

ORIGINAL ARTICLE

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Angle-supported intraocular-lens implantation for the correction of moderate to high myopia

ABSTRACT

Objectives

This study evaluated the efficacy and safety of an angle-supported phakic intraocular lens (PIOL) for the treatment of moderate to high myopia.

Methods

This is a case series of 13 eyes of 8 patients with moderate to high myopia that underwent implantation of an acrylic, angle-supported PIOL. The main outcome measures were manifest refraction, uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), endothelial-cell count (ECC), intraocular pressure (IOP), and adverse events.

Results

The mean spherical equivalent (SE) improved from -11.79 ± 4.12 diopters (D) preoperatively to -0.08 ± 0.58 D postoperatively ($p = 0.000$), UCVA from 0.016 ± 0.015 to 0.79 ± 0.29 postoperatively ($p = 0.000$), and BCVA from 0.76 ± 0.33 to 0.86 ± 0.27 ($p = 0.017$). The ECC slightly decreased from 3033.57 ± 367.71 cells/mm² preoperatively to 2947 ± 279.86 cells/mm² (2.8% loss) postoperatively ($p = 0.400$). The mean preoperative IOP was 16.36 ± 3.53 mm Hg while the mean three-month postoperative IOP was 15.72 ± 4.15 mm Hg ($p = 0.659$). Two (15%) eyes experienced transient postoperative IOP rise on the day of the surgery, which resolved by postoperative day 1 using topical timolol maleate. The mean follow-up was 2.54 ± 1.39 months (range, 1 to 5 months).

Conclusion

Acrylic angle-supported phakic intraocular lens (PIOL) implantation is an effective and safe method of correcting moderate to high myopia.

Keywords: Angle-supported phakic intraocular lens, Refractive surgery, Endothelial-cell count, High myopia

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MYOPIA is the predominant refractive error among Southeast Asians. In a recent study, the overall prevalence of myopia was 11%, with high myopia (at least -6.00 D) at 0.2%. The prevalence of hyperopia, astigmatism, and anisometropia was 1.4%, 8.6%, and 0.6%, respectively.¹

Laser in-situ keratomileusis (LASIK) is a highly successful method for myopia correction but the range of treatment is limited by available corneal thickness. In addition, LASIK may produce sight-threatening complications, including severe dry eye, microbial keratitis, corneal ectasia requiring keratoplasty, diffuse lamellar keratitis, and epithelial ingrowth.²

Phakic intraocular lens implantation (PIOL) is an alternative technique for correction of refractive errors outside the range of corneal refractive surgical techniques. PIOL offers accurate and predictable correction of moderate to high myopia^{3,4} because full correction for a high myope can be built into the power of the lens and the accuracy is not dependent on corneal-wound healing and reshaping or removal of corneal tissue. The use of PIOL avoids complications associated with refractive laser.

The safety of the Acrysof acrylic angle-supported PIOL has been assessed in several clinical studies. In a seven-year cumulative analysis of complications after implantation of angle-supported PIOL, it appeared to be well tolerated by the corneal endothelium with a low rate of complications.³ Reported complications and long-term safety concerns included endothelial-cell loss, cataract formation, secondary glaucoma (pupillary block, pigment dispersion), iris atrophy (pupil ovalization), IOL dislocation, halos, glare, high intraocular pressure, and retinal detachment.^{3,6}

Various generations of angle-supported PIOL have been developed through time utilizing significant technological improvements. The Acrysof angle-supported PIOL (Cachet, Alcon Surgical, Fort Worth, TX, USA) is a recently introduced design that utilizes a foldable hydrophobic acrylate and delivered using an existing IOL injecting system. Its haptics allow compression within the angle to avoid excessive force on angle tissue, pupil ovalization, and improve IOL stability.

This study evaluated the efficacy and safety of Acrysof angle-supported PIOL for the treatment of moderate to high myopia.

METHODOLOGY

Thirteen eyes of 8 patients underwent angle-supported PIOL implantation at Asian Eye Institute (Makati, Philippines) from June 2009 to March 2010.

Included into the study were patients who were at least 21 years old with moderate to high myopia (range, -7 D to -16.5 D). Excluded were eyes with an anterior-chamber

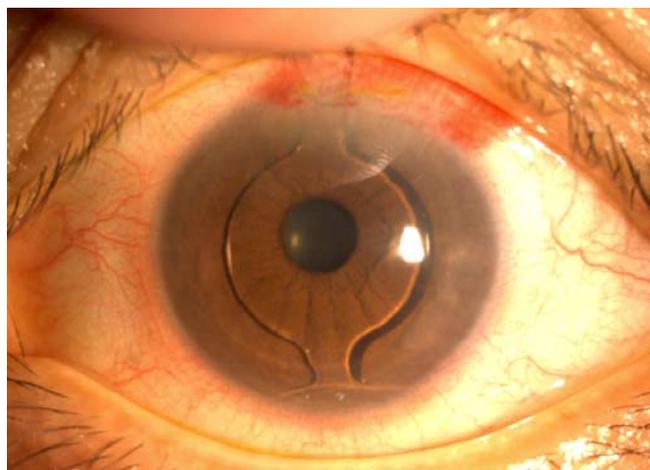


Figure 1. Slitlamp photograph demonstrating an acrylic, angle-supported phakic intraocular lens within the anterior chamber. Note the presence of a subconjunctival hemorrhage in the superior area where the limbal wound was created.



Figure 2. Slitlamp photograph demonstrating phakic intraocular-lens haptic supported by the angle.

depth less than 3.2 millimeters (including corneal thickness), irregular or abnormal anterior-chamber anatomy, mesopic pupil diameter greater than 7 millimeters, non-qualifying preoperative endothelial-cell density according to age, preoperative astigmatism greater than 2.0D, stable manifest refraction of less than 1 year, chronic or recurrent anterior- or posterior-segment inflammation, existing cataract, retinal conditions or predisposition to retinal conditions, history of ocular trauma or intraocular surgery, and history of glaucoma and ocular hypertension. None of the eyes included previously received any eye medication. The patients gave their informed consent before initiation of any surgical procedure.

All underwent detailed history taking. Preoperative eye examination included assessment of uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA),

manifest refraction, slitlamp biomicroscopy, applanation tonometry, dilated-fundus examination, and optical coherence tomography (OCT). Endothelial-cell counts were determined using specular microscopy (CellChek XL, Konan Medical Instruments, Hyogo, Japan).

The PIOL power, model, and size needed to correct the refractive error were selected preoperatively. The PIOL power was determined using the online Acrysof Phakic Lens Calculator (www.phakiciolcalculator.com) which is based on the Van der Heijde equation. The PIOL size was based on the white-to-white diameter measured as the width of the cornea from the nasal limbus to the temporal limbus using an optical biometer (IOLMaster, Zeiss Meditec, Carlsbad, Germany).

After aseptic preparation, the pupil was constricted using topical pilocarpine 2% (Isoptocarpine, Alcon Laboratories, Fort Worth, TX, USA) to protect the crystalline lens from potential contact with the PIOL. Proparacaine hydrochloride (Alcaine, Alcon Laboratories, Fort Worth TX) was instilled to anesthetize the eye. The white-to-white diameter was confirmed using intraoperative caliper. Side ports were created using a 15-degree blade. Ophthalmic viscoelastic device (OVD) consisting of sodium chondroitin sulfate 4% and sodium hyaluronate 1.65% (Provisc, Alcon Surgical, Fort Worth, TX, USA) was used to form and maintain the anterior chamber. Corneal tunnel incisions on the steep axis were created using a 3.4 millimeters keratome. The Acrysof Cachet PIOL, previously loaded into the IOL delivery-system cartridge, was injected midpupil using an IOL injector (Monarch, Alcon Surgical, Fort Worth, TX, USA). The distal haptics were positioned on the angle opposite the entry wound, the optic was delivered midpupil, and the proximal haptics was initially delivered just outside the incision and subsequently manually inserted into the anterior-chamber angle one haptic at a time using a dialing hook. All 4 haptics were positioned in the anterior-chamber angle. The remaining OVD was flushed out of the anterior chamber using a syringe filled with balanced saline solution. Vancomycin 5 mg was injected intracamerally, and lens position and wound integrity were inspected. No sutures were used. Postoperative medications consisted of gatifloxacin (Zymar, Allergan, Irvine, CA, USA) and prednisolone acetate (Pred Forte, Allergan, Irvine, CA, USA) eye drops applied 4 times daily for 4 weeks. All surgeries were performed by two surgeons (HSU and PCU).

The eyes were examined 4 hours, 1, 7, 30 days after surgery, then quarterly. The following examinations were performed during the follow-up visits: UCVA, BCVA, slitlamp biomicroscopy, applanation tonometry, and dilated-fundus examination. The lens position was assessed at each visit. UCVA, BCVA, manifest refraction,

Table 1. Refractive, corneal endothelial cell, and intraocular pressure outcomes following PIOL implantation in eyes (N = 13) with moderate to high myopia.

Parameters	Preoperative	Postoperative	p
	Mean		
Spherical equivalent (D)	-11.79 ± 4.12	-0.08 ± 0.58	0.000
UCVA ¹	0.016 ± 0.015	0.79 ± 0.29	0.000
BCVA ²	0.76 ± 0.33	0.86 ± 0.27	0.017
Endothelial-cell count (cells/mm ²)	3033.57 ± 367.71	2947.00 ± 279.86	0.400
Intraocular pressure (mm Hg)	16.36 ± 3.53	15.72 ± 4.15	0.659

¹Uncorrected visual acuity

²Best-corrected visual acuity

and specular microscopy were repeated on the first-month visit.

Statistical analysis was performed using the SPSS 17.0 for Windows (SPSS, Chicago, IL, USA). Descriptive analysis was calculated for the variables and measured outcomes. Paired *t*-test was performed, with the probability level at <0.05 considered statistically significant, to compare baseline preoperative and postoperative values.

RESULTS

Mean patient age was 34.54 ± 10.5 years (range, 21 to 47 years) and mean postoperative follow-up period was 2.54 ± 1.39 months (range, 1 to 5 months). Mean preoperative spherical equivalent (SE) was -11.79 D (range, -18 to -6.75 D) and mean postoperative SE was -0.08 D (range, -1 to 0.88 D). The average change in SE was 11.71 D (*p* = 0.000) (Table 1).

Mean preoperative UCVA was 0.016 (range, 0.01 to 0.05) and mean postoperative UCVA was 0.79 (range, 0.2 to 1.0). The average change in UCVA was +0.77 (*p* = 0.000) (Table 1). The preoperative UCVA was counting fingers in 11 eyes (85%) and 20/400 in 2 eyes (15%). The postoperative UCVA was 20/40 or better in 11 eyes (85%) and 20/20 was achieved in 7 eyes (53%).

Mean preoperative BCVA was 0.76 D (range, 0.05 to 1.0) and mean postoperative BCVA was 0.86 D (range 0.2 to 1.0). The average change in BCVA was +0.10 (*p* = 0.017). Preoperative BCVA was 20/20 in 5 eyes (38%) and postoperative BCVA was 20/20 in 9 eyes (76%).

Mean preoperative endothelial cell count (ECC) was 3033.57 cells/mm² and the mean postoperative ECC was 2947 cells/mm² (*p* = 0.400) (Table 1). The mean change in ECC was 2.8%. Mean preoperative intraocular pressure (IOP) was 16.36 mm Hg (range, 11 to 20 mm Hg)

and mean postoperative IOP was 15.72 mm Hg (range 10 to 22 mm Hg) ($p = 0.659$) (Table 1).

Two eyes had increased IOP 1 day postoperatively (30 and 36 mm Hg), which returned to normal the next day after treatment with timolol maleate eye drops applied twice daily. No other adverse events were observed.

DISCUSSION

Acrylic, angle-supported, PIOL implantation is a novel alternative to laser refractive surgery and refractive-lens exchange. PIOL produces acceptable refractive results for moderate and high myopes while preserving accommodative ability. The visual outcomes were excellent with 60.8% achieving an UCVA of 20/40 or better in a report by Alio⁵ and 99.4% in a report by Perez-Santoja.⁷ The efficacy and predictability in correcting myopia in this series were similar to those reported by other authors.^{4,7,9-11} Results showed significant reduction of high myopia, stable refractive outcomes, and marked improvement in UCVA and BCVA after surgery. Fundamental requirements for achieving good visual outcomes are good surgical technique, small surgical incision, and accurate lens-power calculation. The availability of an online IOL calculator allows accurate and rapid determination of the appropriate lens power to achieve desired postsurgical refractive results.

The effects of PIOL implantation on the corneal endothelium have been reported to be insignificant over as long as a 10-year follow-up period.^{3,12} In our study, the decrease in ECC was minimal. None of our subjects suffered a cell loss of more than 12% (mean ECC loss 8.4%). These results corroborated the findings of separate studies done by Alio,⁵ and Baikoff⁷ that suggested that the Alcon Acrysof Cachet, a hydrophobic acrylic, angle-supported PIOL, may be superior to other kinds of anterior-chamber PIOLs as it appeared to be better tolerated by the corneal endothelium. A recent publication revealed that the one-year ECC loss was -4.77% in a group of 139 eyes.¹³ Three-year Alcon data revealed annualized rate of central ECC loss at -0.41 to -0.91%.¹⁴ However, long-term examinations on large numbers of eyes are needed to establish long-term safety.

Of special consideration is the accurate sizing of the PIOL. The use of inappropriate PIOL lengths may lead to PIOL instability and displacement. In a report by Coulet,⁸ 3 eyes suffered from rapid and severe postoperative endothelial-cell loss that required PIOL removal and Descemet's-membrane repair. The main risk factor identified was the implantation of oversized PIOLs that caused excessive vaulting into the anterior chamber. However, aging and accommodation may affect accurate PIOL sizing because aging changes can modify anterior-chamber internal diameters.⁵ Modern anterior-chamber

biometry methods may help improve accuracy of PIOL-size determination.

In this case series, the incidence of increased IOP that required topical IOP lowering drugs (15%) was higher than that noted in another study (7.2%). This transient increase in IOP occurring right after implantation was recognized to be related to retained OVD.⁸ Since these were initial cases, OVD may not have been removed completely but adjustments in washout techniques in subsequent patients led to the elimination of IOP rise. There were no cases of elevated IOP after the first-day postoperative visit. These findings highlight the need for careful OVD removal during surgery and close monitoring in the immediate postoperative period.

Other adverse events that occurred in other reports, such as IOL dislocation, corneal haze, secondary glaucoma, iris atrophy, cataract development, pupil ovalization, retinal detachment, and endophthalmitis,^{3,7-11} were not seen in this study. A comprehensive preoperative workup, good surgical technique, and proper loading of PIOL avoided such adverse events. Two cases were reported in another study wherein the PIOLs were implanted upside down resulting in iatrogenic cataracts.⁸ The ensuing addition of side-up indicators in the PIOL structure eliminated the risk of improper loading of the PIOL.

In conclusion, acrylic, angle-supported, PIOL implantation produces excellent, predictable, and stable refractive outcomes in moderate to high myopic eyes after a mean follow-up of 2.5 months. PIOL implantation is a safe technique that can be easily learned and requires few additional instruments for incorporation into a practice.

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