INTRODUCTION

Implantation of phakic refractive lenses PRL® (Phakic Refractive Lens; IOLTech/Carl Zeiss Meditec AG, Jena, Germany) is one of the options available for the correction of moderate to high myopia, although there are few reports on the outcomes. In those cases where a corneal laser-assisted surgical procedure is not indicated because of the great amount of tissue to be removed, small optical zones or the possibility of the worsening of the image quality due to the alteration in the corneal shape, posterior chamber refractive lenses implanted in selected patients represent one of the best options of management for many refractive surgeons1. The correction of high ametropia with corneal laser-assisted procedures may result in ectasia, regression, low image quality and visual discomfort particularly under mesopic conditions. Implantation of phakic

ARTICLE

Phakic Refractive Lens to Correct Moderate to High Myopia Five Years after Implantation

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PURPOSE: To assess refractive and visual outcomes five years after surgical implantation of silicone phakic refractive lenses (PRL®, Zeiss/Meditec. Jena. Germany) in moderate to high myopia.

METHODS: A prospective clinical study involving 35 eyes of 20 patients (8 men, 12 women, mean age 31.83±8.87 years) implanted with PRLs was conducted. Uncorrected visual acuity (UCVA), best-distance-corrected visual acuity (BDCVA), objective and subjective refraction and intraocular pressure (IOP) were assessed before and after surgery. Mean time post-surgery was 57.34±9.24 months. Mean preoperative spherical equivalent was -10.25 D±3.19 (range -7.25 to -22.50 D). Target refraction was emmetropia in all eyes.

RESULTS: Preoperative UCVA was 2.40±0.19 logMAR and mean preoperative BDCVA was 0.19±0.05 logMAR after surgery (P<0.001). Postoperative UCVA was 0.3 logMAR or better in 34 eyes (97.14%) and 0.1 logMAR or better in 24 eyes (68.57%). Mean BDCVA changed from 0.19±0.05 to 0.2±0.09 logMAR after surgery (P<0.001). After surgery BDCVA was 0.2 logMAR or better in 34 eyes (97.14%) and 0.1 logMAR or better in 30 eyes (85.71%). Overall efficacy index was 1.09. Fourteen eyes gained more than 2 lines of BDCVA. Safety index was 1.29. After surgery, all eyes were within ±1.00D and 32 (91.43%) within ±0.50D of targeted refraction.

CONCLUSIONS: Present results suggest correction of moderate to high myopia by means of PRL implantation safe, effective and predictable after five years. Candidate selection seems crucial for avoiding the presence of undesirable complications such as zonular dehiscence or cataract.

KEYWORDS: Phakic lens, myopia, mid-term assessment, visual performance.

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intraocular lenses (pIOL) should not alter corneal shapes significantly, is potentially reversible, and preserves accommodation, thus becoming a suitable option for younger patients.

Anterior chamber pIOL appeared as another option for correcting high refractive defects maintaining the crystalline lens. Currently there are mainly two types of anterior chamber pIOLs depending on their fixation to intraocular structures: angle-fixated and iris-supported models.

The PRL has been developed since 1987 and was conceived to be implanted in the posterior chamber through a clear self-healing corneal incision. The third generation model of PRL floats in the posterior chamber without contacting the crystalline lens and it centres due to its special design. It moves forward during accommodation and allows the normal circulation of aqueous humour in the posterior chamber. Implantation requires a learning process and adequate patient selection in order to avoid potential complications. Trying to get a lighter and more gas and nutrient permeable material, a small quantity of collagen (0.2%) was added to the first silicone model, thus improving biocompatibility.

Until now, PRL lens has shown promising refractive results in short-term follow-up series, but there are still some concerns with regards to the long-term safety. Pigmentary dispersion due to the mechanical abrasion of the posterior iris, secondary pigmentary glaucoma, posterior lens dislocation, pupillary block and lens opacification are some potential complications after lens implantation.

The aim of the present study is to assess visual performance five years after implantation of PRL pIOLs.

PATIENTS AND METHODS

The present prospective study included 35 eyes of 20 patients in whom LASIK was contraindicated and were treated with PRL implantation by the same surgeon (J.B-M). Inclusion criteria required subjects to be myopic in 1 or both eyes and to be between 18 and 50 years of age. Exclusion criteria for corneal refractive procedures included postsurgical central keratometry lower than 36 D and residual corneal width lower than 400µm after the programmed laser ablation. The exclusion criteria for PRL™ implant were being younger than 18 years of age, previous intraocular surgery, anterior chamber depth lower than 3 mm, history of glaucoma, uveitis, crystalline lens opacity, peripheral retinal lesions not prophylactically treated, unreal expectations, scotopic pupillary block and lens opacification are some potential complications after lens implantation.

Written consent was signed by all patients before procedures according to the Declaration of Helsinki. Full ethical approval was obtained from the Medimar International Hospital Ethics Committee.

All patients completed a preoperative ophthalmologic examination including uncorrected visual acuity (UCVA), best distance-corrected visual acuity (BDCVA), using LogMAR acuity charts under photopic conditions (85 cd/m²), objective, subjective and cycloplegic refractions, assessment of binocular motor and sensorial status, slit-lamp biomicroscopy, Goldmann applanation tonometry, pupil size measurement under scotopic conditions, corneal topography, ultrasonic pachymetry (DHG 5100, DHG Technology Inc, Exton, Pa), white to white distance, axial length and anterior chamber depth through partial coherence interferometry (IOLMaster, Carl Zeiss/Meditec, Germany), and dilated funduscopy.

One week prior to the procedure two basal peripheral iridotomies were performed to avoid blockage by the PRL haptics.

Mean patient age was 31.83 ± 8.87 years old (range 19 to 49). 40% of patients were male and 60% were female. Mean preoperative spherical equivalent was -10.25 ± 3.19 D (range -7.25 to -22.50 D). The mean preoperative cylinder was -1.5 ± 0.7 D (range 0 to -3 D). Target postoperative refraction was emmetropia in all eyes. Preoperative uncorrected visual acuity (UCVA) was 2.40 ± 0.19 LogMAR (range 3 to 2.08) and mean best corrected preoperative visual acuity (BCVA) was 0.19 ± 0.05 LogMAR (range 0.30 to 0).

Lens power calculation was performed using IOL Master optical biometer and subjective and cycloplegic refraction values. In all cases horizontal white to white distance was up to 11.3 mm and the chosen model to implant was PRL™ 101 therefore, with an optical zone that varies from 4.5 to 5 mm depending of the dioptric power. The mean power of the PRL™ lens was -8.25 ± 1D (range -6 to -16 D).

Mean follow-up time was 57.34 ± 9.24 months (SD) (range 48 to 74 months).

PRL description

The PRL™ (Carl Zeiss/Meditec AG, Germany) pIOL to correct mild to high myopia is a monofocal and biconcave spherical lens (fig. 1). It has a single-
piece plate design and is made of medical-grade silicone with a high refractive index of 1.46 and a relative density of 0.99. Though, the material is ultrathin, elastic and hydrophobic. The PRL has spherical, thin and flexible haptics in order to adapt itself to the anatomy and dynamic changes of the eye. The refraction range of the myopic implant is from -3 D to -20 D with 0.5 D increments. Its optic diameter varies from 4.5 to 5 mm depending on refractive power. There are two models for myopia: PRL™ 100 with a total diameter of 10.8 mm and PRL™101 with a total diameter of 11.3 mm. In order 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.

Surgical Technique

All PRL® pIOLs were implanted through a 2.75 mm clear corneal tunnel incision made with a diamond knife on the steeper axis to minimize postsurgical astigmatism. In all cases peribulbar anaesthesia was administered and pupillary dilation was induced with a combination of tropicamide and phenylephrine 10% every 15 minutes half an hour previous to the procedure. Iodine solution 5% was instilled on the eye ten minutes before the operation. A paracentesis was made 60° to 90° clockwise from the main incision and the anterior chamber was filled with 1% sodium hyaluronate lifting the pupillary border to ease the proper settlement of the lens. In all cases the folding forceps provided by the manufacturer was used to introduce the lens. The lens wings were settled very gently with a spatula under the iris. Finally, the surgeon proceeded to retrieve the viscoelastic material using the irrigation-aspiration (IA) system. The pupil was constricted with acetylcholine and the procedure finished with the injection of cephuroxime in the anterior chamber. Routinely we prescribed Diamox 250 mg at the end of the surgery, and the eyes remained patched for at least six hours.

A combination of topical steroid and antibiotic was prescribed four times daily for a week.

Postoperative follow up

Patients were examined on the day after and then scheduled to return 1, 3 and 6 weeks after the surgery. Regular examinations every six months were recommended during the first year and then every year. The visits involved a complete ophthalmological examination including visual acuity, subjective refraction, binocular status, slit-lamp microscopy, applanation tonometry and fundus examination under pharmacological pupil dilation using tropicamide and phenylephrine.

Statistical analysis

Power vector notation was used for the analysis of refractive outcomes. Using this notation any spherocylindrical refractive error can be expressed by 3 dioptric powers: M, J0 and J45; Being M a spherical lens equal to spherical equivalent of the given refractive error, and J0 and J45 two Jackson crossed cylinders equivalent to the conventional cylinder. These numbers are the coordinates of a point in a three-dimensional dioptic space, being the power vector the vector from the origin of this space to the point (M, J0, J45). Consequently, the length of this vector is a measure of the overall blurring strength B of a spherocylindrical refractive error. Manifest refractions in conventional script notation [S (sphere), C (cylinder) x ϕ (axis)] were converted to power vector coordinates and overall blurring strength (B) by the following formulas: M = S + C/2; J0 = (–C/2) cos (2 ϕ); J45 = (–C/2) sin (2 ϕ); and B = (M2 + J02 + J452)1/2.

Data analysis was performed using SPSS for Windows, version 14.0 (SPSS Inc., Chicago, IL). Normality was checked by the Kolomogorov-Smirnov test, and a t-test was performed to compare outcomes. Differences were considered to be statistically significant when the p value was <0.01.

RESULTS

Visual Acuity

The mean UCVA changed from 2.40 ± 0.19 LogMAR before surgery to 0.11 ± 0.09 LogMAR (range -0.08 to 0.52) (about 20/25) after surgery (P<0.001). Postoperative UCVA was 0.3 LogMAR (about 20/40) or better in 34 eyes (97.14%) and 0.1 LogMAR (about 20/25) or better in 30 eyes (85.71%).

The mean BCVA changed from 0.19 ± 0.05 LogMAR before surgery to 0.2 ± 0.09 LogMAR (range -0.08 to 0.30) (about 20/20) after surgery (P<0.001). After surgery BCVA was 0.02 LogMAR (about 20/32) or better in 34 eyes (97.14%) and 0.1 LogMAR or better in 30 eyes (85.71%).

Efficacy

The overall efficacy index (given by mean postoperative UCVA/ mean preoperative BCVA) was 1.09 (see fig. 2). No eyes lost 2 or more lines of BCVA, 1 eyes lost 1 line, 9 eyes did not change BCVA after surgery, 4 eyes gained 1 line, 7 eyes gained 2 lines and 14 eyes gained more than 2 lines of BCVA (see fig. 3).

Safety

The safety index (given by the ratio of postoperative and preoperative BCVA) was 1.29.
Refractive Change

Table 1 shows a summary of distribution of manifest refractive error before and after PRL implantation, following the power vector method. There was a statistically significant reduction in the B value after surgery (P<0.001).

<table>
<thead>
<tr>
<th></th>
<th>Before</th>
<th>After</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>-12.366 ± 3.335</td>
<td>-0.107 ± 0.346</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>J0</td>
<td>0.418 ± 0.47</td>
<td>0.279 ± 0.272</td>
<td>0.07</td>
</tr>
<tr>
<td>J45</td>
<td>0.049 ± 0.348</td>
<td>0.049 ± 0.348</td>
<td>0.5</td>
</tr>
<tr>
<td>B</td>
<td>12.386 ± 3.338</td>
<td>0.550 ± 0.312</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

Data are shown as mean ± standard deviation.

Manifest refraction in conventional script notation [S (sphere), C (cylinder) × ϕ (axis)], were converted to power vectors coordinates and overall strength blur by the following formulas:

\[
M = S + C/2; \quad J_0 = (-C/2) \cos (2 \phi); \quad J_{45} = (-C/2) \sin (2 \phi); \quad B = (M^2 + J_0^2 + J_{45}^2)^{1/2}.
\]

T-test revealed non statistically significant differences in either power vector component after the follow up period (P=0.21 for M; P=0.38 for J₀ and P=0.28 for J₄₅). Deviation of achieved from calculated M refraction was calculated. After surgery, all eyes were within ±1.00D of the desired refraction (fig. 4; R=0.99). Thirty-two (91.43%) eyes were within ±0.50D of the targeted refraction.

Intraocular Pressure (IOP)

The mean preoperative IOP was 14.17 ± 2.16 mmHg (range from 10 to 20). After PRL implantation the mean IOP was 14.4 ± 2.55 mmHg (range from 10 to 20). Though, there is no clinical significant differences between both values of IOP (p=0.611).

One case of acute IOP increase related to viscoelastic retention the day after the surgery resolved with the adequate systemic and topical treatment.

DISCUSSION

Correction of moderate to high myopia still remains a challenge for refractive surgeons. Laser-assisted corneal procedures have several disadvantages, particularly on the integrity of the corneal structure, as well as the decrease in image quality due to the induction of higher order aberrations, particularly spherical aberration. pIOLs came up as an option to leave the cornea unaltered. Anterior chamber pIOLs provide good refractive results but the incidence on endothelial cell density and subclinical and chronic inflammation is a big concern9. Posterior pIOLs have risen as an excellent choice giving excellent refractive results 3, 5, but there is still some concern due to the location where the lens has to be implanted since there are
potential adverse effects on the integrity of the intraocular structures.

The PRL pIOL has shown very promising refractive results in short-term follow-ups3-7,10 but longer term follow-ups are still necessary due to the related potential complications.

In the present study the implantation of PRL is reported as a safe, secure and predictable procedure to correct moderate to high myopia in terms of refractive and visual outcomes. The PRL showed accurate correction of the intended refractive change. However, it must be taken into account that endothelial cell count, contrast sensitivity or high order aberrations have not been assessed in the present report. Other authors have studied the impact of PRL lenses on the endothelial cell density1 and in the root mean square (RMS) wavefront error10 showing no negative influence. On the other hand some studies have demonstrated a significant improvement in contrast sensitivity for all frequencies and across all lighting conditions11.

It has been reported a lens rotation of 10° or more in the majority of the eyes studied, but only during the first year after implantation12. The rotation of the lens could indicate the right haptic position on the zonules without capture in the sulcus, the floating design is not capable of providing an accurate correction for the astigmatism and it would be therefore necessary to perform a further corneal refractive procedure (bioptics), or implanting a toric implantable collamer lens (ICL; STAAR Surgical, Monrovia, California) as primary procedure instead. Koivula et al6 established stability in the majority of the eyes studied, but only during the first year after implantation12. The rotation of the lens probably due to a longer ciliary sulcus diameter than the length of the lens. None of them required any additional surgery.

The recommended diameter of the lens is dependent on the white to white distance, which cannot be assumed as equivalent to the ciliary sulcus diameter20. It would be desirable to measure it preoperatively in order to choose the adequate size of the lens21. Appropriate candidate selection is a likely reason for the good outcomes reported in the present study.

The present results show no significant differences between preoperative and long term postoperative IOP values. This is probably because all the risk factors for an increased IOP like topical steroid drug treatment, retained viscoelastic or inflammatory cells and membranes in the anterior chamber had already disappeared by the time of measurement. On the other hand, it is mandatory to assure the permeability of the iridotomies in every follow-up visit.

From the results reported in the present study, correction of moderate to high myopia by means of PRL implantation seems safe, efficient and predictable. Candidate selection is likely to be the main reason for the remarkably positive outcomes reported. Future studies evaluating the same parameters on a different cohort of patients and by different surgeons would be desirable to corroborate these results, as well as longer term results and larger samples of eyes.

REFERENCES


