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

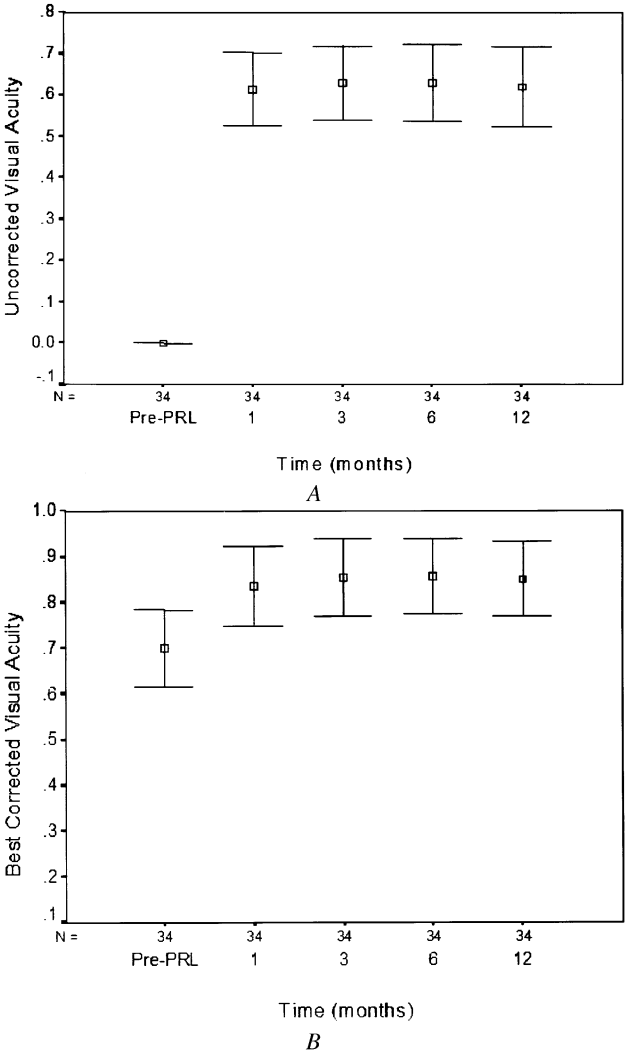

Figure 1. (Pallikaris) Changes in mean UCVA (*A*) and BCVA (*B*) (decimal scale) during the follow-up period. The error bars indicate 95% confidence intervals for the means.

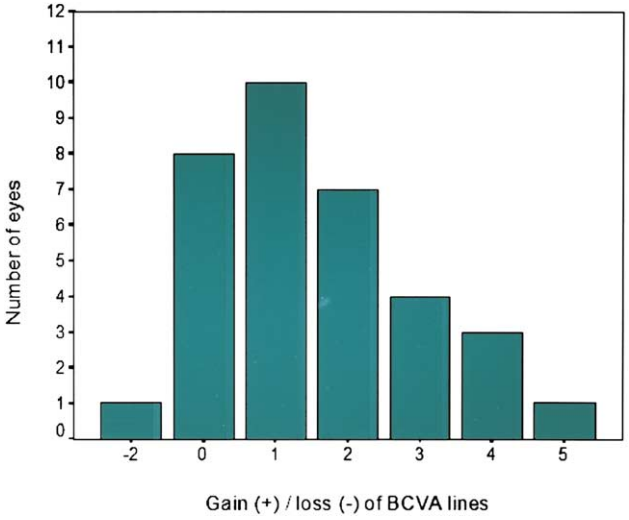

Figure 2. (Pallikaris) Changes in BCVA (lines in decimal scale) between preoperative and the last postoperative follow-up.

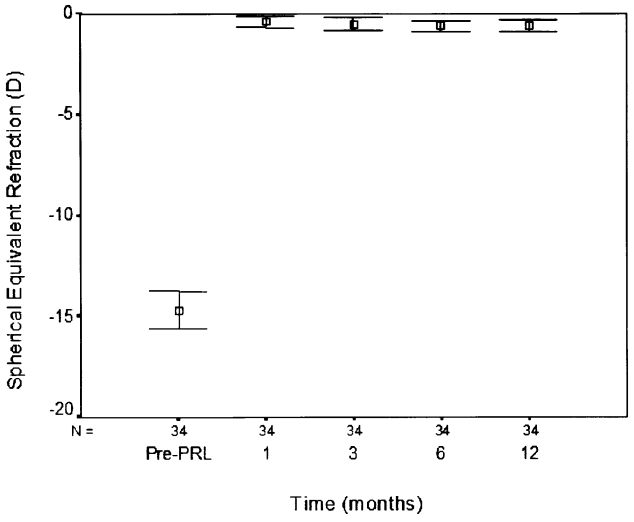

Figure 3. (Pallikaris) Changes of mean spherical equivalent refraction after PRL implantation. The error bars indicate 95% confidence intervals for the means.

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.

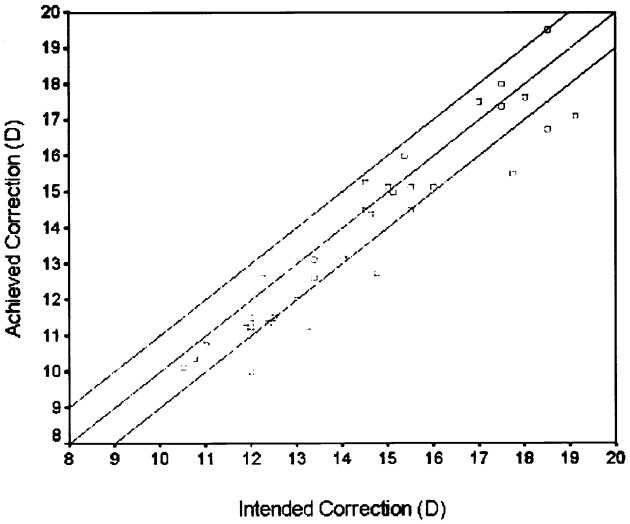

Figure 4. (Pallikaris) Scattergram between achieved and intended spherical equivalent refractive change after PRL implantation. The diagonal lines show equality and over- and undercorrection by 1 D.

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]

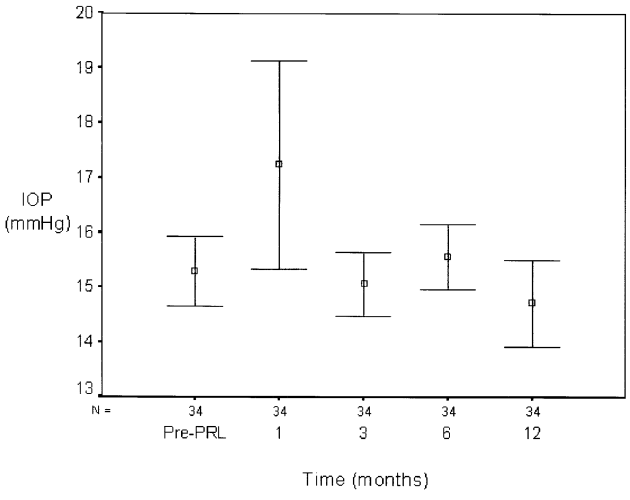

Figure 5. (Pallikaris) Changes in IOP after PRL implantation. The error bars indicate 95% confidence intervals for the means.

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

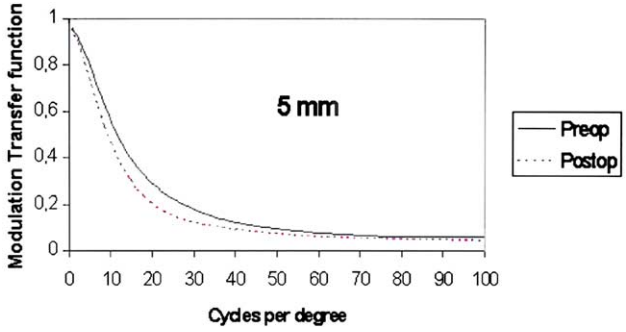

Figure 6. (Pallikaris) Average MTF before and after PRL implantation computed from the wave aberration for 5 mm pupil diameter.

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

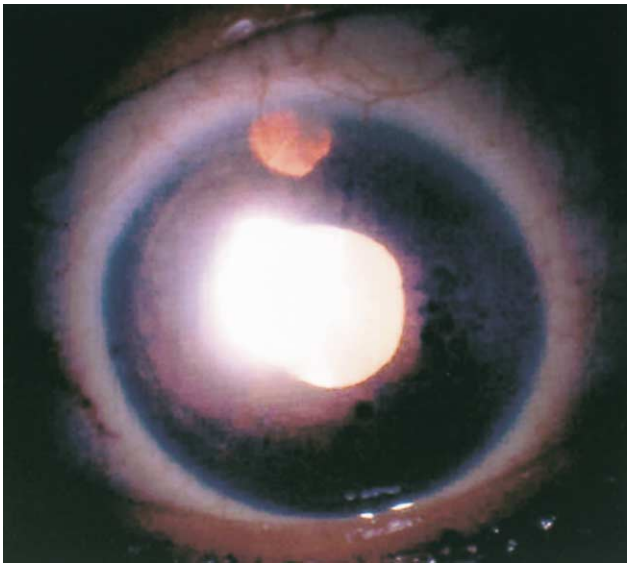

Figure 7. (Pallikaris) Slitlamp photograph of patient 3 months after PRL implantation shows focal opacity behind iridectomy because of damage to the anterior capsule.

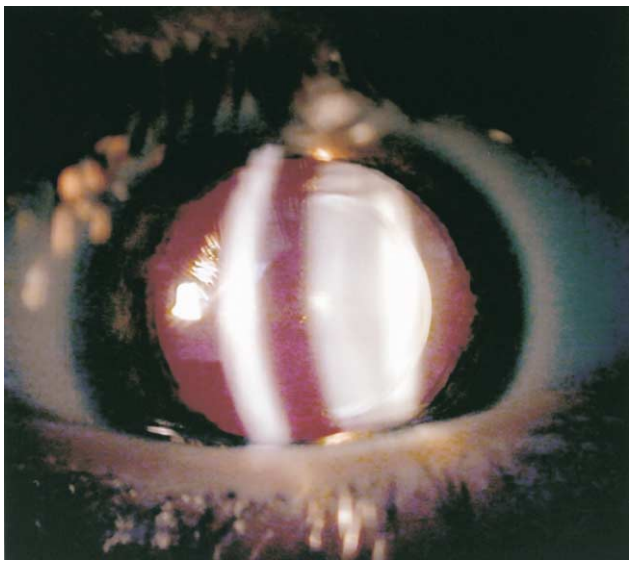

Figure 8. (Pallikaris) Slitlamp photograph shows anterior subcapsular opacification 1 year post-PRL implantation.

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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