Medennium Posterior Chamber Phakic Refractive Lens to Correct High Myopia

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ABSTRACT

PURPOSE: To determine the efficacy and safety of phakic refractive lens implantation to correct high myopia.

METHODS: In this prospective study, a phakic refractive lens was implanted in 90 myopic eyes in which refractive errors ranged from −6.00 to −20.00 diopters (D) and laser refractive surgery was contraindicated. Uncorrected visual acuity (UCVA) and best-spectacle corrected visual acuity (BSCVA), manifest and cycloplegic refractions, and intraocular pressure (IOP) were assessed during a 1-year follow-up period. Possible complications, including endothelial cell counts, were evaluated.

RESULTS: Spherical equivalent refraction measurements revealed a significant change from the preoperative mean value of −11.90±5.00 D to 0.04±0.20 D 1 year postoperatively (P=.001). The UCVA and BSCVA significantly improved postoperatively (P=.001 and P=.01, respectively). Seventy-two (80%) eyes and 61 (68%) eyes were within ±1.00 D and ±0.50 D of the target refraction, respectively. A significant increase in IOP was found at every postoperative visit (P=.01). There was a trend toward decreased endothelial cell density postoperatively, although the difference did not reach significance. No major complications were found during the 1-year follow-up period.

CONCLUSIONS: The implantation of a phakic refractive lens seems to be a predictable and well-tolerated procedure for correcting high myopia. Complications such as development of cataract, implant dislocation, decreases in endothelial cell counts, or development of glaucoma did not occur in this study. [*J Refract Surg.* 2007;23:900-904.]

Although corneal refractive surgery is the preferred technique to correct mild to moderate myopia, the treatment of severe ametropia continues to generate controversy. Current techniques to treat high levels of myopia include corneal surgery and clear lens extraction. With the former, the effectiveness and predictability decrease with increasing degrees of preoperative refractive error,[1] and with the latter, the procedure is irreversible and associated with loss of accommodation and higher risk of complications.[2] Implantation of a phakic intraocular lens (PIOL) is a recent and satisfactory procedure to correct high myopia. The advantages of PIOLs for this level of refractive errors include excellent refractive results with rapid recovery of good quality vision. In addition, the technique is potentially reversible, preserves accommodation, and can be combined with corneal refractive procedures (bioptics) to correct associated astigmatism and in cases of extreme myopia.[3,4]

Although anterior chamber phakic lenses were the first to be implanted, posterior chamber lenses are increasing in popularity. Fyodorov et al were the first to introduce posterior PIOLs,[5] which were refined over time to reduce the incidence of uveitis and endothelial cell loss.[6]

The phakic refractive lens (Medennium Inc, Irvine, Calif), a posterior chamber PIOL, is a single-piece plate made of medical-grade silicone with a refractive index of 1.46 and powers ranging from −3.00 to −20.00 diopters (D) for myopic correction. The silicone material is soft, elastic, and hydrophobic.[7-9] When the implant is placed in the posterior chamber, it is a greater distance from the corneal endothelium and therefore

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long-term endothelial damage may be less than with an anterior chamber intraocular lens (IOL). On the other hand, the phakic refractive lens location between the iris and the crystalline lens could lead to the development of cataracts and pigment dispersion.[4] The phakic refractive lens is not intended to be supported in the sulcus angle but to float over the crystalline lens without coming into contact with the anterior capsule,[9] thus reducing the risk of crystalline lens opacification.

Although some authors[9,10] have reported the short-term optical results after phakic refractive lens implantation are excellent and stable, the results of these implants were analyzed in small series of patients. Hoyos et al[9] and Pallikaris et al[10] studied 31 and 34 eyes, respectively.

In addition, different reports on phakic refractive lens-related complications have raised some concerns regarding the long-term safety of the IOL. Despite the fact that the incidence of cataract development is low with phakic refractive lenses,[10] some cases of posterior dislocation and pupillary block after implantation have been reported.[11,12]

Phakic IOLs also are associated with ocular hypertension (5.3% to 15.6%)[13] and pigment dispersion caused by chronic abrasion of the posterior iris on the anterior surface of the implant[14]; moreover, a consideration is that myopia per se is a strong risk factor for the development of open-angle glaucoma. Patients with myopia have an increased risk of primary open-angle glaucoma,[15] pigment dispersion syndrome, and pigmentary glaucoma.[16] For these reasons, this study analyzed the safety of phakic refractive lens implantation in a large number of patients with high myopia.

PATIENTS AND METHODS

Inclusion and Exclusion Criteria

This prospective study included 51 consecutive patients who fulfilled the inclusion criteria and agreed to participate. Patients with myopia (range: −6.00 to −20.00 D) who wished to undergo refractive surgery and for whom laser refractive surgery was contraindicated were included in the study. The nature and purpose were explained in detail to all participants, and informed consent was obtained before patients were enrolled in the study.

Exclusion criteria were age younger than 18 years or over 50 years, anterior chamber depth less than 3 mm, endothelial cell count less than 2000 cells/mm^2, glaucoma or intraocular pressure (IOP) greater than 20 mm Hg, pupil size greater than 6 mm under mesopic conditions, white-to-white corneal diameter greater than 11.5 to 12 mm measured using a caliper, and regular astigmatism of 3.00 D. Patients with uveitis, cataract, or any other intraocular or systemic disease also were excluded from the study.

Preoperative Evaluation

Visual acuity (in decimal notation) was measured using Snellen letters. The preoperative examination included measurement of uncorrected visual acuity (UCVA) and best spectacle-corrected visual acuity (BSCVA), manifest and cycloplegic refractions, corneal topography (Dicon CT 200; Paradigm Medical Industries Inc, Salt Lake City, Utah), ultrasound pachymetry (DGH 5100; DGH Technology Inc, Exton, Pa), endothelial cell counts with a non-contact specular microscope (SP-2000P; Topcon Corp, Tokyo, Japan), slit-lamp microscopy, pupil size measured under mesopic conditions (Colvard pupillometer; Oasis, Glendora, Calif), white-to-white corneal diameter measured with a caliper, Goldmann applanation tonometry, and dilated funduscopy. Keratometry was obtained with an autorefractometer (ARK-700; NIDEK Co Ltd, Gamagori, Japan) and used to evaluate preoperative corneal curvature. Ultrasound measurement (OcuScan, version 3.02; Alcon Laboratories, Ft Worth, Tex) of the axial length, by the applanation method, and anterior chamber depth also were obtained; anterior chamber depth was considered to be the contact ultrasonic depth plus the pachymetry, so the final value of the anterior chamber depth was from the epithelium to the anterior lens capsule. Lens power calculation was performed using a nomogram provided by the manufacturer and was based on the preoperative cycloplegic spherical equivalent, the average keratometric power, horizontal white-to-white distance, anterior chamber depth, and the target postoperative refraction (emmetropia in all eyes).

Lens Implantation

Three laser YAG iridectomies (at the 10, 12, and 2 o'clock positions) were performed at least 1 week preoperatively. A combination of cyclopentolate 0.75% and tropicamide was applied three times 30 minutes before surgery to obtain good pupil dilation. In all cases, the same surgeon implanted the phakic refractive lens under regional anesthesia through a 3.2-mm clear corneal incision, performed in the steeper corneal meridian. The anterior chamber was filled with a low-viscosity viscoelastic agent, and the lens was inserted using forceps; a lens manipulator was used to place the lens' haptics beneath the iris. Balanced salt solution was infused into the anterior chamber to eliminate the remaining viscoelastic material, and the pupil was closed by injecting acetylcholine.

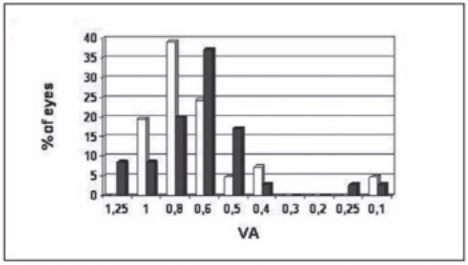

Figure 1. Comparison of postoperative uncorrected visual acuity (black bars) and preoperative best spectacle-corrected visual acuity (white bars) in 90 myopic eyes implanted with a phakic refractive lens.

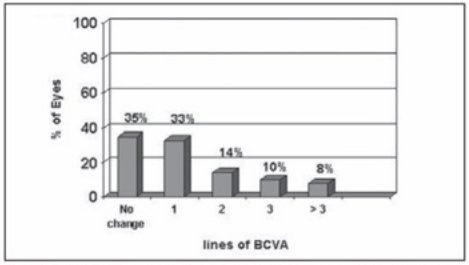

Figure 2. Percentage of eyes with improvement in best spectacle-corrected visual acuity 1 year after phakic refractive lens implantation in 90 myopic eyes.

POSTOPERATIVE PERIOD

Postoperatively, patients received three tablets of acetazolamide 250 mg to be taken on the first postoperative day. Antibiotic-steroid (dexamethasone) combination drops were prescribed four times daily for 1 week, followed by tapered doses of fluorometholone for 3 weeks.

Patients were examined on the first postoperative day, at 1 week, and at 1, 3, 6, and 12 months. In all cases, length of follow-up after phakic refractive lens implantation was at least 1 year. Follow-up examinations included UCVA, BSCVA, manifest and cycloplegic refraction, IOP, gonioscopy, slit-lamp evaluation (to assess phakic refractive lens centration, lens opacity, transillumination defects of the iris, and inflammation), and endothelial cell counts.

STATISTICAL ANALYSIS

Statistical analysis was performed using Statview SE + Graphics (Abacus Concepts Inc, Berkeley, Calif) software on a Macintosh personal computer (Apple Computer Inc, Cupertino, Calif). Data are expressed as the average ± standard deviation. Analysis of variance (ANOVA) and Student's t test were used for comparisons between groups when appropriate. Visual acuity (in decimal notation) was converted to logMAR units for the statistical analysis. The exact P value is expressed for each comparison. A P value $<.05$ was considered significant.

RESULTS

Ninety myopic eyes of 51 patients were included in the study. Mean patient age was 33.3±6 years. Mean preoperative anterior chamber depth was 3.43±0.3 mm (range: 3.01 to 3.95 mm). Mean cylinder was −1.60±1.00 D (range: 0 to −3.00 D) preoperatively and −1.03±0.90 D (range: 0 to −3.50 D) postoperatively.

EFFICACY

Mean UCVA changed significantly from less than 0.1 preoperatively to 0.7±0.2 (range: less than 0.1 to 1.2) at the last follow-up examination ($P<.001$) (Fig 1). All eyes had an increase of UCVA from 1 to 12 lines. The efficacy index (ie, postoperative UCVA/preoperative BSCVA) was 0.98.

SAFETY

Mean BSCVA changed significantly from 0.70±0.2 (range: 0.1 to 1) preoperatively to 0.9±0.2 (range: 0.1 to 1.2) postoperatively ($P<.01$). In 65% of the eyes, BSCVA improved, with 30 eyes gaining 1 Snellen line, 13 eyes gaining 2 lines, 9 eyes gaining 3 lines, and 7 eyes gaining more than 3 lines. No eye lost any line of BSCVA (Fig 2). The safety index (ie, postoperative BSCVA/preoperative BSCVA) was 1.22.

PREDICTABILITY

Spherical equivalent refraction measurements revealed a statistically significant change from the mean preoperative value of −11.90±5.00 D (range: −6.00 to −20.00 D) to 0.04±0.20 D (range: −4.50 to 1.50 D) at 1 year postoperatively ($P<.001$). Seventy-two (80%) eyes and 61 (68%) eyes were within ±1.00 D and ±0.50 D of the target refraction, respectively (Fig 3).

POSTOPERATIVE COMPLICATIONS

Minor decentration of the intraocular implant was observed in five eyes, none of which required a second surgery. No cataract formation, pupillary block, or other major complications were observed during the 1-year follow-up period.

Mean preoperative IOP was 12.5±2 mmHg (range: 8 to 18 mmHg). A significant increase in IOP was found at every postoperative examination ($P<.01$) (Fig 4). Sixteen eyes required antihypertensive medication;

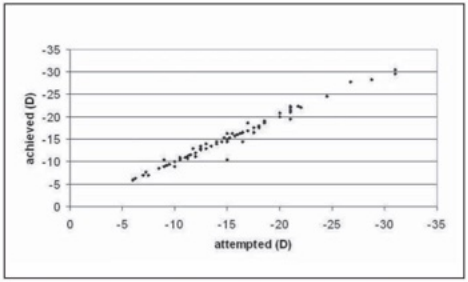

Figure 3. Scattergram showing the achieved versus intended spherical equivalent refractive change 1 year after phakic refractive lens implantation in 90 myopic eyes.

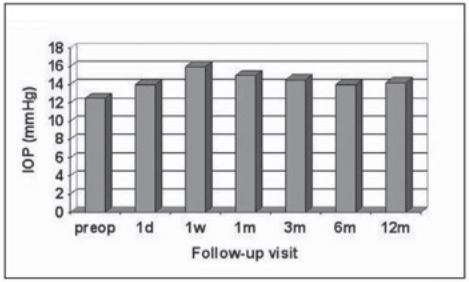

Figure 4. Comparison of intraocular pressure levels during the first year after phakic refractive lens implantation in 90 myopic eyes.

12 eyes received monotherapy with topical beta-blockers, and four eyes received a combination of acetazolamide, brimonidine, and a beta-blocker. All eyes with ocular hypertension had open anterior chamber angles, no pigment dispersion, and patent iridectomies. Only one of these patients required antihypertensive treatment for 3 months.

Preoperative endothelial density was 2900±245 cells/mm^2, which was greater than the postoperative measurements of 2850±245 cells/mm^2 at 3 months and 2848±245 cells/mm^2 1 year. The difference between the preoperative and the postoperative values did not reach significance (P>.05).

DISCUSSION

According to our results, phakic refractive lens implantation to correct high myopia is efficacious, predictable, and stable. The BSCVA levels improved in 65% of the eyes after a phakic refractive lens was implanted. These results are similar to the results previously reported with the phakic refractive lens[9] and other PIOLs.[17] This postrefractive surgery improvement in BSCVA could have resulted from optical minification of retinal images and visual disturbances[6] induced by the diverging glasses used to correct high refractive errors.

Regarding the safety of this procedure, cataract formation is a possible complication after PIOL implantation. None of our patients had crystalline lens opacification. In contrast, the incidence of cataract development has been reported to range from 2.7% to 33.3% after implantation of implantable contact lenses.[6] The causes of lens opacities after PIOL implantation include intraoperative surgical trauma, extended surgical time, intracameral substances such as viscosurgical ophthalmic devices or anesthetic agents, perioperative subclinical inflammation, patient age, preoperative crystalline lens status, IOL material and design, IOL position relative to the crystalline lens, or compromised nutrition of the natural lens from a foreign body in front of it.[18]

In contrast to other reports,[11,12] no case of implant luxation occurred in our series. Cases of both phakic refractive lens[11,12] and implantable contact lens[19] luxation have been described in the literature as a consequence of a zonular fiber rupture, caused either by a possibly undetected surgical trauma or by the position and rotation of the phakic refractive lens in the posterior chamber, which could account for both early and delayed lens dislocation. Incorrect determination of IOL size also can contribute to postoperative dislocation into the vitreous as an oversized lens that impinges on the zonules exerts more pressure and possibly causes zonular damage.[20] In addition, it might well be that preexisting zonular weakness could be responsible for this complication. Thus, we believe adequate patient selection is mandatory, and the fact that we have not had a single case of dislocation may support this statement. Because IOL luxation is a severe complication, we believe a thorough preoperative evaluation and the correct surgical technique are essential for improving safety with this type of PIOL implant.

Our results showed an average IOP increase at every visit after phakic refractive lens implantation. Different factors may explain ocular hypertension after PIOL surgery.[21] First, IOP can increase acutely in the immediate postoperative period because of retention of viscoelastic material or pigment particles in the anterior chamber. In addition, acute angle-closure glaucoma can develop from inflammatory membranes or the appearance of a pupillary block by the lens resulting from impermeable iridotomies. Early IOP increases with shallowing of the anterior chamber also could be secondary to malignant glaucoma or suprachoroidal hemorrhage (forward displacement of the crystalline

lens and IOL), phakic posterior chamber IOL pupillary block (forward displacement of the lens from aqueous block between the implant and the crystalline lens), an oversized phakic posterior chamber IOL,[4] or retained viscoelastic material posterior to the phakic posterior chamber IOL (posterior chamber viscoelastic block).

Second, in the first postoperative month, ocular hypertension developed previously as the result of postoperative inflammation and steroid drug treatment. Intraocular pressure also can increase progressively during follow-up because of pigment dispersion resulting in pigmentary glaucoma; pigment dispersion syndrome occurs when the phakic refractive lens abrades the posterior surface of the iris, releasing pigment into the aqueous humor.[14]

Despite an absence of pupillary block or apparent pigment dispersion in our patients, there was a sustained increase in IOP over time after phakic refractive lens implantation in this highly myopic population. Although there was an increase in the mean postoperative IOP compared with the preoperative values, the mean IOP was within normal levels (ie, <20 mmHg) at every follow-up visit. Only one patient with postoperative hypertension required antihypertensive treatment for 3 months. Intraocular pressure should be evaluated over the long term to identify increases, evolution, and possible consequences.

Finally, we identified a trend toward a sustained decrease in endothelial cell density postoperatively. However, the difference between the preoperative and postoperative values did not reach statistical significance.

Our findings suggest implantation of a phakic refractive lens seems to be a predictable and effective way to correct high myopia, with few undesirable effects during the first postoperative year. Although complications such as cataract, lens dislocation, and glaucoma have not been observed in our patients, it is clear IOP should be evaluated over the long term. More studies with longer follow-up and greater numbers of patients are needed to draw final conclusions about the efficacy and safety of the posterior chamber phakic refractive lens.

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