# Experience with the Artisan phakic intraocular lens in Asian eyes

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***Purpose:*** To investigate the efficacy and safety of implantation of an iris-claw phakic intraocular lens (PIOL), Artisan Myopia, in Asian eyes.

***Setting:*** Minamiaoyama Eye Clinic, Tokyo, Japan.

***Methods:*** Forty-four eyes of 32 Japanese patients and 1 Korean patient with high myopia had Artisan Myopia lens implantation to correct their refractive errors. Lens models, 5/8.5 or 6/8.5 (optic diameter/overall diameter), were chosen as standard lens model. A smaller lens model (5/7.5-Artisan Myopia Small) was implanted in eyes with corneal diameter less than 11.0 mm. Postoperative examinations were performed on 1 day, 1 week, 1 month, 3 months, 6 months, 1 year, and 2 years after surgery. Uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), manifest refraction, corneal endothelial cell counts, intraocular pressure, and complications were evaluated.

***Results:*** Artisan Myopia Small lenses were implanted in 4 eyes (9.1%) and 8.5 mm diameter lenses were implanted in 40 eyes. Preoperative UCVA (logMAR) improved from 1.57 to 0.09 at 1 month after surgery and no regression was observed thereafter. Postoperative manifest refraction was $-1.02 \pm 0.87$ D ($-3.25$ to $-0.00$ D), and within 1.0 D in 20 eyes (55.6%), within 2.0 D in 32 eyes (88.9%) at 1 month after surgery, and stable during the follow-up period. The final BCVA decreased 2 lines in 2 eyes (4.5%) due to progression of age-related cataract. No serious complications such as angle closure or progressive endothelial cell loss were observed.

***Conclusion:*** Implantation of an Artisan iris-claw PIOL implantation may be a safe and effective procedure for Asian eyes.

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Correction of high myopia by the implantation of a phakic intraocular lens (PIOL) is an attractive alternative to other types of refractive surgery that involve ablating the corneal stroma.[1–3] Artisan Myopia PIOL (OPHTEC BV, Groningen, The Netherlands) is a convex-concave iris-claw type anterior chamber phakic IOL, which includes 3 different lens models; 5.0/8.5, 6.0/8.5, and 5.0/7.5 (optic diameter/overall diameter).

The safety and efficacy of Artisan PIOLs have been recently reported in several studies.[4–10] However, most of these studies were performed in white eyes and not in Asian eyes. Darker pigmentation of the iris is usually observed in Asian eyes. The color of the iris is known to be dependent on the number and pigment content of the stromal melanocytes.[11] Pigment dispersion during surgery therefore may be greater in Asian eyes possibly leading to intraocular pressure (IOP) elevation.

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Another characteristic of Asian eyes is that the corneal diameter is reported to be significantly smaller compared with white eyes.[12,13] This difference may cause some difficulties especially related to fixation of the lens during the surgical procedure.

The Artisan PIOL were implanted for the correction of high myopia in Japanese and Korean patients and evaluated the postoperative outcome.

## Patients and Methods

*Patients*

Forty-four eyes of 33 patients (32 Japanese and 1 Korean, 16 men and 17 women, mean age 37.7 ± 8.6 years; subjective refraction, −12.8 ± 2.9 diopters [D]), who had PIOL implantation at the Minamiaoyama Eye Clinic, were enrolled in this study. Written informed consent was obtained from all patients in this study. All patients revealed no abnormal findings by routine preoperative ophthalmologic examination. All patients were excluded for laser in situ keratomileusis (LASIK) due to myopia greater than −12.0 D or insufficient corneal thickness for laser ablation (total corneal thickness was less than 450 μm, or estimated residual thickness of the stromal bed became less than 250 μm after laser ablation) or preoperative detection of mild keratoconus by videokeratography indices.[14,15] Patients with endothelial cell counts less than 1500/mm$^2$, anterior chamber depths less than 3.0 mm, abnormal iris or pupillary functions, or other eye diseases were excluded. The anterior chamber depth, defined as distance between anterior surface of the cornea and anterior surface of the lens, was evaluated by AL-2000 ultrasound (Tomey, Aichi, Japan). The corneal diameter was evaluated by Orbscan (Canon, Tokyo, Japan).

*PIOL Implantation*

Phakic intraocular lens power was calculated according to the manufacturer's instructions. The standard protocol was to use the 6/8.5 lens model. However, the 6/8.5 lens model is available up to −15.0 D. If higher PIOL power more than −15.0 D was required, the 5/8.5 lens model was used. For patients with corneal diameter smaller than 11.0 mm, the 5/7.5 lens model was used.

A single laser iridotomy was performed on the peripheral iris at 1 or 11 o'clock prior to the PIOL implantations. The anterior chamber and iris condition was examined 1 week after the procedure. The PIOL implantation was then performed, following a standard protocol.

Corneoscleral incisions of 6.0 or 6.5 mm were made at 12 o'clock and two paracenteses were placed at 10 o'clock and 2 o'clock. A viscoelastic agent (Healon, Pfizer) was injected into the anterior chamber to maintain its depth. After implantation of the PIOL with the use of an implantation forceps (P1318B, Duckworth & Kent), the lens was fixed to the iris with an enclavation needle (model OD125, OPHTEC BV). The corneoscleral wound was closed with sutures (10-0 Nylon), and the viscoelastic agent was removed by manual irrigation. All eyes received topical ofloxacin (Cravid), betamethasone (Sanbetason), and diclofenac sodium eye drops (Dichlod) 5 times per day for 1 month after surgery. Oral cefdinir (Cefzon [100 mg]) and serrapeptase (Dasen [10 mg]) were administered 3 times per day for 5 days.

*Postoperative Examinations*

Postoperative examinations were performed on 1 day, 1 week, 1 month, 3 months, 6 months, 1 year, and 2 years after surgery. The uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), manifest refraction, intraocular pressure and corneal endothelial count were measured in addition to the usual ophthalmologic and funduscopic examinations. Corneal endothelial cells were counted by specular microscope (Noncon Robo SP-9000, Konan). The pupil morphology was evaluated on the transparent mode of the corneal topography (TMS-II, Tomey).

*Statistical Analyses*

A paired Student $t$ test was used for the analyses of corneal endothelial counts. A $P$ value less than .05 was considered statistically significant.

## Results

The 5/7.5 lens model was implanted in 4 eyes, the 5/8.5 lens model in 9 eyes, and the 6/8.5 lens model in 31 eyes. Mean follow–up period was 12.4 months. Nineteen eyes were followed up for 6 months, 14 eyes for 1 year, and 11 eyes for 2 years.

*Visual Acuity*

Uncorrected visual acuity logMAR of the patients was 1.62 preoperatively, and improved to 0.30 at 1 day, 0.23 at 1 week, 0.14 at 1 month, 0.19 at 3 months, 0.11 at 6 months, 0.01 at 1 year, and 0.14 at 2 years after surgery (Figure 1).

The changes in BCVA are summarized in Figure 2. The final BCVA improved by 2 lines in 8 eyes (18.2%), 1 line in 17 eyes (38.6%), and was unchanged in 17 eyes (38.6%). However, 2 eyes (4.5%) had lost 2 lines of BCVA.

Manifest refraction of 1 patient, who revealed 2 lines loss of BCVA in both eyes, increased from −1.0 D OD and 0 D OS at 1 week to −1.75 OD and −1.5 D OS at 24 months after surgery. This case showed BCVA

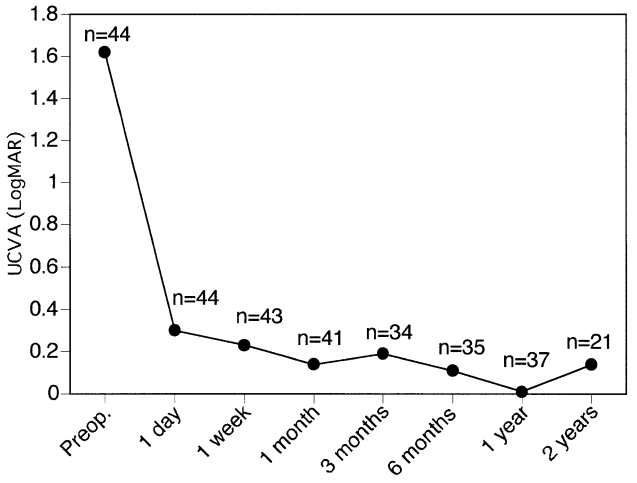


**Figure 1.** Changes in UCVA (logMAR).

identical to the preoperative value until 12 months examination. Although patient's consent to close examination with instillation of mydriatic agent at 24 months examination could not be obtained, the anterior segment of the eye, including implanted PIOL, crystalline lens, and posterior pole of the retina also revealed no abnormal findings. The decreased BCVA may be due to the age-related progression of nuclear cataract.

*Manifest Refraction*

Manifest refraction (spherical equivalents) was −12.80 ± 2.94 D (range −20.75 to −7.625 D) preoperatively, and improved to −0.86 ± 1.08 D (range −3.5 to −2.0 D) at 1 week, −1.02 ± 0.87 D (range −3.25 to 0.0 D) at 1 month, −0.94 ± 0.96 D (range −3.25 to +0.25 D) at 3 months, −0.68 ± 0.86 D (range −3.5 to +0.75 D) at 6 months, −0.42 ± 0.41 D (range −1.375 to 0.0 D) at 1 year, and −0.71 ± 0.81 D (range −1.75 to +0.5 D) at 2 years after surgery (Figure 3). Manifest refraction was within 0.5 D in 13 eyes (36.1%), 1.0 D in 20 eyes (55.6%), and within 2.0 D in 32 eyes (88.9%) at 1 month after surgery, and remained stable during the follow-up period (Figure 4).

In 5 eyes, manifest refraction at 1 month was not within 2.0 D. Three had high postoperative induced astigmatism more than 2.0 D, and one eye had corneal epithelitis at the time of examination, which might have resulted in a greater refractive error. The refractive error decreased to within 0.5 D in 3 eyes during the follow-up period.

*Corneal Endothelial Count*

Corneal endothelial count was 2831 ± 304 cells/mm$^2$ before surgery, 2828 ± 386 cells/mm$^2$ at 3 months, 2875 ± 260 cells/mm$^2$ at 6 months, 3007 ± 222 cells/mm$^2$ at 1 year, and 2750 ± 284 cells/mm$^2$ at 2 years after surgery (Figure 5). The corneal endothelial counts showed no significant loss during the follow-up period.

*Complications*

No intraoperative complications were observed. On the first postoperative day, 1 eye revealed a fibrin coagulum in the anterior chamber that limited the BCVA to 20/100 at 1 week postoperative. The coagulum

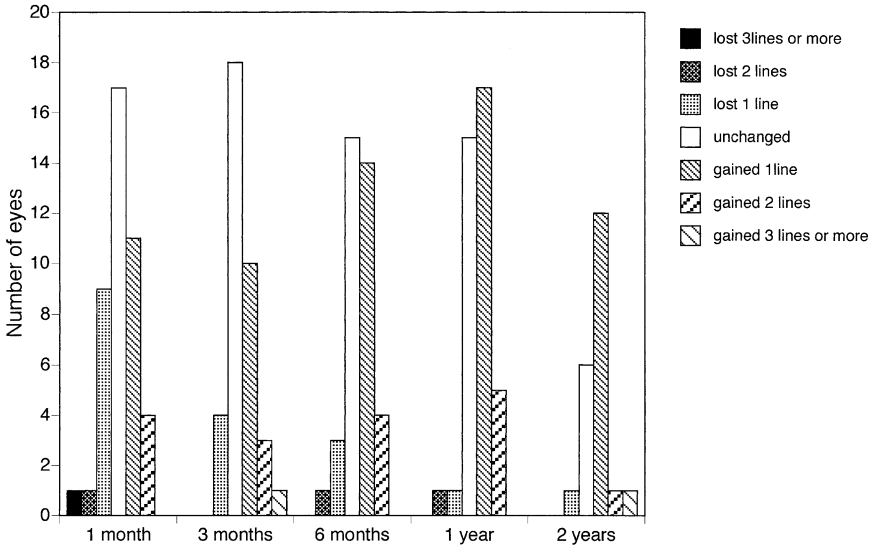


**Figure 2.** Changes in BCVA.

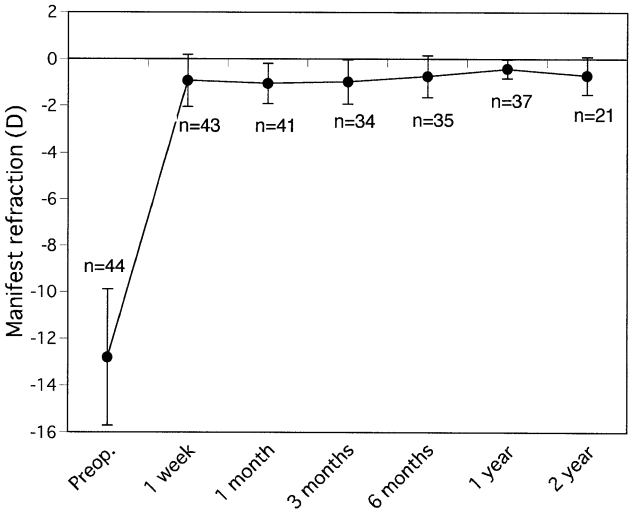


**Figure 3.** Changes in manifest refraction.

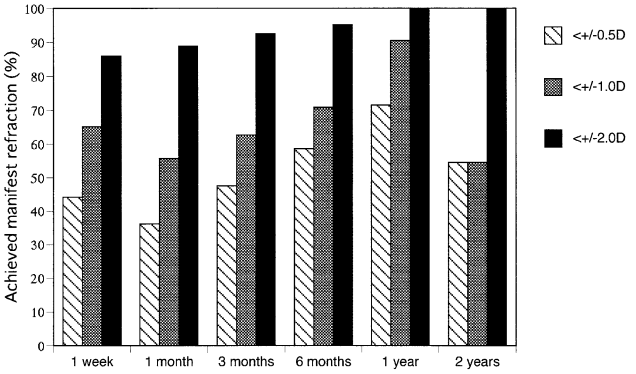


**Figure 4.** Postoperative manifest refraction.

disappeared with the use of routine postoperative eye drops and BCVA of this eye improved to 20/20 at 1 month after surgery.

Wound leakage was observed in 1 eye until 1 week after surgery. Leakage resolved using a therapeutic soft contact lens. No additional sutures were required.

Intraocular pressure was elevated to more than 21 mm Hg in 3 eyes 1 week after surgery, and 1 eye had an IOP of 37 mm Hg. These patients were prescribed beta-blocker eyedrops (0.5% Timoptol, Santen) twice a day. Intraocular pressure recovered to the normal range within 1 month in 2 eyes, and 3 months in the other case. Intraocular pressure medications were discontinued.

Astigmatism more than 2.0 D was induced by surgery in 4 eyes of 4 cases, and one of them required removal of suture at 1 week examination. In the other 3 eyes, surgically induced astigmatism spontaneously decreased thereafter, and became less than 1.5 D after the 3 month-examination.

Pigment precipitation on PIOL was observed in 2 eyes, but did not affect visual acuity. Oval pupillary deformations were not observed. None of the eyes developed angle closure, cataract, or cystoid macular edema during the postoperative follow-up period.

## Discussion

The refractive errors of enrolled patients with high myopia were successfully corrected without any serious complications by an Artisan PIOL implantation. These results are consistent with previous multicenter studies in Europe or United States (Table 1) indicating efficacy and safety of Artisan PIOL for the correction of myopia.[5–7]

The Artisan lens is designed with 2 haptics, which fixate on the iris by enclavation of midperipheral immobile iris stroma. The overall diameter of the standard PIOL designed for white eyes is 8.5 mm. Asian people including Japanese, Korean, or Chinese have been reported to have smaller corneal diameter than whites.[12] It is likely that the use of this standard lens in smaller eyes increases the difficulties of the surgical procedure, leading to intraoperative complications. In Asian eyes, the enclavation points probably are situated more peripheral than in white eyes. This could lead to lens movement and accompanying pupil movement, resulting in corneal endothelial damage or cataract formation.

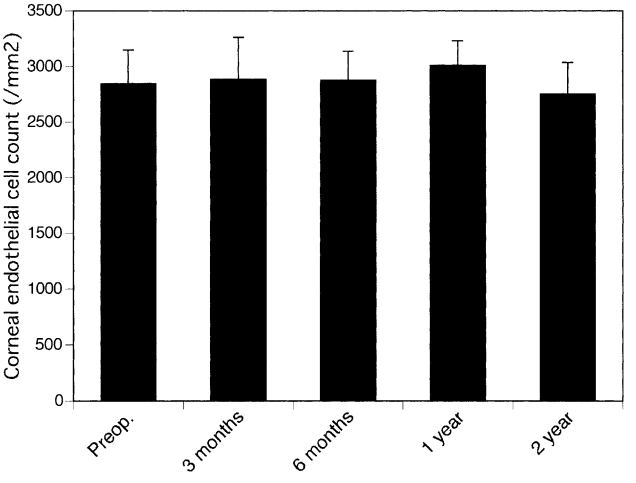


**Figure 5.** Changes in corneal endothelial cell counts.

**Table 1.** Summary of Previous Artisan PIOL Implantation.

| Author | Country<br>No of Eyes<br>Follow-up | Lens Type | BCVA Loss<br>More Than<br>2 Lines | Endothelial<br>Cell Loss | Others |
|---|---|---|---|---|---|
| Landesz[4] | The Netherlands | 5/8.5 | 5 eyes | 10.9% at 36 mo | Cataract in 2 eyes |
| | 73 eyes | | | | |
| | 35 mo | | | | |
| Budo[5] | European multicenter study | 5/8.5 | 1.2% | 4.8% at 6 mo | Age-related cataract formation in 2.4% |
| | 518 eyes | | | | |
| | 6 mo–3 yr | | | | |
| Maloney[6] | USA | 5/8.5 | 1.2% at 2 mo | NS | Pupil irregular in 1.2–3.1% |
| | 155 eyes | 6/8.5 | 0% at 6 mo | | |
| | 6 mo | | | | |
| Dick[7] | European multicenter study | 5/8.5 | None | 4.5% at 6 mo | |
| | 70 eyes | Toric | | | |
| | 6 mo | | | | |
| Saxena[8] | The Netherlands | 5/8.5 | None | 8.5% at 2 yrs | Posterior synechia of the iris to crystalline lens in 2 eyes |
| | 26 eyes | Hyperopia | | 11.7% at 3 yrs | |
| | 22.4 mo | | | | |

NS = not significant

The corneal diameter of the operated eyes was used as an indicator for selection of the PIOLs in this study. In eyes with corneal diameter less than 11.0 mm, the small lens model (5/7.5) was implanted. As no major complications were observed by this method, it is believed to be a good criterion for lens selection.

Intraocular pressure was transiently elevated in 3 eyes shortly after surgery. The use of beta-blocker eyedrops reduced the IOP to normal levels and showed no recurrence even after the discontinuation of antiglaucomatous agents. This transient IOP elevation was probably due to postoperative inflammation. Laser iridotomy was not likely to cause postoperative transient IOP elevation, because the procedure was done at least 1 week prior to the surgery and we progressed to the PIOL implantation in all cases only when the inflammation in the anterior chamber resolved.

In Asian pigmented eyes, more pigment dispersion leading to the development of glaucoma could occur. However, there were no cases with long-term continuous elevation of IOP or optic disc cupping during the follow-up period. The Artisan PIOL cannot affect the pigment dispersion in the anterior chamber as long as the lens is appropriately fixed because the amount of melanin granules in the anterior stroma of the iris is less than in the iris pigment epithelium.[11]

In conclusion, the implantation of an Artisan PIOL appeared to be a safe and effective method for the correction of high myopia in Asian eyes. The risk for complications was not higher compared with the white eyes. The surgeon, however, should take care in selecting appropriate sizes of PIOLs since Asian patients frequently have smaller eyes compared to other races. Further investigations of larger number of subjects and longer follow-up periods are warranted.

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