Medennium Posterior Chamber Phakic Refractive Lens to Correct High Myopia

Celeste Marina Verde, DOO; Miguel A. Teus, MD, PhD; Esther Arranz-Marquez, MD, PhD; Raquel Gil Cazorla, DOO

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.

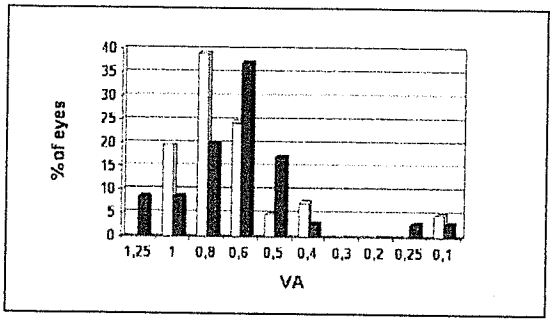

Figure 1. Comparison of postoperative uncorrected visual acuity (black bars) and preoperative best spectacle-corrected visual acuity (white bars) in 90 myopic eyes implanted with a phakic refractive lens.

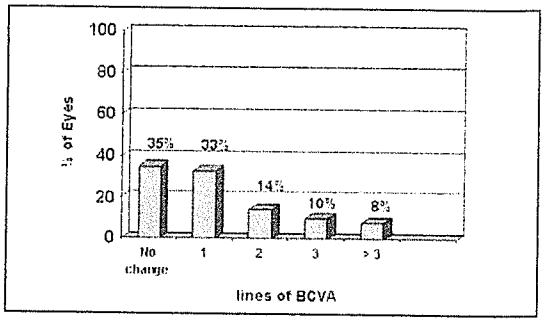

Figure 2. Percentage of eyes with improvement in best spectacle-corrected visual acuity 1 year after phakic refractive lens implantation in 90 myopic eyes.

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;

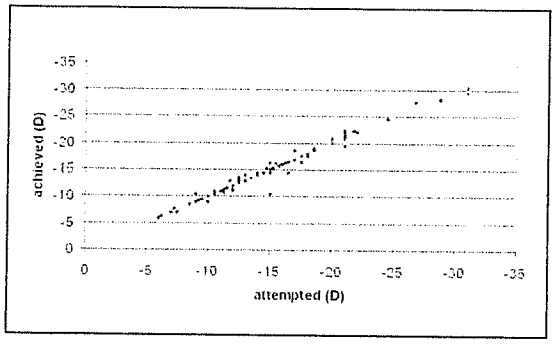

Figure 3. Scattergram showing the achieved versus intended spherical equivalent refractive change 1 year after phakic refractive lens implantation in 90 myopic eyes.

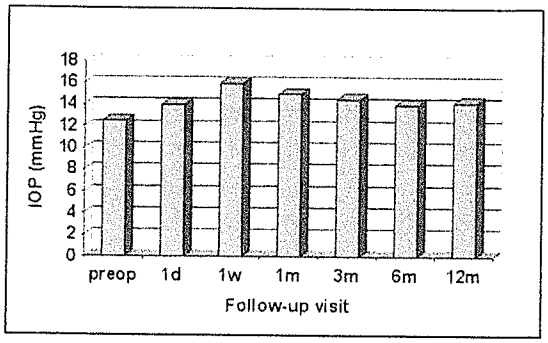

Figure 4. Comparison of intraocular pressure levels during the first year after phakic refractive lens implantation in 90 myopic eyes.

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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ABSTRACTS

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• **Deep sclerectomy for the treatment of exfoliation and primary open-angle glaucoma.** Rekonen P*, Kannisto T, Puustjärvi T, Teräsvirta M, Uusitalo H. Acta Ophthalmol Scand 2006;84:507–511.

IN THIS RETROSPECTIVE STUDY, THE EFFICACY OF DEEP sclerectomy was compared in the treatment of primary open-angle glaucoma (POAG) and exfoliation glaucoma (ExG). Deep sclerectomy with either collagen or hyaluronate implants was performed in 31 eyes with POAG and 38 eyes with ExG. Complete success was defined by the achievement of postoperative intraocular pressure (IOP) ≤21 mm Hg without antiglaucomatous medication. Qualified success was defined by the achievement of IOP ≤21 mm Hg with or without medication. If IOP was ≥22 mm Hg with medication, the operation was considered to have failed. At 18 months, complete success was achieved in 56.3% of POAG eyes and 44.9% of ExG eyes. Qualified success had been achieved in 83.1% and 71.6% of POAG and ExG eyes, respectively. The mean IOP was 18.6 mm Hg in POAG eyes and 16.3 mm Hg in ExG eyes. YAG-descemetotomies were performed in nine eyes in each group. There were no serious intraoperative or postoperative complications. There were no statistically significant differences between the groups in IOP (except at one week postoperatively in favor of POAG; $P = .05$), success rates, needed for postoperative glaucoma medication or number of complications. Reoperations were needed in three (10%) POAG eyes and seven (18%) ExG eyes. The authors conclude that deep sclerectomy is equally effective in controlling IOP in both POAG and ExG and has low rates of serious complications.—Michael D. Wagoner

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• **Clinical results with the Medennium phakic refractive lens for the correction of high myopia.** Jongsareejit A.* J Refract Surg 2006;22:890–897.

THE AUTHORS PERFORMED A PROSPECTIVE, NONCOMparative, interventional case series to determine the efficacy, predictability, and stability of the posterior chamber, floating, foldable phakic intraocular lens (PRL) for the correction of myopia with a mean myopic refractive error of −12.54 ± 4.22 diopters (D) (range, −4.50 to −23.50 D) and a mean astigmatic error of −1.38 ± 1.24 D (range, −1.00 to −4.50 D) in 50 eyes of 31 patients. Thirty eyes received PRL alone, 13 eyes received PRL combined with relaxing incision for astigmatism >2.00 D, and seven eyes received PRL combined with laser epithelial keratomileusis (LASEK) for astigmatism >3.00 D. After three months, the mean spherical equivalent was −0.21 ± 0.42 D (range, +1.00 to −1.75). At six and 12 months, the mean spherical equivalent was −0.23 ± −0.38 D (range, 0 to −1.25 D). At the last examination uncorrected visual acuity was ≥20/40 in 42 eyes (84%) and ≥20/20 in 27 eyes (54%). Comparison of pre- and postoperative best-spectacle corrected visual acuity at 12 months showed that 36.4% eyes gained ≥1 lines and that 21.2% gained ≥2 lines, while 2% loss 1 line. There were no intraoperative complications. Postoperative complications included anterior subcapsular cataract requiring lens exchange (one eye), acute angle closure glaucoma requiring YAG capsulotomy (one eye), and macular hemorrhage (onie eye). The authors conclude that good visual outcome and refractive stability are achieved in the first postoperative year after PRL, but that serious complications, such as cataract and acute angle closure glaucoma can occur. —Michael D. Wagoner

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• **Twelve-year follow-up of photorefractive keratectomy for low to moderate myopia.** O'Connor J, O'Keefe M,* Condon PI. J Refract Surg 2006;22:871–877.

THIS REPORT DESCRIBES A RETROSPECTIVE STUDY TO evaluate long-term stability in 120 eyes of 80 patients who underwent photorefractive keratectomy (PRK) ≥12 years ago. All patients were treated with the Summit UV200 excimer laser with a 5-mm ablation zone. Among the original group, 58 eyes of 34 patients returned at 12 years (mean 12.7 ± 0.79 years) for follow-up evaluation. The mean patient age was 32.4 ± 8.45 years (range, 20 to 54). The mean spherical refractive equivalent (MSRE) was −4.40 ± 1.58 diopters [D]

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Clinical Results With the Medennium Phakic Refractive Lens for the Correction of High Myopia

Amporn Jongsareejit, MD

ABSTRACT

PURPOSE: To evaluate the predictability, safety, stability, complications, and biocompatibility of the phakic refractive lens (PRL) as a posterior chamber intraocular lens to correct high myopia.

METHODS: Fifty eyes of 31 patients who underwent posterior chamber PRL implantation were evaluated prospectively. Mean preoperative myopia was −12.54±4.22 diopters (D) (range: −4.50 to −23.50 D) and mean astigmatic refractive power was −1.38±1.24 D (range: −1.00 to −4.50 D). Surgical implantation was performed through a 3.0- to 4.0-mm clear cornea sutureless incision using parabulbar (sub-Tenon's) anesthesia. Intra- and postoperative complications were recorded.

RESULTS: Three months after surgery, the mean spherical equivalent refraction was −0.21±0.42 D (range: +1.00 to −1.75 D). At 6 and 12 months, mean spherical equivalent refraction was −0.23±0.38 D (range: 0 to −1.25 D). At the last examination, uncorrected visual acuity was ≥20/40 in 41 (82%) eyes and ≥20/20 in 22 (44%) eyes. Best spectacle-corrected visual acuity (BSCVA) was ≥20/40 in 42 (84%) eyes and ≥20/20 in 27 (54%) eyes. Comparison of pre- and postoperative BSCVA at 12 months showed that 12 (36.4%) of 33 eyes gained ≥1 lines of BSCVA and 7 (21.2%) of 33 eyes gained ≥2 lines. One (2%) eye developed anterior subcapsular cataract requiring lens exchange, and 1 (2%) eye developed acute angle closure glaucoma requiring YAG-iridotomy. One (2%) eye developed macular hemorrhage.

CONCLUSIONS: At 6 months and 1 and 2 years, PRL implantation yielded encouraging visual and refractive results with excellent biocompatibility. The efficacy, stability, and short-term safety of this lens was established. Serious complications, such as cataract and acute angle closure glaucoma, may occur, and long-term safety needs to be evaluated. [*J Refract Surg.* 2006;22:890-897.]

Excimer LASIK is currently the most commonly performed procedure for the correction of myopia. The efficacy, stability, and safety of LASIK have been thoroughly studied.[1-5] The perception that LASIK can successfully treat a wide range of myopia, while achieving fast and painless return to excellent visual acuity, and can be enhanced in the event of undercorrection, has led many surgeons to adopt LASIK for the correction of low, moderate, and high myopia. However, the initial enthusiasm for this procedure has been tempered by further understanding of its potential complications, especially for high corrections in which small optical zone diameter and deep ablation are used. Iatrogenic keratectasia, optical aberrations, severe night glare, flap-related complications, and significant loss of spectacle-corrected visual acuity have recently been reported.[6-9] Clear lens extraction for high and extreme myopia exposes the patient to the risk of retinal detactment[10] and cystoid macular edema. Younger patients also face the problem of loss of accommodation, and the complexity of intraocular lens power calculations makes predictable refractive outcomes difficult.

Since 1983, many phakic intraocular lens (PIOL) designs have emerged. To date, there are three types of PIOLs: 1) anterior chamber, originally introduced by Baikoff and Joly[11]; 2) iris-supported, introduced by Fechner and Worst[12]; and 3) posterior chamber, introduced by Fyodorov[13] and modified by Staar Surgical Company (Implantable Contact Lens; Staar Surgical Co, Monrovia, Calif).[14] Another posterior chamber PIOL was modified by Medennium Inc (Irvine, Calif), the phakic refractive lens (PRL).[15] This lens is made of a highly

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The author has no proprietary or commercial interest in the materials presented herein.

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TABLE 1

Demographic Data of Patients Who Underwent PRL Implantation for Myopia

Characteristic	Result
No. eyes	50
Right/Left	22/28
Mean age (y) (range)	30.94±9.07 (19 to 52)
Men:women	12:19
MRSE (D) (range)	−12.54±4.22 (−4.50 to −23.50)
Mean astigmatic refractive power (D) (range)	−1.38±1.24 (−1.00 to −4.50)

purified silicone, which floats over the existing crystalline lens in the eye. The PRL has no support in the sulcus and due to its hydrophobic properties it can "float" on the surface of the crystalline lens. However, the potential complications of intraocular surgery together with the relatively unknown long-term complications of most of these lenses are the remaining obstacles to their popularity among refractive surgeons.

In this prospective, non-comparative, interventional case series, we reported the efficacy, predictability, stability, and short-term safety of the posterior chamber, floating, and foldable PIOL (PRL) for the correction of high myopia between −4.50 and −23.5 diopters (D) in 50 eyes of 31 patients.

PATIENTS AND METHODS

Between March 2002 and November 2004, 50 eyes of 31 patients were enrolled in this study. Thirty eyes received the PRL (Medennium), 13 eyes received the PRL combined with limbal relaxing incision for astigmatism >2.00 D, and 7 eyes received the PRL lens combined with laser epithelial keratomileusis (LASEK) for astigmatism >3.00 D. Patients selected for the study met the following inclusion criteria: age between 18 and 55 years, anterior chamber depth >3.0 mm (including the epithelium of the cornea), endothelial cell count >2000 cell/mm^2, and intraocular pressure (IOP) <20 mmHg. Uncorrected visual acuity (UCVA) on the eye to be operated was <20/40, whereas best spectacle-corrected visual acuity (BSCVA) on the fellow eye was >20/200. Mean preoperative spherical equivalent refraction was −12.54±4.22 D (range: −4.50 to −23.50 D). Mean preoperative refractive astigmatism was −1.38±1.24 D (range: −1.00 to −4.50 D). Mean patient age at surgery was 30.94±9.07 years (range: 19 to 52 years) (Table 1). Exclusion criteria included lack of corneal transparency, cataract, lens subluxation, narrow angle or glaucoma, uveitis, diabetes, and retinal problems.

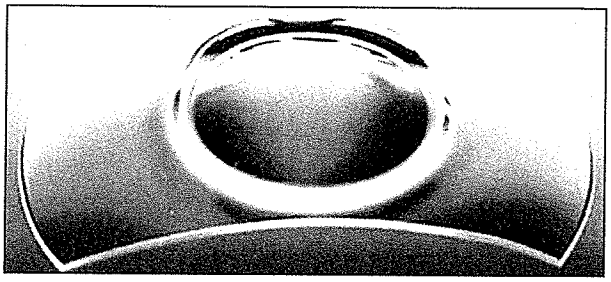


Figure 1. Phakic refractive lens (PRL; Medennium Inc, Irvine, Calif): model 100—optic diameter 5 mm, width 6 mm, and length 10.8 mm; model 101—optic diameter 5 mm, width 6 mm, and length 11.3 mm.

All patients signed an informed consent as approved by the Mettapracharak Hospital research committee.

CLINICAL EXAMINATION

All eyes had a complete preoperative ophthalmic examination including slit-lamp microscopy, applanation tonometry, indirect ophthalmoscopy, ultrasonic pachymetry, and specular microscopy. Assessment of the posterior segment in eyes with pathological myopia was done by a vitreoretinal specialist. Manifest and cycloplegic refraction was performed. Uncorrected and spectacle-corrected visual acuity were tested using the Nikon NP-3S chart projector (Nikon Ltd, Miyagi, Japan). Corneal topography (Orbscan; Bausch & Lomb, Salt Lake City, Utah) was performed. Endothelial cell count was done using the contact EM-1000 specular microscope (Tomey Technologies, Houston, Tex).

The PRL was used in all patients. Lens power calculations were performed by CIBA Vision Surgical (Embrach, Switzerland). The PRL power was calculated based on the manifest and cycloplegic refraction, keratometry, and axial length. The PRL was sized according to the horizontal corneal diameter (white-to-white distance) obtained by caliper and Orbscan.

Postoperatively, patients were examined at 1 day, 1 week, and 1, 3, 6, 12, and 24 months. Slit-lamp examination and measurement of manifest refraction, UCVA, and BSCVA were performed during follow-up.

SURGICAL TECHNIQUE

All operations were performed by one surgeon (A.J.).

YAG peripheral iridotomies were performed in the upper peripheral iris approximately 90° apart, ≥1 week before the operation. The lens was implanted using sub-Tenon's anesthesia (2% lidocaine 2 mL; ASTRA, Ayuthaya, Thailand) in all patients; PRL model 100 was used in 49 eyes and PRL model 101 in 1 eye (Fig 1).

A 3.0- to 4.0-mm (depending on astigmatism power) clear corneal incision at steep axis from topography

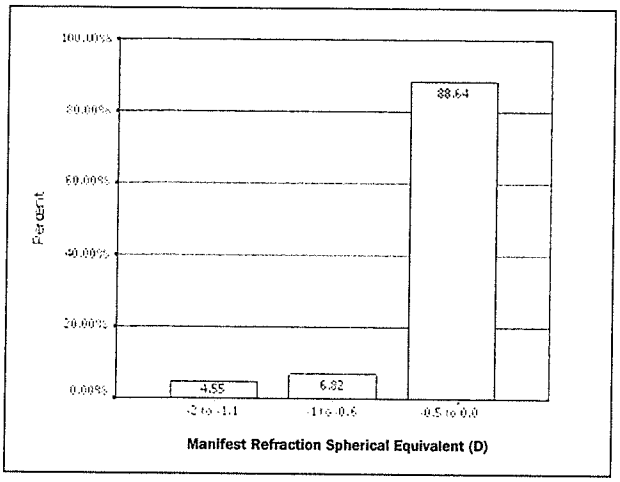


Figure 2. Distribution of manifest refraction spherical equivalent at 3 months postoperatively.

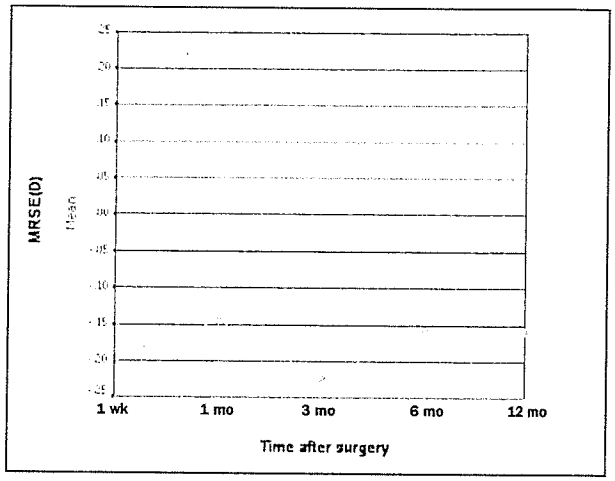


Figure 3. Mean manifest refraction spherical equivalent (MRSE) over time.

was made with a diamond knife, and low molecular weight viscoelastic substance (Ophthalin Plus; CIBA Vision Surgical) was injected into the anterior chamber. The PRL was inserted into the anterior chamber with Dementiev PRL implantation forceps (CIBA Vision Surgical). Both lens haptics were placed under the iris using a Dementiev PRL double-ended haptic spatula (CIBA Vision Surgical), and the pupil was constricted with one drop of 2% pilocarpine in 5 mL of balanced salt solution. Viscoelastic material was removed from the anterior chamber and exchanged for balanced salt solution. The corneal wound was self-sealing, using the stromal hydration technique in all cases (sutureless corneal wound). The surgery ended with the application of 0.5% timolol maleate, 1% tobramycin, and 1% prednisolone acetate.

Postoperative treatment included topical 1% tobramycin 4 times a day, 0.5% timolol maleate 2 times a day, and 1% prednisolone acetate 4 times per day for 1 week and acetazolamide (250 mg) 4 times a day for 2 days. In eyes that had astigmatism ≥2.00 D, limbal relaxing incision was performed opposite of the corneal incision on the steep axis. In eyes that had astigmatism ≥3.50 D, LASEK was performed after PRL implantation at 2 to 3 months postoperatively. Seven eyes were corrected using the LASEK technique. Long-term follow-up was arranged to enable full documentation of the outcome in all cases.

All patients were advised to contact us if at any time they feared a possible complication. All potentially vision-threatening events were reported. The number of eyes seen at each follow-up were: 44 (88%) eyes at 3 months, 33 (66%) eyes at 6 months, 33 (66%) eyes at 12 months, and 20 (40%) eyes at 24 months.

DATA ANALYSIS

Refractive outcome and postoperative UCVA and BSCVA were analyzed as measures of efficacy of the procedure. The baseline manifest refractions, UCVA, and BSCVA were compared with the refractions and visual acuities at the last postoperative examination. Stability of the refractive outcome was analyzed using analysis of variance of the mean spherical equivalent refraction at 1 week and 1, 6, and 12 months. The refractive outcome in patients with at least 12-month follow-up was evaluated as the primary measure of refractive stability.

RESULTS

SLIT-LAMP MICROSCOPY

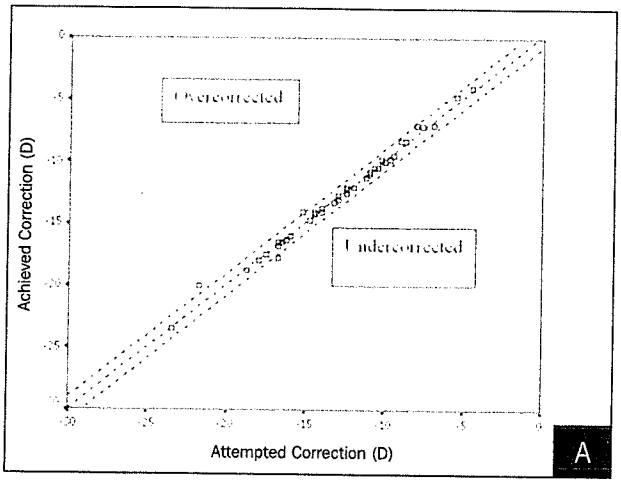
On postoperative day 1, 45 (90%) of 50 eyes had a clear cornea and 5 (10%) eyes had mild to moderate corneal edema, which resolved in 1 week. All eyes had secure wounds, deep anterior chamber, and round and reactive pupils. By the end of the first week, all eyes were quiet, with no anterior chamber cell or flare.

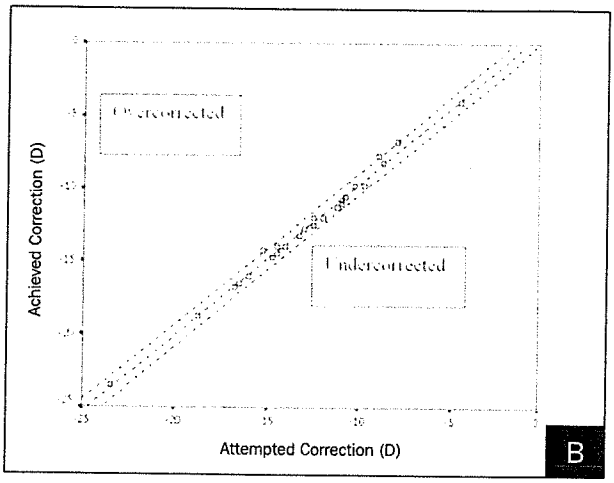
REFRACTIVE OUTCOME

Mean spherical equivalent refraction was −0.27±0.54 D (range: +1.00 to −2.50 D) at 1 month, −0.21±0.42 D (range: +1.00 to −1.75 D) at 3 months, and −0.23±0.38 D (range: 0.00 to −1.25 D) at 6 and 12 months.

Spherical equivalent refraction at the last examination was within ±0.50 D in 44 (88%) eyes and within ±1.00 D in 48 (96%) eyes.

The distribution of the refractive outcome of all eyes is shown in Figure 2. Figure 3 shows the mean spherical equivalent refraction at each examination.





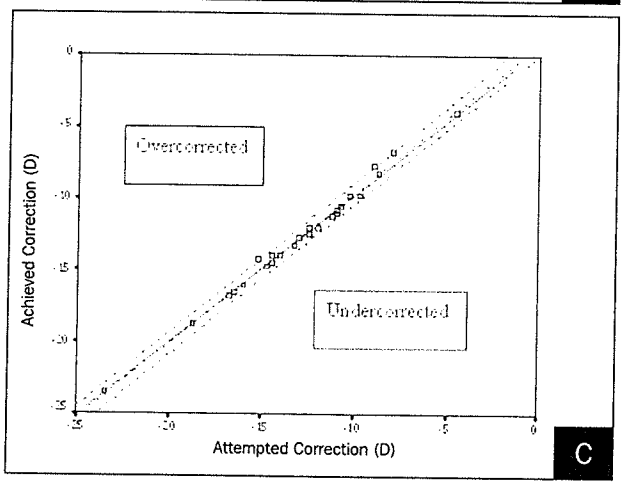


Figure 4. Attempted versus achieved correction (manifest refraction spherical equivalent) at **A)** 3 months, **B)** 6 months, and **C)** 12 months. Dotted lines represent ±1.00 D.

At 12 months, the mean refractive cylinder was −0.34±0.68 D (range: −0.25 to −2.50 D); 33 (66%) eyes had a refractive cylinder <1.00 D. All eyes had a refractive cylinder <2.50 D. The attempted versus achieved correction of the spherical equivalent refraction at 3, 6, and 12 months postoperatively is shown in Figure 4.

The stability of the refractive correction was evaluated throughout the first year after surgery by comparing the spherical equivalent refraction at 1-week and 1-, 3-, 6-, and 12-month follow-up. The greatest change was noted between 1-week and 1-month follow-up. The mean change between all examinations was <1.00 D. A repeated measures analysis of variance revealed no significant difference over time (P=.22).

Visual Outcome

Preoperative UCVA was <20/200 in all eyes. Preoperative BSCVA was ≥20/40 in 38 (76%) eyes and ≥20/20 in 22 (44%) eyes. At the last examination at 12 months, UCVA was ≥20/40 in 41 (82%) eyes and ≥20/20 in 22 (44%) eyes and BSCVA was ≥20/40 in 42 (84%) eyes and ≥20/20 in 27 (54%) eyes (Fig 5).

Figure 6 compares pre- and postoperative BSCVA at 1, 3, 6, and 12 months. At 12 months, 12 (24%) of 50 eyes gained ≥1 lines of BSCVA and 7 (14%) eyes gained ≥2 lines. One (2%) eye lost 1 line of BSCVA.

Intraocular Pressure

Mean preoperative IOP was 13.88±2.82 mmHg (range: 7 to 19 mmHg). Postoperatively, mean IOP was 12.98±3.71 mmHg (range: 6 to 26 mmHg) at 1 day, 14.45±4.17 mmHg (range: 6 to 29 mmHg) at 1 week, 13.03±2.81 mmHg (range: 7 to 18 mmHg) at 1 month, and 12.56±2.73 mmHg (range: 7 to 18 mmHg) at 3 months. Steroid-induced glaucoma was found in five eyes in the first week, which resolved with the discontinuation of topical steroids and the administration of antiglaucoma drug treatment. Intraocular pressure remained within normal range in all eyes thereafter (Fig 7).

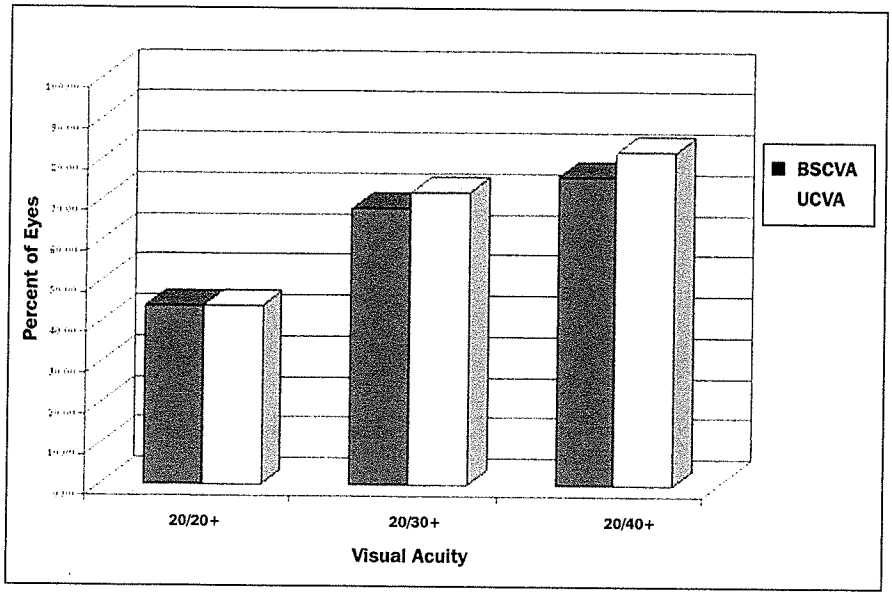


Figure 5. Preoperative best spectacle-corrected visual acuity (BSCVA) and postoperative uncorrected visual acuity (UCVA) at last examination.

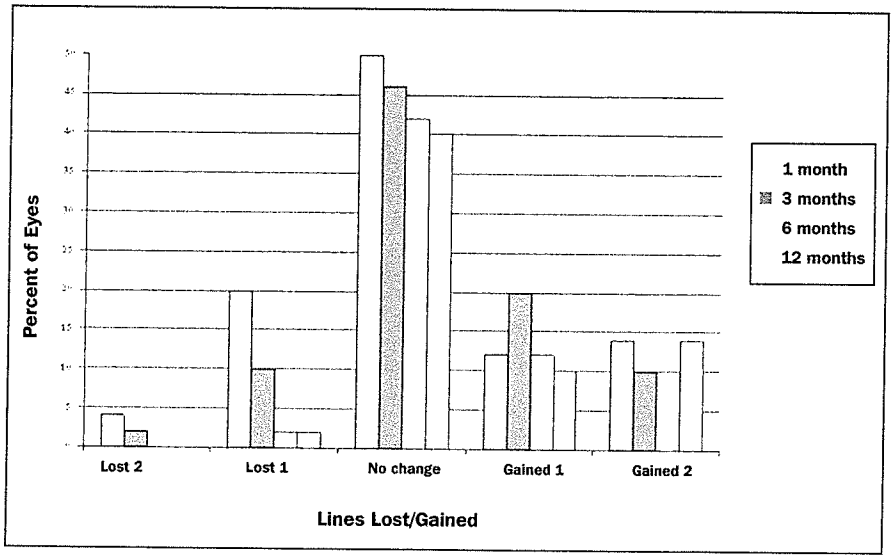


Figure 6. Best spectacle-corrected visual acuity at 1, 3, 6, and 12 months with loss or gain of Snellen lines.

COMPLICATIONS

No operative complications occurred, and all implantations were uneventful. Postoperative complications are shown in Table 2. Five eyes of three patients developed steroid-induced glaucoma within 1 week postoperatively. Five eyes of three patients developed mild corneal edema on postoperative day 1, which resolved in 1 week. Five eyes of four patients had small white plaques on the anterior surface of the natural lens (sodification), which disappeared within 1 month. Due to preoperative refractive cylinder >3.00 D and postoperative refractive cylinder >2.00 D, seven eyes underwent PRL+LASEK. Mild night halos were reported in 23 (46%) eyes, but this symptom did not disturb daily activities.

Three weeks postoperatively, one eye of a 29-year-old patient developed macular hemorrhage and BSCVA decreased to 20/100. Preoperative BSCVA was 20/70 with a refraction of −18.00 D and mild myopic degeneration. Vision improved to 20/30 within 2 months after macular hemorrhage resolved without treatment. One eye developed acute angle closure glaucoma 19 months postoperatively. Synechiae were found between the iris and the corneal wound and the iridotomy was closed. Laser iridotomy was performed and IOP decreased to within normal limits.

At 2 years postoperatively, one eye developed an anterior subcapsular cataract. Visual acuity decreased from 0.6 to 0.2 and the patient reported poor vision.

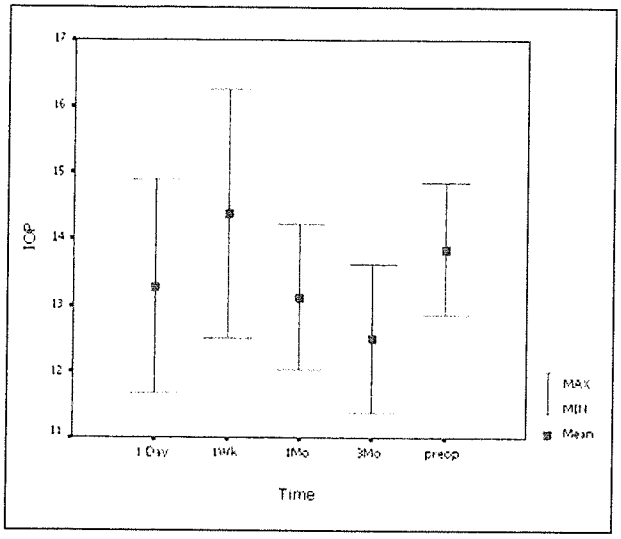


Figure 7. Change in mean (standard deviation) intraocular pressure (IOP).

Scheimpflug photography was used to examine the anterior chamber of the eye, which showed no contact between the PRL and the anterior surface of the natural lens in 360° of imaging. Phacoemulsification with IOL implantation was performed after PRL removal.

DISCUSSION

Phakic intraocular lenses have become another option for the correction of highly myopic eyes because of their refractive predictability and stability. Unlike other surgical procedures, corneal thickness, healing process, flap complications, corneal ectasia, oblate cornea, severe night glare, and dry eye are not concerns. In our series, 96% of eyes were within ±1.00 D of the targeted refraction. These results are better than those recently reported for LASIK procedures in a similar population (myopia between −9.00 and −22.00 D) in which the predictability and refractive stability were 66% and 77%, respectively.[16] For bioptic surgery, we prefer LASEK over LASIK because flaps created during LASIK can induce aberration and complications.

Postoperatively, visual acuity was excellent, and the majority of patients were satisfied with the visual results from the first postoperative day. Also in these eyes, the efficacy results (preoperative BSCVA/postoperative UCVA) were better. A gain of ≥1 lines of BSCVA was seen in 24% of eyes and a gain of ≥2 lines was noted in 14% of eyes. The marked gains in BSCVA occur, in part, because of the magnification of the retinal image and the preservation of the corneal asphericity after PRL implantation. Improvement of BSCVA with PIOL implantation has been reported by other authors.[14,17,18]

TABLE 2

Complications in 50 Eyes That Underwent PRL Implantation for Myopia

Complication	No. Eyes (%)	Comment
Night halos	23 (46)	No treatment
Corneal edema	5 (10)	No treatment
Steroid-induced glaucoma	5 (10)	Antiglaucoma drug
Sodification	5 (10)	Resolved in 1 month
Macular hemorrhage	1 (2)	Resolved in 4 months
Cataract formation	1 (2)	Anterior subcapsular cataract
Acute angle closure glaucoma	1 (2)	Caused by occluded iridotomy; treatment, laser iridotomy

We found that the refractive outcome at 6 months was better than that at 3 months because LASEK was performed in some eyes for astigmatic correction after 3 months postoperatively. One eye in a 19-year-old patient developed an anterior subcapsular cataract 24 months after PRL implantation. Using Scheimpflug photography, no contact was found between the PRL and anterior surface of the natural lens. Other studies[13,19,20] reported cataract formation 6 months postoperatively due to intraocular manipulation or contact between the PIOL and the natural lens. Bechmann et al[21] reported that the lens vault (the distance between the IOL and the anterior lens capsule) was found to change in accommodation by optical coherence tomography. Contact between the PRL and anterior capsule of the natural lens during accommodation may be the cause of cataract formation.

In five eyes of three patients, the response to topical steroid (1% prednisolone acetate) after only 3 days increased IOP to >40 mmHg, which decreased vision. Intraocular pressure decreased within 1 week after discontinuation of the topical steroid and administration of antiglaucoma drugs. One eye developed acute angle closure glaucoma 19 months postoperatively. Laser iridotomy was performed and the IOP decreased to normal range. Closure of the previous iridotomy occurred due to synechiae between the corneal wound and peripheral iris.

Our safety results compare favorably with those of corneal surgery, in which relatively few complications are reported.[22-24] Steroid-induced glaucoma occurred in five eyes of three patients. One eye developed macular hemorrhage 3 weeks after surgery and visual acuity improved within 2 months. Twenty-three (46%) eyes had mild symptoms of night halos, which did not

disturb normal activity. Corneal decompensation was not found in any case. Mean endothelial cell loss in this study was 5.28%, 5.31%, 5.32%, 5.36% at 1 week, 1 month, 3 months, and 6 months postoperatively, respectively (as reported in another study).[25]

Reported complications of the iris claw PIOL (Artisan; Ophtec, Groningen, The Netherlands)[17,18,26] include pupil ovalization, lens decentration, early postoperative iritis, and iris atrophy. These complications were not found with the use of the PRL because this lens is designed for autocentration on the papillary rim of the iris. Another advantage is the 3.0-mm clear cornea incision, which induces less astigmatism when compared with the 5.5-mm limbal incision of the Artisan lens. In the near future, a foldable iris claw PIOL (Artiflex, Ophtec) could reduce the incision size and postoperative astigmatism. Budo et al[26] reported a 10% incidence of halos with the Artisan lens (refractive error between −15.00 and −20.00 D), which is less than the incidence reported in our study (46%). Cataract formation in their study was similar to our reported incidence—2.4% versus 2%.

A disadvantage of the PRL is its small optical zone, which induces halo effect, pigmentary dispersion, and cataract formation due to intraocular manipulation. A 2001 European clinical trial study[27] (1000 implantations, longest follow-up 12 months) reported the following complications: traumatic cataract 0.1%, PRL decentration 0.4%, PRL overcorrection 0.5%, increase IOL 0.5%, iridocyclitis 0.2%, and dislocation of PRL into vitreous cavity 0.1%. In our study, there was increase IOL in one (2%) eye due to inappropriate size of the lens (implanted PRL model 101). We found sodification (white plague on the anterior surface of the natural lens) in five (10%) eyes due to incomplete viscoelastic substance removal, which disappeared within 1 month with no visual disturbance in any eye.

In this study, no serious complications developed due to anesthesia. The sub-Tenon's anesthesia technique, which decreases the chance of globe perforation and explosive hemorrhage, was used in all eyes. Subconjunctival hemorrhage was noted in some eyes but resolved within 2 weeks.

Although follow-up was not long-term, our study demonstrates excellent predictability, refractive stability, and visual results with few complications. Better uncorrected and corrected visual acuity, quality of vision, stability, and exchangeability are the main advantages of a PIOL. Continued monitoring of patients is required to confirm the long-term safety and efficacy of this lens.

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Correction of High Myopia With Phakic Refractive Lens

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ABSTRACT

Purpose: To describe the surgical technique for the implantation of the phakic refractive lens (PRL) in phakic eyes.
Setting: University of Crete, Medical School, Vardinoyannion Eye Institute of Crete, Heraklion, Crete, Greece.
Methods: Phakic refractive lens is a hydrophobic silicone lens, which is implanted in the posterior chamber of the phakic eye to correct high myopia and hyperopia. This lens is positioned between the iris and the natural crystalline lens. Lenses were implanted following Pallikaris technique with single trapezoidal incision.
Results: We have performed a total of 96 PRL implantations since 2001. In the myopic group, comprising 85 eyes, the mean follow-up period was 1.76 ± 1.35 years (range, 3 months–4 years). The mean uncorrected visual acuity significantly improved from counting fingers preoperatively to 0.64 ± 0.25 ($P < 0.001$) at 12 months postoperatively (n = 57). The mean postoperative best corrected visual acuity significantly improved from 0.72 ± 0.22 to 0.83 ± 0.23 ($P < 0.001$). The mean values for spherical equivalent refraction decreased from −13.83 ± 2.99 D to −0.23 ± 0.53 D, and 73% of the treated eyes were within ±1.00 D of target refraction. Very few complications were observed in this series. The most frequent complications have been intraocular pressure spikes after surgery followed by transitory corneal edema, which was resolved after a few days. We had no case of cataract formation, no lenses luxated into the vitreous cavity, no endophthalmitis, and no uveitis.
Conclusions: The results from this series indicate that the PRL lens is a predictable, effective, and safe method to treat high myopia. Longer follow-up period is important to prove long-term safety concerning cataract formation, pigment dispersion, and glaucoma induction.

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Dr. Claudio Spera is a consultant of Ioltech SA, a company of Carl Zeiss Meditec AG.

The surgical technique used and the clinical results of a series of 85 eyes implanted with the PRL phakic posterior chamber lens are described.

INTRODUCTION AND HISTORY

Myopia is fairly common in all continents. Between 22% to 25% of the populations of the United States, Western Europe, and Australia are myopic to some degree, affecting men and women equally.[1] The incidence rate is much higher in certain Asian countries. Taiwan and China experience one of the world's highest rates. In a recent study, the authors have diagnosed some degree of myopic refractive error in 36.71% of Chinese children from Hong Kong.[2] There are several proposals to classify myopia. One of the most used proposals classifies myopia on the basis of its severity: (1) mild myopia is any refractive error between −0.5D and −3.0D, (2) moderate myopia is between −3.25D and −6.0D, (3) severe myopia is between −6.25D and −9.0D, and (4) extreme myopia is a refractive error higher than −9.0D. In a recent evaluation on the classification of myopic patients referred to our refractive department in 2004, we found that about 38% presented mild myopia; 38%, moderate myopia; 16%, severe myopia; and 8%, extreme myopia. There are several surgical options for the treatment of myopic patients, depending on the preoperative measurements and inclusion/exclusion criteria. In our service, around 85% of the patients are

treated with excimer laser (laser-assisted in situ keratomileusis (LASIK), photorefractive keratectomy, Epi-LASIK), 8% are treated with intraocular phakic lenses, 3% with presbyopic lens exchange (clear lens extraction), and the remaining 4% with other techniques.

Device Description

In 1986, the Moscow Eye Institute implanted the first design of posterior chamber phakic intraocular lenses (IOLs). This lens had a mushroom shape, with the optic placed within the pupil and the haptics positioned behind the iris. This lens was implanted in Russia until 1990. Despite the good optical results, several issues occurred, mainly iridocyclitis, endothelial cell decompensation, and cataract formation. The initial design was changed, and the second generation of lenses has been manufactured between 1990 and 1995. The entire lens was moved to the posterior chamber. The lens was flat in its posterior surface and had a sulcus fixation. In 1995, the design was modified to decrease the overall diameter of the lens. Moreover, the posterior surface curvature has been modified to a greater diameter, and the lens lost its sulcus fixation. This third-generation lens, the phakic refractive lens (PRL; Ioltech SA, La Rochelle, France), is a phakic intraocular device available in different sizes for intraocular implantation in the posterior chamber of the eye between the iris and the crystalline lens (Fig. 1). The optical portion is biconcave or concave-convex, and is made from silicone elastomer. The haptics are spherical and very flexible. The posterior surface of the lens is designed to conform to the shape of the anterior capsule of the human natural lens and to move with the dynamic changes of the eye.

PRL: No-fixation Support System

Ideally, the overall diameter of the PRL lens should be smaller than the sulcus-to-sulcus distance. Therefore, the lens is not fixed at the ciliary sulcus. The PRL rests and slides in its self-centered position over the zonula without compression to internal ocular structures. Precise centration is achieved through the iris self-centering design. Silicone is a hydrophobic material. A layer of aqueous humor surrounds the PRL lens, avoiding contact with the crystalline lens and the pigment epithelium of the iris. In optimum position, a gap is maintained at all time between the posterior surface of the PRL and the crystalline lens. This gap may vary during the follow-up period and during accommodation, but the hydrophobicity of the lens will avoid the continuous contact of the 2 structures. This is responsible for the low rates of lens-related cataracts after PRL implantation and will be important during the long-term period. The crystalline lens is an intraocular structure that grows about 18 to 20 μm per year, mainly toward the cornea.[3] The anterior chamber depth (ACD) slowly decreases because of the increase in the crystalline lens thickness. Because of the PRL features (hydrophobicity and no-fixation position), the phakic lens will move anteriorly as the crystalline grows with time, always keeping a distance to the anterior capsule of the crystalline. With time, we could expect the shallowing of the anterior chamber and the decrease of the iridocorneal angle, rather than induced lens opacifications related to crystalline lens contact.

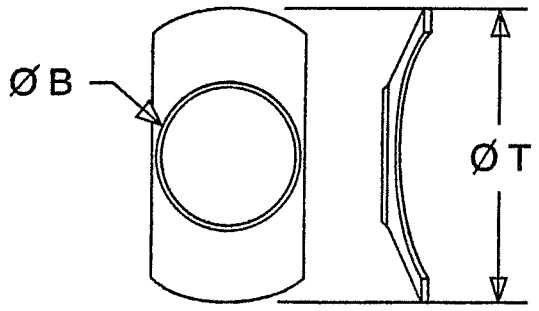

FIGURE 1. Phakic refractive lens dimensions according to model: PRL101 (ØB, 5.0 mm; ØT, 11.3 mm), PRL100 (ØB, 5.0 mm; ØT, 10.8 mm), and PRL200 (ØB, 4.5 mm; ØT, 10.6 mm). ØB indicates optic diameter; ØT, overall diameter.

The PRL lens is smaller than the posterior chamber diameter; therefore, it can rotate in its axis. Koivula et al[4] had measured PRL positions during the first year and had observed that 75% of lenses rotated by more than 10 degrees from implantation direction in a series of 20 eyes. In our own series of patients, we have observed that lenses implanted horizontally (3–9 o'clock position) can be frequently found in an oblique or vertical positions at 3 to 6 months after the surgery. We think that PRL rotation is mainly an advantage for the patients rather than a disadvantage. Rotation means that the lens is not fixated and can slide over a layer of aqueous humor. Nevertheless, we know that for this reason, the actual design of the PRL lens does not allow it to be a toric lens.

Phakic refractive lenses can be found in myopic and hyperopic models. There are 2 myopic models, PRL101 and PRL100, which are 11.3 mm and 10.8 mm, respectively, in overall diameter. There is only 1 model for hyperopic eyes, PRL200, which is 10.6 mm in length. The refractive index of the silicone is 1.46, and its specific gravity in the aqueous humor is 0.99. The available diopter range for negative lenses is from −3.0 D to −20.0 D, and between +3.0 D and +15.0 D in the positive range. We have elected the Holladay refractive formula for power assignment, whose calculation is based on the refraction, ACD, axial length, and keratometry.[5]

■ PRL SURGICAL TECHNIQUE

Although the surgical technique for PRL implantation is not difficult, we strongly encourage new users to go through an in-hands wet laboratory session to get familiarized with surgeries in a fully dilated phakic eye.

Careful patient screening and nontraumatic surgery are key points to avoid zonular damage and PRL luxation.

Iridotomy/Iridectomy

Every eye submitted to posterior phakic IOL implantation should have a patent iridotomy/iridectomy at the end of the surgical procedure. Nd:YAG-laser iridotomies can be performed at least 1 week before surgery, 1 at 2 o'clock position and the other at 10 o'clock. Iridotomies should not be performed immediately before the surgical procedure; otherwise, some amount of iris pigment would still be floating around in the anterior chamber during the surgical procedure, which could attach to the PRL silicone.

Another option is to perform a surgical iridectomy at the end of the PRL implantation procedure. This should be at around the 12 o'clock position; therefore, the superior eyelid will cover the opening and avoid potential monocular diplopia. The iridectomy can be performed with either vitreotome probe or Vannas scissors. In my personal surgical technique with single corneal incision, the iridectomy is performed with the vitreotome handpiece.

In all cases, the iridotomies/iridectomies should be performed as peripheral as possible. The PRL lens can rotate in the posterior chamber and the haptics can block an iridotomy/iridectomy performed in the middle of the iris. However, very peripheral openings will remain clear of the haptic during the long follow-up period.

Preparation of the Patient

On the day of the surgery, 30 minutes before the procedure begins, the pupil is dilated as a usual cataract surgical procedure. The ideal dilation is between 8.0 and 9.0 mm. The patient is brought to the surgical room, asepsis is done, the sterile drape is placed around the eye, and the ocular speculum is positioned. Anesthesia could be topical, general, or retrobulbar/peribulbar. We recommend that the first cases be performed under retrobulbar/peribulbar anesthesia. Usually, refractive patients are young and stressed. They can move during the surgery and cause intraocular trauma.

Initial Surgical Steps

Our surgical procedure for the PRL implantation is based on the forceps technique and single corneal incision. The PRL instrumentation set used is from Duckworth and Kent (Baldock, Hertfordshire, England): PRL Dementiev implantation forceps (DK7760-2), Pallikaris spatula (DK 6-481), and PRL loading block (DK7718-1). The Pallikaris spatula has a round tip, with the underside textured to provide a firm grip on the upper surface of the plate haptics to enable them to be manipulated within the eye and finally tucked behind the iris. We perform a single 3.2-mm trapezoidal clear cornea incision. The surgical blade is moved laterally to produce a trapezoidal shape, which will expand the excursion limits of the spatula (Fig. 2). This is followed by the injection of 1% NaHa cohesive ophthalmic viscosurgical device (OVD) inside the anterior chamber and behind the iris to open the space between the iris and the crystalline lens. We do not recommend dispersive or high-viscosity OVD because it may remain captured behind the PRL lens at the end of the procedure and produce intraocular pressure (IOP) spikes. We perform the single incision at the temporal side (but it can be performed at any meridian) to reduce corneal astigmatism.

We recommend a single 3.2-mm trapezoidal clear cornea incision. The surgical blade is moved laterally to produce a trapezoidal shape, which will increase the excursion limits of the spatula.

Preparation of the PRL Lens

The PRL is a hydrophobic lens, which is always upside-down inside the packaging. The PRL should be grasped with the PRL implantation forceps, turned over, and placed upside up on the PRL loading block (previously moistened with basic salt solution). The

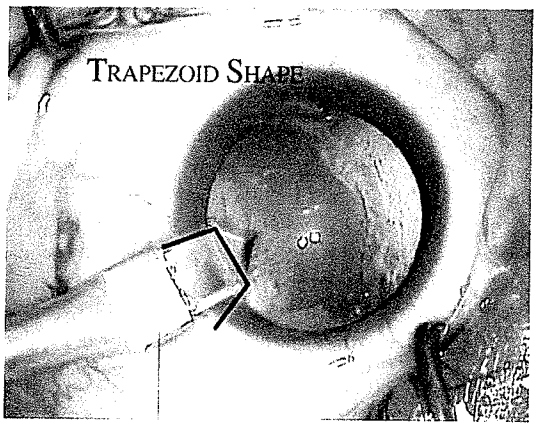

FIGURE 2. Single-incision surgical technique (3.2-mm clear cornea incision). Both sides of the incision are increased laterally to give a trapezoidal shape to the incision.

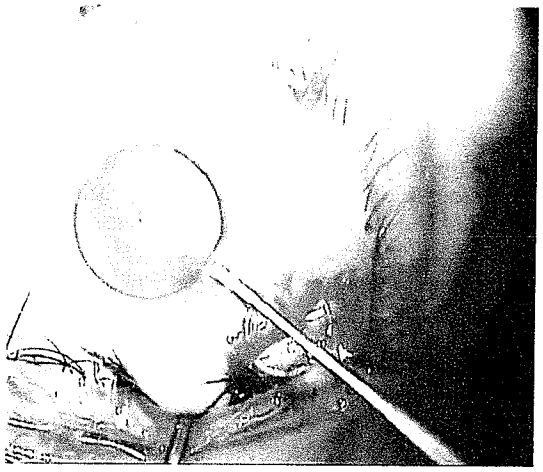

FIGURE 3. Phakic refractive lens, grasped with the PRL implantation forceps, ready for implantation. The lens will fold inside the incision.

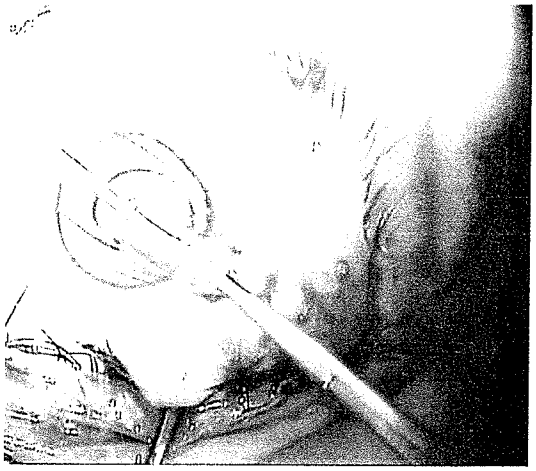

FIGURE 4. Phakic refractive lens implanted inside the anterior chamber of the eye. When the optic is fully unfolded, the implantation forceps is released and removed from the eye.

PRL fits in the bottom groove of the loading block, which will help in the grasping of the lens. With the PRL implantation forceps opened, the PRL is grasped through its longest diameter. The PRL implantation forceps has a special curved shape in its upper jaw to protect the optic from being smashed. The lens is ready for implantation (Fig. 3).

PRL Implantation

The PRL implantation forceps should be introduced parallel to the iris plane inside the anterior chamber. While introducing the implantation forceps inside the incision, a small pressure can be performed to open the incision borders and facilitate the implantation. The lens will fold by its own at the incision level and unfold inside the anterior chamber (Fig. 4). Once the optic is completely unfolded, the jaws of the PRL forceps are released and the instrument is removed from the eye. Do not attempt to implant the lens directly into the posterior chamber—the implantation forceps may damage the anterior capsule of the crystalline lens. At this point, a potential issue may arise. Lenses with very low diopter values (ie, PRL −4.0 D) may remain attached to the instrument, and the lens may be withdrawn with the forceps. One may use a surgical sponge to hold the haptic that is still outside the eye, preventing the lens to come out. When the PRL lens is fully inside the eye, additional OVD can be applied over the optic to push back the PRL toward the crystalline lens.

Haptics Manipulation

Haptics manipulation is the most delicate step of the surgical procedure. If strong and aggressive movements are applied over the lens, one can damage the zonula of the eye and produce traumatic holes, which could be the cause of luxations in the future. A good recommendation is that whenever the PRL is entirely inside the anterior chamber, the optic should not be moved from the center of the pupil. If the main incision and iridotomies/iridectomies are both performed superiorly, the PRL lens should be rotated horizontally inside the anterior chamber before the haptics are placed behind the iris. With the Pallikaris spatula, the 4 corners of the lens should be folded and unfolded behind the iris (Fig. 5). The Pallikaris spatula is introduced from the

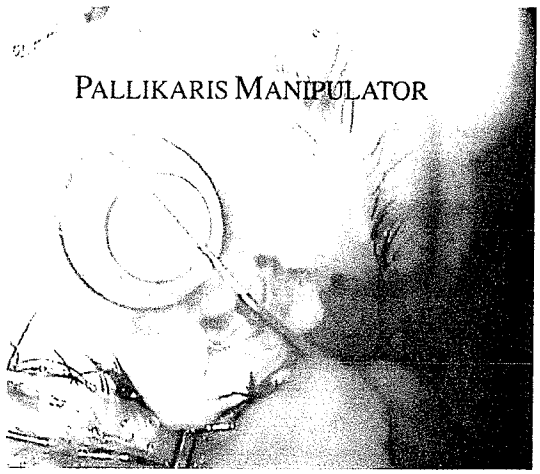

FIGURE 5. With the PRL spatula, the edges of the haptics are folded and released under the iris. The lens should not be moved from the center of the pupil to avoid damage to the zonula.

single corneal incision and touches one of the haptic's corners. The PRL haptic is folded and released under the iris. This maneuver is done in the 4 corners. A rotational movement of the PRL lens is helpful for the placement of the haptics behind the iris. Another technique is to perform a surgical paracentesis at 90-degree angle from the main incision and use the Pallikaris spatula from this additional incision to reach the haptics. When the haptics are well placed behind the iris, the pupil is constricted with 1% acetylcholine. The OVD is completely removed from the eye either with the use of simple manual irrigation or with the use of irrigation/aspiration probe from the phacoemulsifier. At the end of the procedure, the incision is sealed by hydration and checked for leakage; then, if needed, a 10-0 nylon suture is performed.

Do not move the PRL lens from the center of the pupil while manipulating the haptics with the PRL spatula. Strong movements may damage the zonula and produce zonular holes.

The PRL haptics are manipulated with the Pallikaris spatula, which has a round tip and is textured at the bottom. The PRL haptics are folded and released under the iris. A rotational movement of the PRL lens is helpful to position well the haptic behind the iris.

At the end of the procedure, the iridotomies/iridectomies should be cleared from behind the haptics to avoid pupillary block after surgery. We do recommend always having 2 lenses of the same power and model for each eye. If the first lens is damaged, the surgery could still be performed with the second lens.

Postoperative Treatment

The patient leaves the hospital with the following treatment: (1) acetazolamide (dosage, 500 mg bid for 2 days) and (2) tobramycin 0.8% + dexamethasone 0.1% qid for 15 days.

■ DISCUSSION AND CLINICAL RESULTS

Inclusion/Exclusion Criteria

Our personal indications for PRL implantation are the following: patients older than 18 years, refraction stability of more than 12 months, associated astigmatism level of 2.5 D or lesser, endothelial cell count of 2000 cells/mm^2 or greater, IOP measurement less than 20 mm Hg at initial screening, ACD greater than or equal to 3.0 mm (from corneal apex to crystalline), iridocorneal angle grades 3 or 4, and horizontal white-to-white measurement (W-W) greater than or equal to 10.5 mm. For astigmatic eyes, we treat the spherical equivalent up to 2.5 diopters of astigmatism. Above this limit, we prefer to treat the remaining astigmatism with another refractive technique (relaxing incision, astigmatic keratotomy, Intacs, LASIK, PRK, or Epi-LASIK). The risk of correcting the entire spherical equivalent in highly astigmatic patients is the patient's overcorrection; thus, myopic patients be come hyperopic after surgery, which is not well accepted by the patient.

Phakic lenses are indicated to all patients, including low ametropias. Nevertheless, the strongest indications are patients not suitable for laser-assisted refractive procedures. We could include in this category dry eye syndrome, subtle topographical abnormalities (apex displacement, epithelial irregularity, corneal asymmetry, and subtle keratoconus), insufficient pachymetry, nystagmus, corneal ectasia, undercorrected/overcorrected radial keratotomy, multiple corneal refractive procedures, predicted postoperative average keratometry less than 35 diopters in myopic eyes, and predicted postoperative average keratometry greater than 48 diopters in hyperopic eyes (each diopter treated by laser would modify the average keratometry by about 0.9 diopters).

We would exclude patients with the following conditions from any phakic IOL implantation: glaucoma, diabetes with ocular manifestations, untreated retinal detachments, cataract, previous history of uveitis, and preexisting zonular damage.

Correct Patient Selection

The correct position of the PRL in the posterior chamber is very much dependent on the integrity of the zonulas of the treated eye. Although there were recent publications in the literature on PRL dislocations to the vitreous cavity,[6–8] we think that these cases could have been avoided by a cautioned preoperative examination of the zonular integrity and careful IOL manipulation during the surgical procedure.

In our service, we have been implanting PRL lenses since 2001 and had no lenses that luxated into the vitreous cavity to date. All candidates for a posterior chamber implantation are fully dilated and have the zonula screened from all angles at the slitlamp.

In addition to the exclusion criteria listed, we would exclude patients with weak, damaged zonula and presenting previous history of ocular trauma, Marfan syndrome, and exfoliation syndrome at the time of the screening visit. Moreover, we would exclude patients

presenting chronic systemic diseases that could interfere in the integrity of the zonula, such as ulcerative colitis, systemic lupus erythematosus, Crohn disease, collagen vascular disease, rheumatoid arthritis, and all bleeding diathesis.

Long-Term Endothelial Survey

A strict follow-up of the corneal endothelium is mandatory before and after any phakic IOL implantation. At each visit, the same technician should take 3 pictures from the same area in the same eye. At each picture, a total of 50 to 100 cells are counted. The final result is the average of the 3 measurements. We perform the first measurement after surgery at 3 to 4 months, when we usually observe a decrease of 5% to 7% on the endothelial cell population that is related to the surgical procedure itself. After this initial measurement, the patients are requested to have an annual examination. Patients without complications should be expected to have a physiological annual decrease of 0.5% to 1% on the endothelial cell count, which is comparable with the normal aging process of the cornea. We would follow closely any patient with a decrease greater than 15% and would remove the lens if there were a loss of 50% or more of cells from baseline.

Sizing of the Eye

Sizing has become a critical point to all phakic lenses. In recent publications, different authors have demonstrated that W-W does not correlate with any intraocular distance.[9–11] Therefore, it should not be used as basis for any IOL implantation. Several optical devices available in the market can measure intraocular structures within microns. The Ultrasound Biomicroscope model 840 (Zeiss Humphrey, Dublin, CA) has a high resolution and provides a precise view of intraocular structures; therefore, it is an important tool to measure localized structures.[12,13] Because of its maximum excursion of 5.5 mm, it is not possible to measure the overall diameters of the anterior and the posterior chambers. The new Visante OCT (Carl Zeiss Meditec, Jena, Germany) is a noncontact device—very appropriate for measurements of structures above the iris of the patient.[14] At this level, in patients with dark pupil, the wavelength of the light source is stopped by the pigmented epithelium; thus, the device cannot capture images from the posterior chamber.[15] Therefore, sulcus-to-sulcus measurement cannot be easily performed. This measurement could be performed in the eyes with less-pigmented pupil and in the eyes of albino patients. Artemis 2 (Ultralink LLC, St Petersburg, FL)[16] and HF35-50 UBM (Ophthalmic Technologies Inc, Toronto, Canada) can reach the posterior chamber and therefore allow sulcus-to-sulcus distance measurement. Eyes with posterior chamber diameter greater than 11.3 mm would request a PRL101, and smaller eyes would need a PRL100. For surgeons not equipped with such devices, the company recommends to use the W-W measurement. Eyes with preoperative W-W measurement greater than or equal to 11.3 mm would require a PRL101, and smaller eyes would require a PRL100. Hyperopic eyes do not need special sizing measurements. All hyperopic patients would need a PRL200.

Intraoperative Complications

During surgery, the most severe complications one could face are anterior capsule rupture and zonular damage. Both are caused by aggressive manipulation of the instruments inside the eye. Although small peripheral anterior capsule breaks might not progress to cataract, central damage will probably quickly impair the vision of the patient. Zonular damage may be the reason for PRL luxation in the long-term follow-up. Additional complications are athalamia, incision leakage, iris prolapse, hyphema, pupil constriction, and endothelial touch.

Early Complications

In the immediate postoperative period, the most common complications are IOP spikes and transitory corneal edema 24 hours after surgery in up to 19% of patients. This is usually related to OVD retention inside the eye. Pupillary block is a medical urgency that may arise in the case that the iridotomies/iridectomies are not fully patent after surgery. The treatment is conducted by means of additional opening using Nd:YAG laser. Additional complications are subluxation to the anterior chamber, uveitis, endophthalmitis, and pigment dispersion related to iris manipulation.

Long-Term Complications

Correct preoperative patient selection and a proper surgical technique are very important to avoid late complications. The PRL is a hydrophobic lens, which will maintain a distance from the crystalline lens. Cataract formation with the PRL lens is rare. Potential long-term complications include endothelial cell decrease, lens luxation/subluxation, natural lens opacification, glaucoma, and anterior chamber shallowing.

Clinical Results

Our personal experience with the PRL lens is based on 96 PRL lenses implanted between 2001 and 2005. We have operated on 11 hyperopic eyes and 85 myopic eyes. In the myopic group, the average follow-up period is 1.76 ± 0.35 years (range, 3 months–4 years). In our series of patients, the visual outcome and the predictability in refraction are high.

Efficacy

Efficacy is the relation between the postoperative uncorrected visual acuity (UCVA) and the preoperative best corrected visual acuity (BCVA). Our results are comparable with previously published articles on the PRL lens.[4,17–20] The mean UCVA significantly improved from counting fingers preoperatively to 0.64 ± 0.25 (range, 0.1–1.5, decimal scale; $P < 0.001$) at 1 year (n = 57) and to 0.65 ± 0.29 (range, 0.1–1.5; $P < 0.001$) at 2 years postoperatively (n = 34). At 1 year postoperatively, the postoperative UCVA was equal or better than the preoperative BCVA in 49% of the treated eyes (n = 28).

Safety

Safety is the relation between the postoperative BCVA and the preoperative BCVA. The mean BCVA significantly improved from 0.72 ± 0.22 preoperatively to 0.83 ± 0.23 ($P < 0.001$) at 1 year (n = 57) to 0.86 ± 0.25 ($P < 0.001$) at 2 years postoperatively (n = 34). At this follow-up time, 1 eye lost 1 line of preoperative BCVA, 14 maintained pre-PRL BCVA, and the remaining 42 eyes (73%) experienced a 1- to 4-line gain.

Predictability

Predictability is the comparison between the intended and the achieved corrections with the procedure. At the 24-month follow-up, the mean values for spherical equivalent refraction revealed a statistically significant reduction ($P < 0.001$) from −13.83 ± 2.99 D to −0.23 ± 0.53 D. In the myopic group of patients, 73% (25 eyes) and 44% (15 eyes) were within ±1.00 D and ±0.5 D of target refraction, respectively.

In our experience, we had few complications with the PRL lens. The most frequent was IOP increase during the first month after surgery. Some of the cases were related to OVD retention after surgery, and some of them were corticosteroid responders. All patients recovered after treatment. Only 1 patient needed bilateral trabeculectomy. We think that this was a patient with glaucoma who was not diagnosed before surgery. About 20% of the patients reported halo and glare at night, which decreased 6 months after surgery. We had 1 anterior capsule traumatic damage during surgery with localized opacification, which has not progressed for 3 years after surgery. Three cases of rapture of anterior capsule occurred during surgical iridectomy with the use of the probe for vitrectomy. These opacities remained focally and required no further treatment. No pigment dispersion, PRL luxation to the vitreous cavity, uveitis, and endophthalmitis were observed during the follow-up period.

The results of our series suggest that PRL phakic IOL implantation is a predictable, safe, and effective surgical method to treat patients with high myopia. This is in special interest to patients contraindicated for excimer laser treatments. This is a growing population who can benefit very much from phakic lenses techniques.

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Phakic Intraocular Lenses

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Abstract. An analytical review of the data available in the field of phakic intraocular lens implantation was conducted. Particular attention was paid to the more critical issues of intraocular lens sizing and safety guidelines. A comprehensive, competitive analysis of different implantation sites, intraocular lens model designs, and safety guidelines has been included. Specialized biometry techniques, such as very high frequency ultrasound and Scheimpflug imaging, have been reviewed, and a critical review of commercial claims regarding intraocular lens technologies has been included. Clinical studies of phakic intraocular lenses demonstrate increasing promise for the correction of refractive errors not amenable to mainstream excimer laser refractive surgery. The main issues currently revolve around adequate lens design (VHF ultrasound study suggests that custom-design and sizing may be the most effective and safest approach for every phakic IOL model), because these devices will be required to remain physiologically inert and anatomically compatible with internal ocular structures and relations for several decades. The possibility of safe removing or exchanging the IOL should remain a feasible option over time. It is of utmost importance that we continue to critically evaluate current encouraging short-term outcomes, which are being extrapolated to the longer term by ongoing high resolution imaging and monitoring of the anatomical and functional relations of implanted phakic IOLs. (**Surv Ophthalmol 50**:549–587, 2005.

Key words. high myopia (surgery) • hyperopia (surgery) • lens implantation intraocular • phakic IOL • phakic intraocular lens • refractive IOL • refractive surgery

Introduction

The surgical solutions to correct refractive errors exploit three anatomical possibilities, and each is highlighted below.

First, the corneal lens of the eye has an excellent life-long stability, because its natural prolate architecture has evolved to deliver very high vergence, while minimizing optical aberrations, to provide excellent image quality. Because the cornea is responsible for about three-quarters of the total focusing power of the eye, even small alterations to its anterior surface can be used to modify ocular refraction to correct a large proportion of the ammetropias. This has been successfully achieved by sculpting methods afforded by the excimer laser (LASIK, PRK, or LASEK) as well as a number of mechanically based procedures, such as incisional, thermal, and additive techniques.

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Corneal procedures are subject to challenging—although now less common—surgical complications, and to issues relating to wound healing and biomechanics, both of which will influence the precision and stability of the results.[182] The optical quality of the outcomes can be less than ideal when treating high ammetropias and patients with large mesopic pupil sizes[20,173] due to inadequate optical zone dimensions and centration, excessive corneal flattening or steepening, as well as unwanted surface microirregularities. Highly sophisticated optimized and customized laser based treatments are beginning to provide ablations that minimize the induction of higher order aberrations, but physical limitations of corneal thickness as well as biomechanical behavior will limit the ability to maintain the minimal aberrational structure of the physiological cornea,[214] particularly in high ammetropic eyes.

Second, the crystalline lens affects one-fourth of the refractive power of the eye's optical system. It grows and becomes sclerotic throughout life, causing changes of refraction and presbyopia.[108,257] Preliminary evidence has shown that modern, minimally invasive clear lens extraction (CLE)[109,112] plus toric, piggy-back,[79,130] aspheric,[131] multifocal, or accommodating[23,79,154,160,177,183] IOL implantation can be considered sufficiently effective, predictable, and stable. However, as multifocal optics decrease contrast sensitivity and much doubtful data do not allow us, yet, to consider accommodating IOLs as a valid dynamic substitute for the natural lens, CLE causes loss of accommodation in young people. Long-term safety is also a concern, due to the risk of retinal detachment and maculopathy in eyes naturally prone to posterior segment pathology (i.e., high myopia).[32,66,98,109]

Third, a supplementary IOL (phakic IOL) implanted between the cornea and the lens, fixated in the angle, enclavated to the mid-peripheral iris with a claw or placed in the posterior chamber, gives rise to a condition called *duophakia* or *artiphakia*[111] and has several advantages:[165]

1) It allows the crystalline lens to retain its function and may possibly protect against vitreoretinal side effects of CLE
2) Because the quality of the lens implant surfaces is above the optical limits of the eye, its nodal points are nearer the pupil and the optic (especially with the newest materials and designs) can be conveniently wide, it maintains and potentially could even improve the natural properties of the eye's optical system to enhance the quality of the retinal image, allowing excellent vision even in dim light conditions.[54,120,127,129] Post-LASIK eyes have been found to yield two to three times more spherical aberration and coma than eyes implanted with a posterior chamber collamer phakic IOL (ICL)[226]
3) The lens is removable and exchangeable, permitting potential reversibility to the preoperative condition[134,241]
4) The result is predictable,[4,13,18,36,72,77,113,156,157,175,194,202,218,243,247,250,263] easily adjustable with complementary fine-tuning corneal surgeries,[19,115,219,261] and immediately stable, because the refractive outcome depends less on healing processes

The drawbacks of phakic IOLs are related to the risks of an intraocular operative procedure. Although extremely rare, catastrophic complications with irreversible, severe iatrogenic damage to the delicate inner structures are possible, and the potential consequences of the surgical opening of the eye with decompression of the anterior chamber in uneventful procedures is an issue that still requires to be thoroughly addressed.[163] Once inside the eye and over time, each site of haptic fixation has its own area of unique concern. Angle-fixated IOLs stay in contact with peripheral iris and chamber angle structures. Iris-supported lenses pinch the mid-peripheral iris tissue. They can potentially induce acute and recurrent subchronic iritis, ischemic subatrophy of the iris, pupil distortion, progressive endothelial cell loss, secondary glaucoma, and alteration of the blood/aqueous barrier with persistent aqueous flare and cystoid macular edema.[10,41,105,141,178,197,198,199,225,251]

Posterior chamber phakic IOLs are vaulted between the posterior pigmented layers of the iris and the anterior crystalline lens with the anterior zonules. They may cause angle closure and malignant glaucoma, ischemic blown pupil (Urrets-Zavalia syndrome), cataract, chafing of the posterior iris and ciliary processes with pigmentary dispersion syndrome, damage to the zonules with dislocation of the IOL in the vitreous, cyclitis, chronic uveal inflammation, and macular edema.[2,46,52,73,83,97,147,150,220,221,246,252]

Historical Overview

ANTERIOR CHAMBER PHAKIC LENSES (ACP-IOLS)

Angle-Fixated Lenses

The irido-corneal angle was chosen by Dannheim,[69] Baron,[30,31] and Strampelli[236] in the early 1950s as the first, easy-to-maneuver anatomical space reached by the surgeon for inserting a lens into a phakic eye. The frequent corneal decompensation of Baron's early polymethylmethacrylate (PMMA) lens (1952), originally designed to float in the

anterior chamber, led him to conclude that "fixation points would be required to maintain the implant in situ." The model designed by Strampelli, the prototype for an entire generation of IOLs (Fig. 1),[47,236] had a tripod shape with three points to be fixated in the chamber angle. The trailing haptic was swallow-tailed to facilitate iridectomy at the end of the operation. To calculate the power of the lens, the same spectacle power was chosen for a meniscus optic of 6.0 mm and an overall length of 11–12 mm. After several years of anecdotal reports by European pioneers who adopted this model with small further changes,[35,47,60,168] Barraquer,[34] in 1959, reported the first statistically significant study on 239 angle-fixated phakic IOLs followed up for 5 years.[33] Since then, the correct choice of the overall length of the lens appeared particularly critical, as the haptics were not flexible enough to accommodate angle diameters smaller than the implant overall length. Even a slightly longer implant caused undue pressure with angle recession, intraocular pressure rise, and hyphema because of erosion of gonio-structures, low-grade recurrent inflammation with anterior synechiae, pupil distortion, and sectorial atrophy of the iris. On the other hand, while the crucial role of the endothelium in preserving corneal transparency was poorly understood, too short a lens caused undesired movements with progressive endothelial cell loss secondary to intermittent contact with corneal inner layers, and iris chafing. The optic became decentered, causing visual symptoms. More than 60% of the implants had to be removed because of disastrous consequences such as corneal decompensation or what was subsequently called the 'UGH-syndrome' (uveitis-glaucoma-hyphema).[35,82,148]

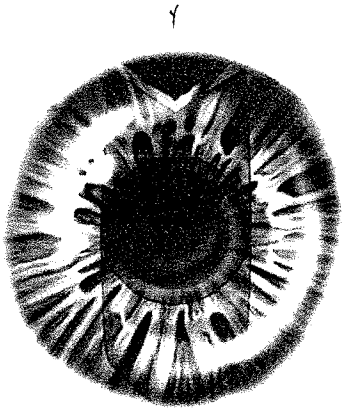

Fig. 1. Artist's remake, from the original drawings, of the Strampelli anterior chamber phakic IOL for myopia. (Reprinted from Lovisolo and Pesando[165] with permission of Fabiano Editore.)

The difficulties reported by surgeons at that time—who had none of the modern sterilization techniques, operating microscope, ophthalmic viscosurgical devices (OVDs), microsutures, and quality grinding and polishing of the IOL to avoid sharp edges—were considered insurmountable. This report marked the end of the pioneering phase of phakic IOL implantation and influenced more than 40 years of bad reputation, or even actual ostracism. Die-hard prejudices are still strong against a procedure that, since its arrival, has been controversial.

For approximately 20 years, anterior chamber IOLs gained from continued improvements in loop flexibility and design, but only for correcting aphakia.[61,62,145] Baikoff[25,28,139] and Momose reviewed the old abandoned idea for phakic eyes in 1987. Momose invented his spider lens, a two-piece lens with a glass optic (refractive index 1.62) surrounded by a polyamide ring that formed the four-curved haptics, to be fixated at the chamber angle. The overall length ranged between 12.5 and 13.5 mm. The first reports described no significant intraoperative complications and no loss of best spectacle-corrected visual acuity (BSCVA).[208] The mean endothelial cell loss amounted to 5.3–7% and was stable at 3 years. However, gonio-synechiae formation with the haptics, and frequent decentering (sunset) of the heavy glass optic made the spider lens go down in history as a curious example of ACP-IOL.

The Baikoff ZB lens[26] (Domilens, Lyon, France), a modified version of the highly popular Kelman AC-IOL for aphakia,[145] started the modern era of phakic IOLs fixated in the irido-corneal angle. It was a one-piece PMMA lens, with four fixation points and an optic diameter of 4.5 mm. The surgeon chose the most suitable of the three available overall lengths (12.5, 13.0, and 13.5 mm) by adding 0.5 or 1.0 mm to the external horizontal 'white-to-white' distance, measured with a surgical caliper. The manufacturer's recommendations included an endothelial cell count of at least 2,500/mm^2, a central chamber depth (including the corneal thickness) of at least 3.2 mm for powers from −7.0 to −15.0 D, 3.4 mm for stronger lenses and a minimum irido-corneal angle opening larger than 2 using the Shaffer grading classification.[234]

The initial results were encouraging,[65] as 80% of the eyes fell within 1.0 D of the expected outcome, although the power calculation was very empirical. Up to −10.0 D, the same spectacle refraction was used as the lens power; +1.0 D was added to values between −10.0 and −15.0, and +2.0 D to refractions in excess of −15.0 D.

Unfortunately, 3 years later at least 10% of these eyes showed worrisome signs of progressive endothelial loss, caused by the traumatic contact between the edge of the optic and the nearby internal layers of the cornea, that were too close together.[181] In 1991 two-year outcomes on animal (monkey) eyes[59,193,207] showed some degree of erosion and/or uveal envelopment of the haptic and a decrease in endothelial cell counts, despite good positional stability, no significant inflammation, and no evidence of cataracts or cystoid macular edema. To overcome this problem, the second-generation model (called ZB5M or ZB5MF by Domilens)[58] reduced the effective diameter of the optic to 4.0 mm (0.5 mm of carrier ring with no optical power; this gave a total diameter of 5.0 mm), thus limiting the peripheral thickness of the optic and increasing the "safety distance" between the edge and the endothelium[27] with a reduced vault height (Fig. 2). More refined criteria were introduced for power calculation.

In 1994, a French multicenter study with 18 months of follow-up gave the same predictability as for the ZB (75% of the eyes were within the range of ±1.0 D). Iridopathy was the most significant complication,[225] with pupil ovalization, low-grade inflammation, peripheral synechiae, and sectorial atrophy of the iris. Pupillary block glaucoma was occasionally observed in eyes where iridectomy was not done. Almost all the patients implanted with this ACP-IOL experienced nighttime visual symptoms. In a more recent study[199] including 134 myopic implanted eyes, the mean endothelial cell loss was 3.3% at 6 months, 4.4% at 1 year, 4.5% at 2 years, and 4.6% at 3 years.

In 1997, the third generation of rigid Baikoff ACP-IOLs, the NuVita MA20 (Bausch & Lomb, Salt Lake City, UT, USA) incorporated further changes of the optic: the PMMA material was smoothed by a fluorine-plasma treatment to minimize tissue friction and cell adhesion; the effective optical zone was increased to 4.5 mm; and 'peripheral detail technology' was applied to the edges.[27] The haptics were re-styled to improve their conformity with the chamber angle shape and to achieve a smoother distribution of the compression.

However, despite good preliminary results[13]—all the eyes lay within the ±1.0 D range, a small proportion (5%) of pupil ovalization, no disabling glare (an increase in mesopic vision was reported in 80% of cases and there was no loss of contrast sensitivity at different spatial frequencies), with 2.35% endothelial cell loss at 1 year—the NuVita was withdrawn from the market.

Three other rigid PMMA, angle-fixated lenses deserve mention because of their widespread use in Europe:

1) The ZSAL-4/Plus lens (Morcher, Stuttgart, Germany) is the fifth generation of the ZS series. It has long, thin, flexible Z-shaped haptics with an effective 5.3-mm plano-concave optical zone and a transitional edge to reduce night halos. The haptic geometry has been designed to increase flexibility and disperse compression forces against angle structures by ensuring a mean distance of 1.54 mm from the edge of the optic (Table 1) and the endothelium, which seems to cause less cell loss.[137,199,245]
2) The Safety Flex Phakic 6 H2 (Ophthalmic Innovations International, Ontario, Canada) is

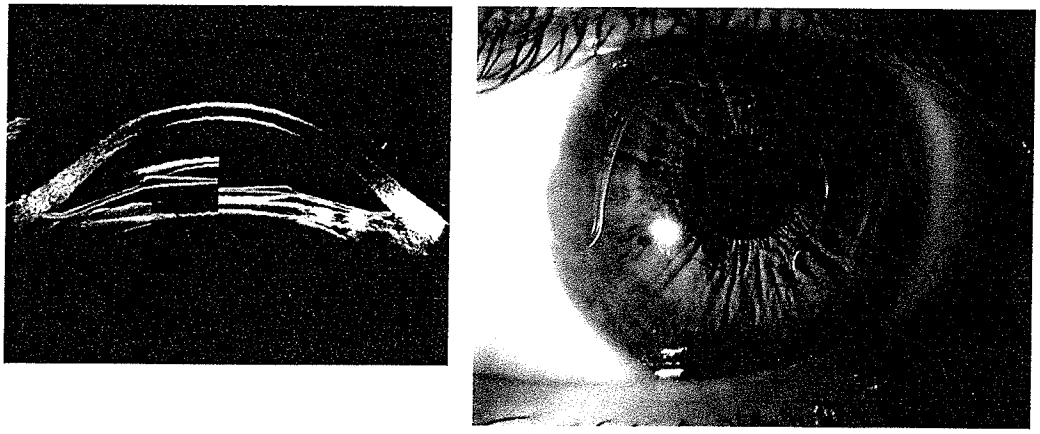

Fig. 2. Left: Four superimposed VHF echographic images (Artemis 2) showing the evolution of the "safety distance," that is, the clearance from mid-peripheral endothelium and edge of the myopic optic of different generations of angle-fixated phakic IOLs. Compared to the old ZB (*top left*) and ZB5MF (*bottom left*), the Nuvita (*top right*) and the foldable GBR/Vivarte (*bottom right*) show the modern trend for a significantly lower vault to respect the corneal endothelial cell layer. *Right:* Eye with ZB5MF intraocular lens implant.

TABLE 1

Distances to Endothelium of Different Anterior Chamber Myopic Phakic IOLs

IOL (optic)	ZSAL-4 (5.0 mm)	I-CARE**** (5.75 mm)	Artisan/ Verisyse (5.0 mm)	Nuvita (4.5 mm)	Phakic 6 (6.0 mm)	GBR/ Vivarte (5.5 mm)	Kelman Duet (6.3 mm)	Artisan/ Verisyse (6.0 mm)
V	0.8*	0.84/1.35**	0.9/0.9**	0.93*	1.00/0.75**	0.66/0.63**	0.75*	0.9/0.89**
D_c	2.05*	2.01/1.5**	1.95/1.95**	1.92*	1.85/2.1**	2.19/2.22**	2.10*	1.95/1.94**
D_p	1.64*	1.85/1.1**	1.75/1.69**	NA	1.66***	1.60/1.78**	1.5*	1.52/1.53**

Distances to endothelium of different anterior chamber myopic phakic IOLs assuming average values of corneal curvature (K-reading = 43.0 D), symmetrical ACD (central depth: 3.0 mm, 3.0-mm mid-peripheral depth: 1.9 mm), phakic lens power of −10.0 D and central lens thickness of 0.15 mm. Distance data provided by the company are compared with averaged data obtained with VHF echography (Artemis 2). D_c = central distance from endothelium; V = vaulting, central distance from anterior crystalline lens; D_p = mid-peripheral (3.0 mm eccentricity) clearance from the endothelium to the edge of the optic. NA = Not available.

*Data provided by the firm / literature, not verified by VHF echography.

**Data provided by the firm vs. data obtained by VHF echography.

***Data not provided by the firm, empirically obtained from VHF echography.

****Value estimated taking into consideration proper sizing of the lens.

a heparin-coated ACP-IOL whose optic diameter is particularly wide (6.0 mm, 5.5 mm in powers greater than −20.0 D). According to the main investigators,[110] who now claim more than 8 years of follow-up, the disadvantages linked to the width of the incision are fully compensated by the gain in quality of vision. Furthermore, thanks to the considerable flexibility of the haptics, a reduced incidence of progressive ovalization of the pupil may be expected (Fig. 3). The company is now creating a foldable model, which will allow a smaller incision.

3) The ACRIOL (Soleko, Rome, Italy) comprises a similarly wide (5.4 to 5.6 mm) optic and an original tripod haptic designed to ensure optimal stability to the three available overall lengths of 12.3, 12.8 and 13.3 mm (McGrath D: Surgeons review phakic IOLs at the 2005 ESCRS Winter Symposium. EuroTimes 10:12, 2005).

The latest generation of angle-fixated phakic lenses (Table 2) has a foldable optic to be inserted through a self-sealing small incision (less than 3.5 mm). Preliminary studies with these newest ACP-IOLs showed promising results in terms of safety ratio and accuracy of the refractive outcomes:

1) The Vivarte/GBR lens (previously co-marketed by Ciba Vision, Salt Lake City, UT, USA, and IOLTECH, La Rochelle, France, now exclusively commercialized by Zeiss-Meditec, Jena, Germany) is a composite, two-material, single-piece lens, with two tripod asymmetrical haptics

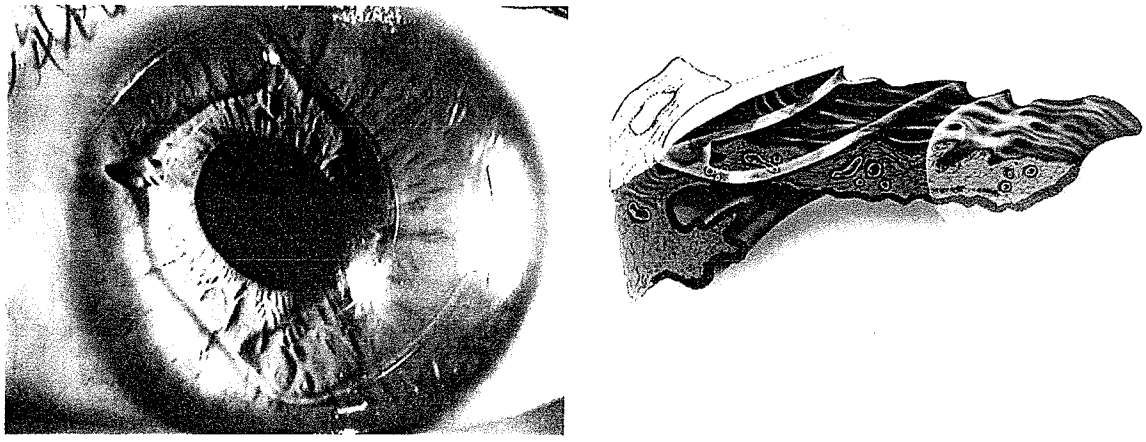

Fig. 3. Chronic iridopathy resulting in pupil distortion (*left*) may be due to three different mechanisms: 1) inherently to the fixation system itself, the rigid haptics induce a backward pressure of the iris root; 2) (*right*) an ischemia from prolonged compression of the arterial iris blood supply, resulting in iris stroma and pigment epithelial layer subatrophy; 3) inflammation leading to iris retraction. All three mechanisms could be expected with oversized lenses in particular.

TABLE 2A

Summary of Current Angle-fixated AC Phakic IOL Models

Brand Name™ (Manufacturer)	Model Optic Geometry Total/ Effective Diameter (mm)	Haptic Angulation	Optic Material (*n* at 35°C)	Special features	Power range / Max correction (D)	Overall Length (mm)	FDA Status	Power Calculation Formula	Incision size (mm)	−10 D Thickness (mm) Central Optic Edge Optic Footplate	Safety Guidelines Central ACD (mm)	Peripheral ACD	ECC (cells / mm^2)	IC Angle Width (Shaffer)	Iridotomy
Phakic 6 H2 (O.I.I)	Single-piece Plano-spherical 5.5 ≧ 10.0 D) 6.0 (≦ 10.0) 6.0 (Hyperopic)	18°	PMMA (1.492)	Heparinized Surface Foldable under trial	−4 to −20 / −22 +2 to +10 / +8	11.5 to 14 (0.5 steps)	Phase II	Calculation Chart	7.0		2.5	Not provided	2,500	>2	2 YAG PIs or Surgical
Vivarte/GBR (ZEISS-IOLTECH)	Composite One-piece Biconcave 5.5 / ?	0° (12° to iris plane)	Flexizone (Hydrophilic Acrylic) (1.47) PMMA Haptics	Forceps Foldable Multifocal (−5 to +5) Near Add +2.50	−7 to −22 / −21	12, 12.5, 13	Not Submitted	Holladay Refractive	3.5		2.7 (<−13) 2.9 (−13< D <−18) 3.1 (−18< D <−22)	1.308	2,500 (<40 yo) 2,000 (>40 yo)	>2	Unnecessary
ZSAL-4 Plus (MORCHER)	Single-piece Plano-spherical 5.8 / 5.3	19°	PMMA (1.492)	NO	−6 to −20 / −23	12, 12.5, 13	Not Submitted	Van der Hejide	6.0		2.7	1.5	2,300	>2	Surgical
Kelman Duet (TEKIA)	Two-piece Biconcave 6.3 / 5.5	8.9° to 11–14°	Silicone (1.43) PMMA Haptics	Injectable Glare shield	−6 to −20 / ?	12, 12.5, 13, 13.5	Not yet submitted Trials expected in 2004	Van der Hejide	2.0	0.20 0.53	2.8 (≦−13) 3.0 (≧−13)		2,000	>2	Optional
I-CARE (CORNEAL)	Single-piece Meniscus 5.75 / ?	?	Hydrophilic (26% water) Acrylic (1.47)	Injectable Low-pressure Haptic	−3 to −20 / −23 +3 to +10 / +9	12, 12.5, 13, 13.5	Not Submitted	Proprietary Refractive Formula	3.0		2.9		2,500	>2	2 YAG PIs

Acrysof ALCON	Single-piece	?	Hydrophobic Acrylic (?)	Injectable	?	?	Phase I	?	3.0		?	Not Provided ?
	Meniscus 5.5 / ?											
Vision Membrane VM Technology	Single-piece	?	Silicone (?)	Injectable	?	?	Not yet submitted	?	2.0	Ultrathin (not specified)	?	Not provided ?
	Diffractive						Trials expected in 2004					
	7.0 / ?											
ThinPhAc THINOPT-X	Single-piece	?	Hydrophilic (18% water) Acrylic (?)	Rollable	−30.0 to +30.0	13, 14	Not yet submitted	?	2.0	< 0.1	?	Not provided ?
	Diffractive						Trials expected in 2004			0.35		
	7.0 to 8.0 / ? ?									0.05		

? = Not disclosed as "confidential" by the manufacturing company.
• = Not provided by the manufacturing company, measured with VHF echography (Artemis 2).

(one regular Z-shaped and one modified C-looped) made of PMMA-based, hydrophobic (0.2% water) acrylic polymers, and soft terminal acrylic cushions (Fig. 4). They are grafted onto a hydrophilic (28% water) acrylic optic, mainly hydrossiethylmethacrylate (HEMA) and methylmethacrylate (MMA), which is folded and inserted with an appropriate device and forceps.[81]

2) The I-CARE (Corneal, Pringy, France) is a hydrophilic acrylic monobloc lens, with 5.75 mm optic size and four independent feet to provide a wider contact surface in the angle support (Fig. 5). The forces developed under compression are therefore supposed to be smaller, so as to maximally preserve iridocorneal angle and iris structures. Despite its geometrical shape, it was designed to provide a longer mid-peripheral distance from the endothelium to the optic's edge (Sourdille et al. I-CARE, a new phakic IOL. Presented at the VII ESCRS winter meeting, Rome, January 2003), the lens turned out to be excessively vaulted once implanted intraocularly and observed with VHF echography (Table 1). Further refinements of the design are expected soon.
3) The Kelman Duet Implant (Tekia, Irvine, CA, USA) is a two-part ACP-IOL, implantable through a 2.0-mm incision. The tightly compressed silicone optic is inserted independently, after the tripod PMMA haptics. Two specially fitted tabs enable the optic to be attached to the haptics and offer the chance of an independent exchange of the haptic or the optic.[8] A glare-preventing shield has been added to the periphery of the 6.3-mm (effective diameter: 5.5 mm) optic. A potential concern, common to the GBR/Vivarte, is the tendency to move around the angle when a patient blinks or rubs his eye,[142] as it was found with previous tripod lenses.
4) The Acrysof ACP-IOL (Alcon, Forth Worth, TX, USA) is a single-piece foldable lens in acrylic material with 5.5-mm meniscus optic and peculiar T-shaped haptic design (Colin J: Surgical technique for inserting the AcrySof Phakic ACL. Presented at the ASCRS meeting, San Francisco, April 2003).
5) The ThinPhAc (ThinOpt-X, Medford Lakes, NJ, USA) is an ultra-thin (100 to 150 μm) lens made of hydrophilic acrylic material. The large optic (7 to 8 mm) has been designed to enhance quality of vision by controlling spherical aberration—one surface is lathe-cut to retain a traditional continuous curvature, and the second surface presents a series of

TABLE 2B

Summary of Current Iris-supported AC Phakic IOL models

Brand Name™ Manufacturer	Model Optic Geometry Total/ Effective Diameter (mm)	Haptic Angulation	Optic Material (n at 35°C)	Special features	Power range / Max correction (D)	Overall Length (mm)	FDA Status	Power Calculation (Formula)	Incision size (mm)	−10 D Thickness (mm) Central Optic Peripheral Optic Footplate	Safety Guidelines Central ACD (mm)	Peripheral ACD ECC (cells / mm^2)	IC Angle Width (Shaffer) Iridotomy
Artisan 204 / Verisyse OPHTECH/ AMO	Single-piece	0°	PMMA (1.492)	Toric	−3 to −15.5 / −15	8.5	3-year clinical outcomes file submitted for PMA Pending Approval Expected 2004	Van der Hejide	6.5		2.8	2,500	Surgical
	Meniscus				+1 to +12 / +10		Toric: clinical study start 2003 (1-year study required)						
	6.0 / ?												
Artisan 206 / Verisyse OPHTECH/ AMO	Single-piece	0°	PMMA (1.492)	Toric	−3 to −23.5 / −24	8.5	3-year clinical outcomes file submitted for PMA Pending Approval Expected 2004	Van der Hejide	5.5		2.8	2,500	Surgical
	Meniscus			Pediatric	+1 to +12 / +10	7.5	Toric: clinical study start 2003 (1-year study required)						
	5.0 / ?												
Artiflex/ Veriflex (OPHTECH/ AMO)	Two-piece	0°	Polysiloxane (?)	Flexible	−3 to −23.5 / ?	8.5	Clinical study start 2003	Van der Hejide	3.5		2.8	2,500	Surgical
	Meniscus		PMMA haptics		+3 to +12 / ?								
	6.0 / ?												
Nikai SOLEKO	Single-piece	35°	PMMA (1.492)	Anterior-Posterior Fixation	−3 to −25 / −32	13	Not Submitted	Russian Vertex Chart	7.0		2.8	2,500	Surgical
	Meniscus				+2 to +30 / +25								
	6.0 / ?												

TABLE 2C

Summary of Current Posterior Chamber Phakic IOL Models

Brand Name™ Manufacturer	Model Optic Geometry Total/ Effective Diameter (mm)	Haptic Angulation	Material (*n* at 35°C)	Special features	Power range / Max correction (D)	Overall Length (mm)	FDA Status	Power Calculation (Formula)	Min Incision size (mm)	−10 D Lens Thickness (mm) Central Optic	Peripheral Optic Footplate	Vaulting (mm) of ideally sized IOLs	Safety Guidelines Min ACD (mm)	Min ECC (cells / mm^2)	Average IC Angle Reduction (%)
ICL STAAR	Single-piece	?	Collamer (37.5% water) (1.453)	Toric	−3 to −21 / −18	11.5, 12, 12.5, 13 (M)	3-year clinical outcomes file submitted for PMA Pending Approval (M) Expected 2004	Olsen-Feingold Formula	2.5	0.10 / 0.23**		0.30 to 0.50 (M)	2.8	2,000 to 2,500 (depends on age)	28
	Plano-spherical			Custom	+3 to +17 / +13	11, 11.5, 12, 12.5 (H)	Toric: clinical study start 2002 (1-year study required)	Proprietary Nomogram		0.55		0.20 to 0.30 (H)			
	5.5 / 5.5 (H & M <−12) 5.25 / 5.25 (−12 <M <−14) 5.0 / 5.0 (−14 < M <−16.50) 4.65 /4.65 (≥ −17.0)									0.07					
PRL IOL TECH	Single-piece	?	Hydrophilic silicone (1.46)	NO	−3 to −20 / −27	10.8, 11.3 (M)	Phase III	Holladay Refractive	1.8	0.22		0.35 (M)	2.5	2,000	20
	Plano-spherical 5.0 (M <−16.0 D) 4.5 (H & M >−16.0D)				+3 to +15 / +11.50	10.6 (H)				0.52 0.08		0.25 (H)			
Sticklens IOLTECH	Single-piece	?	Hydrophilic (28% water) acrylic (?)	NO	−7 to −25 / ?	11.5	Not Submitted	Van der Hejide	3.0	?		Almost zero	2.8	2,200	< 10
	Meniscus 6.5 / ?				+4 to +7 / ?										

M = Myopic, H = Hyperopic, T = Toric.

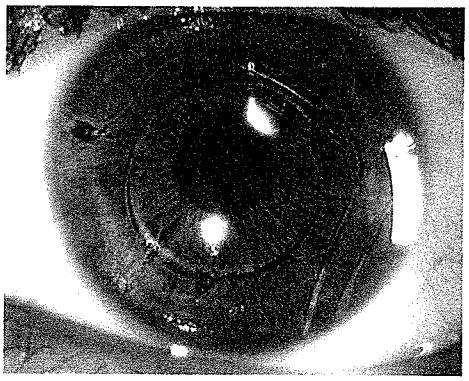

Fig. 4. The GBR/Vivarte foldable angle-fixated phakic IOL in situ.

steps/rings 50 μm in height, each with a slightly different curvature, to remain within microns of the opposite surface, along the principle of Fresnel optics. The lens, provided without limits of correction (±30.0 D), is rolled in an injector device, and then gently inserted through a micro incision (1.5 mm) to get fixated in the irido-corneal angle. The lens' extremely light weight should limit the forces that may potentially disrupt internal tissues, with the pliable haptics that compensate for size error by simply rolling or unrolling at the fixation site (Alio J: ThinPhAc phakic IOL. Presented at the Alicante Refractiva Congress, Alicante, March 2004).

6) The Vision Membrane Lens (Vision Membrane Technology, Carlsbad, CA, USA) is a minimal-incision, silicone ACP-IOL with a large optic diameter (7.0 mm) and a remarkable thinness achieved through diffractive technology (Haddrill M: Status report: Phakic IOLs. EyeWorld, April 2003, pp 62–3).

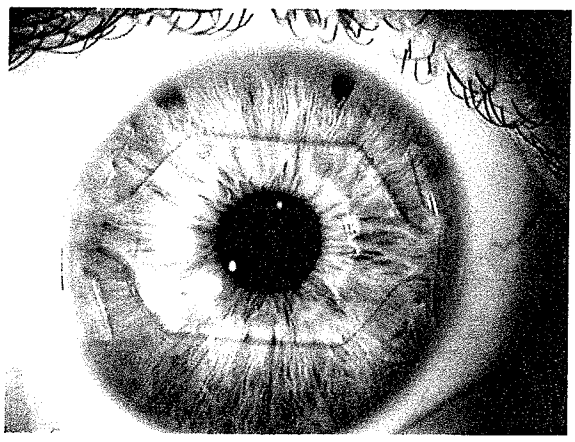

Fig. 5. The I-CARE foldable angle-fixated phakic IOL in situ.

The Vivarte/GBR, the I-CARE, and the Kelman Duet implants have already obtained the CE mark and are commercially available in Europe. The Acrysof, the ThinPhAc, and the Vision Membrane lenses are in the very initial phase of small, controlled clinical trials in a few study centers in Europe and Russia.

Iris-Supported Lenses

Using the iris structure to support the IOL was initially suggested in aphakic globes with a view to avoiding the main problems encountered with angle fixation. Starting in 1953, the first-generation models with anterior and posterior loops (like Epstein's Maltese cross, Binkhorst's iris-clip,[42,43] the Sputnik by Fyodorov,[101] and Worst's Medallion lens[255]) were supported by the highly mobile iris sphincter, close to the pupillary border. These invariably created problems with progressive erosion of the iris stroma and breakage of the blood/aqueous barrier, eventually leading to IOL dislocation, uveitis and glaucoma.

Those complications inspired Worst to design the iris-claw, also known as the "lobster-claw" lens, a coplanar one-piece PMMA IOL. The haptics had fine fissures to capture, through enclavation with a specific needle or forceps, a fold of mid-peripheral iris stroma, a virtually immobile portion halfway between the pupillary edge and the iris root. As this is less vascularized and reactive, it was expected to safely bear the pressure of the 'claws' without inhibiting the iris function.

Many surgeons used the iris-claw lens after intracapsular cataract extraction or as secondary implantation in aphakia. In 1980, Worst[91] implanted an opaque optic iris claw lens in a phakic eye for the first time, to solve untreatable diplopia. In 1986, Fechner implanted the first sighted myopic eye.[89] In 1993, he reported the results of a 5-year retrospective study on 127 eyes implanted with an iris-claw model known as the Fechner-Worst lens, which has now been discontinued.[85,86,88] Predictability was fairly good (68% of the eyes fell within the ±1.0 D range), no intraoperative complications were observed, but there was progressive endothelial cell loss (around 7%). Menezo reported a similar figure (7.5% cell loss) at 1 year.[178] In 1993, a multicenter international trial published by the manufacturer on 99 eyes reported excellent results in terms of BSCVA lines gained. Predictability was as good as with the Baikoff lenses (81% of the eyes between

±1.0 D). At 1 year, the percentage of endothelial cell loss was the same (7%).

While most angle-fixated ACP-IOLs have involved significant developments, the currently available iris-claw model, the Artisan lens (Ophtec, Groeningen, The Netherlands), also known under the brand name of Verisyse (after the exclusive distribution agreement with Advanced Medical Optics, Santa Ana, CA, USA), is basically the original IOL with a long track record as its most distinctive advantageous feature.[50]

It is a one-piece PMMA IOL (Fig. 6), available in two meniscus-shaped optic diameters of 5.0 and 6.0 mm (the wider optic comes up to −15.50 D);[157,158,169,170] in the hyperopic lenses the optic diameter is always 5.0 mm.[227] The fixed overall diameter of the lens (generally the "one size fits all" length is 8.5 mm, with a 7.5-mm diameter available for pediatric implantations or to adapt to small eyes) is perceived as a great advantage to the surgeon who does not wish to deal with sizing measurements and expensive instrumentation. The average vaulting, that is, the central distance from the crystalline lens, is 0.9 mm. To select the correct power, the firm suggests the nomogram, perfected by van der Heijde,[120] which takes into consideration spectacle refraction, keratometric value and the anterior chamber depth (ACD).

Throughout the years, the "claw" principle has enjoyed continuous success, even in hyperopic eyes, with the longest and most reassuring follow-up in the field of phakic IOL. According to updated figures issued by the company more than 40,000 Worst lenses have been implanted for aphakia, and another 25,000 in phakic eyes.[88] The findings regarding endothelial behavior over the years are encouraging. Endothelial cell loss seems similar to the loss occurring after routine cataract surgery (3–5%) and over time the mean cell change does not seem significantly greater than the natural loss (0.57% annually).[4,9,50,119,142,171] The prospective clinical trial evaluating the endothelial cell count change on the first 765 eyes enrolled at the FDA sites showed no statistically significant postoperative cell loss at 2 years.[204] In the same population, complications that occurred at 2 years, such as pigment precipitates (8.3%), lens anterior capsule vacuoles (2.8%), and irregular pupil (2.8%) were considered clinically insignificant. Only visual symptoms like glare and halos reached a significant rate with the 5-mm optic (11.7% vs. 3.2% with the 6-mm optic).[142] Nevertheless, for many international authorities, the potential progressive endothelial cell loss remains a matter of concern. In the small incision era, the foldable iris claw phakic IOL, called the Artiflex/Veriflex, has recently obtained the CE mark and become commercially available in Europe. It has rigid PMMA haptics attached to a soft silicone (polysiloxane) 6.0-mm optic.[51] The unfolded lens flexes through the 3.2 mm incision and returns to its original shape inside the anterior chamber when implanted with an appropriate device.

Anterior-Posterior Phakic IOLs

In 1986, when Baikoff and Fechner started investigating the anterior chamber fixation, Fyodorov and Zuev[101] began implanting IOLs with "anterior-posterior" placement. The first model, called a "collar button" or "mushroom," was a one-piece silicone lens, with a 3.2-mm optic concave on the frontal surface that projected anteriorly through the pupil and was fixated behind the iris plane by two haptics, with a total length of 8.0 mm (Fig. 7). The small diameter of the optic created nighttime disturbances and photophobia under bright lighting, because

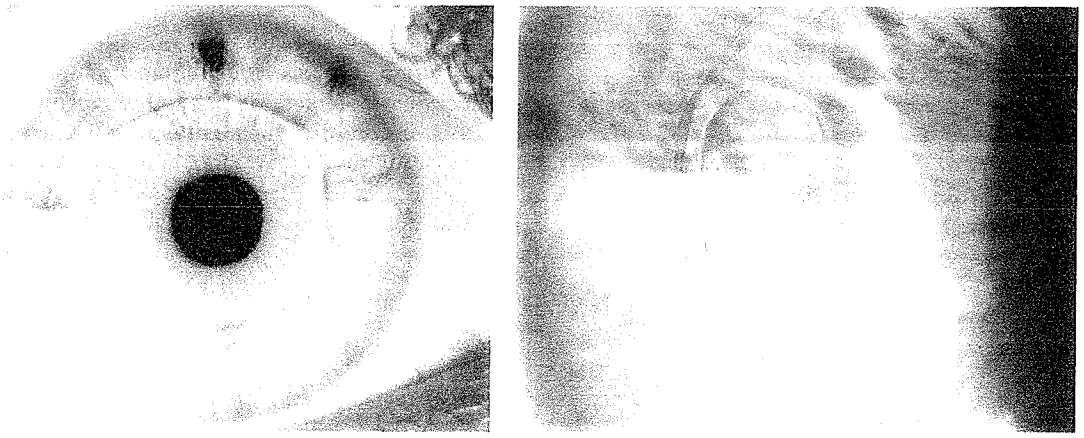

Fig. 6. The Artisan/Verisyse iris-fixated phakic IOL in situ (*left*) with a detail of the mid-peripheral iris stroma enclavated by the haptic claw (*right*).

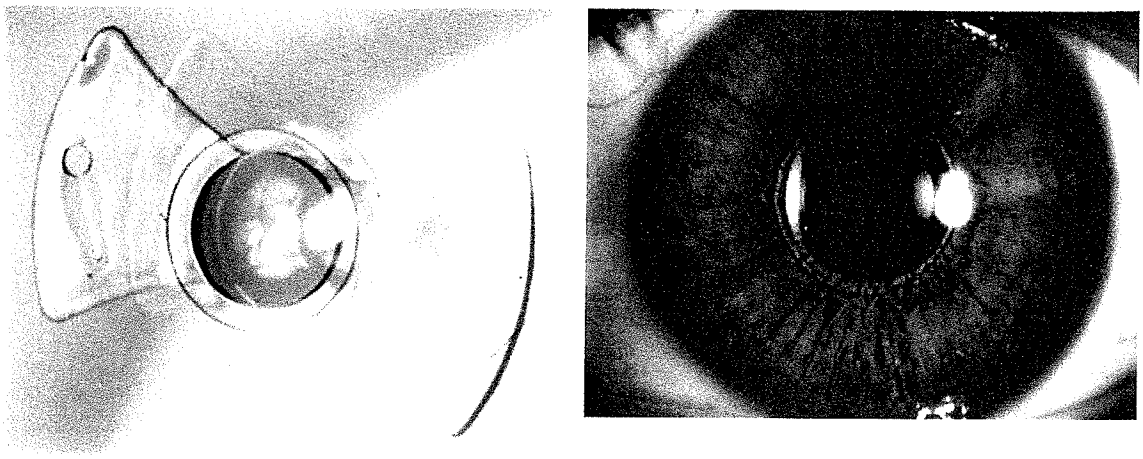

Fig. 7. First-generation 'collar button' anterior-posterior phakic IOL, outside the eye (*left*) and in situ (*right*). (Photographs courtesy of Dimitri Dementiev.)

the pupil was unable to constrict beyond 4.0 mm. Pupillary block glaucoma and iridocyclitis were also frequent. At a later stage, corneal decompensation, late-onset uveitis, and cataract were reported.[100,102] Therefore, Fyodorov decided to interrupt the study of these implants, and started to explore whether the posterior chamber (PC) might be a more welcoming environment for a phakic IOL.

The only anterior-posterior phakic IOL currently available is the Nikai lens (Soleko, Rome, Italy), a one-piece PMMA lens with a 6.0-mm optic and a total length of 13.0 mm. A single spiral-shaped C-loop that is unusually long (260° circumference), lies 0.95 mm more posteriorly to the optic plane. The loop is inserted in the ciliary sulcus through the iridectomy, while the optic plane stays in the anterior chamber, in the pre-pupillary area.[165] At the time of this writing, only anecdotal reports but no reliable data have been presented.

POSTERIOR CHAMBER PHAKIC LENSES (PCP-IOLS)

In 1990, after the collar button lens, the project at the Moscow Eye Institute stumbled along and second-generation lenses were introduced. The optic was enlarged, and the haptics were made flat and rectangular, similar to the modern plate haptic IOL for aphakia.[100,165] For the first time the implant was placed entirely inside the posterior chamber.

In order to calculate the power of the implant, surgeons employed the same rule of thumb already used for anterior chamber models, according to which for up to 10.0 D of myopia the dioptric power of the IOL corresponded to the refraction on trial frames; +1.0 D was added to values between −10.0 and −15.0, +2.0 D to refractions in excess of −15.0 D.

In the short term, the most frequent complications were decentration (the overall length of 10.0–11.0 mm was too short for stable positioning) and endothelial cell loss, as the ophthalmic viscosurgical device (OVD) was used very sparingly.[100,102] In the long term, these lenses have been subject to considerable criticism, due to the appearance of corneal decompensation, secondary glaucomas, and subcapsular cataract.[46,144,253] Thus they are no longer available commercially in Europe, but can still be obtained (Optimap, Moscow, Russia) with greater overall length (11.5–12.5 mm) and optical zones (4.5–5.5 mm, depending on the dioptric power).

On the heels of the first experience outside Russia,[84] Fechner moved from the pre-pupillary site of the iris claw to the retro-pupillary space,[87] with an elastomer model produced by Adatomed (Munich, Germany). With a wide range of powers (up to −25.00 D), the characteristic features were the long overall length (up to 12.5 mm) and a larger optic diameter (5.5 mm). This model fell slowly into disuse because of anterior lens fibrotic opacities in the contact zones with the thick edges of the IOL (Fig. 8).[165,174,179,180] There is no convincing evidence that the initial suspect (hydrophobic properties and the low refractive index of the elastomer, causing pronounced edge thickness) was the issue. Some authors think contour was more likely to be responsible for cataractogenesis.

The latest version of these lenses is the PRL (Phakic Refractive Lens),[75,76] now marketed by Zeiss-Meditec (Jena, Germany), formerly by Ciba Vision (Salt Lake City, UT, USA) and IOLTECH (La Rochelle, France), after the commercial rights were purchased in 2000 from developer Medennium International Vision (Cincinnati, OH, USA) (Fig. 9). The PRL is made of a new-generation,

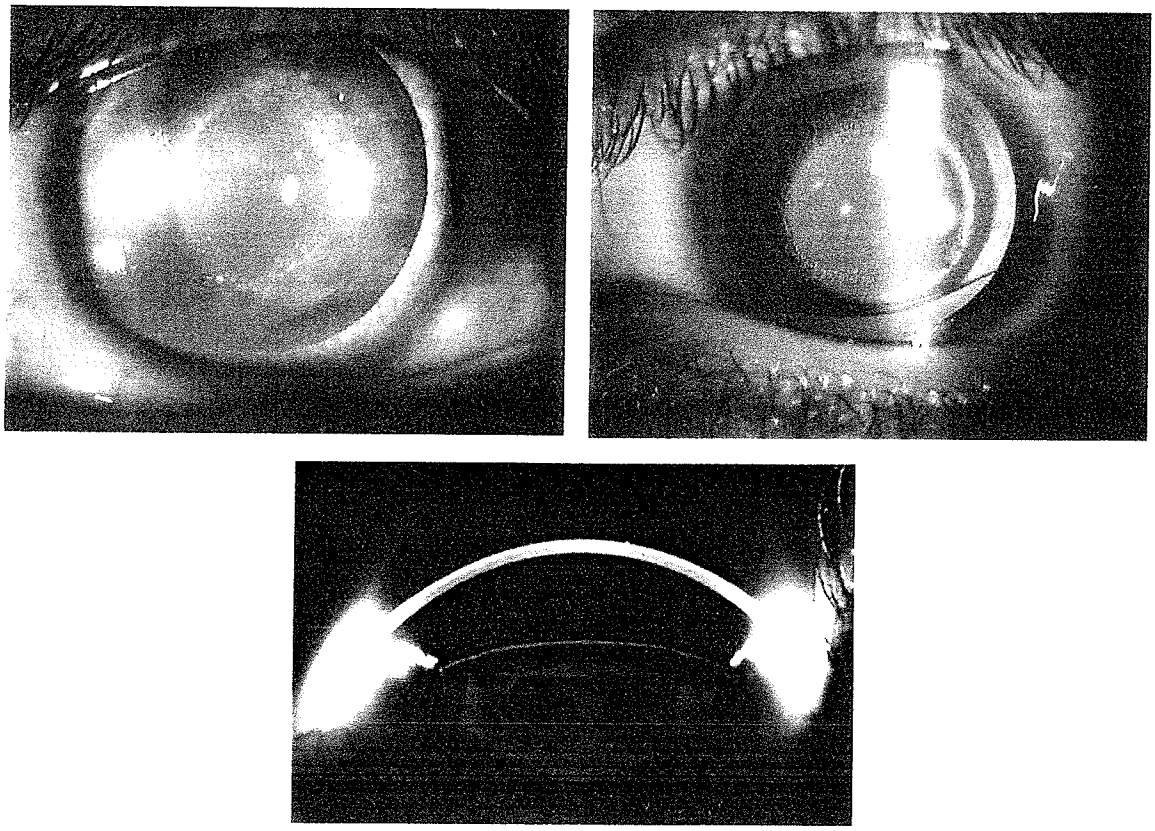

Fig. 8. Slit-lamp (*top left*) and retroillumination view (*top right*) of an iatrogenic anterior fibrotic subcapsular cataract induced by an elastomer posterior chamber phakic IOL (Adatomed) 28 months after surgery. Twelve months postoperatively, the Scheimpflug camera had shown good crystalline lens transparency (*bottom*).

ultra-thin hydrophobic silicone with a refractive index of 1.46. The diameter of the optic is 4.5–5.5 mm, depending on the lens power. The posterior base curve is concave to mimic the anterior curvature of the crystalline lens (10.0-mm radius of curvature). The front curve varies with correction; in myopic lenses it starts with a large-radius convex surface approaching an almost flat surface, then shifting to a concave surface for the higher powers. The hyperopic lens has a convex front surface. Central thickness is less than 0.5 mm and is constant for myopic lenses, but varies with hyperopic lenses.

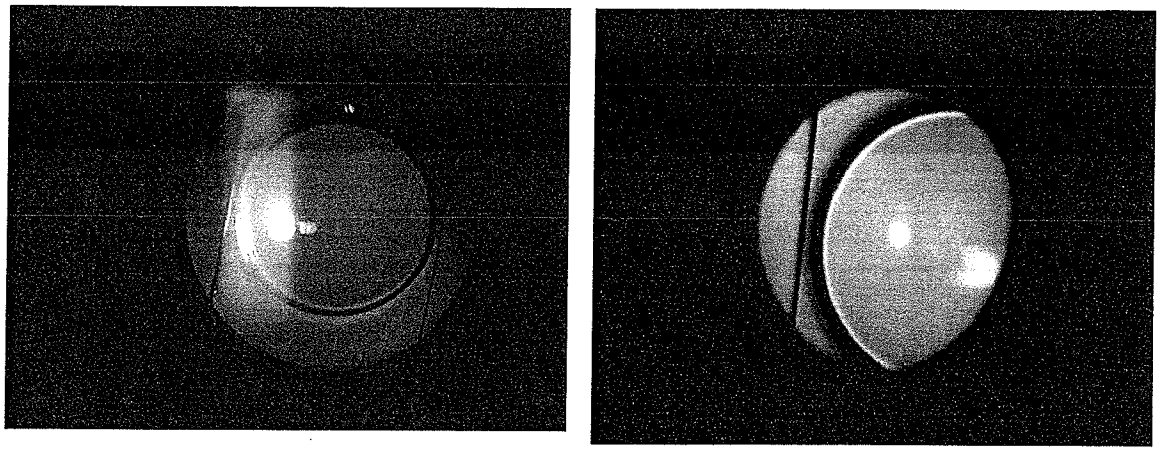

Fig. 9. The PRL posterior chamber phakic IOL in situ (*left*). Retroillumination Scheimpflug camera (EAS 1000, Nidek, Japan) image of a decentered PRL (*right*).

The edge thickness is always less than 0.2 mm. It is constant in hyperopic lenses and varies in the myopic ones. Although a 10.8-mm version is available for horizontal corneal diameters (white-to-white distance) less than 11.0 mm—a very rare finding—one single size is more commonly used, the 11.3-mm for myopic eyes, the 10.6-mm overall length for all hyperopic eyes. The company claims the lens has no anatomical fixation sites and floats on a layer of aqueous humor inside the posterior chamber, exerting no pressure on the ciliary structures and without coming into contact with the anterior capsule of the crystalline lens.[46,133] Possible complications are decentration (Fig. 9), cataract formation, pigmentary glaucoma,[246] and dislocation into the vitreous (Lovisolo CF: Posterior chamber phakic IOLs. ISRS/AAO 2003 Refractive Surgery comes of age. American Academy of Ophthalmology, pp 33–41). Particular features are the lowest safety limits suggested by the company (a minimum endothelial cell count of 2,000 cells/mm^2 and a central anterior chamber depth not less than 2.5 mm) and the highest effective myopic correction achievable on the market (−28.0 D at the spectacle plane).

In an attempt to make the lens material lighter, more hydrophilic, and permeable to gas and nutrients, a small proportion (0.2%) of porcine collagen was added to the silicone in the early 1990s. Collagen addition increased biocompatibility with the nearby structures by attracting the deposition on the lens surface of a monolayer of fibronectin, which inhibits aqueous protein binding, thus making the lens invisible to the immunitary system.[232]

Staar (Monrovia, CA, USA) patented[92] this material made of 60% poly-HEMA, water (36%), and benzophenone (3.8%) and called it the Collamer (collagen-copolymer). The lens was called the ICL (implantable contact lens), as initially it was thought that it would come into contact with the anterior surface of the crystalline lens.[215]

In fall 1993, Pesando, Assetto, Benedetti, Zaldivar and Skorpik implanted the first ICL prototypes (IC2020).[22] The optic was small (3.5–4.5 mm) and, in view of the sketchy knowledge of the physiological optics of in vivo implants, the concern was that the considerable thickness of larger optics would have caused problems. Nighttime visual symptoms were the immediate postoperative complication, and about one patient out of three had early angle-closure glaucoma. Since then, two well-patent peripheral Nd:YAG iridotomies performed two weeks before surgery or an intraoperative surgical iridectomy, have become mandatory.

In 1994, a new version became available (IC2020-M, overall length 11.5 mm and optic 4.5 mm) with better results.[165] Decentration was still an issue, because of the small overall length of the lens, but the main problem was undercorrection. For some still unknown reason,[165] the in vivo effective power of the ICL, calculated by the Feingold-Olsen formula, appeared to be underestimated by 25% of the in vitro predicted value. This was the start of a long period of work to improve the theoretical formula used for the predictability of the refractive outcome. It ended in 1998 thanks to the regression analysis that finally allowed users to achieve results in the range of ±1.00 D in the vast majority of patients.[165,262,264]

At least four clone models followed the IC2020 prototypes. Until the second half of 1996, the lens had no identifying marks. As a result, when it was injected, it was hard to recognize if the lens had folded over on itself and entered the chamber upside-down. To avoid this risk of inversion, many surgeons preferred to implant the lens using forceps. The injection technique became popular when the manufacturer produced a model (ICM115,120,125 or 130; V2 [Version Two]) with orientation markings on the haptics, allowing control during the unfolding maneuvers and ensuring the advantages of a small incision.

For the older versions (V2 and V3 in particular), the complications reported were small percentages of pupillary block glaucoma and pigment dispersion. However, late anterior subcapsular opacities of the crystalline lens occurred in 5–30% of cases after 1 to 3 years of follow-up (9.2% of the FDA cohort V3 series[224]).

The current model (the Visian ICL V4 [Version Four]) is a rectangular one-piece lens, 7.5–8.0 mm wide, available in four overall lengths (11.5, 12.0, 12.5 and 13.0 mm for the myopic lenses, 11.0, 11.5, 12.0, and 12.5 mm for the hyperopic ones). The optic diameter ranges from 4.65 to 5.5 mm in the myopic lenses, depending on the dioptric power, and is always 5.5 mm for hyperopic ICLs.[70,165,223] Its basic design change is in the vaulting. The V4 has an additional 0.13 to 0.21 mm of anterior vault, due to the steeper radius of curvature of the base curve and depending on dioptric power.[224] Myopic lenses (ICM) are plano-concave with the plano surface facing anteriorly, whereas the hyperopic ones (ICH) are meniscus-shaped (concave-convex), with convex on the anterior surface (Fig. 10).[223] According to updated figures issued by the manufacturer, about 30,000 ICLs have been implanted throughout the world and late cataract incidence, after properly sized V4 models, is less than 0.6%.[224] It is important to emphasize that this percentage might differ from other reports, including the FDA experience, due to differences in the criteria of how cataract is defined.

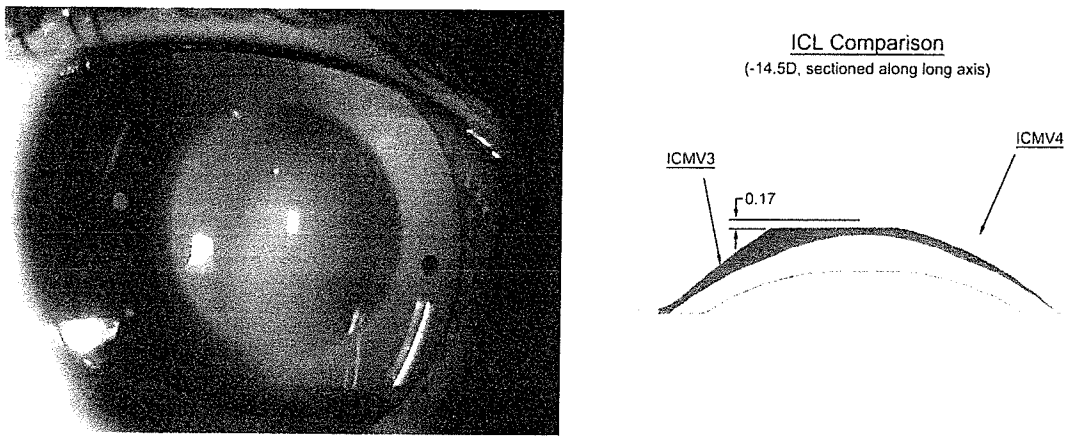

Fig. 10. A V4 myopic Visian ICL in situ (*left*). If compared with the previous generation, the last version (V4) has a steeper base curve to provide a higher vault (*right*). (Reprinted with permission of Staar Surgical.)

The Sticklens (IOLTECH, La Rochelle, France) is a newest posterior chamber phakic IOL made of a single piece of hydrophilic (28% water) soft acrylic material, which has already shown excellent biocompatibility when used for aphakic implants. Its main feature is that it sticks firmly to the anterior surface of the crystalline lens, hence the name. Only the anterior radius of curvature varies, while the overall length (11.5 mm), the posterior shape, and curvature are fixed to match the anterior surface of the crystalline lens. The thickness of both optic (6.5 mm wide) and haptics is minimal, and a smooth slippery surface optimizes the contact with the anterior crystalline and posterior iris surfaces. Four closed-loop haptics with large apertures seem to ensure a sort of piston-suction effect to maintain the supply of nutrients to the crystalline lens from aqueous flow, so it is claimed that, contrary to what was previously thought, vaulting is not necessary to prevent cataract formation (Lorenzo JA: Sticklens Phakic Acrylic IOL for High Myopia: 53-Month Results. Presented at the ASCRS meeting, San Francisco, April 2003).

The Sticklens is in the preliminary phase of clinical trials in a few study centers in France and Argentina.

Preliminary Work-Up

CHOICE OF LENS

Calculating the Power

Phakic IOL surgery can no longer afford postoperative refractive surprises, as in all cases the current standard-of-care precision must be ±1.0 D from attempted refraction. Therefore, the theoretical approach to calculating lens power is as important as the proper surgical technique, and the old empirical golden rules need to be abandoned. Fortunately, the latest generation formulas are very accurate, provided that the measurements they require are precise. Inaccuracies still arise, mainly due to human errors in measuring corneal curvature (especially in contact lens wearers or in eyes that have already undergone kerato-refractive surgery) and irido-corneal angle or ciliary sulcus dimensions.[128,206]

As in secondary IOL implantation in aphakic eyes, or piggy-back implantation, the power of a phakic IOL positioned at a given distance behind the main corneal surface is equivalent to the power of the lens measured at a given distance (V) from the corneal vertex.[126,211] The most commonly used formula is the following:

$$P_{IOL} = \frac{1336}{\frac{1336}{\frac{1000}{R_{preop}} - V} + K - ELP} - \frac{1336}{\frac{1336}{\frac{1000}{R_{des}} - V} + K - ELP}$$

It takes into account six classical parameters:

- corneal power (K), in diopters
- effective power of the IOL (P_{IOL}), in diopters
- preoperative refraction (R_{PREOP}), in diopters
- desired postoperative refraction (R_{des}), in diopters
- distance of the refraction plane from the corneal vertex (V), in mm
- effective or expected position of the IOL (ELP), in mm, that is, the distance between the secondary principal plane of the cornea and the principal plane of the IOL

The classic approximations of thin lenses are assumed,[42,96] or rather the corneal and IOL thicknesses are ignored, so the vertices of the anterior and posterior surfaces coincide. It is not necessary to determine the biometric dimensions of the globe (axial length, crystalline lens thickness,

and vitreous chamber), as they remain completely unchanged.

To select the power of anterior chamber phakic IOLs, many manufacturers recommend the formulas devised by Van der Heijde:[90,120]

$$P_{IOL}=\frac{1336}{\frac{1336}{K+Refc}-ELP}-\frac{1336}{\frac{1336}{K}-ELP}$$

where Refc = refraction at the corneal vertex, in diopters.

The effective lens position (ELP), in meters, is calculated as the difference between the anterior chamber depth including the corneal thickness (ACD) and the distance between the IOL and the crystalline lens (around 0.8 mm in the Artisan/Verisyse lens, 0.6 mm in the Baikoff ZB5MF, 1.0 mm in the ZSAL-4)[165] (Vaz F, et al: Anatomical Evaluation of Three Types of Phakic IOL. Presented at the XVI ESCRS Meeting, Nice, September 1998). For example, if we have a myopic eye with a spectacle correction (vertex distance 12 mm) of −18.0 D, K 44.0 D and ACD 3.8 mm, the power of the three ACP-IOLs can be calculated as follows:

$$ELP(Artisan/Verisyse)=0.003(0.0038-0.0008);$$

$$ELP(ZB5MF)=0.0032\,(0.0038-0.0006);$$

$$ELP(ZSAL\text{-}4)=0.0028\,(0.0038-0.001)$$

For an ICL implant, the majority of users employ the formula perfected by Feingold and Olsen,[99,188,189] which starts the calculation from the 12-mm spectacle plane or the vertex refraction. Again, a crucial factor is the ELP, or rather the expected position occupied by the ICL. The so-called equivalent contact lens power (ECL) at the corneal level is calculated as follows:

$$ECL=(1{,}000\cdot S.E.)/1{,}000-(V\cdot Rres)$$

Different values of a surgical constant (c) are introduced to achieve the ECL in myopic (C_M=8.0) and hyperopic (C_H=12.0) corrections. The power of the ICL (P_{ICL}), in D, is calculated as follows:

$$P_{ICL}=\frac{1336}{\frac{1336}{K+E_{CL}}-T-ACD-0.1}-\frac{1336}{\frac{1336}{K-T-ACD-0.1}}$$

where

K = mean corneal power [(K1 + K2) / 2)], in D
T = corneal thickness, in mm
ACD = depth of the anterior chamber, in mm
BCL = power of the contact lens, in D
R_{Res} = residual refraction, in D

An adjustment factor of 5% is added to the calculated dioptric value.

To calculate the PRL power, many surgeons still rely on the Russian Vertex Chart, where the spherical equivalent of the most accurate refraction on the spectacle plane (V = 12 mm) is used to interpolate the power of the lens. Rough as it may seem, this method appears to provide acceptable accuracy.[75]

Sizing the Overall Length

Despite the lack of scientific proof behind it, the vast majority of surgeons worldwide still behave like the early pioneers, selecting the overall diameter of the phakic IOL according to the golden rule of thumb by adding 0.5–1.0 mm to the horizontal corneal diameter (white-to-white distance, W-to-W) obtained externally, with the exceptions being the Artisan/Verisyse and the PRL, marketed as one size fits all lenses. Although obviously empirical, the W-to-W based sizing protocol is considered sufficiently safe and effective by many authorities. In the ICL FDA study that adopted the protocol, the replacement rate due to symptomatic over-undersizing issues[224] was 1.5% (8 out of 526 implanted eyes).

When done preoperatively at the slit-lamp by comparison with a ruler or gauge, or using the surgical caliper, the reproducibility margin (±0.79 mm) of this direct-view type of W-to-W measurement is poor because the "landmarks"—the points where white begins and gray starts at the limbus—are open to each surgeon's personal interpretation. More standardized strategies, based on the analysis of digital photographs from videokeratography or laser partial coherence interferometry images (IOLMaster) have slightly improved the precision (in our hands) achieving reproducibility tolerances of 0.4-0.6 mm for the different systems on the market. Moreover, although the Orbscan seems to provide smaller measurements, the white-to-white values provided by the IOLMaster look larger when compared with the measurements obtained with the surgical caliper.

The findings from in vivo ultrasound studies[21] and anatomic observations on cadaver eyes[252] were recently confirmed by a MRI study (Fea AM et al: MRI measurements of white-to-white and sulcus-to-sulcus distances for ICL implantation. Presented at the AAO Meeting, Orlando, FL, November 2002). Contrary to previous anecdotal reports, the ciliary sulcus diameter (sulcus-to-sulcus distance) is generally smaller than the anterior chamber diameter (angle-to-angle).[206] In Caucasians, a mean horizontal W-to-W distance of 11.7 mm (vertical W-to-W 11.0 mm) corresponds to a mean horizontal A-to-A distance of 11.9 mm and a mean horizontal sulcus-to-sulcus (S-to-S) distance of 11.2 mm. Whether the

anatomical shape of the ciliary sulcus is oval (some eyes show vertical dimensions longer than the horizontal ones, some others do the opposite) or round is a controversial matter of debate. The standard deviation of all measurements is in the range of 0.9 mm. However, regardless of the accuracy of the measurement of W-to-W, there is no proportional anatomical correspondence between external measurements and internal dimensions of the anterior segment compartment (Fig. 11).[15,21,165,252]

As a consequence, W-to-W distance alone cannot predict either angle or sulcus size and seems totally inadequate for sizing phakic IOLs.[165,206]

Instead, the exact internal linear anterior chamber depth, angle-to-angle (A-to-A) and S-to-S distances, the distance between the iris and the ciliary processes, and angular dimensions—the width of the irido-corneal angle, the iris-crystalline angle, the irido-scleral angle, and the sclero-ciliary angle—measured point-by-point at different levels, should be used. Images of these hidden anatomical sites can be obtained with high-resolution ultrasound devices that use very high frequency (VHF) waves in the 50-MHz range. The first-generation VHF ultrasound systems (the UBM, Humphrey Zeiss/Paradigm, Salt Lake City, UT, USA, and the I^3ABD, Innovative Imaging, Sacramento, CA, USA), operate at frequencies of 50 MHz and 20 MHz, respectively, and provide corresponding axial resolutions of approximately 30 microns and 75 microns. However, because lateral scan width is limited to 5 mm (UBM) and 8 mm (I^3), these instruments cannot measure the angle and sulcus dimensions in one scan sweep. Their use is limited to the combination of multiple images pasted together, which is fraught with inaccuracy because of the necessary eye movements and the difficulty of registration of separate image frames.

Both systems also use sector scan geometry. Wide-angle sector scans of the anterior segment must necessarily have an increasingly oblique angle of incidence upon the surface of the eye as the transducer direction becomes more peripheral to the ocular axis. The effect of this is two-fold: first, oblique incidence results in deflection rather than reflection of the ultrasound beam, with consequent loss of signal. Second, because the speed of sound in the cornea and sclera are significantly different from normal saline or aqueous fluid, these structures act as acoustic lenses, refracting the ultrasound beam, distorting intraocular anatomy and causing measurement inaccuracies.

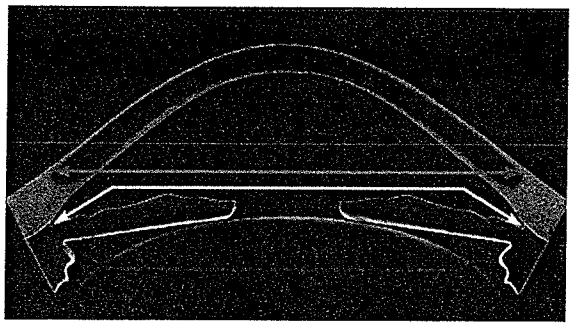

Fig. 11. Schematic image of external, white-to-white (W-to-W) and internal measurements, angle-to-angle (A-to-A) and sulcus-to-sulcus (S-to-S) distances, relevant for sizing phakic IOLs.

The Artemis 2 system developed by Ultralink (St. Petersburg, FL, USA) uses a 50 MHz transducer that is swept in an arc matching the curvature of the anterior of the eye. In addition, the Artemis uses a more sophisticated system for acquisition of data, storing the actual echo data (from which images are formed) instead of the image itself. An optical system for eye fixation and alignment allows direct visualization to confirm the exact position where measurements are taken. Then a computer-controlled scan along multiple clock-hours permits 3D biometric mapping of the eye.[210]

Zeiss provides surgeons with all three sizes with their Vivarte/GBR angle-fixated lenses and recommends intraoperative measurements of the angle-to-angle distance with an internal ruler inserted through the main incision. A similar intraoperative method has been proposed using a two-piece device (BioShape AG, Berlin, Germany), a centration ring with an outer diameter of 11.0 mm placed on the eye and an angled spatula with a scale on the handle simulating the shape of the haptics (Tetz M: Instrument provides exact measurements for anterior chamber intraocular implants. Ocular Surgery News Jan 2000). The eye is filled with a cohesive OVD and the ruler or spatula is pushed forward until it comes into contact with the angle; the measurement is taken by making the scale of the ruler and the handle of the spatula correspond with the center of the pupil or the center of the cornea, which is previously marked with a Sinskey hook. Because there are several sources of potential bias, like the movement of the center of the pupil induced by pharmacological miosis, or the surgeon pushing more or less strongly towards the angle, the centration on the top of the cornea has to be based on the white-to-white reference, so the tolerance of this method (in our hands: ± 0.65 mm) is still unacceptable for our purposes.

For ACP-IOLs, the externally invisible irido-corneal angle diameter can be visualized with an indirect no-contact procedure, using the LED SIZER (IOLTECH, La Rochelle, France) or by infrared light optical coherence tomography (OCT-Visante, Zeiss-Meditec, Jena, Germany) (Fig. 12). The LED

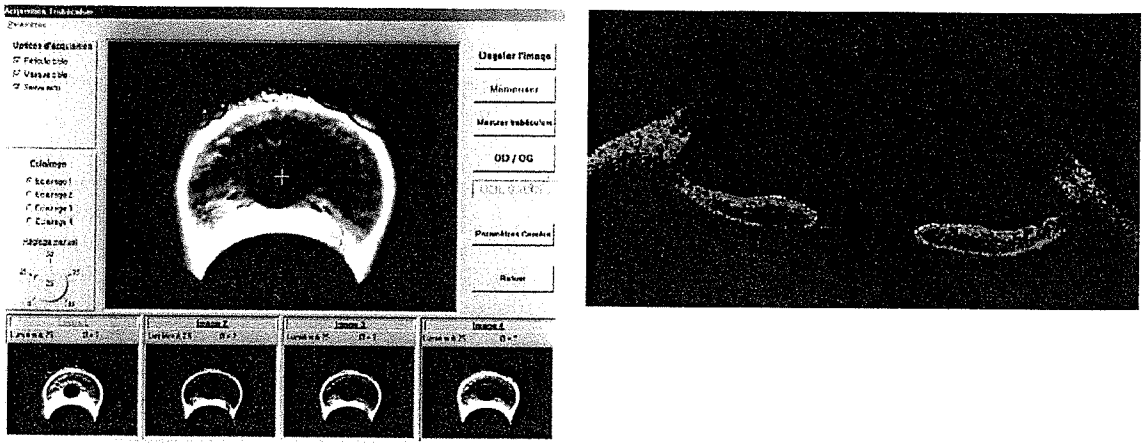

Fig. 12. LEDSIZER (*left*) and OCT-Visante (*right*) images of the anterior segment of the author's right eye.

SIZER provides automatic measurements of the angle-to-angle distance in different meridians through an analysis of the contrast changes of the images produced by a visible-light source (an electroluminescent diode) passing through the sclera covering the trabecular meshwork. The OCT permits high-resolution cross-sectional anterior segment imaging with excellent reproducibility of measurements by using the interference profile of the reflections from the cornea, the iris, and the crystalline lens.[38,254] These methods are less interesting for sizing PCP-IOLs because the retroirideal space cannot be perfectly visualized by optical devices and the statistical correlation between angle and sulcus diameters is as poor as between external white-to-white and internal dimensions. However, the choice of the proper overall length of the implant is equally crucial for PCP-IOLs, particularly the ICL.[165] Excessive vaulting induced by too long lenses may cause the iris diaphragm to bulge forward, with narrowing of the irido-corneal angle, chafing of the posterior iris surface, pigment dispersion and subsequent risk of angle closure and pigmentary glaucoma (Fig. 13), ocular pain or tenderness due to nerve irritation by excessive pressure in the ciliary sulcus.

On the other hand, lack of vaulting because of short ICLs has caused iatrogenic anterior subcapsular cataract.[165] A full circle of mechanical contact—all 360°—between the edges of the myopic ICL and the crystalline lens trapped the aqueous circulation in the prelenticular space and prevented nutritional turnover on the lens surface, with negative repercussions on the vitality of the lens subcapsular epithelial cells.

The consequences of unpredictable vaulting include refractive inaccuracy due to inappropriate positioning of the nodal points of the lens.[106] The ideal vault height for an ICL seems to be around 350 (300–400) μm in myopic (Fig. 13) and 250 (200–300) μm in hyperopic implants, to provide safe separation from the anterior surface of the crystalline lens and minimize untoward effects on aqueous hydrodynamics.[165] Hyperopic ICLs can have a lower

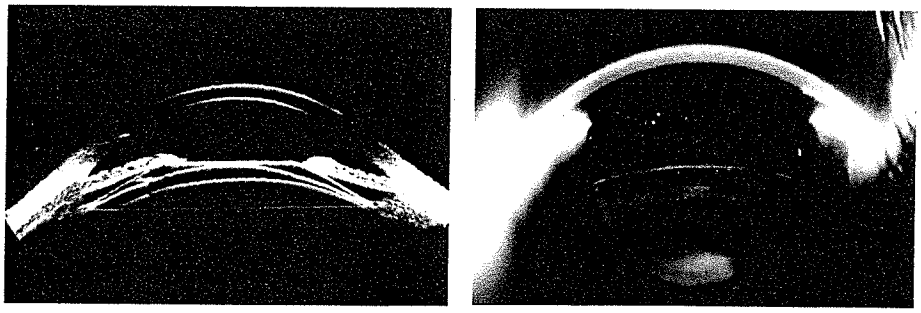

Fig. 13. VHF echography (Artemis 2) image of a perfectly sized V4 myopic ICL with a vaulting of 305 microns (*left*). Scheimpflug camera (EAS 1000) image of an excessively vaulted V2 myopic ICL (*right*).

vault than their myopic counterparts because the peripheral geometry of positive lenses leaves more space in the periphery to the circulation of nutrients and hyperopic eyes tend to have shallower chambers with narrower angles.[209] It is the opinion of many ICL-surgeons, the authors included, that a minimum mid-peripheral clearance of 150 μm is required. When we observe lower vaulting or mechanical contact, ICL explantation and/or exchange with a larger overall size should be considered for the high risk of iatrogenic cataract. The surgical choice is not easy, as a second open-eye procedure carries its own disadvantes.

A modified trigonometric formula can be employed to size the ICL, and thus to predict vault height precisely. The variables entered into the formula include the sulcus-to-sulcus distance and the radius of curvature of the anterior surface of the crystalline lens, obtained with the Scheimpflug camera, standard (the EAS 1000, Nidek, Tokyo, Japan) or rotating (the Pentacam, Oculus, Wetzlar, Germany), as well as with VHF echographers. The constants in the formula include the elasticity of the collamer and the base-curve of the ICL.

Since 2002, we have been using a software devised by Lovisolo and Calossi to simulate the expected clearances between corneal endothelium, iris and crystalline lens for all our phakic lens implantations. The software (Fig. 14) takes into consideration:

1) The three-dimensional map of the biometric data of the patient's anterior segment as obtained from VHF ultrasonography (Artemis 2) and optical tomography (Orbscan II, Bausch & Lomb).
2) The specific features of the chosen lens implant (overall length, vault, central and peripheral optic thickness, flexibility).
3) The age of the patient (an average reduction of the anterior chamber depth of 0.015 mm per year is calculated to predict the behavior over time).

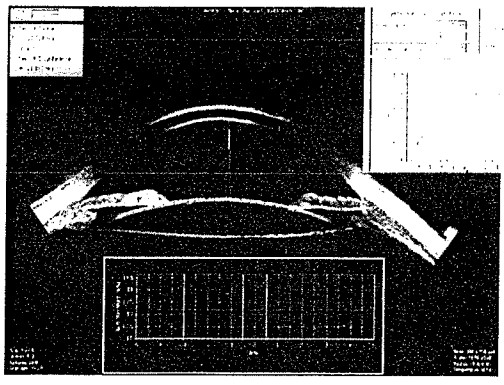

Fig. 14. The Lovisolo-Calossi Phakic IOL Sizing Software helps to predict the expected clearances between different implant sizes and intraocular tissues.

Surgeons lacking access to expensive equipment, such as VHF ultrasonography,[205] a Scheimpflug camera,[37,71] or other technologies,[152,258] may resort to different regression analysis-based nomograms taking into consideration the following variables: white-to-white, anterior chamber depth, corneal curvature, and irido-corneal angle width measured with the Haag-Streit slit-lamp gonioscope[165] (Potgieter FJ: *Semi-quantitative assessment of sulcus diameter to predictably achieve optimum vaulting of the Staar ICL.* Presented at the XVI ESCRS meeting, Nice, France, September 1998). Once lens length has been determined, because ICLs come only in 0.5-mm step sizes so far, it is often necessary to round up or down. In such cases (e.g., 12.75 mm) the overall length is selected on the basis of the irido-corneal angle width. For an angle larger than 0.7 mm, we would round up (in this example to 13.00 mm) and for one less than 0.7 mm we would round down (to 12.50 mm). However, in our experience, this method has not improved our vaulting predictability enough to significantly affect refractive accuracy and provide optimal long-term safety.

SELECTION OF PATIENTS

Preoperative Examination

Regardless of the site of implantation, the guidelines recommended by the different manufacturers about patient recruitment and preoperative work-up agree that the candidate for a phakic implant must have a thorough preliminary eye examination, including clinical history, standard slit-lamp exploration of the anterior segment, gonioscopy, and refractive measurements. Skiascopy, autorefractometry, automated and manual keratometry, best spectacle-corrected visual acuity (BSCVA) at a vertex distance of 12 mm are taken under miosis and cycloplegic conditions. With high ammetropias, a soft contact lens of known power and curvature is often used, and the refractive measurements are repeated. Then the following tests are always required: an orthoptic examination, videokeratography and photographic measurement of the horizontal white-to-white distance, endothelioscopy (cell count and morphological indices), applanation tonometry, ultrasound central corneal pachymetry, A-scan echobiometry of the eye chambers, mesopic infrared pupillometry, and, finally, a careful examination of the fundus under complete mydriasis.[21]

Exclusion Criteria and Critical Parameters

Many of the usual exclusion criteria (Table 3) can now be considered relative. Age, for instance, is not an absolute preclusion to surgery. An original excess of caution made it wise to avoid implanting phakic IOLs in children, but special cases of unilateral ammetropia or high anisometropia with contact lens intolerance and functional strabismus are worth reassessing, to prevent amblyopia.[39,57,161,228]

In certain cases, old contraindications have proved too conservative, like in the case of stable keratoconus and other ectatic corneal disorders, such as pellucid marginal degeneration or trauma, infection and sequelae from unsatisfactory previous corneal surgeries (like PKP, LKP, RK, ALK, epikeratoplasty, LTK, PRK, LASIK).[7,58,67,77,93,165,185,237]

Ideal candidates are young, able to take full advantage of the accommodation potential of their natural lens, but have high ammetropia not correctable by excimer laser surgery and a problematic relationship with spectacles and contact lenses.[36,165] If we respect the widely accepted, although not scientifically demonstrated, safety guideline of leaving a residual stromal bed of 250 μm or more,[233] with average mesopic pupil diameter,[55] corneal thickness, and curvature, this means that the implant surgery is indicated in myopic errors in excess of −8.0 D and in hyperopic errors in excess of +5.0 D.

Eyes with anterior chamber depth (ACD, endothelium to anterior crystalline central distance) less than 2.8 mm and endothelial cell count less than 2,500/mm^2 should be evaluated case-by-case and taking into account age, IOL model to be implanted, and alternatives.

Measurement of the ACD has always been considered an important guideline and is still a medical-legal reference point. It is usually done preoperatively at the slit-lamp with an optical device (the Depth Measuring Device II, Haag-Streit, Switzerland[21,165]), by conventional A-scan ultrasound biometry, or by laser partial coherence interferometry[203,235] (IOLMaster, Carl Zeiss, Jena, Germany). However, a single central distance is particularly significant only for hyperopic eyes, but not for the overwhelmingly myopic candidates, as there is no precise correlation between central and mid-peripheral depths where the endothelium could be damaged by intermittent contact with the edge of the optic (Lovisolo CF: Sizing phakic IOLs. Presented at the ASCRS meeting, San Francisco, CA, April 2003). Using VHF echotomography (Artemis 2) and scanning optical tomography (Orbscan II)[209,244] we realize that the majority of eyes show a progressive narrowing from center to periphery with the nasal regions about 20% shallower than the temporal counterparts. However, some are strangely shallower in the center. The deepest value is usually obtained 0.3 mm temporally and 0.12 mm inferiorly to the center of the pupil (it corresponds to an average kappa angle of 5°). In the area of critical distance for myopic lens implantation (2.5–3.0 mm eccentric to the pupil) the depth is reduced, on average, by the following amounts: temporal 14%, nasal 26%, superior 20%, and inferior 16%. Moreover, each single eye seems to have its own anterior chamber shape and volume, with no general rule (Fig. 15).

In our opinion, for anterior chamber myopic phakic IOLs, the most important measurement is the mid-peripheral distance from the endothelium to the thickest part of the lens, the edge of the optic (2.5–3.0 mm of eccentricity). For posterior chamber lenses, the geometry of the chamber and the opening of the irido-corneal angle are critical issues to ensure safe implantation.[164]

An optical tomographer like the Orbscan II,[24] or more sophisticated instruments like the EyeShape interferometer (BioShape, Berlin, Germany), the anterior segment optical coherence tomographer (OCT-Visante, Zeiss), or the VHF ultrasonographers,[210] whose scans provide point-by-point three-dimensional maps of the geometric features of the anterior chamber, could be used.[21] However, these are expensive devices, most of them depend on skilled operators and highly cooperative patients, because they need long measuring times for the scanning as eye movements reduce the reliability of measurements. At the moment, they still need to be

TABLE 3

Widely Accepted Criteria for Implanting Phakic IOLs

- Ages 21 to 50
- General good health
- Stable manifest refraction (± 0.50 diopter 6 months apart)
- Ammetropia not correctable with excimer laser surgery
- Unsatisfactory vision with / intolerance of contact lenses or spectacles
- ACD (endothelium to anterior crystalline central distance) ≥2.8 mm
  Note: ≥2.5 mm for PRL
- Irido-corneal angle aperture ≥30° (Shaffer grade 3 and 4[234] or Scheie grade 0 and 1[229])
- Endothelial cell count >2,500 cells/mm^2 at 20 years of age
- Endothelial cell count >2,000 cells/mm^2 at 40 years of age
- No ocular pathology (corneal disorders, glaucoma, uveitis, cataract, maculopathy, etc.)
- No previous ocular surgery

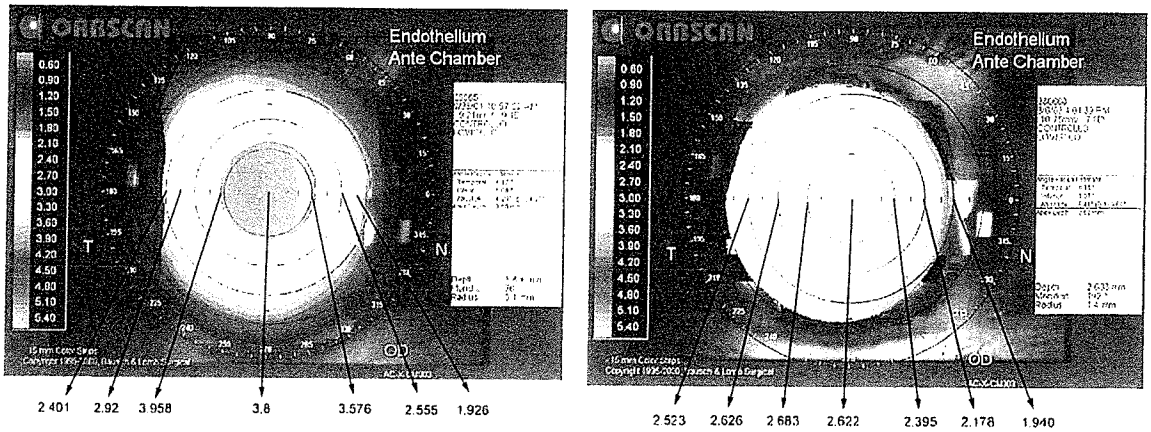

Fig. 15. The Orbscan images of a myopic *(left)* and a hyperopic eye *(right)* show completely different shapes and volumes of the anterior chamber. Notice that similar mid-peripheral depths (about 1.9 mm at 3 mm of eccentricity) correspond to significantly different central depths (3.8 mm [*left*], 2.6 mm [*right*]).

properly evaluated regarding accuracy of measurements in living eyes.

Age is a relevant factor, as the human lens gradually grows, doubling its thickness and displacing anteriorly by 0.4 mm during the lifetime of a 90-year-old,[187] due to the life-long mitotic activity of the sub-capsular epithelial cells at the lens equator. As a consequence, the anterior chamber depth drops by 0.75 mm over a 50-year span,[94,108,187] particularly in the periphery. It is thus essential to bear these points in mind when dealing with very young patients with shallow chamber volumes and flat corneas, as is often the case in the hyperopic patient. Nobody knows how much the anterior chamber volume available to the aqueous circulation of a normal eye (average 157 µl) can be reduced by the physical presence of an implant, without risking angle-closure glaucoma. Long-term effects of the redirection of aqueous flow have yet to be determined, for posterior chamber phakic IOLs in particular. One potentially useful figure is the average central anterior chamber depth (1.84 mm) and volume (95 µl)[14,63,74,159,166] measured in eyes with naturally occurring angle closure glaucoma.

In cases with doubtful biometric measurements, it may be advisable to exclude surgery or to prefer less vaulted models, like the Artisan/Verisyse or the PRL. In hyperopic patients over 55 years of age, particularly those with a narrow irido-corneal angle, an almost general consensus would indicate that phacoemulsification with in-the-bag IOL implantation may possibly be a safer choice and give a more successful outcome.[11,165]

Age is an obvious factor for endothelial cell count, too. The average 30-year-old undergoing phakic IOL surgery has a mean endothelial count of 2,600 cells/mm^2. The physiological annual loss of 14 cells/mm^2 reduces the count to 2,320 cells/mm^2 at the age of 50, and to 1900 cells/mm^2 at 80.[165] To ensure a minimum cell density of 1,000 cells/mm^2 to the eyes implanted with a phakic IOL at the statistical time of cataract removal (around 70 years of age), a safety calculation may be done by applying a loss rate of 2.31% per year, the upper 90% confidence interval of the average cell loss for eyes implanted with the Artisan/Verisyse lens with anterior chamber (including the corneal thickness) deeper than 3.2 mm. Starting from a minimum cell density of 3,500 cells/mm^2 at 21–25 years, the following safety values can be considered per age group: 3,175 cells/mm^2 at 26-30 years; 2,825 at 31–35; 2,500 at 36–40; 2,225 at 41–45; and 2,000 cells/mm^2 over 45 years. However, as a consequence of cell centripetal migration and enhanced metabolism after stopping wearing contact lenses, a retrospective review of the last 200 eyes operated showed that, after uneventful surgeries, the endothelial cell count increased and the morphological indices improved in 42% and remained unchanged in 39% of eyes at 6 months post-operation, independent on the type of foldable phakic IOL implanted (Lovisolo CF: Complications of phakic IOLs. Presented at the XXI ESCRS meeting, Munich, Germany, September 2003). Only a minority of cases (19%) showed a moderate reduction of the cell count (from 1–4%) with altered pleiomorphism and polymegatism indices. These results are not consistent with the literature that considers acceptable a moderate, although not progressive, initial postoperative drop in endothelial cell count. They would indicate that the concept of intraoperative endothelial cell sacrifice needs to be reviewed on the basis of age, IOL characteristics

(power, type, site of fixation) and individual biometric features of the eye to be implanted. Also, the safety limits recommended by the companies (from 2,000 to 2,500 cells/mm^2 of minimum cell density at the time of implantation) appear to be excessively dogmatic and not evidence-based.

Every phakic IOL candidate requires special attention. Whereas the high hyperopes must be carefully evaluated for their narrow intraocular environment, eyes with pathological myopia must be examined by a vitreo-retinal specialist to thoroughly assess the conditions of the posterior segment, including indirect ophthalmoscopy with scleral indentation under maximal pupil dilatation, to detect zonular defects, which may predispose to decentration or vitreous luxation of posterior chamber phakic IOLs, or rhegmatogenous lesions of the peripheral retina in particular. In some cases fluorescein and/or indocyanine green angiography may be helpful to document the macular conditions and identify the risk of problems that are likely to need treatment in later years.[165]

Until a full range of toric models is available, at the moment only the ICL and the Artisan/Verisyse lens have undergone clinical trials,[77,107,116,171,224] associated astigmatism in excess of 1.00 D may require corneal or limbal relaxing incisions, which can be combined intraoperatively or completed at a later stage.[44,107,165] Second-step excimer laser surgery is a valid alternative, like for myopic errors in excess of −20.0 D. In Zaldivar's *Bioptics*,[260,265] the surgeon waits for the small incision to heal (approximately 30 days to make sure it will not reopen under the stress of the suction ring) and then performs LASIK surgery in the usual fashion. To avoid the risks of touching the endothelial layer (when an ACP-IOL is implanted) and dislocating the lens during the suction and microkeratome pass, the surgeon may opt for the ARS (adjustable refractive surgery) to prepare the eye by making the lamellar cut immediately before implanting the IOL.[115] After allowing at least 4 weeks for complete refractive stabilization, the flap can be lifted and the stromal bed photoablated to adjust the corneal central curvature to the desired final refraction. To avoid peripheral retinal traction during suction activation and release, the surgeon may consider PRK or LASEK to fine-tune the refractive outcome in high myopic eyes.

The Concept of Custom Phakic IOL

There is no doubt that the same concepts behind the universal trend toward customization of corneal refractive surgery could be immediately applied to phakic IOL procedures. Considering the wide variability of biological presentations, the variety of anatomical shapes and sizes and range of optical errors, the need for a custom-made lens implant would appear even more obvious than personalized corneal laser treatment.

Lenses that perfectly fit the individual anatomy of each single eye are safer than conventional ones, as late postoperative complications relate mainly to unstable implants and less than ideal distances from the internal structures.

Accurate preoperative assessment of the lens vault height is vital to avoid concerns about endothelial cell loss, cataract, and glaucoma from significant aqueous flow disruption, anterior and posterior synechiae, iris ischemia, and pigment dispersion. The choice of overall length, central and peripheral thicknesses of the optic, optic geometry (front and base curve), and elasticity of the material will have important repercussions, too.

With regard to efficacy and functional performance, the same concerns about the quality of vision in kerato-refractive surgery apply equally to phakic IOLs. To prevent the visual symptoms of the "GASH-tetrad syndrome" (glare, arcs, starbursts, halos), the optic should have the following:

1) The necessary sphero-cylinder power. This calculation depends very much on precise refractive measurements, but also on the ability to predict the lens vault height, that is, the intraocular position of the nodal points of the lens (effective lens position, ELP). Refined toric optics are currently available with Visian ICL (Fig. 16) and Artisan/Verisyse lenses to meet the needs of perhaps the most motivated candidates for refractive surgery, highly astigmatic patients.[7] Successful toric correction requires an astigmatically neutral surgical

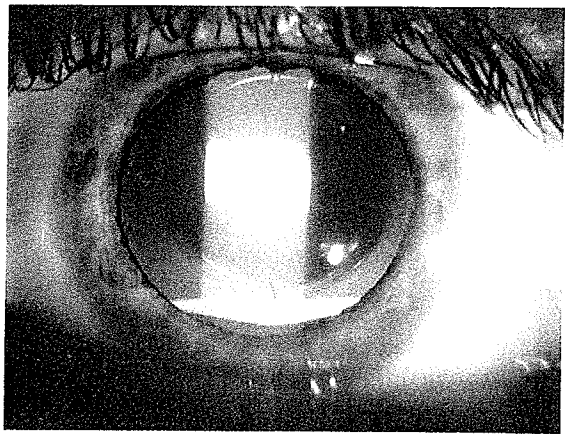

Fig. 16. The Staar Visian Toric ICL in situ.

incision and robust fixation site to provide rotational stability over time. For that reason the 6- to 7-mm opening of the eye needed for implanting the rigid lenses may seem too challenging for the average surgeon, while the minimal size (2.8 mm) achievable in many foldable models seems ideal. The rotational stability[238] of the implant is even more important, as the cylinder correction decreases with increasing deviation of the implant from the target axis by following a non-linear relationship. Because the PRL floats in the posterior chamber, it is likely to continuously rotate behind the iris, making astigmatic correction impossible. As shown in a study where the positions of a group of ICLs sized with VHF echography were documented by superimposable slit-lamp photographs (Carlo Lovisolo, unpublished data), the mean lens deviation from the original meridian over time (3 years) is less than 5°, that is, compatible with a maximum of 10% loss of astigmatic correction. Once again, accurate sizing is mandatory.

2) An effective diameter, at least as large as the mesopic entrance pupil diameter. Infrared pupillometry has shown that scotopic pupil diameter in myopic patients is significantly larger than in the emmetropic group. Our personal data on European patients support those obtained by Chaidaroon and colleagues[55] who reported, in an Asiatic myopic population, a mean scotopic pupil diameter of 6.98 ± 0.67 mm, the range of minimum-maximum value ranging from 5.5 to 8.5 mm. For that reason, due to the limited diameter of the optical zone, all currently available phakic IOLs have been reported to induce different degrees of nighttime visual disturbances (mainly halos and glare when driving vehicles).[176,239] As opposed to what was measured in eyes implanted with an ICL, which had a pupil dimension increased by a mean of 0.2 mm,[165] the eyes implanted with an iris-fixated phakic IOL showed a decrease of pupil size[78]—about 1 mm on average, slightly higher in the axis of enclavation—which may help limiting the visual disturbances generated by the edge of the optic. The successful trend of combining different surgical approaches (Bioptics and/or Adjustable Refractive Surgery)[115,260] has highlighted not only the concept of fine-tuning residual refractive errors after implantation but also the need for a wide functional optical zone. For a −17.00 correction in a patient with a 6.0-mm mesopic pupillary diameter, for instance, postoperative quality of vision is unquestionably better if we select a wide-optic implant (a −12.00 ICL has a 5.5-mm diameter and corrects approximately −10.00; a −10.00 iris-claw Artisan/Verisyse lens achieves the same effective correction with an optical zone of 6.0 mm and a safer distance to mid-peripheral endothelium), and combine it with a −7.00, 6.5-mm optical zone excimer laser ablation, instead of implanting a −20.00, 4.65-mm optic ICL or a −16.00, 5.0-mm optic Artisan/Verisyse correcting −17.00. As a trend, the 7- to 8-mm optic diameter of the newcomer lenses like Vision Membrane and ThinPhAc (Table 2) makes it easy to foresee that the average effective optical zone of future lenses will soon be made larger.

3) A proper geometric shape factor (asphericity) to respect physiology.[173,191] Conventional high-power (more than −12.0 and +7.0 D of correction) spherical phakic IOLs with an average optic size of about 5.0 mm inevitably result in significant spherical aberration in the duophakic eye, thus increasing glare and halos for the average mesopic pupil (Fig. 17).[48] Although contrast sensitivity measurements have been reported to improve at all spatial frequencies in eyes implanted with an ICL if compared to preoperative values,[138] they remain below normal for high spatial frequencies.[165] An aspheric phakic lens can be designed on the basis of theoretical assumptions (to limit spherical aberration without reducing the depth of focus[132]), or wavefront analysis from aberrometers (to correct not only on-axis aberrations like spherical aberration, but also higher-order aberrations like trefoil and coma). The weak point of aspherical lenses is the need for perfect alignment with the

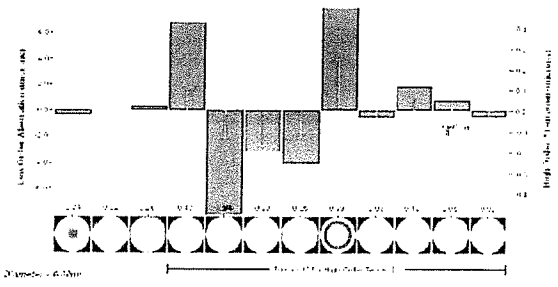

Fig. 17. Hartmann-Shack wavefront data (LadarWave, Alcon, Forth Worth, TX, USA) three months after uneventful implantation of a conventional −23.0 D 4.65 mm optic phakic IOL. Despite apparently optimal lens centration on the pupil, high coma and spherical aberration values with a 7.5 mm pupil caused significant though non-disabling visual symptoms.

cornea and crystalline lens (centration and tilt). When measured as a modulation transfer function, the optical performance of an aspheric IOL is only minimally degraded if the IOL is decentered less than 0.4 mm and tilted less than 7°.[132,191] Larger discrepancies between lens optical center and visual pathway could cause significant symptoms. Our observations with infrared photography and VHF echography on a group of patients implanted with different phakic IOLs (I-CARE, Vivarte/GBR, and ICL) showed that pupil decentration is 0.32 mm and tilt is 5° on average (Carlo Lovisolo, unpublished data). However, in patients with largely positive angle kappa,[248] even an accurate sizing of angle-supported and posterior chamber phakic IOLs, whose fixation depends on an even distribution of the anatomical structures, could cause a significant misalignment with the line of sight.[153] Once this becomes more accurate and standardized, we can foresee a demand even for haptic customization, with asymmetrical loops and wings to match individual pupil decentration. Otherwise, iris-fixated lenses that can be nicely centered over the pupil will be preferred to sulcus or angle-supported lenses.[153]

Similar concepts apply to the multifocal phakic, the Vivarte Presbyopic/GBR NewLife, marketed by Zeiss to cover the potentially widest market in refractive surgery, the presbyopic patients.[29] The implant in fact has an aspheric optic (+2.50 D fixed addition, plus distance corrections from +5.0 to −5.0 D in 0.50 D steps) inducing a controlled amount of spherical aberration to increase the depth of focus and allow reading. Because a certain amount of side effects are almost inevitable (reduced contrast sensitivity at different frequencies, halos, glare),[183] a precise evaluation of the angle kappa and a preliminary trial with loose contact lenses that simulate the implant optical geometry to test the individual tolerance to the postoperative quality of vision are highly advisable.

4) Quality of the surfaces higher than the eye's optical limits, possibly designed or postoperatively modified on the basis of wavefront detection. Eventually, the search for new indications (to retreat complications and side effects of previous surgeries in particular) takes a well-trod path. Innovative technologies always start overcautiously. As experience builds up and the learning curve proceeds, many contraindications that seemed absolute become relative and are reviewed on a case-by-case basis, sometimes even becoming elective indications. Phakic IOL surgery could therefore be indicated for cosmetic purpose,[190] in piggybacking pseudophakic eyes with significant residual ammetropia,[56] as well as in pediatric patients with aniridia, albinism, anisometropic amblyopia, or in eyes with stable corneal disorders (forme fruste keratoconus, marginal pellucid degeneration, post-radial keratotomy or post-LASIK visual errors, post-trauma or post-keratoplasty astigmatism), which cause significant higher order aberrations and may theoretically be tackled by making the compensating corrections intraocularly instead of on the corneal surface. Note that once the implant position is stabilized intraocularly, technologies like the Light Adjustable Lens (Calhoun Vision, Pasadena, CA, USA) could possibly allow postoperative optimization of the eye's overall aberrations through ultraviolet irradiation of the photosensitive silicone polymer matrix.[231]

ND:YAG LASER PERIPHERAL IRIDOTOMY

One, if not two, preliminary Nd:YAG laser peripheral iridotomies (PIs), well-patent, and sufficiently wide (at least 500 μm) 1–2 weeks before any phakic IOL surgery have been recommended,[16,162,165,240] to allow re-absorption of blood, pigment, and inflammatory factors, or else an intraoperative surgical iridectomy.[124] The iridotomies should be classically positioned superiorly (from 11 to 1 o'clock), under the upper lid, to avoid the risk of monocular diplopia or ghost images, for esthetic reasons,[1] and well away from the haptics placement to prevent the pressure on the ciliary body exerted by a haptic that ended up in the iridectomy. However, on account of the elastic properties of the acrylic material of the modern flexible ACP-IOLs, the issue has become controversial and some surgeons no longer consider PIs or surgical iridectomy strictly necessary.[29]

PERIOPERATIVE MEDICATION

The patient is prepared, prepped, and draped as for any routine intraocular surgery. To ensure intraoperative comfort and reduce the post-operative reaction and risks, the following drugs are commonly used:[165]

- antibiotic eye drops (usually fluoroquinolones) to prevent infection
- benzodiazepine drops (10 mg of valium orally) for sedation
- 5% povidone iodine solution for disinfecting skin and conjunctiva

- mydriatic eye drops (10% phenylephrine, 1% tropicamide, and 1% cyclopentolate) to prepare the pupil for PCP-IOL implantation. Preservative-free epinephrine can be injected intraoperatively
- miotic eye drops (2% or 4% pilocarpine) to prepare the pupil for ACP-IOL implantation. Some surgeons prefer the intraocular use of preservative-free acetylcholine during the surgery in order to better control the center of the real pupil
- topical anesthetic eye drops (4% xylocaine, 0.4% benoxinate, proparacaine), intraocular 1% xylocaine and other anesthetic solutions (2% mepivacaine, 0.5% bupivacaine) can be used or injected depending on the surgeon and/or patient's preference
- steroid (dexamethasone or fluorometholone) and NSAID eye drops (sodium diclofenac or similar) are administered postoperatively and then tapered in 7–10 days
- carbonic anhydrase inhibitors (acetazolamide tablets) to prevent an excessive rise in IOP

Surgical Technique

ANGLE-FIXATED ACP-IOLS

The actual procedure varies depending on the kind of IOL to be implanted, rigid or foldable/flexible. Both require pharmacological pupillary miosis. Through a side-port incision, the anterior chamber is filled with a cohesive OVD (sodium hyaluronate or 2% hydroxypropylmethylcellulose). Although Baikoff suggests a clear-cornea temporal incision, some surgeons prefer a limbal or a sclero-corneal incision placed superiorly or on the steep corneal axis. The optic of the rigid ACP-IOL is held with a Kelman-McPherson forceps and carefully pushed across the AC, until both ends of the trailing haptic come to rest in the distal region of the angle. A 5.0-mm silicone slide can be used to help protect the iris and crystalline lens during the positioning maneuvers. The dialing loop is then positioned in the proximal region of the angle, using the one-handed technique with a Sinskey hook. The surgeon checks that the pupil is round, and then performs a superior peripheral iridectomy using Vannas scissors or the vitrector. The incision is sutured with two or three single sutures or three-bite, running 10-0 nylon; the viscoelastic substance is removed and, with the gonioscope, the surgeon verifies the correct positioning of the loops to make sure they are not tucking the iris root.

Foldable ACP-IOLs can be implanted through a self-sealing corneal incision. The most demanding part of the procedure is the forceps folding or loading in the cartridge/injector. The I-CARE lens is folded in the cartridge with the four feet bent under the optic. Then it is gently injected and completely unfolds in the AC. The surgeon helps position the lens by gently maneuvering with a hook or the viscoelastic cannula through the side port.

The Vivarte/GBR lens cannot be injected, because of the rigid trailing loop. It is grasped and put in a special folder then folded with a specially designed forceps. Under viscoelastic protection and pharmacological miosis, the Z-shaped knee is inserted first into the AC. The folded lens is inserted parallel to the iris plane and released. After unfolding and withdrawal of the implantation forceps, the single trailing haptic is placed in the angle under the edge of the corneal incision, using a hook. According to the manufacturer's recommendations, the Vivarte/GBR lens must not be rotated in the AC. The main incision is hydrated with BSS and left sutureless.

The silicone optic of the Kelman Duet lens is injected independently, then the tripod haptics are inserted and clipped to an internal ring of the optic, designed to hold them, and fixated in the angle.

IRIS-SUPPORTED ACP-IOLS

The Artisan/Verisyse lens is implanted under pharmacological miosis. Two 1.2-mm stab incisions are made at the 10 and 2 o'clock positions and sodium hyaluronate is usually injected to fill the anterior chamber. Although it can be placed on the temporal or on the oblique side, the 5.5–6.5 mm incision (limbal or sclero-corneal) is usually superior and this may be a limit in handling concomitant astigmatism (oblique or against-the-rule). The lens is grasped with curved holding forceps and inserted through its smaller dimension (5.0 or 6.0 mm of the optic), with the option of a protecting glide. Once in the anterior chamber, it is rotated to a horizontal position and centered to the pupil. While firmly holding the lens with forceps, first a temporal mid-peripheral iris strip is enclavated with a special needle or forceps, and then a nasal fold of iris is gently pushed and caught by the claw.[256] These critical steps require skill and dexterity to capture enough iris tissue to ensure lens stability. The operation is completed with an iridectomy (if the iris prolapses during surgery, this step should be done immediately to facilitate repositioning of the iris), the viscoelastic substance is removed and 10-0 nylon sutures are usually placed.

The flexible iris-claw ACP-IOL (the Artiflex/Veriflex) is not folded, but stretches and flexes through the incision, returning to its original shape inside the anterior chamber when implanted with

an appropriate implantation spatula. Once the spatula has been retracted, a cannula keeps the lens steady by exerting counter-pressure on the haptic rim. Then the lobster claws are enclavated in the usual way.

POSTERIOR CHAMBER PHAKIC IOLS

Injection Technique

The correct loading of the PCP-IOL in the cartridge-injector is essential for easy implantation. Using a modified McPherson forceps with long, blunt, curved tips, the lens is carefully grasped and checked under the microscope. The ICL has two tiny holes on the footplates (distal-right and proximal-left) to indicate the anterior side. The current PRL model, however, has no landmarks. In order to avoid inverted implantation, the surgeon can make two tiny dots on the haptics with a cautery, without damaging the lens. The cartridge is partially filled and lubricated with a mixture of saline solution and viscoelastic substance, to eliminate static forces. The lens can be loaded with the dome convex-down (U-shape) or dome-up (M-shape). A piece of soft material (Staar Foam-Tip, a silicone sponge, or a wet piece of Merocel) is positioned to protect the PCP-IOL from contact with the plunger of the shooter. Broad pharmacological mydriasis is obtained.

Two side-port incisions of about 1.0 mm are created. A cohesive OVD is then injected (low-viscosity sodium hyaluronate, such as Healon, or 2% HPMC, such as Ocucoat, is normally used), taking care not to overfill the chamber. A 1.8–3.2 mm clear-cornea temporal incision is made. The cartridge is inserted bevel-down and must be rotated through 180° if the lens has been loaded U-shaped. During delivery, the tip of the injector must not penetrate too deeply inside the chamber, as would be normal for the cataract surgeon implanting a foldable IOL in the capsular bag. The lens moves along the funnel in a cylindrical fashion and gradually unfolds as it enters the chamber.

Forceps Technique

Many PCP-IOLs have been implanted worldwide using one or two regular McPherson or similar customized forceps. Manufacturer's guidelines still recommend this technique for implanting the PRL, which is still marketed with no landmarks, like the early ICL models. The main advantage of the forceps technique is that the surgeon has almost complete control over the unfolding procedure. He can easily avoid implanting the lens upside-down. However, there are drawbacks:

- it requires a larger incision (3.5–4.0 mm)
- it is technically more demanding
- it carries a higher risk of intraocular trauma

The forceps technique can be used for reimplantation, once a phakic lens has been explanted through an enlarged incision.

Retropupillary positioning of the footplates involves maneuvering the haptics through the side ports, with a sandblasted visco-cannula or specifically designed "tuckers." Only a small degree of dialing is acceptable and manipulations must be extraordinarily smooth and gentle.[165] When posterior chamber positioning has been completed, because the OVD must be removed as completely as possible, bimanual I/A must begin under pupillary mydriasis to allow the aspiration tip to reach the viscoelastic substance trapped behind the lens. Then acetylcholine may be injected intraocularly to constrict the pupil and the wound is hydrated.

Complications

The natural history of the average candidate for phakic IOL implantation (the high myope) involves a well-known risk of sight-threatening complications during his or her lifetime, even though he or she does not undergo surgery. In high myopic eyes the incidence of retinal detachment is 40–100 times greater than in the normal population,[12,68,95,114] because of the posterior staphyloma, a distention and atrophic thinning of the choroid and the sclera, with various degrees of vitreous syneresis and posterior detachment and consequently traction of the equatorial and peripheral retina. The same abnormalities are behind the tendency to form macular puckers and neovascular sub-retinal membranes. High myopic eyes are also well-known steroid-responders and prone to developing chronic open-angle and pigmentary glaucoma. The age-related cataract appears more early than the statistical average for the normal population. Does phakic IOL surgery encourage these naturally occurring phenomena? There is no answer to this long-open question, because it is very hard to predict whether, and when, these complications are likely to show up.[12,17,155,163,192,216] On the other hand, the prognostic scenario for high hyperopic eyes does involve a significant risk of angle-closure glaucoma, which is, however, easier to predict on the basis of the preliminary biometric measurements.[14,63,74,94,104,159,166,209]

INTRAOPERATIVE COMPLICATIONS

It is our opinion that intraoperative complications are almost exclusively connected to human error in the preliminary work-out (not done; not patent or small iridotomies can cause intraoperative pupillary

block), in the anesthesiological modalities (peribulbar injections can cause bleeding or even perforate the globe) or in the surgical technique, leading to irreversible damage to the endothelium, iris, crystalline lens, or the phakic IOL.

Although it can happen with all models, inverted implantation is a rare complication of PCP-IOLs. With additional cautery marks on the PRL and the latest models of ICL, intervening on the injector before the optic has completely unfolded in the anterior chamber easily prevents upside-down insertion. If, however, an inverted implantation does occur, the surgeon must never try to turn the lens round inside the anterior chamber, because of the high risk of damaging the crystalline lens or the corneal endothelium. The solution is to enlarge the incision to 4.0 mm, remove the lens with specially textured forceps under the protection of a viscoelastic substance, and reimplant it with appropriate forceps. A suture may be required to ensure incision tightness and astigmatic neutrality. The same technique should be used in the event of cataract surgery or a phakic IOL exchange.[64,135]

POSTOPERATIVE COMPLICATIONS

Acute Glaucoma

Pupillary block is a common mechanism responsible for early acute glaucoma in eyes implanted with a phakic IOL.[16,52] It happens when, in the retropupillary space, resistance prevents the physiological flow of aqueous through the pupil opening, pushing forward the iris and closing the irido-corneal angle. Because the space between the anterior crystalline lens surface and the posterior pigment epithelium of the iris is very narrow indeed, pupillary block is more likely to occur after PCP-IOL implantation.

In these cases, because no correlation has been found with VHF ultrasound and Orbscan optical tomography between central, mid-peripheral depths and irido-corneal angle aperture, (Lovisolo CF: Posterior chamber phakic IOLs. ISRS/AAO 2003 Refractive Surgery comes of age. American Academy of Ophthalmology, pp 33–41)[21] we believe that a minimal central distance between the endothelium and the anterior crystalloid, as provided by the manufacturer's guidelines (ACD $\geq$ 2.5–2.8 mm), gives only indirect and inaccurate information on the more important safety parameters, the peripheral depth of the anterior chamber and the width of the irido-corneal angle. Nonetheless, surgeons should stick to the manufacturer's guidelines for medico-legal purpose, even if they seem too dogmatic.

Taking into consideration that, with a properly sized myopic ICL, vaulted an ideal 350 microns, the irido-corneal angle, as evaluated with the Orbscan, is reduced by an average of 30% after implantation (from about 42° to 29°[165]) and that the limit to risk angle closure is classically put around 15°,[234] a minimal angle aperture $\geq$ 30° seems a more reasonable guideline.

With Vivarte/GBR lenses, the manufacturers claim that angle closure from pupillary block is not possible, because of the forward movement of the elastic acrylic optic in case of posterior thrust. Therefore, although many surgeons worldwide disagree, an iridotomy may be unnecessary.[29]

Malignant glaucoma is a potentially devastating, although very rare, postoperative event where a sudden, severe IOP rise is associated with near-abolition of the anterior chamber. The entire irido-lenticular system is pushed forward and the aqueous inverts its physiological direction (ciliary block), moving towards the vitreous, where it forms pools of fluid. Only a few cases have been anecdotally reported after ICL implantation.[150,165] If this happens, iridectomy is typically useless and miotics worsen the situation, because the aqueous flow is blocked posteriorly.[121] If prompt medical therapy with atropine and osmotic agents to dehydrate the vitreous does not achieve results in a few hours, the surgeon must intervene, removing the implant and, in extreme cases, performing Chandler's procedure (three-port pars plana vitrectomy and phacoemulsification plus IOL implantation).

When viscoelastic substance removal has been incomplete, IOP rises because of transient trabecular blockage by the residual viscous molecules (the chamber is deep and the angle open) (Fig. 18). It happens within the first 6–24 hours, and resolves spontaneously in 24–72 hours. However, potentially dangerous side effects, such as atonic pupil, may occur and should always be prevented with appropriate medical therapy or by creating a slight decompression from the side-port incision in extreme cases.

An intermittent pupillary block occurring at night after intraocular surgery causes the Urrets-Zavalia syndrome.[118,242] With no apparent symptoms, sudden ischemia from a steep IOP rise paralyses the muscles of the iris sphincter, causing a blown pupil in moderate mydriasis (around 7 mm) with direct and indirect areflexia. The wide atonic pupil causes the mesopic visual symptoms induced by the edge of the optic. It is often irreversible and will not respond to pharmacological treatment. Phakic IOL removal will not change the situation to any degree and disappointing results have been reported after pupilloplasty with Mersilene 11/0 purse-string suture,[165] given the atrophic fragility of the iris stroma.

If the patient does not complain about these problems, the surgeon should leave the lens inside

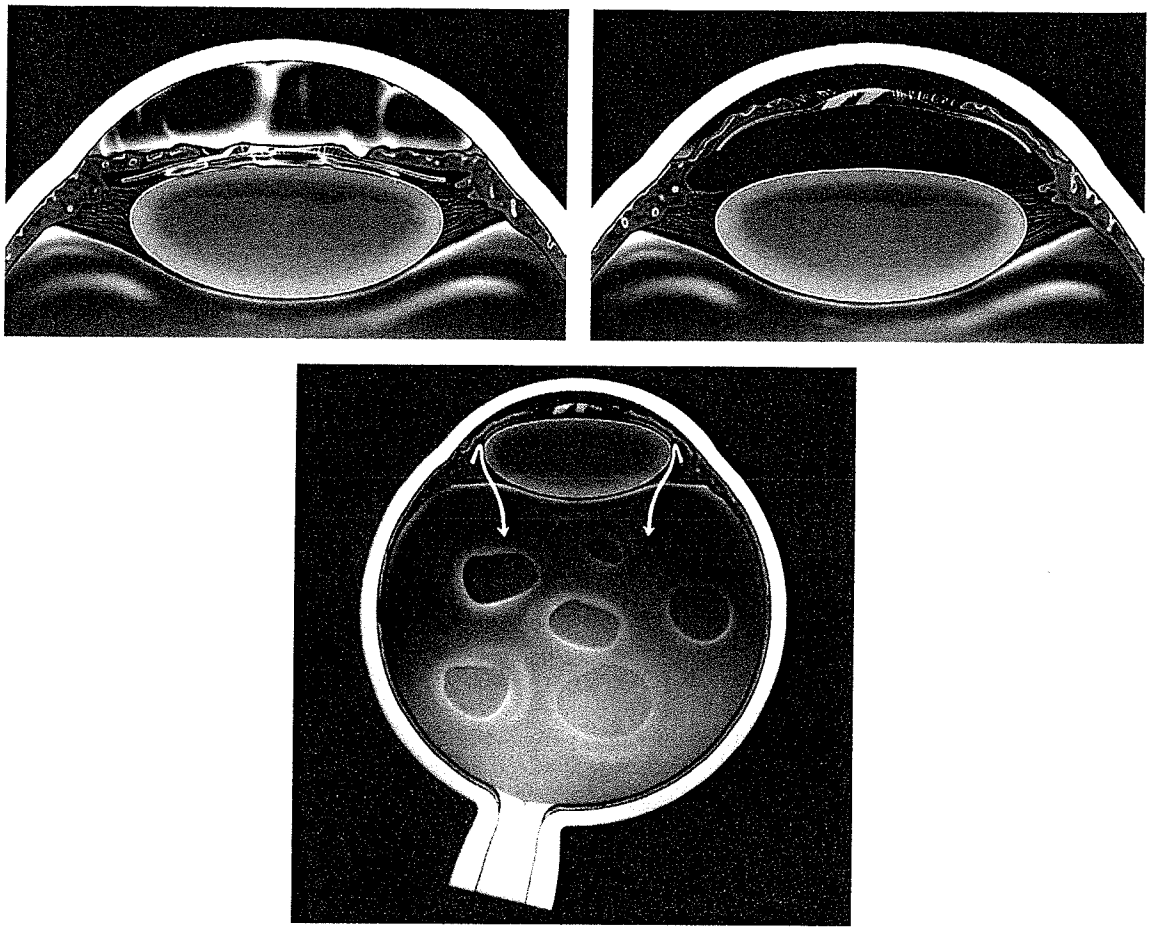

Fig. 18. Differential diagnosis of acute IOP rise after posterior chamber phakic IOL surgery. Pre-trabecular block caused by retention of viscoelastic substance. The chamber is as deep and the lens as vaulted as expected (*top left*). Pupillary block: the anterior chamber is deep but exaggerated lens vaulting pushes the iris forward to cause angle closure (*top right*). Malignant glaucoma: the chamber is shallow, with both the crystalline lens and the PCP-IOL pushing forward (*bottom*).

the eye, possibly widening the iridotomies (re-YAG). A phakic IOL exchange with the newest wide-optic models or a clear-lens extraction with implantation of a low-power wide-optic IOL in the capsular bag are possible alternatives.

High-dose postoperative cortisone in a recognized steroid-responder population almost invariably creates a gradual but considerable steroid-related IOP rise, which always subsides to the preoperative values with the suspension of treatment, 2–4 weeks after surgery, but sometimes requires topical therapy with beta-blockers. Today this should no longer be a problem, because the duration of post-surgical anti-inflammatory therapy has been greatly reduced.

Chronic Glaucoma and Uveitis

Due to the surgical trauma (including the preliminary iridotomies) and the prolonged contact with the trabecular meshwork and iris root (angle fixation), mid-peripheral iris stroma (iris support) and posterior iris epithelium (posterior chamber IOLs), some degree of erosion, vessel disturbance, pigment dispersion, and synechiae formation is inevitable after phakic IOL implantation, hence the concern about pigmentary dispersion syndrome (PDS)-glaucoma,[46,53,140] iridocyclitis, and breakdown of the blood–aqueous barrier. Although moderate evidence of pigment loss ('window' iris defects with transillumination and trace deposition in the trabecular meshwork—a small inferior Sampaolesi line)[2] can often be seen after phakic IOL surgery, a few sporadic cases of true pigmentary glaucoma with postoperative elevated intraocular pressure, Krukemberg spindles, and dense pigmentation of the trabecular meshwork,[45] which occasionally required filtering surgery,[221,263] have been described after posterior chamber phakic IOL implantation. In general, phakic IOL surgery leads

to a slight and transient increase of the IOP during the first months after surgery, then the IOP returned to preoperative baseline.[3,165] Transient low-grade acute postoperative iritis has been observed in 3.4–10.7% of cases after anterior chamber (both iris and angle-supported) implant surgery.[9,10]

With regard to the long-term inflammatory response within the eye, the evidence to date appears to support the safety of phakic IOLs, although fluorophotometric evaluations in eyes implanted with Baikoff and Worst ACP-IOLs are controversial, as some reports indicate a prolonged breakdown of the blood-aqueous barrier and a reduction in the transmittance of the crystalline lens.[40,197] In a preliminary study run in 1997, iris fluorangiography of 12 eyes implanted with an ICL showed limited dye leakage from the vascular trunk of the iris in the early postoperative period, and it had disappeared 3 months after surgery.[165] In a study including more than 500 ICL-implanted eyes, clinical flare and cellular reaction was reported as absent in 99.6–100% of cases. In a small subset of the study participants who were tested with the laser flare and cell meter, measurements taken between 3 months and 3 years after surgery were within the normal range.[222] There is hope that the improvements of thinness and biocompatibility of current lens implants will limit the mechanical chafing to moderate and self-limiting pigment dispersion that will never reach a level of clinical importance.[165]

Iatrogenic iris pathology resulting in pupil ovalization and iris stroma subatrophy from prolonged, excessive compression of blood supply by oversized lenses or over tightening claws (some authors think that such complications with angle supported IOLs are inherent to the fixation system itself) seems to be the major concern of actual anterior chamber models (Fig. 3). In fact, if severe "cat-pupils" secondary to iris tucking from inappropriate surgical positioning of the haptics are excluded, and the smaller degrees of pupil distortion after angle-fixated phakic IOL implantation are considered, there is some reasonable concern that the complication's percentages, ranging from 5.9 to 16.2%, [10] are going to increase in the future. Although some variable degree of pupil changes (reduced reactivity time and amplitude, prolonged latency and duration of pupil constriction) have been registered[147,165] after posterior chamber phakic IOL implantation, these have not proved to be clinically significant to date.

Infection

Endophthalmitis can complicate any open-eye procedure. However, the literature offers only anecdotal reports of septic intraocular inflammation after phakic IOL implantation,[165,200] with an exceedingly low incidence that can be roughly estimated at one case in 8,000. Compared to cataract surgery, the severity of the complication could be limited by the maintenance of the crystalline lens barrier, which may delay the catastrophic spread of the infection to the vitreous chamber.[165]

Cataract

Iatrogenic crystalline lens opacification may be caused by excessively traumatic surgery. Experience has shown that only very delicate (butterfly-like) intraoperative contact with the crystalline lens is without consequences. Any rough, aggressive maneuvers can cause immediate focal opacity or spread progressive anterior cataracts, showing up from 3 weeks to 6 months after surgery.[165] Another cataractogenic factor associated with vitreo-retinal surgery, air bubbles, must be meticulously avoided. A cohesive OVD that tends to adhere to itself and is easily removed, such as sodium hyaluronate, should always be used to help the surgeon by maintaining the intraocular spaces and it must be thoroughly removed. A dispersive OVD, like the sodium hyaluronate 3.0%-chondroitin sulfate 4.0% (Viscoat, Alcon, Forth Worth, TX) should not be used, as it may induce changes in lens epithelial cells.[49]

Postoperative minor trauma[184] and inadequate medical treatment is another potential cause of cataract formation, for instance, an excessive postoperative steroid regimen. Apart from these conditions and despite significant rates are reported for angle-supported phakic IOLs (3.42% incidence of nuclear cataract at 4 years average, 8 years maximum follow-up),[6] the question of a cataract-stimulating role of phakic IOLs is awaiting judgment above all for the PCP-IOLs, sandwiched in a narrow space so close to the anterior lens surface.[46,64,83,220]

On the topic of etiology, until a few years ago it was believed that the hydrophilic nature of the collamer was crucial for avoiding cataract formation—the exact opposite of what happens with hydrophobic silicone.[165] Now more attention is paid to proper sizing of the PCP-IOL, to achieve adequate vaulting, or rather, a big enough space between the IOL and the crystalline lens to leave the latter undisturbed. Given the aspherical shape of the anterior crystalline lens surface and the optic geometry, the vaulting of myopic lenses is reduced peripherally, especially when higher powers and thicknesses are involved. If the overall length of the PCP-IOL is short, the optic edges make mechanical contact to the semi-peripheral regions of the

crystalline,[104] thus preventing adequate aqueous circulation and causing subcapsular opacification.

This theory is confirmed by the fact that, to date, very few hyperopic ICL-induced opacities have been reported, even if in these short eyes the implant is closer to the crystalline lens. The geometry of the hyperopic optic is such that aqueous circulation is not impaired.[165] We recently presented preliminary outcomes of new ICL-models with four oblique symmetrical thru-channels, 0.6 mm in diameter, placed close to the optic edge (Lovisolo CF: Custom ICL. Presented at the VIII ESCRS Winter Meeting, Barcelona. Spain, January 2004). They were engineered to allow physiological flow of nutrients to crystalline lens by ensuring a uniform aqueous pressure on both sides of the holes, to prevent IOP rise because of the implant presence (pupillary block), to decrease the implant stiffness, and to safely improve intraoperative handling by inducing no significant change in ICL vault height (axial displacement).

The issue of potential intermittent touching during accommodation,[104] when the crystalline lens moves forward, was recently addressed with partial coherence interferometry studies.[203] As the sulcus retracts with accommodation no significant changes in distance between the ICL and the crystalline lens were found; the ICL vaulting increases as necessary, compensating the 200- to 600-μm forward movement of the anterior lens surface. On the other hand, under photopic environmental conditions or after application of pilocarpine, pupil constriction reduces the vault height by forcing the ICL against the crystalline lens.[203]

The rate of iatrogenic cataract ranges from 0.82% (for the PRL)[76,253] to 4.38–12%[220,224] at 1–5 years for the previous version of ICL. In our most recent personal series on 494 eyes implanted with the ICL V4 since April 1998, with a mean follow-up of 37 months (Lovisolo CF: Posterior chamber phakic IOLs. ISRS/AAO 2003 Refractive Surgery comes of age. American Academy of Ophthalmology, pp 33–41), we have not yet observed any cases of iatrogenic cataract. While recognizing that researchers are still far from fully understand the detailed mechanisms of cataract formation, we attribute these results to the precise sizing of the implanted lenses, allowing a precise prediction of ideal lens vaulting.

Once bilensectomy in the duophakic eye (phakic IOL plus cataract removal) becomes necessary, a mathematical correction to the axial length (AL) measurement obtained with ultrasound or optical devices must be made to obtain an accurate calculation of the dioptric power of the IOL to be implanted.[123] For A-scan US biometry, Hoffer[122,125] suggests the following formula:

$$CAL = AL + X \times T$$

where CAL = corrected axial length, AL = axial length obtained with an average US speed of 1,555 m/sec, X = correcting factor, T = central thickness of the phakic IOL

Central lens thickness T should be provided by the manufacturer or measured with VHF ultrasound device. The correcting factor X depends on the material of the lens implant (Hoffer[122] gives the following values: X = 0.42 for PMMA, X = 0.23 for acrylic, X = 0.11 for collamer, X = −0.59 for silicone).

Corneal Decompensation

In view of the high rates of corneal decompensation reported after the first implantations[33,97,101] and assuming that the phakic lens would be kept into the eye until natural cataract development—an average functional life of about 40 years—maximum long-term preservation of the corneal endothelium is an obvious core issue for the entire area of phakic IOL implantation. The intraoperative sacrifice of a certain amount of endothelial cells (between 2.1% and 7.6%) depends largely on the surgeon's experience and is generally accepted as inevitable. The main concern is the likelihood of further ongoing cell loss through intermittent mechanical contact with the anterior chamber IOL, which must be prevented by ensuring a minimum recommended clearance of 1.5 mm between the endothelium and the thickest portion of the anterior chamber lens, the edge of the myopic optic (Table 1). This critical mid-peripheral distance must be carefully established preoperatively by performing accurate biometric measurements. The majority of ACP-IOL studies rate cell loss at three months and one year at about 7%, no greater than after modern cataract surgery. Alio[10] reports the longest follow-up of angle-fixated lenses. After 7 years, the cell loss was 9.6% with the ZB5M. With the Artisan/Verisyse lens, the loss ranged between 9.6% at 3 years[50] and 17.6% at 2 years.[196] The recent results of the prospective clinical trial including the first 765 eyes enrolled at the FDA sites and implanted with a myopic Artisan/Verisyse IOL, a percentage cell loss was 0.09 ± 16.39% at 6 months, 0.87 ± 16.35% at 12 months and 0.78 ± 17.41% at 24 months was found, with no statistically significant postoperative change from baseline.[204]

The iris barrier between the posterior chamber IOL and the cornea should protect against this feared complication, although some doubt has been raised.[136,172] In a series of 34 patients implanted with an ICL, Dejaco-Ruhswurm and coauthors

reported a progressive loss with rates ranging from 5.5% at 1 year, 7.9% at 2 years, 12.9% at 3 years, and 12.3% at 4 years during a 4-year follow-up,[73] thus suggesting a non-contact, inflammatory mechanism for endothelial cell deprivation. However, only the first-year data were statistically significant and the cell morphological indices (polymorphism and polymegathism) remained stable during that period. Moreover, our personal experience on 12 anisometropic patients implanted with the ICL in one eye and evaluated for 8 years (the fellow eye was used as control) showed a loss rate similar to that due to physiological aging (about 0.7% per year) (Carlo Lovisolo, unpublished data).

It is important to keep in mind that endothelial issues are controversial and evoke substantial debate (Food and Drug Administration Ophthalmic Devices Panel, report of the 107th meeting, Feb 5, 2004). Is 0.6% the normal cell loss rate due to aging? What is the lowest count for concern? Should we remove the phakic IOL on the basis of a certain progressive loss (for instance, a deprivation greater than 50% of the cell patrimonium) or of an absolute value (i.e., a cell count lower than 1000–1500 cells/mm^2)? Does corneal integrity depend on the absolute number of the endothelial cells or on their real functions? How many patients have we seen with endothelial cell dystrophy and progressively decreasing densities that did not decompensate over the years? Do we need other indices (thickness, morphology)? Are the actual methods of examination reliable? How many variables do affect evaluations and changes? No definitive answer is available. At minimum, patients should be asked not to rub their eyes and to periodically repeat specular or confocal microscopy to check the behavior of the endothelial layer quantitatively and morphologically.

Posterior Segment Complications

In high myopia (over –10.0 D), the natural history of the first 60 years of life (before ARMD age) carries a significant risk of retinal detachment and macular pathology (respectively, 2.4% vs. 0.06%, and 6% vs. 0.002% in the normal population).[68,114,217] Phakic IOLs may affect the posterior retina through a mechanism of acute (intraoperative trauma) or chronic inflammation that extends from the iris or the ciliary body to the posterior uvea, to cause cystoid macular edema.[5,105,198]

As far as it is known, vitreous hemorrhages,[186] choroidal neovascularization,[217] and ischemic optic neuropathy[195] are scantly reported after anterior chamber phakic IOL implantation in high myopic patients. The cumulative risk does not seem to increase significantly. Also, a few cases of retinal detachment have been anecdotally reported in subjects implanted with a phakic IOL, some of them with giant tears and an avulsion of the corresponding vitreous base.[12,155,165,213] Excessively aggressive YAG-PI or rough surgical maneuvers causing intraoperative loss of anterior chamber depth with a pressure gradient and forward movement of the vitreous body may disturb the vitreous base, influencing traction in an already predisposed posterior segment. Maintenance of the anatomical separation between the posterior and anterior segments of the eye should protect from severe vitreo-retinal complications. Decompartimentalization of the eye, with the creation of a connection between the two segments after Nd:YAG capsulotomy, requires a series of events (iatrogenic or natural cataract, phacoemulsification, posterior capsule opacification, laser capsulotomy, endophthalmodonesis with vitreous traction) eventually leading to retinal detachment. Episcleral buckling procedures can cause anterior displacement of the ciliary bodies and crystalline lens, reducing anterior and posterior chamber volume[230] and simulating the clinical condition called "plateau iris syndrome" when an IOP rise is caused by an inverse pupillary block without angle closure.[165] Compressing buckles may impair choroidal venous drainage and cause edema of the ciliary body. In these cases, once we decide for a phakic lens implantation, an ACP-IOL may be preferred to a PCP-IOL.

Our personal experience confirms that the presence of a phakic lens implant does not prevent good pupil dilation for observation of the retinal periphery, the execution of fluorangiographies and even complex surgeries like posterior vitrectomy and macular translocation.[117] However, on account of the internal thrust if gas is injected into the vitreous chamber and the need to keep the prone position that could displace the lens, the surgeon should consider the possibility of explanting the IOL, and eventually reimplanting it.

The vitreo-retinal surgeon may have to tackle the complications of phakic IOL surgery. The surgeon has an important role in providing documentation and in the prophylaxis of any pathology before surgery, and the treatment of postoperative problems.

Phakic IOL Dislocation

Both anterior chamber and posterior chamber phakic IOLs can luxate. Small angle-fixated lenses rotate and should be replaced with longer ones. Iris-fixated lenses may subluxate spontaneously in case of poor iris attachment or ocular or head trauma.[201,259] PCP-IOL decentration is more common

with PRL than with properly sized ICL, as the only two sizes available do not always fit big eyes well.[135,212] Vitreous displacement of the PRL has been reported at meetings in numerous cases (Lovisolo CF: Posterior chamber phakic IOLs. ISRS/AAO 2003 Refractive Surgery comes of age. American Academy of Ophthalmology, pp 33–41). Unrecognized zonular incompetence, excessive surgical trauma or an etiologic role of the shape and contour of the PRL haptics, which cause progressive erosion of the zonules are suspected.

Competitive Analysis

A self-sealing, sutureless, small (less than 3.5 mm) incision is an unquestionable advantage of the foldable PCP-IOLs and ACP-IOLs over the rigid PMMA implants, which require 5.5–7.0-mm incisions. These procedures have greater anesthesiological needs; they carry greater intraoperative difficulties and risks of early inflammatory reactions, infection and endothelial cell loss. Nevertheless, the main problem is the difficulty of managing astigmatism.

Late, intermittent, or subchronic inflammation is more frequent with the angle-fixated ACP-IOLs, often leading to pupil distortion and haptics entrapment by fibrotic gonio-synechiae.

If we consider bilensectomy the inevitable fate of every duophakic eye, which sooner or later will develop cataract for natural or iatrogenic reasons, the ease of removal of the lens through a small incision can make all the difference when lens exchange or phacoemulsification becomes necessary. Strong synechiae and the large incision necessary to remove a rigid IOL can jeopardize the surgical procedure. In PCP-IOL implanted eyes, no synechiae have been described, although further follow-up is obviously needed to confirm the ease with which these lenses can be explanted through a small incision. The challenging calculation of proper IOL power has already been discussed.[122,125]

Nighttime symptoms are caused by the optic size not matching the mesopic pupillary diameter and/or intraocular reflections.[176,239] The incidence of glare and halos ranges from 23.4–100% and is far lower for 6.0-mm optic lenses and eyes with small pupil diameters.[103] The difference in maximum effective dioptric correction achieved by the various models is not significant. The maximum power available with the ICL corrects significantly less than the other models (about −18.50 versus an average −23.0 with ACP-IOLs and a maximum of −28.0 with the PRL), but the firm (Staar Surgical) can now supply special powers to prescription.

Esthetically, the early effects (patched eye, bruising, swelling of the eyelid, etc.) are connected more with the type of anesthesia than with the type of implant. However, the cosmetic appearance of ACP-IOLs (those in PMMA in particular) can be a problem to certain patients, who may prefer PCP-IOLs, which are completely invisible to the naked eye.

In the long run, the risk of endothelial decompensation is higher for ACP-IOLs than for PCP-IOLs, thus balancing the lower risk of cataract. The risk of early glaucoma complications seems to be the same. However, pigment dispersion would appear to be greater in eyes implanted in the posterior chamber, for anatomical reasons (the small distance between the lens and the posterior pigmented layer of the iris).

Future Developments and Conclusions

We can roughly estimate that around 70,000 phakic IOLs (equally divided among angle-fixated, iris-supported, and PCP-IOLs) have been implanted to date throughout the world. The international ophthalmic community largely agrees that progress is still needed on several points:

1) The surgeon's learning curve and experience in sorting out intraoperative difficulties
2) The biocompatibility of the material
3) The lens design in order to achieve adequate vaulting, or at least to leave the edge of the optic at a safe distance from the endothelium and from the crystalline lens
4) The smooth, uniform distribution of minimal pressures at the fixating points without losing intraocular stability
5) The performance of the optic (fine quality of the surfaces, physiological geometry and diameter wide enough to match the patient's scotopic pupil diameter)
6) The lens sizing, to improve the stability of the implant

When these aims have all been achieved, current minimally invasive techniques of phakic IOL implantation are likely to produce excellent results in terms of precision, predictability (the percentage of eyes obtaining ±1.00 D from the desired refraction will soon be close to 100%), and stability of the refractive outcome, with acceptable postoperative complication rates.

Transient uveal reactions with postoperative inflammation (2–13% in the literature)[5,198] and IOP rises (7–29%) occur with ACP-IOLs, but they respond well to conventional therapy. The rates of IOL dislocations (0–18%), glaucoma (0–21%), and pupil deformations (6–18%)[10,110,194,245] are due mainly to human errors in sizing and surgical maneuvers, so they can be expected to become less

frequent as surgeons gain experience. The incidence of catastrophic events like endophthalmitis (only anecdotal reports) and retinal detachment (0.6–4.5%)[12,155] is acceptably low if considered in the balance of the risk/benefit ratio of a population naturally prone to posterior segment diseases. Time will tell us whether prevalence will rise and the risk-benefit balance will modify as technology moves down into the lower levels of ammetropia.

Nighttime visual symptoms (halos, arcs, and glare) are very frequent (6–72%) but are disabling only in a minority of cases. They are destined to become minor issues with the latest and future generations of wide-optic lenses. With adequately sized current models of PCP-IOLs, iatrogenic cataract should become avoidable too.

However, we must emphasize that it is not certain whether these short-term reassuring features will apply to phakic lenses in the longer term. Because the implant is generally inserted into young patients' eyes, it must theoretically stay in a harmonious relationship with the internal structures with no optical and physical decay of the material, probably for at least 30 years, if not life-long. The absence of synechiae and chronic inflammatory phenomena encapsulating the haptics will facilitate future IOL exchange or the bilensectomy procedure when the time comes for cataract surgery in these subjects. The widespread clinical applications of PMMA and non-PMMA implants (collamer, silicone, hydrophobic, and hydrophilic acrylic) have given enough proof of biological compatibility[35,69] and the endurance of properties like elasticity and permeability to gases and nutrients.[146]

With time, we must remain aware of the unknowns involved in the lasting anatomical-functional integrity of the endothelial layer (with corneal decompensation as a major risk), of the anterior uvea (chronic uveitis, irreversible ovalization of the pupil, iris subatrophy, and pigment dispersion), of the iridocorneal angle structures (with glaucoma as a worst-case scenario, particularly for eyes with a reduced anterior segment, as is often the case in severe hyperopia), and of the crystalline lens (with cataract extraction, posterior capsule opacification, laser capsulotomy, and final eye decompartimentalization carrying the risk of facilitating the onset of invalidating vitreo-retinal complications in high myopes).[167] As usual, only time will be the judge through further studies and experience.[80,136,143,149,151,249]

Method of Literature Search

The authors conducted a search of the MEDLINE database (1960–2003) using the search words *phakic IOL, high myopia surgery, lenses, corneal pathology, intraocular lenses, refractive IOLs, hyperopia surgery, iris pathology, crystalline lens physiopathology, and power calculation.* All articles judged to be of clinical importance were included, and priority was given for reports of large series and long follow-ups. The search was updated during the review process to include key articles published after the article was submitted. Peer-reviewed journal articles were cited when available, but in cases where that was not possible, other sources of information such as personal data, meeting abstracts, and so on, were cited.

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Phakic refractive lens implantation in high myopic patients: One-year results

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Purpose: To evaluate the efficacy and safety of implantation of a new posterior chamber phakic refractive lens (PRL, Ciba Vision Surgical) in highly myopic eyes.

Setting: Department of Ophthalmology, Medical School, University of Crete, Vardinoyannion Eye Institute of Crete, Crete, Greece.

Methods: Thirty-four myopic eyes of 19 patients were treated for high myopia with implantation of a silicone PRL in the posterior chamber. Mean patient age was 29.0 years ± 7.9 (SD) (range 18 to 44 years). Manifest refraction in spherical equivalent (MR), uncorrected (UCVA) and best corrected (BCVA) visual acuity (decimal scale), intraocular pressure, higher-order aberrations (root-mean-square [RMS] wavefront error measured with a Shack-Hartmann wavefront sensor WASCA analyzer [Carl Zeiss, Meditec]), possible complications, and subjective symptoms were evaluated.

Results: Phakic refractive lenses were successfully implanted in all eyes. Mean follow-up was 17.17 ± 3.76 months (range 12 to 24 months). There was a statistically significant reduction in the MR (from −14.70 D ± 2.65 D [range −20.75 D to −10.50 D] to −0.61 D ± 0.89 D [range −2.25 D to 1.00 D]) ($P<.001$). Twenty-seven (79%) and 15 eyes (44%) were within ±1.00 D and ±0.50 D of target refraction, respectively. Mean UCVA significantly improved (from counting fingers to 0.62 ± 0.28 (range 0.08 to 1.20) ($P<.001$). Mean BCVA also improved from 0.70 ± 0.24 (range 0.10 to 1.00) to 0.85 ± 0.24 (range 0.10 to 1.20) ($P<0.001$). Overall, there was a mean increase in BCVA of 1.5 ± 1.5 lines (range loss of 2 lines to gain of 5 lines). There was no statistically significant difference in higher-order aberrations after PRL implantation (pre-PRL RMS: 0.18 μm ± 0.08 μm [range 0.09 μm to 0.38 μm]; post-PRL RMS: 0.21 μm ± 0.08 μm; [range 0.05 μm to 0.38 μm]) ($P = .12$).

Conclusion: The PRL showed encouraging results in treating high myopia. Additional patients and longer follow-up period are needed to detect the long-term efficacy and safety of this refractive lens.

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Phakic intraocular lenses constitute an evolving technique in the field of refractive surgery for the correction of moderate to high refractive errors. In such cases, excimer laser treatment is limited by the amount of corneal tissue that can be removed safely.[1,2] Furthermore, there is evidence that altering the shape of the cornea in attempted high corrections may result in poor quality of vision.[3] The implantation of a phakic intraocular lens (IOL) does not affect the shape of the cornea. The technique has been proven to be stable and potentially reversible. In comparison with clear lens extraction, another treatment option for high refractive errors, phakic IOL implantation preserves accommodation and, therefore, is suitable for younger patients.

The PRL is a posterior chamber phakic refractive lens developed by Medennium Inc. and distributed by

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Ciba Vision Surgical.[4] It is made of silicone with a high refractive index (1.46), which allows its ultrathin design. The PRL is not supported in the sulcus angle but "floats" in the posterior chamber over the crystalline lens and is made of hydrophobic material.[4] Its centration is achieved by its self-centering design.

The purpose of this prospective study was to evaluate the efficacy and safety of PRL implantation in highly myopic eyes.

Patients and Methods

Thirty-four myopic eyes of 19 patients were treated with PRL implantation by the same surgeon (I.G.P.). Mean patient age was 29.0 years ± 7.9 (SD) (range 18 to 44 years). Each patient had been informed about the procedure, its risks, and its benefits and signed a consent form according to the Declaration of Helsinki. Exclusion criteria included age less than 18 years, previous intraocular surgery, anterior chamber depth less than 3 mm, glaucoma, or intraocular pressure (IOP) at initial measurement greater than 20 mm Hg, any sign of cataract, and any intraocular or systemic disease.

Preoperative examination included manifest and cycloplegic refractions, corneal topography, pachymetry, A-scan ultrasonography (Axis-II, Quantel Medical), slitlamp microscopy, pupil size measurement under scotopic conditions, white-to-white corneal diameter measurement with the use of a caliper, applanation tonometry, measurement of high-order aberrations with the WASCA analyzer (Carl Zeiss, Meditec), and dilated fundoscopy.

Mean preoperative spherical equivalent was −14.70 ± 2.65 diopters (D) (range −20.75 D to −10.50 D). Mean preoperative refractive cylinder was −2.02 D (range 0 to −5.50 D). Manifest refraction was performed over a soft contact lens in all eyes. The target postoperative refraction was emmetropia in all eyes. Preoperative uncorrected visual acuity (UCVA) was finger counting in all eyes; mean best corrected visual acuity (BCVA) was 0.70 ± 0.24 (range 0.10 to 1.00).

Lens power calculations were performed by Ciba Vision Surgical and were based on the preoperative cycloplegic spherical equivalent, the average keratometric power, the anterior chamber depth calculated with the use of A-scan ultrasonography, and the target postoperative refraction. The model of the myopic PRL implanted was based on the horizontal white-to-white diameter. Because this was more than 11.3 mm in all eyes, PRL101 was used in all cases.

Surgical Technique

One hour before surgery, cyclopentolate 1% and phenylephrine 5% were used every 15 minutes to dilate the pupil. Phakic refractive lenses were implanted under retrobulbar anesthesia through a 3.2 mm clear cornea temporal incision made with a diamond knife. The anterior chamber was then filled with a low-viscosity viscoelastic agent. At this step, the special loading block was filled with balanced salt solution and the PRL was placed on the recess with the special forceps. The lens was inserted through the main incision parallel to the iris. With the forceps or a manipulator, the haptics of the lens, one after the other were placed under the iris. An iridectomy was performed at 12 o'clock as peripherally as possible using the probe of a vitreotome.

Postoperative Period

At discharge, each patient was given 1 tablet of acetazolamide 250 mg. Antibiotic-steroid combination drops were prescribed for 2 weeks.

Patients were examined on the first postoperative day, at 1 week and at 1, 3, 6, 9, and 12 months. After the first postoperative day, the examination included UCVA, BCVA, manifest refraction, corneal topography, slit-lamp microscopy, tonometry, and wavefront aberrometry. At 6 and 12 months, the examination also included gonioscopy and dilated fundoscopy.

Statistical Analysis

Group differences for continuous variables were tested using the unpaired and paired Student *t* test. Results are presented as mean ± SD. A *P* value less than .05 was regarded as statistically significant.

Results

Mean follow-up after PRL implantation was 17.17 ± 3.76 months (range 12 to 24 months). A summary of patient data is presented in Table 1.

Efficacy

The mean UCVA significantly improved from counting fingers preoperatively to 0.62 ± 0.28 (range 0.08 to 1.20) at the last follow-up examination ($P<.001$) (Figure 1, *A*). Of the 34 eyes, all eyes experienced 1- to 12-line gain. The mean difference between preoperative and postoperative UCVA was a 6.2-line gain (range 1- to 12-line gain).

Safety

The mean BCVA significantly improved from 0.70 ± 0.24 (range 0.10 to 1.00) to 0.85 ± 0.24 (range 0.10 to 1.20) ($P<.001$) (Figure 1, *B*). Of the 34 eyes, 1 eye lost 2 lines of preoperative BCVA, 8 maintained pre-PRL BCVA, and the rest (25 eyes) experienced a 1- to 5-line gain (Figure 2). Mean difference between

Table 1. Summary of patients' preoperative data.

Variable	Myopic Patients
Age (mean ± SD, y)	29 ± 7.9 (range 18 to 44)
Sex (male/female)	9/10
Eyes	34
Right/Left	18/16
MR (mean ± SD, D)	−14.70 ± 2.65 (range, −20.75 to −10.50)
UCVA	CF
BCVA	0.70 ± 0.24 (range 0.10 to 1.00)
Anterior chamber depth (mean ± SD, mm)	3.53 ± 0.27 (range 3.00 to 4.06)
Axial length (mean ± SD, mm)	28.9 ± 1.53 (range 26.05 to 32.17)
Keratometry (mean ± SD, D)	43.75 ± 1.18 (range 41.78 to 46.29)
IOP (mean ± SD, mm Hg)	15.47 ± 2.04 (range 12 to 20)

BCVA = best corrected visual acuity; CF = counting fingers; D = diopters; IOP = intraocular pressure; MR = manifest refraction in spherical equivalent; SD = standard deviation; UCVA = uncorrected visual acuity

pre-PRL and last follow-up after PRL was a gain of 1.5 ± 1.5 lines (range, loss of 2 to gain of 5 lines).

Predictability

Preoperative and last follow-up mean values for spherical equivalent refraction revealed a statistically significant reduction ($P<.001$) from −14.70 ± 2.65 D (range −20.75 to −10.50 D) to −0.61 ± 0.89 D (range −2.25 to 1.00 D) ($P<.001$) with a mean reduction value of 14.08 ± 2.72 D (range −10.00 to −19.50 D) at the last follow-up (Figure 3). The mean difference between the intended and achieved correction at the last follow-up examination was −0.55 ± 0.86 D (range −2.25 to 1.00 D). Twenty-seven eyes (79%) and 15 eyes (44%) were within ±1.00 D and ±0.50 D of target refraction, respectively (Figure 4).

IOP Measurements

A statistically significant increase in preoperative IOP measurements was found after 1-month follow-up (pre-PRL, 15.29 ± 1.84 mm Hg; 1 month, 17.24 ± 5.44 [$P = .037$]), which returned to preoperative levels at 3 months (6 eyes were corticosteroid responders) (Figure 5).

Wavefront Aberrations

Wavefront aberrations were assessed in 15 eyes (44.1%). Total high-order root-mean-square (RMS) was evaluated for the same pupil diameters (5 mm, 3 mm) pre-PRL implantation and 1-year postoperatively. There was an increase in total high-order aberrations (third and fourth) but not a statistically significant one (pre-PRL RMS: 0.18 μm ± 0.08 μm [range 0.09 μm to 0.38 μm]; post-PRL: 0.21 μm ± 0.08 μm [range 0.05 μm to 0.38 μm]) ($P = .12$) for a pupil diameter of 5 mm. Total high-order aberrations in 3 mm pupil diameter did not change significantly (pre-PRL: RMS 0.035 ± 0.016; post-PRL RMS: 0.045 ± 0.018) ($P = .08$). The spherical aberration (Z4-0 Zernike coefficient) (Table 2) in 5 mm pupils was significantly decreased 1 year postoperatively (pre-PRL, 0.05 ± 0.04; post-PRL: 0.008 ± 0.05) ($P = .012$). More specifically, Zernike coefficients pre- and post-PRL implantation are shown in Table 2. Modulation transfer function (MTF) before and after surgery was computed for each eye from the corresponding wave aberration, for 5-mm pupil (Figure 6) and ignoring apodization imposed the Stiles-Crawford effect. Contribution of tilt, defocus, and astigmatism were cancelled.[5] There was a small contrast sensitivity loss post-PRL implantation. For example, the MTF for 20 cycles/degree decreased by a factor of 1.3.

Adverse Effects and Their Management

During surgical iridectomy with the probe of a vitreotome, 3 eyes experienced damage of the anterior capsule of the crystalline lens. These eyes were examined very closely, and it was noticed that the opacification remained focal behind the iridectomy and did not progress to cataract in the visual axis (Figure 7). Another eye presented focal anterior capsule opacification on

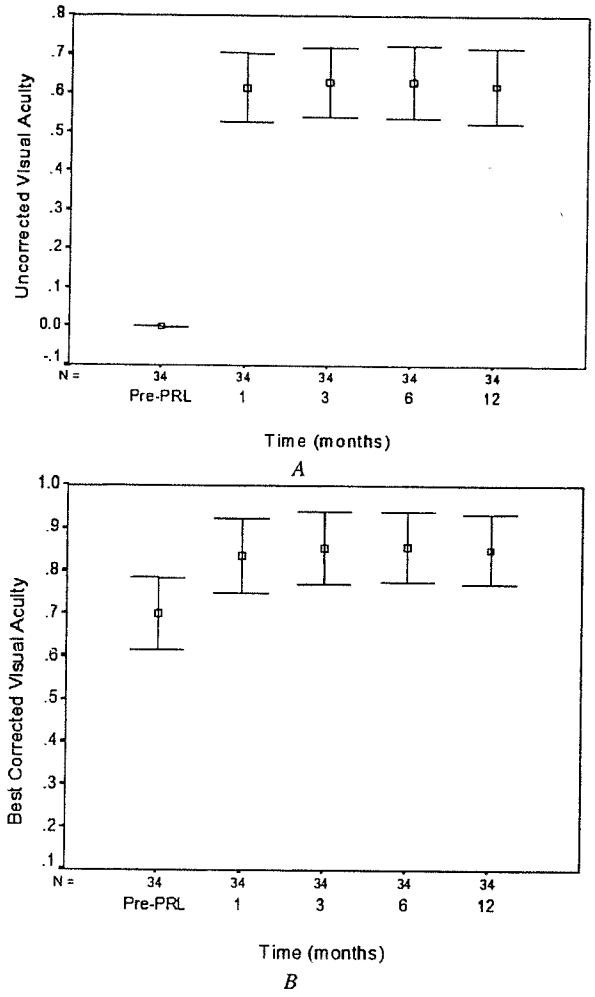

Figure 1. (Pallikaris) Changes in mean UCVA (*A*) and BCVA (*B*) (decimal scale) during the follow-up period. The error bars indicate 95% confidence intervals for the means.

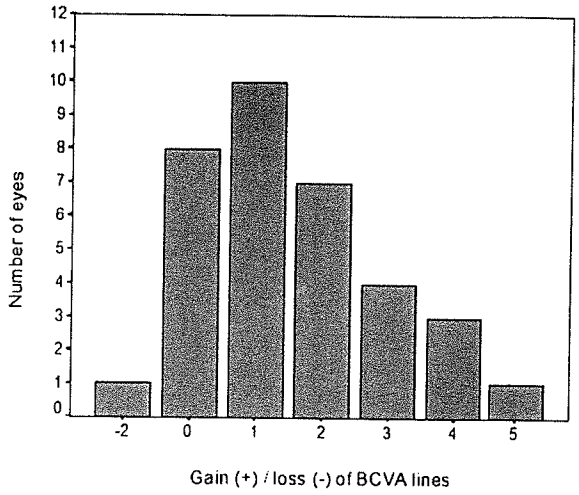

Figure 2. (Pallikaris) Changes in BCVA (lines in decimal scale) between preoperative and the last postoperative follow-up.

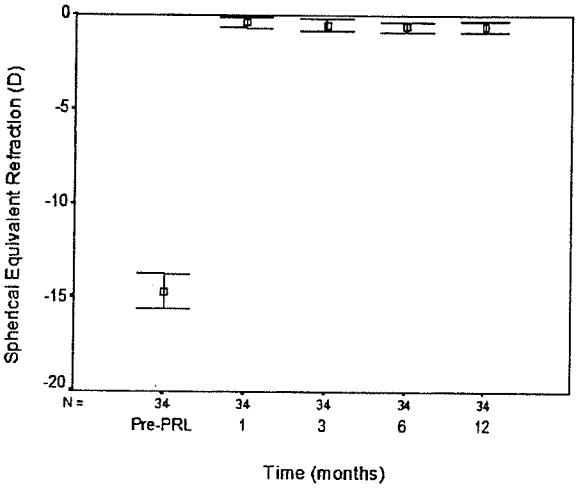

Figure 3. (Pallikaris) Changes of mean spherical equivalent refraction after PRL implantation. The error bars indicate 95% confidence intervals for the means.

the first postoperative day probably because of surgical contact with the crystalline lens. One year after the PRL implantation, the opacification had not progressed or caused any BCVA loss (Figure 8).

Postoperative Complications

Eight eyes experienced IOP higher than 20 mm Hg during the first postoperative month. Six eyes were corticosteroid responders. Intraocular pressure returned to normal levels after discontinuation of steroid drops. The other 2 eyes of the same patient had a resistant increase of IOP with open anterior chamber angle, no pigment dispersion, and patent iridectomies in both eyes. Visual field test was performed 1 month postoperatively and revealed large glaucomatous defects. Intraocular pressure could not be controlled with combination of topical medication (20 mm Hg to 30 mm Hg). Because of the visual field analysis and the lack of other symptoms in relation to the implant, the patient is considered to have had pre-existing, undiagnosed glaucoma. He refused the removal of the implants and underwent successful trabeculectomies in his left and right eye 1 and 2 months after the PRL implantation, respectively. Intraocular pressure was checked closely and was under 16 mm Hg in both eyes in every postoperative examination. Visual fields remained stable 1 year after the trabeculectomies.

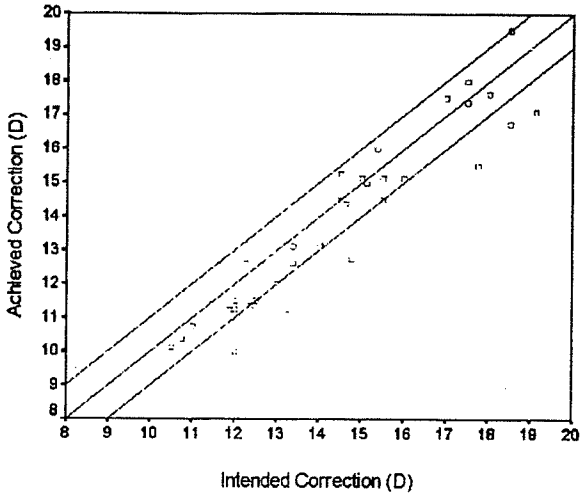

Figure 4. (Pallikaris) Scattergram between achieved and intended spherical equivalent refractive change after PRL implantation. The diagonal lines show equality and over- and undercorrection by 1 D.

Six patients (28.5%) complained of glare and halo at night. These symptoms decreased 6 months after PRL implantation. Five of these patients had pupils greater than 7 mm; the pupil of the other patient was 6 mm. Halo and glare are attributed to the fact that the optic zone of the PRLs used in this study was 5 mm, which is too small in comparison to these patients' scotopic pupil size.

Discussion

The implantation of an IOL in phakic eyes is indicated for the surgical treatment of high ametropia. Laser in situ keratomileusis (LASIK) has been used to treat high levels of refractive errors, but its predictability and stability decrease with the amount of the attempted correction.[1] Large ablation depths also predispose the cornea to the risk for ectasia, which makes surgeons more conservative with the amount of laser corrections.[2] The implantation of an IOL in a phakic eye is a theoretically reversible and stable technique, whereas clear lens extraction is more invasive and results in the loss of accommodation.[6–8]

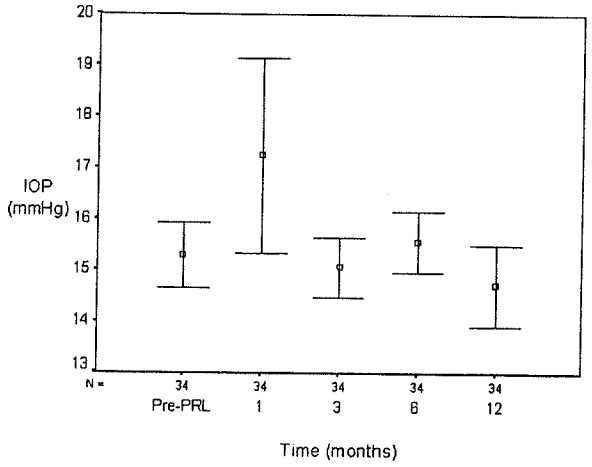

Figure 5. (Pallikaris) Changes in IOP after PRL implantation. The error bars indicate 95% confidence intervals for the means.

Anterior chamber lenses supported in the anterior chamber angle have the advantage of a comparatively simple surgical technique. The complications that might follow the implantation of an anterior chamber lens are damage to the corneal endothelium, mostly during the first year after implantation; pupil ovalization with iris atrophy; anterior uveitis; and elevation of IOP.[9–11] Iris-fixated lenses require a more sophisticated surgical technique.[12] Although they may have a good refractive outcome[13] and are considered safer for the corneal endothelium[14] because they are not fixated in the angle, they also may result in several complications such as localized iris ischemia.[15]

In 1986, Fyodorov and coauthors[16] designed a posterior chamber IOL, which was made of silicone. This lens underwent improvements in its design and passed through 3 generations until the PRL implanted in this study was produced.[17]

In our study, comparison of UCVA and BCVA before and after PRL implantation demonstrates the efficacy and safety of this posterior chamber lens. Seventy-nine percent of myopic eyes were within ±1.00 D of target refraction, whereas 44% were within ±0.50 D of target refraction (Figure 4). To eliminate the effects of magnification, optical distortion, and vertex power imposed by spectacle lenses, we measured the preoperative contact lens BCVA and compared this with the BCVA after the PRL implantation. Seventy-three percent of myopic eyes gained 1 to 5 lines of BCVA postoperatively. These results are even better compared with those of other posterior chamber lenses.[18–22]

Few short-term complications were observed, such as IOP increase during the first postoperative day because of residual viscoelastic[23] and during the first month because of corticosteroid response. Corticosteroids were used to prevent postsurgery inflammation, but it might be useful to use nonsteroidal anti-inflammatory drops

Table 2. Zernike coefficients (mean values, OSA notation) of 15 eyes before and after PRL implantation (pupil = 5 mm).

Type	Pre-PRL	Post-PRL	*P*
Third-order Zernike coefficients			
Z_3^{-3} (triangular astigmatism with base on *x*-axis horizontal)	−0.005	0.012	.45
Z_3^{-1} (third-order coma along *x*-axis horizontal)	0.003	0.017	.49
Z_3^{1} (third-order coma along *y*-axis vertical)	0.024	0.012	.57
Z_3^{3} (triangular astigmatism with base on *y*-axis vertical)	0.003	0.015	.79
Fourth-order Zernike coefficients			
Z_4^{-4} (fourth-foil)	−0.012	−0.02	.155
Z_4^{-2} (fourth-order astigmatism on *y*-axis vertical)	−0.003	−0.005	.888
Z_4^{0} (spherical aberration)	0.05	0.008	.012
Z_4^{2} (fourth-order astigmatism along *x*-axis horizontal)	−0.03	−0.027	.851
Z_4^{4} (fourth-foil)	0.014	−0.010	.083

OSA = Optical Society of America; PRL = phakic refractive lens

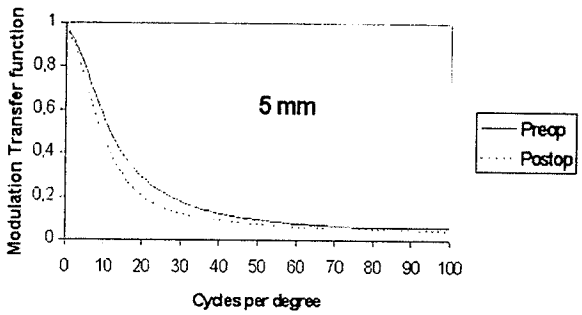

Figure 6. (Pallikaris) Average MTF before and after PRL implantation computed from the wave aberration for 5 mm pupil diameter.

instead to avoid this steroid side effect. Because large, surgical iridectomies were performed, no eye presented angle closure or pupillary block. After proper medication and discontinuation of steroid drops, IOP returned to normal levels, respectively, to the IOP before the operation. This shows that the presence of a PRL inside a myopic eye does not cause a long-term increase of IOP because it is also reported for other posterior chamber lenses.[23]

The main short- or long-term risk from implantation of a posterior chamber lens is cataract formation because of contact between the phakic lens and the

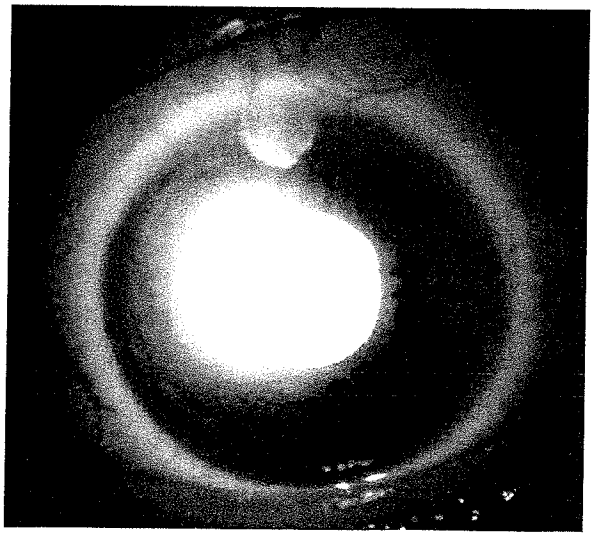

Figure 7. (Pallikaris) Slitlamp photograph of patient 3 months after PRL implantation shows focal opacity behind iridectomy because of damage to the anterior capsule.

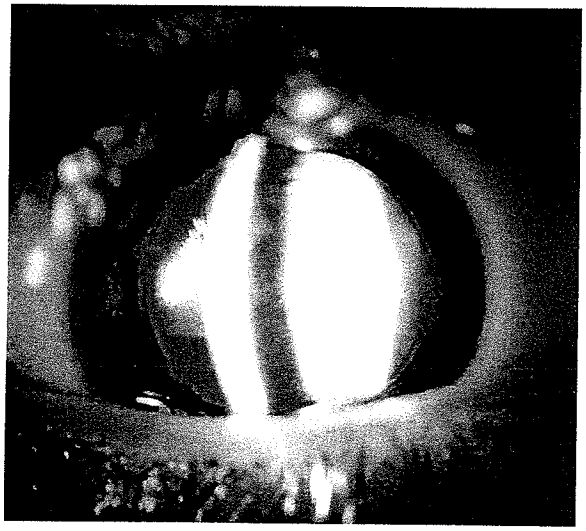

Figure 8. (Pallikaris) Slitlamp photograph shows anterior subcapsular opacification 1 year post-PRL implantation.

crystalline lens or because of metabolic disturbances in the latter.[21,24] In our study, we noticed 1 case of localized anterior capsule opacity on the first postoperative day. This could have been caused by surgical trauma. At all the postoperative examinations, there was no contact between the implant and the crystalline lens. The opacity had not progressed 15 months after PRL implantation and had not caused any visual acuity loss.

Another possible complication following the implantation of a posterior chamber lens is pigment dispersion because of irritation of the posterior surface of the iris by the anterior surface of the implant.[25] No pigment dispersion was noticed in any of the eyes in this study.

Glare and halo at night were mentioned by 6 patients (28.5%) and decreased during follow-up. Because the optic zone of PRL is definite, patients with pupils greater than 7 mm in scotopic conditions should be informed of the possibility of glare and halo at night. However, PRL implantation cannot be totally excluded in these patients because not all patients with large pupils experienced these night phenomena, whereas those who did were quite satisfied with their vision after PRL implantation and considered these symptoms insignificant.

Higher-order aberrations of the 15 eyes measured at pupil of 5 mm remained almost unchanged after the operation. The decrease in spherical aberration after PRL implantation could be a benefit for mesopic vision. In myopic eyes, the MTF, which refers to the retinal image quality, was decreased 1 year post-PRL implantation. Moreno-Barriuso and coauthors[26] reported that in post-LASIK eyes there was an increase in spherical aberration, which decreased retinal image quality (MTF). Higher-order aberrations of more eyes need to be evaluated before and after PRL implantation before we can draw conclusions about the effect of this lens on the quality of vision.

In conclusion, PRL implantation in highly myopic eyes seems to be a safe, effective, and minimally invasive technique without serious intra- or postoperative complications. However, further follow-up and additional patients must be reviewed to draw final conclusions about the efficacy and safety of this new posterior chamber PRL.

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Superior across the board

As recent studies once again confirm, the PRL™ implantation is a superior procedure for correcting high myopia and hyperopia, with a high level of predictability.

Proven efficacy

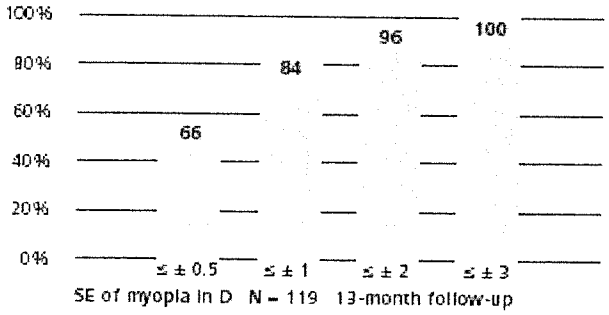
In a study[1] on 90 myopic eyes implanted with the PRL™, one year post-operatively, all eyes showed an increase in UCVA from 1 to 12 lines.

Efficacy indexes of 1.06 (95 eyes for Northern Europe) and 1.05 (36 eyes for Southern Europe) for myopia correction were observed in a retrospective multi-centric European study[2].

Highly predictable outcomes

Graph A shows results from the above-cited study[2]. The graph demonstrates how highly predictable outcomes can be reached with PRL™ implantation in high-myopic eyes:

Graph A – Post-operative refraction deviation to target for myopia correction in Northern Europe from the PRL™ retrospective multi-centric European study[2]

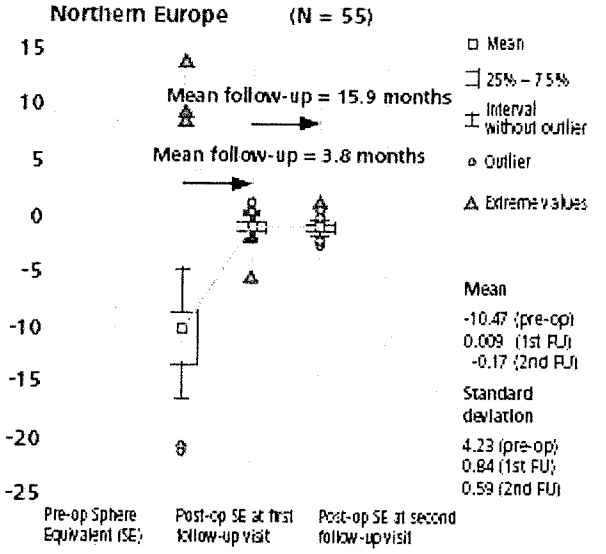


According to the findings of a study[3] on 16 high-hyperopic eyes, 100% of the eyes were within 1.00 D and 93.75% of the eyes were within 0.50 D of the target refraction at the one-year follow-up.

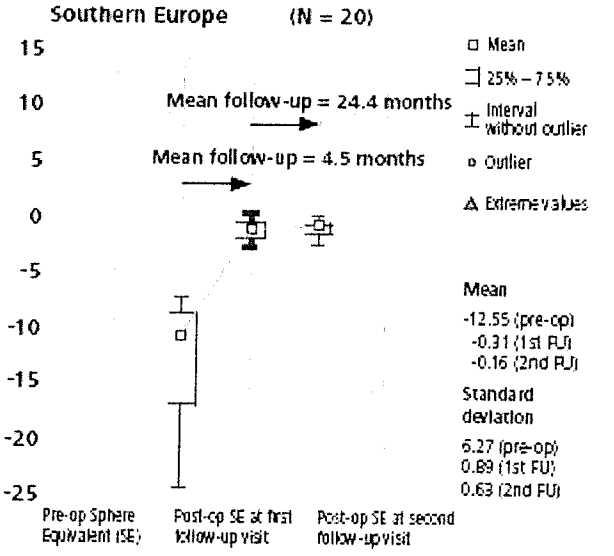
Stability of refraction

Long-term stability of refraction has been demonstrated in a retrospective European study[2] as shown in graphs B and C below.

Graphs B and C – Stability of post-operative refraction for myopia correction from the PRL™ retrospective multi-centric European study[2]



Graph B



Graph C

Excellent safety profile

The PRL™ has proven to be a highly effective solution with an outstanding long-term safety profile.

Overall safety

As shown in table A, the safety indexes (post-operative BSCVA/pre-operative BSCVA) are excellent for the PRL™ at the one-year follow-up.

Table A – Safety indexes from the PRL™ retrospective multi-centric European study[2] (at least 1-year follow-up)

Northern Europe	Myopia	60	1.33
	Hyperopia	15	0.95
Southern Europe	Myopia	76	1.19
	Hyperopia	74	1.02

Studies[1,2,3] show that patients can expect to have little or no complications following surgery. Of course, a thorough pre-operative patient evaluation and the recommended surgical technique will affect the outcome positively.

Extremely low cataract induction rate

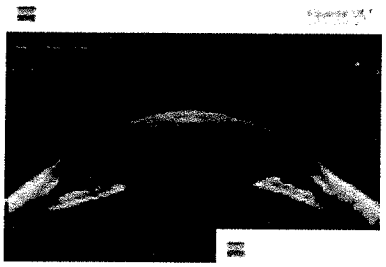
As shown in table B, the cataract induction rate reported with the PRL™ is extremely low. These results are even more impressive when compared to outcomes obtained with a competitive posterior chamber phakic IOL[5].

Safe distances

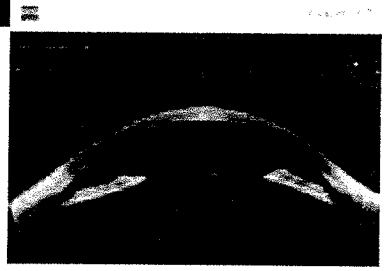
As a posterior chamber phakic intraocular lens, the location of the PRL™ provides a safe distance from its anterior surface to the corneal endothelium. This reduces the risk of non-traumatic progressive endothelial cell loss, as proven in a study[4] by Annemari Koivula, MD, PhD (Stockholm, Sweden) published in Ophthalmology in 2007.

As demonstrated in the same study[4], the posterior surface of the PRL™ is also positioned at a safe and stable distance from the crystalline lens, even with an accommodation of up to 7 D (pictures A and B).

Pictures A and B show a -5.5 D PRL™ 101 implanted in a 25-year-old female at 3 years and 3 months follow-up. Picture A illustrates the PRL™ in the eye with no accommodation and picture B in the same eye with 7 D of accommodation.



Picture A



Picture B

Table B – Cataract induction rates reported in multiple recent studies after the implantation of the PRL™

			N	n	% (n/N)	n	% (n/N)
Höh H et al.[1]	Europe	Up to 5 years	329	1	0.3%	1	0.3%
Teus MA[6]	Spain	Up to 3 years	78	0	0.0%	0	0.0%
Gil-Cazorla R et al.[3]	Spain	Up to 1 year	16	0	0.0%	0	0.0%
Koivula AM et al.[4]	Sweden	Up to 1 year	52	0	0.0%	2	3.8%
Total			475	1	0.2%	3	0.6%

Technical features

PRL™ 100-101	
Pathology	High myopia
Material	Silicone
Optic Diameter	From 4.5 to 5 mm according to power
Total Diameter	PRL™ 100: 10.8 mm PRL™ 101: 11.3 mm
Lens Design	Single-piece, biconcave
Diopter Range	-3.0 to -20.0 D by 0.5 D increment
Implantation in	Posterior chamber

PRL™ 200	
Pathology	High hyperopia
Material	Silicone
Optic Diameter	4.5 mm
Total Diameter	10.6 mm
Lens Design	Single-piece, convex-concave
Diopter Range	+3.0 to +15.0 D by 0.5 D increment
Implantation in	Posterior chamber

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