direct visualization at the slit lamp. Gonioscopy and dilated fundoscopy were performed as needed. Postoperative specular microscopy was performed on 75 eyes.

**Data Analysis**

Data forms were used to help standardize data collection and analysis.

Refractive outcome and postoperative uncorrected and spectacle-corrected visual acuity were analyzed as measures of efficacy of the procedure. Baseline manifest and cycloplegic refractions and visual acuities (uncorrected visual acuity and spectacle-corrected visual acuity) were compared to the refractions and visual acuities at the last postoperative examination. In reporting the refractive and uncorrected visual acuity outcomes, the last refraction and uncorrected visual acuity prior to a secondary refractive procedure were used.

Stability of refractive outcome was analyzed by performing a paired, two-tailed, Student's *t*-test between the mean spherical equivalent refraction at each postoperative examination.

Complications were analyzed as a measure of the safety of the procedures. All potentially visually threatening events were reported (Table 1). A loss of spectacle-corrected visual acuity of more than two lines was considered significant. Preoperative and postoperative endothelial cell micrographs were taken, but because of unreliable quantitative measurements, these results are not presented. The frequency of phakic IOL-related subjective complaints persistent after 1 month was documented.

Refractive outcome at 1, 6, and 12 months was analyzed. Refractive outcome of patients with more than 12 months follow-up was evaluated as a measure of stability during 1 year. Eyes with at least 12 months follow-up that experienced greater than 1 D change in spherical equivalent refraction are reported. Patients with secondary refractive procedures during their first 12 postoperative months were excluded from this analysis. Additionally, the data of the three patients with over 3 years follow-up are discussed (Table 2).

**RESULTS**

Mean preoperative spherical equivalent refraction was $-13.38 \pm 2.23$ D (range, -8.50 to -18.63 D) and mean preoperative refractive cylinder was $2.13 \pm 1.51$ D (range, 0 to 6.00 D).

**Refractive Outcome**

At last follow-up, mean postoperative spherical equivalent refraction was $-0.78 \pm 0.87$ D (range, +1.63 to -3.50 D) and mean postoperative refractive cylinder was $0.96 \pm 0.85$ D (range, 0 to 3.75 D). Spherical equivalent refraction at last examination was within $\pm 1.00$ D of emmetropia in 69% (86 eyes) and within $\pm 0.50$ D of emmetropia in 44% (55 eyes). Figure 2 shows the achieved versus intended spherical equivalent refraction. Stability of the spherical equivalent refraction is demonstrated in Figure 3 ($p > 0.05$ between each postoperative interval).
Visual Acuity

Preoperative uncorrected visual acuity was less than 20/200 in all eyes. Preoperative spectacle-corrected visual acuity of 20/40 or better was present in 80% (99 eyes) and 20/20 or better in 5% (four eyes). Postoperative uncorrected visual acuity at last follow-up was 20/40 or better in 68% (84 eyes) and 20/20 or better in 2% (three eyes, Figure 4). Postoperative spectacle-corrected visual acuity at last examination was 20/40 or better in 93% (115 eyes) and 20/20 or better in 19% (23 eyes).

Figure 5 compares preoperative versus postoperative spectacle-corrected visual acuity (last available refraction was used). A gain of two or more lines of spectacle-corrected visual acuity was seen in 38% (45 eyes). One eye of one patient experienced a loss of two or more lines of spectacle-corrected visual acuity.

Complications

Perioperative and postoperative complications are detailed in Table 1. Of the five eyes that had the original phakic IOL removed (two related to increased intraocular pressure, two secondary to IOL decentration, one secondary to a broken IOL), two had a new phakic IOL placed. These two eyes have done well subsequently. The three eyes in which a new phakic IOL was not placed received phacoemulsification of the clear lens with posterior chamber IOL placement in the capsular bag. In one eye, the phakic IOL was inverted; it was removed from the eye and re-injected without incident.

In total, 14 of the 124 eyes experienced significant intraocular pressure elevations of greater than 26 mmHg or of greater than 5 mmHg above the preoperative pressure. Six of these 14 eyes were corticosteroid responders (intraocular pressure in the high 20s to low 30s mmHg), and intraocular pressure returned to baseline levels following withdrawal of postoperative topical corticosteroids in all six eyes. In six other eyes, the intraocular pressure elevation was attributed to pupillary block and the eyes presented with intraocular pressure of 40 to 50 mmHg. Four of these did not have a preoperative peripheral iridotomy, which may have led to the pressure increase. In the other two eyes, the postoperative peripheral iridotomies were no longer patent. Pupillary block was relieved in all six of these eyes with placement or enlargement of peripheral laser iridotomies.

Two eyes experienced intraocular pressure spikes that were considered phakic IOL-related. No other cause could be identified, although one of these eyes demonstrated excessive pigment deposition on the phakic IOL surface. In each eye, the phakic IOL was removed and phacoemulsification of the clear lens was done with posterior chamber IOL placement in the capsular bag. The intraocular pressure was well controlled in both of these eyes off medications since the removal of the phakic IOL.

Of the three crystalline lens opacities (two anterior or subcapsular and one posterior subcapsular), two were present preoperatively and did not progress during the study period. One, a peripheral anterior
### Table 2
Data on Three Eyes with 3 Years Follow-up after Posterior Chamber Phakic IOL Implantation

<table>
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<th>Eye #</th>
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<th>1 Day</th>
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<th>6 mo</th>
<th>12 mo</th>
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<td>15</td>
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†CF = count fingers

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**Figure 4:** Preoperative spectacle-corrected visual acuity (BSCVA) and postoperative uncorrected visual acuity (UCVA) in 124 eyes at last examination (mean 11 ± 4.2 mo). The percent of 124 eyes with different levels of visual acuity are given. The + sign indicates "or better," i.e., 20/20+ indicates 20/20 or better visual acuity.

Subcapsular opacity, developed in the region of a peripheral laser iridotomy. None of the three lens opacities was considered visually significant.

One eye experienced a loss of spectacle-corrected visual acuity of two or more lines at their last follow-up (Fig 4). The patient was doing well until 3 months after surgery when he presented with a macula-off rhegmatogenous retinal detachment in his operated eye. Spectacle-corrected visual acuity was reduced to 20/800. The patient was referred to a retinologist for definitive treatment, and the outcome is unknown.

Subjective complaints persistent in the operated eye(s) after 1 month included glare (three patients), diplopia (one patient), eye pain (two patients), and decreased vision (two patients). The complaints of glare and diplopia were seen in two patients with

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**Figure 5:** Change in spectacle-corrected visual acuity at last examination as percent of 124 eyes with loss or gain in Snellen lines.
Posterior Chamber Phakic IOL for Myopia of -8 to -19 Diopters/Zaldívar et al

greater than 1 mm of phakic IOL decentration, and in the one patient with a broken phakic IOL. The symptoms tended to increase at night, and, in all eyes, the symptoms were eliminated upon phakic IOL decentration (one eye) or removal (two eyes). The decentration of the phakic IOLs was related to inadequate sizing, as the early model of the phakic IOL was only manufactured in one size. Pain was related to an acute rise in intraocular pressure in both patients who presented with this symptom, and was relieved upon reduction of intraocular pressure. Complaints of decreased visual acuity occurred in one patient with greater than 1 mm of phakic IOL decentration and in the patient with the detached retina. Symptoms of decreased visual acuity improved in the former patient upon phakic IOL exchange, with implantation of a properly sized, later model phakic IOL.

**DISCUSSION**

We currently perform LASIK on myopes with spherical equivalent refractions of -1 to -12 D, and on hyperopes with spherical equivalent refractions from +1 to +6 D. Since 1989, we have been using phakic IOLs for the treatment of refractive errors greater than this range. Although we obtained good efficacy and predictability with the anterior chamber Baikoff ZB and ZBMF multiflex lens, problems of iris retraction with pupillary elongation and complaints of halos were of concern. In December 1993, we began implanting, through a smaller incision, the Staar plate posterior chamber phakic IOL. We report here our initial 124 posterior chamber phakic IOL implantations into myopic eyes with a target postoperative spherical equivalent refraction of emmetropia.

**Efficacy and Predictability**

Good efficacy and predictability have been demonstrated in previous studies of anterior chamber phakic IOLs, with approximately 70% or more of eyes achieving a postoperative refraction within ±1.00 D of emmetropia.26,32,35 The efficacy and predictability of the Fyodorov model silicone posterior chamber phakic IOL have also been good, with 89% of eyes achieving uncorrected visual acuity equal to the preoperative level of spectacle-corrected visual acuity.32,33

The Staar Collamer posterior chamber phakic IOL dramatically decreased the myopia in our study population, although there was a tendency toward undercorrection. Sixty-nine percent (86 eyes) achieved a postoperative spherical equivalent refraction within ±1.00 D and 44% (55 eyes) achieved a spherical equivalent refraction within ±0.50 D of emmetropia at the time of last examination. Limitations in predictability are partly related to choosing phakic IOL powers based on spectacle refractions. In their study of 15 myopic eyes receiving Staar’s posterior chamber phakic IOL, Assetto and colleagues achieved a postoperative spherical equivalent refraction within ±1.00 D of emmetropia in only 31% of eyes.34 Until more accurate lens power calculation formulas are developed, we anticipate some limitations in the predictability of the procedure.

Phakic IOL implantation does not preclude the use of refractive corneal procedures following phakic IOL implantation for the correction of residual myopia and/or astigmatism. Performing these secondary procedures, as was done in 28 eyes (23%) in this series, allows for fine-tuning of the refractive result. Currently we prefer to treat eyes with preoperative myopia of approximately -18 D or greater with a two-step procedure called Bioptics. In these eyes, the posterior chamber phakic IOL is implanted to achieve a target postoperative residual refraction of -1.50 to -12.00 D spherical equivalent refraction (with or without astigmatism). The residual myopia and astigmatism, when present, is corrected with LASIK no sooner than 1 month after phakic IOL implantation. The secondary refractive procedures performed in the present series (radial or arcuate tranverse keratotomy in 23 eyes and LASIK in five eyes), however, were not planned preoperatively, as the target postoperative spherical equivalent was emmetropia in all 124 eyes. These secondary refractive procedures attempted to correct unanticipated residual myopia and/or astigmatism.

We no longer perform radial keratotomy for the correction of residual myopia after phakic IOL implantation (as of November 1995); instead, we treat these eyes with LASIK.

A good measure of the efficacy of a refractive procedure is a comparison of preoperative spectacle-corrected visual acuity to postoperative uncorrected visual acuity. Figure 4 shows that 68% (84 eyes) had 20/40 or better postoperative uncorrected visual acuity compared to 80% (99 eyes) with the same level of spectacle-corrected visual acuity preoperatively.

The marked gains in spectacle-corrected visual acuity occur, in large part, because of elimination of the spectacle-induced mniification experienced by patients with extreme myopia preoperatively.37,38 In our series, 64% of all eyes (79 eyes) gained lines of spectacle-corrected visual acuity, and 36% (45 eyes) gained two or more lines, a trend reported in groups
of eyes that received anterior chamber phakic IOLs.\textsuperscript{24,26} The minimization factor could have been minimized if contact lens-corrected visual acuity had been examined. Contact lens-corrected visual acuity was not examined in this series.

**Safety**

Apart from questions of limited efficacy and predictability, corneal refractive procedures that employ an excimer laser for the treatment of extreme refractive errors necessitate the removal of large quantities of corneal tissue.\textsuperscript{2,4,7} Although refractive surgery with a phakic IOL obviates these issues, other potential problems arise. Corneal decompensation, pupil deformation, chronic low-grade inflammation, and pupillary block have been observed following implantation of anterior chamber phakic IOLs.\textsuperscript{22,24,28,27,36-43} In addition, the danger of microbial endophthalmitis is present whenever intraocular surgery is done.

Significant intraoperative complications in our series included one inverted lens and one broken lense (Table 1). The inverted phakic IOL was removed and then re-introduced into the eye in its proper orientation, without consequence. In the eye in which the phakic IOL broke intraoperatively, the cause was a poorly loaded phakic IOL in the injector with shearing of the haptic within the injector. The phakic IOL was exchanged for another phakic IOL weeks after the initial surgery, without complications.

Because the phakic IOL has a true front and back surface, orientation of the phakic IOL within the eye is essential, both optically and with regard to proper lens vaulting. The addition of positioning holes (which are open on the front surface only) into the new lens design helps guard against unidentified lens inversions (Fig 1B). The placement of a wedge of microsurgical sponge within the injector cartridge has reduced the number of phakic IOLs damaged during injection (Fig 1A).

The pigment dispersion on the phakic IOL surface is probably surgically related, and not induced by rubbing of the iris on the phakic IOL, because the amount of pigment appears to be non-progressive (Fig 6). Since implementing the combination argon and Nd:YAG preoperative peripheral iridotomies (as opposed to Nd:YAG alone), we have seen less pigment deposition on the phakic IOL. Because of travel constraints in our patient population (many patients come to Instituto Zaldivar from distances well over 600 kilometers), we have been performing the laser iridotomies only 1 to 2 days prior to lens implantation. If we were able to perform the peripheral laser iridotomy at least 1 week prior to implantation, the quantity of pigment dispersion would likely decrease. In addition, the implementation of a non-rotational insertion technique—each corner of the haptics is positioned independently; the haptics are not dialed-in—has diminished the pigment dispersion that occurs secondary to surgical trauma.

One eye with a decenthered phakic IOL had the IOL removed 1 year postoperatively because of excessive pigment dispersion and increased intraocular pressure. It was unclear whether the pigment dispersion was related to the phakic IOL decentration or to the phakic IOL itself. Iris transillumination defects indicative of chronic mechanical trauma were not evident. Following phakic IOL removal, phacoemulsification of the crystalline lens, and IOL implantation in the capsular bag, the pigment has diminished, the intraocular pressure has normalized, and the spectacle-corrected visual acuity has remained stable. In 1995, we suggested the incorporation of feet into the haptic design of the posterior chamber phakic IOL in order to increase the stability of the IOL inside the eye. Subsequent models have included this modification, and lens centration has improved; we have seen no additional cases of excessive pigment dispersion with increased intraocular pressure.

The greatest concern about modern anterior chamber phakic IOLs has been endothelial cell loss. Studies of the Worst iris claw lens and the original Baikoff ZB lens have reported widely disparate results, with some investigators demonstrating mean endothelial cell density losses of approximately 4% and others demonstrating average losses in cell density of 20%.\textsuperscript{28,39,44} (Fechner PU. "Phakic PCL is promising for high myopia" by Schonfeld AR,
Ocular Surgery News, Int'l. Ed., 4:12, December 1993. Presented at the ESCRAS Annual Symposium, Innsbruck, Austria, September 1993. Decreasing the haptic-optic angle and the optic thickness in the Baikoff lens (ZBMF) has reduced the average loss in mean endothelial cell density to approximately 4%. In a detailed study comparing endothelial cell loss in eyes with the Worst iris claw or Baikoff ZB5M lens, Perez-Santoja et al found similar average losses in mean endothelial cell density between the two groups at 6 months and 1 year postoperatively. Endothelial cell loss was 11% at 6 months and 13% at 12 months in the Worst iris claw group and 11% at 6 months and 12% at 12 months in the Baikoff ZB5M group. The results at 2 years, however, demonstrated differences between the two populations. The Worst phakic IOL group registered progressive endothelial cell loss (18% loss at 24 months compared to preoperative values), and the Baikoff phakic IOL group showed stable mean endothelial cell density (12% loss 24 months compared to preoperative values). Studies with laser flare-cell fluorophotometry comparing the Worst phakic IOL and Baikoff ZB5M phakic IOL lenses suggest that increased levels of chronic subclinical inflammation in the Worst IOL eyes may be one reason for the progressive endothelial cell loss.

Initial endothelial cell damage in phakic IOL surgery likely results from surgical trauma; progressive loss may occur because of intermittent IOL-cornea touch or because of chronic inflammation. With its relatively straightforward insertion and posterior chamber location, the STAAR Collamer posterior chamber phakic IOL should theoretically be well tolerated by the eye without significant endothelial cell loss, provided that chronic inflammation does not develop. Fyodorov et al have reported mean decreases in endothelial cell density of 5% with the silicone posterior chamber phakic IOL, and Assietto et al found mean losses of 4% in 15 eyes that received the Staar Collamer IOL. The mean endothelial cell density measurements in our series were unreliable because of technical considerations and are therefore not reported. None of the 124 eyes that received a phakic IOL in our series developed signs of endothelial decompensation such as persistent corneal edema. Studies of endothelial cell morphology in eyes with phakic IOLs have not yet been done, and such analyses could also prove useful. In addition, measurements with a laser flare-cell meter or fluorophotometry may help identify eyes with subclinical inflammation that may be at risk for progressive endothelial cell damage.

The most frequent postoperative complication was an increase in intraocular pressure. While 6 of 14 of these intraocular pressure increases were secondary to postoperative topical corticosteroids, eight were directly related to the phakic IOL (including six cases of pupillary block and two cases of lens-related intraocular pressure spikes in which no other cause could be identified). Our incidence of pupillary block and secondary angle closure has been greatly reduced since we began placing preoperative laser iridotomies. The two eyes with lens-related intraocular pressure elevations have done well following removal of the phakic IOL with subsequent clear lens extraction and posterior chamber IOL implantation, experiencing good intraocular pressure control and no evidence of glaucomatous optic nerve damage.

Posterior chamber phakic IOLs raise more concern of cataractogenesis than do anterior chamber lenses. The rate of cataract formation in eyes receiving posterior chamber phakic IOLs has been low, with Fyodorov’s silicone model demonstrating a 1% incidence of lenticular change. Assetto et al performed postoperative axial densitometry on 12 eyes that had received the Collamer IOL and found no opacities of the crystalline lens. We observed only one eye (0.9%) that developed a cataract as a result of surgical manipulations, resulting from the preoperative laser iridotomy. We did not identify any phakic IOL-induced lenticular changes in this series of eyes. We have induced a visually significant cataract in one eye (not reported in this series because the target postoperative refraction was not emmetropia) during phakic IOL implantation. In this eye, the phakic IOL was inserted, and an attempt was made to reposition the IOL within the eye. During the manipulation, the phakic IOL contacted the anterior capsule, causing an anterior subcapsular cataract. We recommend removing inverted phakic IOLs from the eye and then re-injecting the phakic IOL in its proper orientation, minimizing the risk of cataractogenesis.

When considering the potential for cataractogenesis of the posterior chamber phakic IOL in a population such as ours, it is important to remember that patients with extreme myopia are a visually handicapped group, even with spectacle or contact lens correction. If these patients were to develop iatrogenic visually significant cataracts, modern cataract surgery can effectively restore good vision, albeit with a loss of accommodation. The increased risk of retinal detachment following lens extraction in extreme myopes must also be considered. As the posterior chamber phakic IOL procedure is...
considered for patients with intermediate or lower refractive errors, the concern over cataractogenesis becomes greater, and the risk-benefit may increase. In the eye that developed a rhegmatogenous retinal detachment 3 months after phakic IOL implantation, it seemed unlikely that the problem was related to the surgery. The patient had extreme myopia with a preoperative spherical equivalent refraction of -13.25 D and axial length of 32.87 mm and was therefore predisposed to a spontaneous rhegmatogenous retinal detachment. The possibility that mechanical effects during lens implantation (traction of lens zonules on the pars plana, for example) can cause a retinal break and subsequent detachment in high risk eyes must also be considered.19 Three retinal detachments following phakic IOL surgery with the Baikoff ZB5M lens have been reported.62 These eyes all had axial lengths greater than 28.90 mm and occurred 6 weeks, 8 months, and 10 months postoperatively. It is important to perform a detailed dilated fundus examination to look for predisposing retinal breaks in patients at high risk for spontaneous retinal detachment such as those with extreme myopia. Identifying a horsehoe tear may prove, in the end, more visually important to the patient than the refractive procedure itself.

The low incidence of loss of two or more lines of spectacle-corrected visual acuity (one eye, 0.9%) compares favorably to corneal refractive procedures in which patients with much lower refractive errors were treated.2,7 The eye that lost five lines of spectacle-corrected visual acuity was the one with the most serious complication in our series, a retinal detachment.

Stability

Regression of the initial refractive result has concerned investigators who attempt corneal refractive procedures, especially in patients with extreme refractive errors.2,7 In contrast, excellent refractive stability has been demonstrated in eyes with extreme myopia following phakic IOL surgery with either anterior chamber or silicone posterior chamber lenses.26,33,35 Following implantation of the Staar Collamer posterior chamber phakic IOL in our series, good average stability of the spherical equivalent refraction to 12 months is evident (Fig 3). Of the 57 eyes with at least 12 months of follow-up, six of 57 eyes (11%) experienced a change in spherical equivalent greater than ±1.00 D between postoperative examinations. Three eyes experienced a myopic shift, and three eyes experienced a hyperopic shift. Two of the six eyes had decentered phakic IOLs; the original IOL without footplates had been implanted in both cases, which may have contributed to the change in refractive error. One experienced a hyperopic shift of +1.13 D, and the other experienced a myopic shift of -1.63 D.

In the three eyes with more than 3 years of follow-up, stability of visual acuity, intraocular pressure, and pigment dispersion on the phakic IOL surface were observed (Table 2). Two of these eyes had a stable refraction during the entire 3 year period; one demonstrated a -2.25 D myopic shift between the 1 month and 6 month examination. It is unclear why this occurred, but the patient’s refraction remained stable over 6 months to 3 years.

Posterior chamber phakic IOL implantation with the STAAR Collamer plate IOL is an effective method for reducing or correcting high to extreme myopia of -8.00 to -19.00 D. Gains in spectacle-corrected visual acuity are common, and the results suggest good refractive stability and overall safety. Improvements in phakic IOL power calculation formulas will help improve the predictability of the procedure. Better studies of endothelial cell morphology and cataractogenesis are needed before posterior chamber phakic IOL implantation can be offered to patients with middle and low range refractive errors.

REFERENCES

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