Long-term Results of Phakic Refractive Lens Implantation in Eyes With High Myopia

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ABSTRACT

PURPOSE: To evaluate the long-term results of phakic refractive lens (PRL; Carl Zeiss Meditec) implantation in eyes with high myopia.

METHODS: In this retrospective, noncomparative, interventional case series, 143 myopic eyes of 82 patients were treated for high myopia with the implantation of the silicone PRL in the posterior chamber.

RESULTS: Mean follow-up was 3.8±1.7 years (range: 1 to 6 years). Six years postoperatively (n=34), a statistically significant reduction was noted in the cycloplegic spherical equivalent from $-14.08\pm4.00$ diopters (D) (range: $-24.88$ to $-4.75$ D) before PRL implantation to $-0.45\pm0.62$ D (range: $-1.00$ to $1.00$ D) ($P<0.001$). At 6 years, 67.6% (23 eyes) and 91.2% (31 eyes) were within $\pm0.50$ and $\pm1.00$ D of target refraction, respectively. Mean logMAR uncorrected and corrected distance visual acuity improved significantly ($P<0.001$) (counting fingers preoperatively in all eyes to 0.17±0.15 [range: 0.54 to $-0.06$] and 0.19±0.19 [1.00 to $-0.08$] to 0.07±0.10 [range: 0.30 to $-0.10$], respectively). Complications included anterior capsule damage (3 eyes), temporary intraocular pressure increase (14 eyes), pigment dispersion (1 eye), and PRL decentration (1 eye). No eyes presented any signs of cataract up to 6 years postoperatively.


Phakic intraocular lenses (PIOL) have gained their place in intraocular refractive surgery as a relatively new, evolving technique for the correction of moderate to high refractive errors. In certain cases of high myopia and hyperopia, excimer laser treatment is not advised because of residual corneal stromal thickness concerns. The main issue is to avoid the risk of postoperative ectasia, attributed mainly to LASIK, in which the cornea progressively thins and steepens resulting in myopia, irregular astigmatism, and loss of corrected distance visual acuity (CDVA). Furthermore, it has been established that attempted corrections of high myopia/hyperopia induce more higher order aberrations, affecting vision quality and creating problems such as glare, halos, and ghost imaging.

Phakic intraocular lens implantation does not affect the shape and central thickness of the cornea and has the advantage of being potentially reversible. In comparison to clear lens extraction, PIOL implantation preserves accommodation and, as a result, is a better solution for younger patients. Phakic intraocular lens implantation carries risks such as cataract formation, inflammation and infection, decentration, and retinal detachment especially when treating high myopia.

Currently, three types of refractive lenses are used for correcting refractive errors: anterior chamber, iris-fixated, and posterior chamber. Two types of posterior chamber phakic refractive lenses are available for the correction of high myopia and hyperopia—Implantable Collamer Lens (Visian ICL; STAAR Surgical, Monrovia, California) and Phakic Refractive Lens (PRL; Carl Zeiss Meditec, Jena, Germany). The latter is made of silicone with a high refractive index (1.46), which allows its ultra-thin design. The PRL is not supported in the
sulcus angle, but due to its hydrophobic material and aqueous fluid dynamics, it theoretically should avoid contact with the crystalline lens, even during accommodation. Because no true centration is achieved during implantation, minor rotation of the lens might occur during the follow-up period. One- and 2-year clinical results of PRL implantation suggest that it is efficient and predictable for the treatment of high myopia and hyperopia. However, longer follow-up is mandatory to evaluate its safety and stability.

The purpose of our study was to evaluate the long-term efficacy, predictability, and safety of PRL implantation in highly myopic eyes. To our knowledge, this is the longest follow-up of PRL implantation to be reported in the literature.

**PATIENTS AND METHODS**

One hundred forty-three myopic eyes of 82 patients were treated with PRL implantation by the same surgeon (I.G.P.). Mean patient age was 28.7±6.1 years (range: 18 to 45 years). Preoperative evaluation included cycloplegic refraction in spherical equivalent, uncorrected distance visual acuity (UDVA), CDVA, intraocular pressure (IOP), slit-lamp microscopy, pupil size measurement under scotopic conditions, white-to-white corneal diameter measurement with the use of a caliper, dilated funduscopy, and A-scan ultrasonography (Axis-II; Quantel Medical, Clermont-Ferrand, France).

Exclusion criteria were age <18 years, previous intraocular surgery, anterior chamber depth <3 mm, glaucoma, cataract, and active ocular infection.

Each patient was informed about the nature of the procedure, possible outcomes and current clinical experience, and gave written consent according to the Declaration of Helsinki and institutional guidelines. Institutional review board/ethics committee (University of Crete) approval was obtained.

Lens power calculations were based on the preoperative cycloplegic spherical equivalent, average keratometric power, anterior chamber depth calculated with use of A-scan ultrasonography, and target postoperative refraction, and were based on the manufacturers’ nomogram. The model of the myopic PRL implanted was based on the horizontal white-to-white diameter. The two PRL models available are the PRL 101, with a length of 11.3 mm for a white-to-white diameter ≥11.3 mm, and the PRL 100, with a length of 10.8 mm for a white-to-white diameter between 10.5 and 11.3 mm.

**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 corneal temporal incision made with a diamond knife. The anterior chamber was filled with a low-viscosity viscoelastic agent.

Lenses were inserted with the use of special forceps. The haptics of the lens, one after the other, were placed under the iris. At the end of the procedure, a surgical iridectomy was performed with the use of a vitreotome in 76 eyes, whereas 2 YAG-laser iridotomies were performed 1 week before the procedure in 67 eyes.

Patients remained in the hospital on the day of surgery, as they were closely monitored during the first 24 hours for IOP increase. Acetazolamide was administered immediately after surgery. Patients were discharged the following day, and topical antibiotic-corticosteroid drops (tobramycin 0.3%-dexamethasone 0.1%, TobraDex; Alcon Laboratories Inc, Ft Worth, Texas) were prescribed four times daily for 15 days.

**STATISTICAL ANALYSIS**

Statistical analysis was performed using the paired Student t test and Wilcoxon signed rank non-parametric test (SPSS statistical software; SPSS Inc, Chicago, Illinois) in accordance with data normality test. Test for normality was performed using the Kolmogorov-Smirnov test. Results are presented as mean±standard deviation. P values <.05 were considered statistically significant.

**RESULTS**

Mean follow-up after PRL implantation was 3.8±1.7 years (range: 1 to 6 years). Approximately 68.5% of eyes (98/143) had ≥2 year follow-up after PRL implantation. The term “last follow-up” refers to the last reported examination for each eye in the entire cohort.

**Efficacy**

Mean logMAR UDVA significantly improved from counting fingers preoperatively in all eyes to 0.13±0.87 (range: 0.70 to −0.18) at 2-year follow-up (n=62) to 0.17±0.15 (range: 0.54 to −0.06) at 6-year follow-up (n=34) (P<.001) (Fig 1).

Mean logMAR CDVA also improved from 0.19±0.19 (range: 1.00 to −0.08) to 0.07±0.10 (range: 0.30 to −0.10) at 6 years (P<.001). Compared to the preoperative value, 73.5% of eyes (25/34 eyes) gained 1 to 4 lines of CDVA at 6 years postoperatively. Also, compared to the preoperative value, at last follow-up, 57.3% of eyes (82/143 eyes) gained 1 to 4 lines of CDVA (Fig 2). Approximately 8% of eyes lost 1 or 2 lines of CDVA at last follow-up. This loss of lines is presumably not correlated to the PRL implantation.
tion, as those patients were high myopes who developed myopic retinopathy during the follow-up period, which resulted in deterioration of visual acuity.

**STABILITY**

Refractive results remained relatively stable, with a slight change from −0.35 at 2 years to −0.45 at 6 years (Fig 3).

**PREDICTABILITY**

A statistically significant reduction was noted in the cycloplegic spherical equivalent from −14.08 ± 4.00 D (range: −24.88 to −4.75 D) preoperatively to −0.45 ± 0.62 D (range: −1.00 to 1.00 D) 6 years postoperatively (P < .001). At 6 years, 67.6% (23/34) and 91.1% (31/34) of eyes were within ±0.50 and ±1.00 D of target refraction, respectively (Fig 4).

**COMPlications**

No eye presented signs of cataract over 6-year follow-up. During surgical iridectomy with the probe of a vitreotome, 3 eyes experienced damage of the anterior capsule of the crystalline lens with no further consequences. In 14 (~10%) eyes, a statistically significant increase in IOP was found during the first month postoperatively. Intraocular pressure returned to preoperative levels at 3 months (6 patients were corticosteroid responders). One eye had pigment dispersion, high IOP, and PRL extraction 3 years postoperatively due to reverse PRL implantation (ie, the lens was implanted upside down). One eye experienced severe PRL decentration and subsequent extraction 3 years postoperatively (Fig 5).

**DISCUSSION**

In the current study, we evaluated the long-term
results of posterior chamber PRL implantation in highly myopic eyes. The PRL\textsuperscript{10} design used in our study is an improved version of a 1987 Fyodorov\textsuperscript{11} prototype made of silicone.

Six years postoperatively, efficacy, safety, stability, and predictability were adequately proven. At last follow-up, approximately 57\% of eyes gained 1 to 4 lines of CDVA whereas mean UDVA improved significantly and mean cycloplegic spherical equivalent refraction was significantly reduced. Our results are similar in respect to other posterior chamber lenses.\textsuperscript{12-18}

A slight difference is present in the predictability results of our patient series in comparison with the US Food and Drug Administration clinical trials of the ICL, as reported in the 2- and 3-year results.\textsuperscript{17,18} Predictability results with the ICL seem better, but this may be mainly attributed to the difference in the preoperative spherical equivalent refraction in both groups. In our study, mean spherical equivalent refraction was approximately $-14.00$ D compared to $-10.00$ D in the ICL group. Because high myopes do not always provide accurate refractions, this might influence the final predictability result.

A small percentage (~8\%) of our patients lost lines of CDVA at last follow-up (see Fig 2). This finding could be attributed to the myopic retinopathy that patients developed due to high myopia and is probably not correlated to the PRL implantation.

Regarding complications, those that were encountered in our study are similar to the complications included in the report of the American Academy of Ophthalmology.\textsuperscript{19} In our study, only one PRL extraction 3 years after the original implantation was performed due to lens decentration and one was performed due to pigment dispersion and high IOP caused by reverse PRL implantation. The remaining complications, such as postoperative IOP increase, were managed without the need for further surgical intervention.

No eye experienced luxation in the vitreous. Dislocation of the PRL in the vitreous cavity is a potentially severe complication,\textsuperscript{20-22} which can occur in high myopes, especially in cases with previous unrecognized ocular trauma or intraoperative manipulations resulting in spontaneous PRL decentration. The cases reported in the literature suggest that PRL rotation causes excess pressure against the zonules.\textsuperscript{20-22} Pars plana vitrectomy and removal of the PRL are essential to manage this serious complication.

An important limitation of our study is the lack of information regarding endothelial cell loss after PRL implantation. Other studies mention inevitable endothelial cell loss during posterior chamber PIOL implantation, which varies between 2.1\% and 7.6\%.\textsuperscript{23,24} After ICL implantation, a decrease of endothelial cells (12.3\%) has been reported, but stability in size and morphology has been noted 4 years postoperatively.\textsuperscript{25}

Long-term results suggest that PRL implantation is an effective, predictable, stable, and safe method for the treatment of high myopia.

\textbf{AUTHOR CONTRIBUTIONS}

Study concept and design (D.M.P., M.I.K.); data collection (S.I.P., M.A.G.); analysis and interpretation of data (G.D.K., I.G.P.); drafting of the manuscript (D.M.P., S.I.P., M.A.G.); critical revision of the manuscript (G.D.K., M.I.K., I.G.P.); statistical expertise (S.I.P.); supervision (G.D.K., M.I.K., I.G.P.)

\textbf{REFERENCES}


\textbf{Figure 5.} Slit-lamp photograph showing PRL decentration.