ABSTRACT

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

METHODS: We analyzed the results of 24 eyes that received a posterior chamber hydrogel-collagen plate phakic IOL (Staar Collamer Implantable Contact Lens, ICL) for the correction of hyperopia with the goal of emmetropia. Mean follow-up was 8.4 months (range, 1 to 18 mo).

RESULTS: The mean preoperative spherical equivalent refraction was +6.51 ± 2.08 D (range, +3.75 to +10.50 D). Mean postoperative spherical equivalent refraction at last examination was -0.39 ± 1.29 D (range, +1.25 to -3.88 D), with 79% (19 eyes) within ±1.00 D and 58% (14 eyes) within ±0.50 D of emmetropia. Postoperative uncorrected visual acuity at last examination was 20/20 or better in 8% (two eyes) and 20/40 or better in 63% (15 eyes). A gain of two or more lines of spectacle-corrected visual acuity was seen in two eyes (8%) at last examination. One eye (4%) lost two or more lines of spectacle-corrected visual acuity due to progressive neovascular glaucoma initiated by early postoperative pupillary block.

CONCLUSION: Posterior chamber phakic IOL implantation with the Staar Collamer plate lens is an effective method for correcting high hyperopia. Large, patent iridotomies are important in hyperopic eyes to lower the risk of postoperative pupillary block. Improved phakic IOL power calculation formulas will refine predictability of refractive outcome. [J Refract Surg 1998;14:306-311]
PATIENTS AND METHODS

Intraocular Lens
The Staar Collamer posterior chamber phakic IOL (Staar Surgical AG Nidau, Switzerland) is made of a porcine collagen/HEMA copolymer (less than 0.1% collagen) with a refractive index of 1.45 at 35°C. Its design has been described.11 Because the phakic IOL has undergone modifications since we began implanting the lens, several distinct lens designs were implanted during this study. The predominant model used was the IC2020 (12 eyes). In addition, five eyes received the IC2020-P series phakic IOL, five received the IC2020-H series phakic IOL, and two eyes received the IC2020 DES-1 model phakic IOL.

Patient Selection
From March 1994 to August 1996 we implanted posterior chamber phakic IOLs into 24 eyes of 19 patients with high hyperopia (spherical equivalent refraction more than +3.50 D). Mean preoperative spherical equivalent refraction was +6.51 ± 2.08 D (range, +3.75 to +10.50 D). Mean age at the time of surgery was 36 years with a range of 26 to 45 years. Exclusion criteria included previous intraocular surgery, nanophthalmos, 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, pachymetry, specular microscopy, A-scan ultrasonography, slit-lamp biomicroscopy, applanation tonometry, and dilated funduscopy. Visual acuity and cycloplegic refraction are the only preoperative data reported for all eyes.

Intraoperative arcuate transverse keratotomies for astigmatism were performed on two eyes. A second refractive procedure to correct residual refractive error after phakic IOL was performed in seven eyes. The refractive and visual acuity data prior to the secondary procedure are presented.

Surgical Technique
The surgical technique has been described.11 To decrease the incidence of postoperative pupillary block, in June 1994 we began placing peripheral laser iridotomies at least 4 days preoperatively. Until August 1995, patients received a single superior iridotomy; subsequently, we began placing two superior iridotomies positioned 60° to 90° apart in order to decrease the likelihood of iridotomy occlusion by the phakic IOL haptics. Iridotomies were 250-500 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 dispersion on the phakic IOL (Argon settings: 50 µm spot size, 650 to 1000mW power, and 0.2 to 0.5 sec duration).

Lens power calculations were performed with formulas developed by Staar. The independent variables in the formula were 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 for hyperopic eyes. 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 based on the patient's horizontal corneal diameter (white-to-white). The size of the phakic IOL was horizontal corneal diameter plus 0.5 mm, rounded to the nearest 0.5-mm increment. Corneal diameter was measured preoperatively with the computerized calipers on the videokeratoscope (EyeSys Technologies, Houston, TX). The goal was to implant a phakic IOL of slightly larger size than the ciliary sulcus to promote anterior IOL vaulting and secure fixation.

Although the surgical maneuvers are identical in myopic and hyperopic eyes, the shallower anterior chambers of the hyperopic eyes solicited extra care during phakic IOL insertion in order to avoid contact with the corneal endothelium.

Secondary Refractive Procedures
Residual refractive errors were treated with refractive or arcuate transverse keratotomy in three eyes, PRK in one eye, and LASIK in three eyes, according to previously described techniques.12,13 The secondary refractive procedures were performed no sooner than 4 weeks following phakic IOL implantation. Two eyes underwent removal of their initial phakic IOL (Table).

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 8.4 ± 3.6 months following phakic IOL implantation (range, 1 to 18 mo). The follow-up rate was 100% at 1 day and 1 month (24 eyes),
79% at 6 months (19 of 24 eyes that had surgery at least 6 months prior to completion of the study), 80% at 12 months (12 of 15 eligible eyes), and 67% at 18 months (two of three eligible eyes).

All follow-up examinations detailed subjective complaints. Uncorrected visual acuity and spectacle-corrected visual acuity by manifest refraction were elicited at each examination and are reported for all eyes. Automated keratometry, applanation tonometry, and slit-lamp microscopy were performed at each examination, and the significant findings are reported. Phakic IOL vaulting, pigment dispersion, and crystalline lens clarity were particularly documented. Pigment deposition on the phakic IOL surface is reported for all eyes. Gonioscopy and dilated funduscopy were performed as needed. Postoperative specular microscopy was performed on 11 eyes. Because of unreliable preoperative and postoperative measurements, the specular microscopy results are not presented.

Data Analysis

Data forms were used to help standardize data collection and analysis. Refractive outcome and postoperative visual acuity were analyzed as measures of the efficacy of the procedure. Baseline refractions (spherical equivalent refraction and cylinder) and visual acuities (uncorrected visual acuity and spectacle-corrected visual acuity) were compared to the refractions and visual acuities at the last examination. In examining refractive and uncorrected visual acuity outcomes, the last refraction and uncorrected visual acuity prior to a secondary refractive procedure were used.

Complications were analyzed as a measure of the safety of the procedure. All potentially visually threatening events were recorded (Table). A loss of spectacle-corrected visual acuity of more than two lines was considered significant. The frequencies of phakic IOL-related subjective complaints persistent after 1 month were documented.

Refractive outcomes at 1, 6, and 12 months were analyzed. Refractive outcomes of eyes with more than 12 months follow-up were evaluated as a measure of stability of the refractive outcome. Eyes with secondary refractive procedures during their first 12 postoperative months were excluded from this stability analysis.

RESULTS

Baseline Refraction Groups

Mean preoperative spherical equivalent refraction was $+6.51 \pm 2.08$ D (range, $+3.75$ to $+10.50$ D) and mean preoperative refractive astigmatism was $1.41 \pm 1.01$ D (range, 0 to 3.25 D).

Refractive Outcome

Mean postoperative spherical equivalent refraction at last examination was $-0.39 \pm 1.29$ D (range, $+1.25$ to $-3.88$ D) and mean refractive astigmatism was $1.56 \pm 1.47$ D (range, 0 to 4.00 D). Postoperative spherical equivalent refraction at last examination was within $\pm 1.00$ D in 79% (19 eyes) and within $\pm 0.50$ D in 58% (14 eyes). Spherical equivalent
refraction stability is demonstrated in Figure 1. Of the 12 eyes with at least 12 months follow-up, three eyes (25%) demonstrated a change in spherical equivalent refraction of greater than ±1.00 D at any examination interval. Two eyes experienced a myopic shift and one eye experienced a hyperopic shift.

**Visual Acuity**

Preoperative uncorrected visual acuity was less than 20/200 in 74% of eyes. No eyes had preoperative uncorrected visual acuity of better than 20/50. Preoperative spectacle-corrected visual acuity was 20/40 or better in 83% (20 eyes) and 20/20 or better in 21% (five eyes). Postoperative uncorrected visual acuity at last examination was 20/40 or better in 63% (15 eyes) and 20/20 or better in 8% (two eyes, Fig 2).

Figure 3 compares preoperative versus postoperative spectacle-corrected visual acuity (last available refraction). A gain of two or more lines of spectacle-corrected visual acuity was seen in 8% (two eyes). One eye of one patient experienced a loss of two or more lines of spectacle-corrected visual acuity due to secondary angle closure glaucoma (spectacle-corrected visual acuity was 20/30 preoperatively and 20/60 postoperatively at last examination).

**Complications**

Perioperative and postoperative complications are detailed in the Table. The most common complication was early postoperative pupillary block, which occurred in three eyes. Two of these eyes had a single laser iridotomy placed preoperatively, and the other eye did not have a preoperative laser iridotomy. In two of these three eyes, the pupillary block was relieved with placement of two peripheral laser iridotomies. In the third eye, progressive glaucomatous optic nerve cupping developed despite repeated laser iridotomies, two trabeculectomies, and removal of the phakic IOL combined with phacoemulsification of the clear crystalline lens and posterior chamber IOL implantation in the capsular bag. Secondary angle closure developed due to neovascularization of the angle. At last examination, 18 months following phakic IOL implantation, spectacle-corrected visual acuity was 20/60 (three lines worse than preoperative spectacle-corrected visual acuity), and intraocular pressure was controlled (16 mmHg) on multiple medications.

Three eyes had their original phakic IOL removed: the eye with neovascular angle closure glaucoma, one eye with phakic IOL decentration, and one eye with anterior chamber crowding (shallowing of the central anterior chamber on slit-lamp examination and an inability to visualize the trabecular meshwork on gonioscopy). Of these, one had a new, properly sized, posterior chamber phakic IOL placed and has done well subsequently; the one with angle closure glaucoma was just discussed. The third eye had no lens implanted because the original phakic IOL effected such severe overcrowding of the anterior chamber. The spectacle-corrected visual acuity returned to its preoperative level within 2 days after phakic IOL explantation.

There were no cases of corticosteroid-induced intraocular pressure elevation, broken phakic IOL, cataracts, sustained corneal edema, macular edema, or retinal detachment. The mean amount of pigment deposition on the phakic IOL surface appeared stable (mean less than 2+ at all examinations), and there were no cases of pigment dispersion glaucoma.

Subjective complaints persistent after 1 month included glare (two eyes), pain (two eyes), and
decreased visual acuity (one eye). Complaints of glare were seen in the two eyes with more than 1 mm of phakic IOL decentration; symptoms were relieved upon phakic IOL recantation or exchange. Complaints of pain and decreased vision occurred in the eye with progressive glaucoma. The eye of the other patient with complaints of pain had a mild superficial epithelial keratopathy attributed to mild dry eyes.

**DISCUSSION**

Myopic eyes that have relatively large anterior segments are well suited for phakic IOL surgery. Anterior chamber phakic IOLs may be implanted without causing significant damage to the corneal endothelium and well-positioned posterior chamber IOLs do not appear to induce cataracts. In contrast, hyperopic eyes often have relatively small anterior segments, which may make phakic IOL surgery more difficult. The spectrum of hyperopia includes nanophthalmos, and intraocular surgery in nanophthalmic eyes is associated with an increased risk of angle closure glaucoma, uveal effusion, and nonrhegmatogenous retinal detachments. To date, anterior chamber phakic IOLs have been unsuitable for use in hyperopic eyes.

By allowing a relative deepening of the anterior chamber, clear lensectomy with IOL implantation may be a good alternative to anterior chamber phakic IOL surgery for the treatment of high hyperopia, and it has demonstrated good efficacy and safety. Limitations of clear lensectomy with IOL implantation include problems of IOL power calculations, the potential need for implanting more than one IOL (piggyback IOLs), and loss of accommodation.

Posterior chamber phakic IOLs offer potential advantages over clear lensectomy by preserving accommodation. In addition, posterior chamber phakic IOLs offer a potential advantage over anterior chamber models because, by virtue of their location behind the iris, there should be less risk of phakic IOL–corneal endothelium contact and subsequent corneal edema.

**Efficacy and Predictability**

The posterior chamber phakic IOL dramatically decreased the hyperopia in our study population. Seventy-nine percent (19 eyes) achieved a postoperative spherical equivalent refraction within ±1.00 D and 58% (14 eyes) within ±0.50 D of emmetropia at the last examination. This compares favorably to the predictability of our initial 124 eyes with high myopia that received a posterior chamber phakic IOL: 69% (86 eyes) achieved a postoperative spherical equivalent refraction within ±1.00 D and 44% (55 eyes) were within ±0.50 D of emmetropia. Limitations in predictability of posterior chamber phakic IOL surgery relate, in part, to choosing IOL powers based on spectacle corrections. The development of more accurate lens power calculation formulas should help improve the predictability of the procedure.

A good measure of efficacy in refractive procedures is a comparison of preoperative spectacle-corrected visual acuity to postoperative uncorrected visual acuity. Figure 2 shows that 63% (15 eyes) had 20/40 or better postoperative uncorrected visual acuity compared to 83% (20 eyes) with the same level of spectacle-corrected visual acuity preoperatively.

The marked gain in spectacle-corrected visual acuity that has been reported in high myopes following phakic IOL surgery was not observed in our hyperopic population, with 8% (two eyes) demonstrating a gain in spectacle-corrected visual acuity at last examination (Fig 3). In our myopic series, 36% (45 of 124 eyes) gained two or more lines of spectacle-corrected visual acuity, largely due to an elimination of the spectacle-induced minification experienced by these patients preoperatively.

**Safety**

The 12.5% incidence of postoperative pupillary block (three eyes) is more than double the 4.8% incidence of pupillary block observed in our previous myopic series. We attribute this to postoperative anterior segment crowding that can occur when smaller hyperopic eyes receive a phakic IOL. We have seen no cases of pupillary block since we began placing two peripheral laser iridotomies 60° apart.
preoperatively. The progressive glaucoma (beginning with pupillary block and angle closure) that developed in one eye emphasizes the importance of taking measures to avert this complication and identifying predisposed and affected eyes early. This was the only eye in our series that experienced a loss of two or more lines of spectacle-corrected visual acuity. One eye had the phakic IOL removed because excessive vaulting of the IOL produced anterior chamber crowding and caused concern for angle closure. Phakic IOL removal was performed without incident and spectacle-corrected visual acuity returned to its preoperative level.

The pigment deposition on the phakic IOL surface was probably surgically related because the amount of pigment was not progressive (Fig 4). There were no cases of pigment dispersion glaucoma. We think that increasing the time between laser iridotomy and phakic IOL implantation as well as implementation of the non-rotational insertion technique help produce less pigment deposition. We no longer dial-in the corners of the haptics; rather, each corner is individually positioned beneath the iris with an intraocular hook, which minimizes surgical trauma.

**Stability**

Regression of the initial refractive result has occurred after corneal refractive procedures in eyes with high myopia or high hyperopia. In contrast, excellent refractive stability has been demonstrated in eyes with high myopia following phakic IOL surgery with anterior chamber IOLs, silicone posterior chamber phakic IOLs, or silicone-collagen copolymer phakic IOLs. We observed good stability of the spherical equivalent refraction to 12 months in this small series (Fig 1). Longer follow-up in a larger number of eyes will help to better address long-term stability.

**REFERENCES**