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

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## 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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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

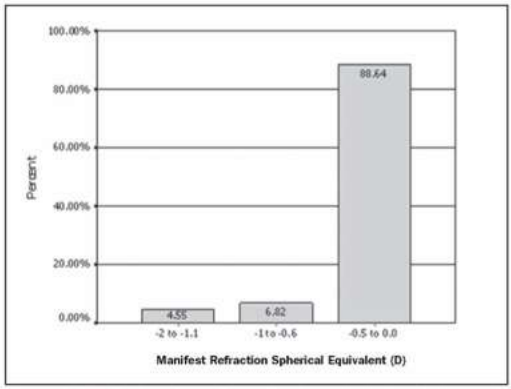



**Figure 2.** Distribution of manifest refraction spherical equivalent at 3 months postoperatively.

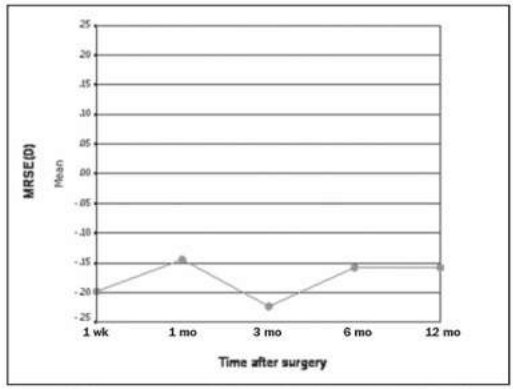



**Figure 3.** Mean manifest refraction spherical equivalent (MRSE) over time.

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

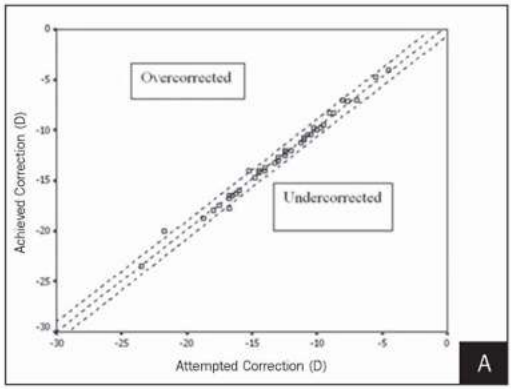
On postoperative day 1, 45 (90%) of 50 eyes had a clear cornea and 5 (10%) eyes had mild to moderate corneal edema, which resolved in 1 week. All eyes had secure wounds, deep anterior chamber, and round and reactive pupils. By the end of the first week, all eyes were quiet, with no anterior chamber cell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

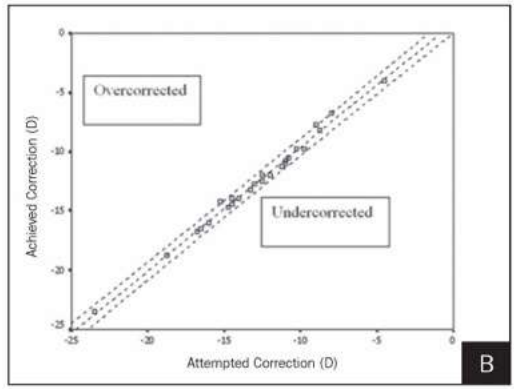
### Refractive Outcome

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

Spherical equivalent refraction at the last examination was within $\pm 0.50$ D in 44 (88%) eyes and within $\pm 1.00$ 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.



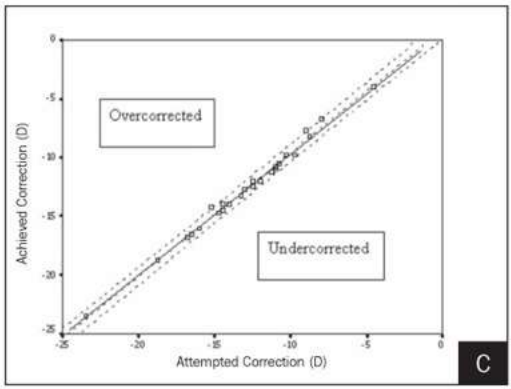




**Figure 4.** Attempted versus achieved correction (manifest refraction spherical equivalent) at **A)** 3 months, **B)** 6 months, and **C)** 12 months. Dotted lines represent ±1.00 D.

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).

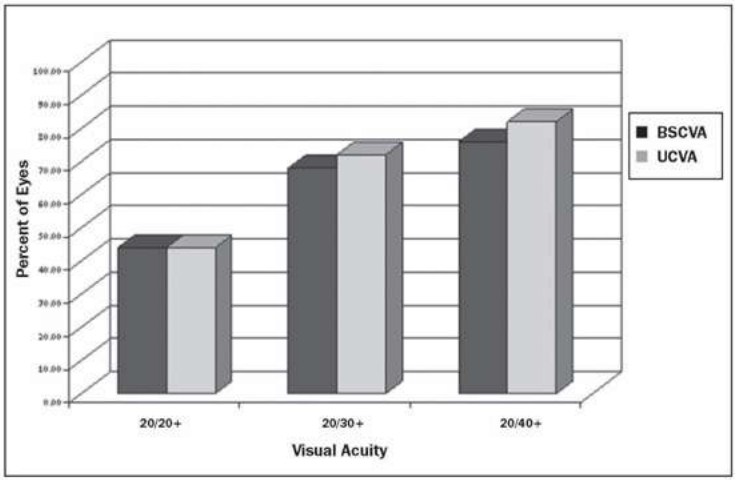



**Figure 5.** Preoperative best spectacle-corrected visual acuity (BSCVA) and postoperative uncorrected visual acuity (UCVA) at last examination.

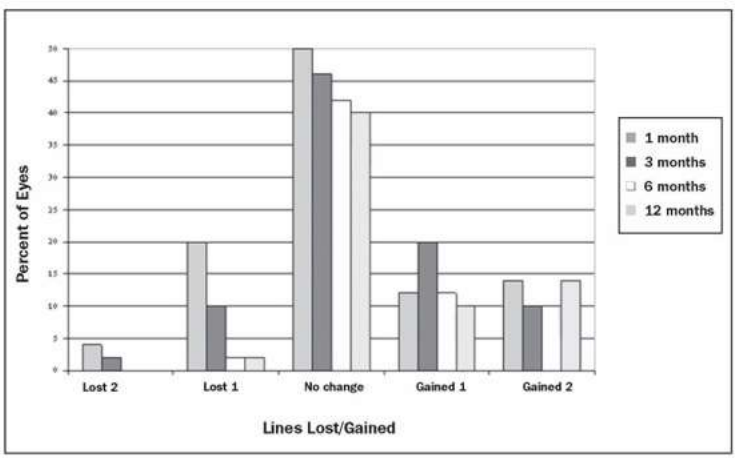



**Figure 6.** Best spectacle-corrected visual acuity at 1, 3, 6, and 12 months with loss or gain of Snellen lines.

## 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.

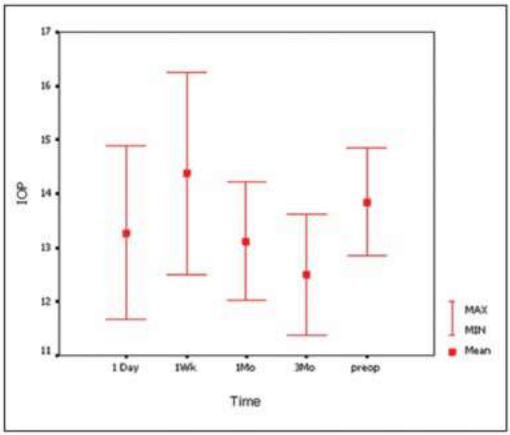



**Figure 7.** Change in mean (standard deviation) intraocular pressure (IOP).

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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