

Three-year follow-up of secondary anterior iris fixation of an aphakic intraocular lens to correct aphakia

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PURPOSE: To evaluate the efficacy, predictability, stability, safety, and complications of secondary anterior iris fixation of the Artisan iris-fixated intraocular lens (IOL) to correct aphakia in eyes without sufficient capsule support.

SETTING: Department of Ophthalmology, Jinling Hospital, School of Medicine, Nanjing University, Nanjing, China.

DESIGN: Cohort study.

METHODS: Eyes having implantation of aphakic iris-fixated IOLs for aphakia correction were followed for 3 years.

RESULTS: The study evaluated 72 eyes (72 patients). After 3 years, the uncorrected distance visual acuity improved in all eyes ($P < .05$); 53 eyes (73.6%) reached 20/40 or better. Two eyes had a postoperative corrected distance visual acuity (CDVA) worse than the preoperative CDVA due to postoperative ischemic optic neuropathy and retinal detachment, respectively. The mean spherical equivalent (SE) decreased from 11.65 diopters (D) \pm 1.21 (SD) to -0.58 ± 0.56 D ($P < .05$); the SE at the last follow-up was within ± 1.00 D of the target refraction in 63 eyes (87.5%). The mean endothelial cell loss 3 years postoperatively was 9.78%. There was no significant postoperative intraocular pressure increase throughout the follow-up. Twelve patients (16.7%) reported glare and halos during night driving. Iris pigment precipitates on the IOLs occurred in 4 eyes (5.6%) 3 years postoperatively. No other serious complications occurred.

CONCLUSIONS: Three-year results indicate that secondary implantation of aphakic IOLs is effective, predictable, and safe for the correction of aphakia in eyes without capsule support. However, longer follow-up with a larger cohort is necessary to confirm these conclusions.

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Several options are available to correct aphakia in eyes without adequate capsule support. Options include aphakic spectacles, contact lenses, and implantation of aphakic intraocular lenses (IOLs). However, results with spectacles are often dissatisfying because of prismatic effects, image magnification, aberrations of images, a limited vision field, and cosmetic concerns.¹ Although contact lenses provide better visual results than spectacles, they have high risk for microbial keratitis and even corneal erosion.² At present, the main procedure to correct aphakia in eyes without sufficient capsule support is implantation of a transsclerally sutured posterior chamber IOL³ (PC IOL), an

angle-supported anterior chamber IOL⁴ (AC IOL), or an iris-fixated IOL.⁵

Angle-supported AC IOLs are not widely accepted because of the high incidence of secondary glaucoma, pupil distortion, endothelial cell loss, and IOL instability.⁶ Transsclerally sutured PC IOLs are more acceptable because they preserve the anterior anatomy better than angle-supported AC IOLs. However, there are concerns about the risk for endophthalmitis caused by conjunctival erosion associated with scleral sutures.⁷ In addition, transsclerally sutured PC IOL implantation is technically more difficult than AC IOL implantation. The iris-fixated AC IOL was first

used by van der Pol and Worst⁸ to correct childhood aphakia in cataract procedures in 1980. The Artisan IOL (Ophtec BV), a poly(methyl methacrylate) (PMMA) iris-fixated IOL, has a better design than previous generations and has been successfully used to correct aphakia^{5,9-13} and high myopia^{1,14,15} in many countries.

In this prospective study, we evaluated the efficacy, predictability, stability, safety, and complications of secondary Artisan IOL implantation to correct aphakia in eyes without sufficient capsule support. The postoperative follow-up was 3 years.

PATIENTS AND METHODS

This prospective clinical study comprised eyes having Artisan IOL implantation between October 2006 and February 2009 by 1 surgeon at the Refractive Center, Department of Ophthalmology, Jinling Hospital, Nanjing, China (Z.H.) and another surgeon at the Department of Ophthalmology, the First Affiliated Hospital of Nanjing Medical University, Nanjing, China (Q.L.). All patients were fully informed of the details and possible risks of the procedure, after which they provided written informed consent.

Inclusion criteria were a personal request for better visual acuity and quality of life, unsatisfactory spectacle or contact lens correction, an endothelial cell count greater than 1800 cells/mm², an intraocular pressure (IOP) less than 21 mm Hg, and a central anterior chamber depth (ACD) greater than 2.8 mm. Exclusion criteria were glaucoma, peripheral anterior synechia, chronic uveitis, abnormal iris or pupil function, retinal detachment, or proliferative diabetic retinopathy.

Ophthalmic Examination

Preoperative and postoperative evaluations included subjective refraction, uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA) (Snellen or "E" chart), keratometry (IOLMaster, Zeiss Humphrey, Carl Zeiss Meditec AG), Goldmann applanation tonometry, endothelial cell density (ECD) (SP-3000P, Topcon Corp.), slitlamp examination, and indirect fundus examination. Postoperative examinations were performed at 1 week, 1 and 6 months, and 1, 2, and 3 years. The surgically induced

astigmatism (SIA) was calculated using the analysis of Jaffe and Clayman.¹⁶

Intraocular Lens

The Artisan aphakic IOL is a biconvex iris-fixated PMMA IOL with a 5.0 mm optic and an 8.5 mm overall length. At the time of this study, the IOL was available in powers from +2.0 to +30.0 diopters (D) in increments of 1.0 D and from +14.5 to +24.5 D in increments of 0.5 D. The IOL power was calculated using the SRK/T formula and A-scan ultrasonic ocular echography; the A-constant was 115.0. The target refraction was emmetropia or slight myopia.

Surgical Technique

Preoperative preparations were as for standard cataract surgery with the instillation of a miotic (pilocarpine 1%) into the surgical eye 30 minutes before surgery. A drop of proparacaine 0.5% was used topically before the preparation to decrease the sensation of irritation caused by the instillation of povidone-iodine 5% into the eye. Surgery was performed using retrobulbar anesthesia.

A standard 5.5 mm straight corneoscleral tunnel incision was created 1.0 mm posterior to the limbus, and 2 paracenteses were placed at 10 o'clock and 2 o'clock. The tunnel incision was made at 12 o'clock to ensure the ergonomic comfort of the surgeon because a certain proportion of Asian patients have flat foreheads and brow areas but high temporal arches, which make superior wounds more accessible than temporal wounds. The anterior chamber was filled with an ophthalmic viscosurgical device (OVD) to maintain its depth and protect the endothelial cells. The aphakic IOL was implanted with a forceps and fixated to the iris with enclavation needles. The OVD was then removed with an automated irrigation/aspiration system (Infiniti Vision System, Alcon Laboratories, Inc.), and the corneoscleral tunnel wound was closed with 3 interrupted 10-0 nylon sutures. Tobramycin-dexamethasone ointment was applied to the eye at the end of surgery. After the first postoperative day, tobramycin and dexamethasone eyedrops were applied topically every hour. The eyedrops were tapered after 1 week and then discontinued after 1 month.

Statistical Analysis

The results were analyzed using SPSS software (version 17.0, SPSS, Inc.). Comparison of preoperative and postoperative parameters was performed using paired Student *t* tests. A *P* value less than 0.05 was considered statistically significant.

RESULTS

The study evaluated 72 eyes of 72 patients. Table 1 shows the patients' preoperative characteristics and the etiology of the aphakia.

Safety

The mean CDVA improved from preoperatively to 0.27 ± 0.18 logMAR (range 0.0 to 1.0 logMAR) 3 years

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Table 1. Preoperative patient data.

Parameter	Value
Age (y)	
Mean ± SD	57.5 ± 12.6
Range	18, 74
Sex, n (%)	
Male	34 (47.2)
Female	38 (52.8)
Etiology of aphakia, n (%)	
Complicated phaco for senile cataract	40 (55.6)
Congenital cataract extraction	12 (16.7)
IOL dislocation	6 (8.3)
Crystalline lens subluxation	14 (19.4)
UDVA (log MAR)	
Mean ± SD	1.18 ± 0.30
Range	0.8, 2.0
CDVA (log MAR)	
Mean ± SD	0.29 ± 0.18
Range	0.1, 0.7
SE (D)	
Mean ± SD	11.65 ± 1.21
Range	8.00, 13.75
ECD (cells/mm ²)	
Mean ± SD	2753.88 ± 320.77
Range	2031.5, 3538.0
IOP (mm Hg)	
Mean ± SD	12.14 ± 2.61
Range	6.0, 18.0

CDVA = corrected distance visual acuity; ECD = endothelial cell density; IOL = intraocular lens; IOP = intraocular pressure; SE = spherical equivalent; UDVA = uncorrected distance visual acuity

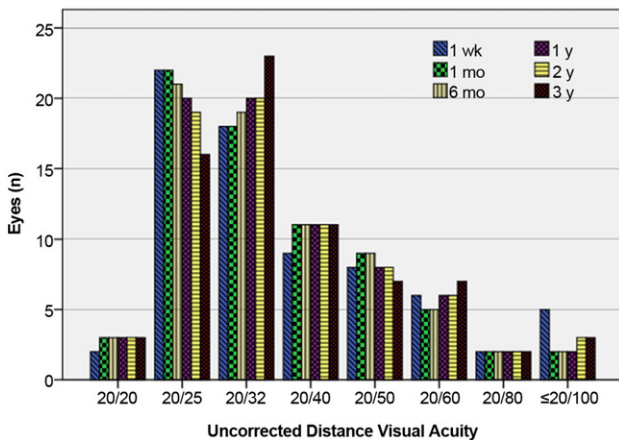


Figure 1. The UDVA over time.

postoperatively. The CDVA was 20/40 or better in 58 eyes (80.6%) at 3 years. The safety index (ratio of mean postoperative CDVA to mean preoperative CDVA) was 1.05 at the last follow-up.

Efficacy

The mean logMAR UDVA improved from preoperatively to 0.28 ± 0.18 (range 0.0 to 1.0) 3 years postoperatively (*P* < .05). The postoperative UDVA was equal to or better than the preoperative CDVA in 70 eyes (97.2%); at the final follow-up, 53 eyes (73.6%) had a UDVA of 20/40 (Figure 1). The efficacy index (ratio of mean postoperative UDVA to mean preoperative CDVA) was 1.02 at the last follow-up.

Predictability

The mean spherical equivalent (SE) decreased from preoperatively to -0.61 ± 0.77 D 1 week postoperatively, -0.57 ± 0.69 D at 1 month, -0.58 ± 0.65 D at 6 months, -0.56 ± 0.65 D at 1 year, -0.56 ± 0.65 D at 2 years, and -0.58 ± 0.56 D at 3 years. After 3 years, 71 eyes (98.6%) were within ±1.50 D of the target refraction and 63 eyes (87.5%) were within ±1.00 D (Figure 2).

Stability

The improvement in UDVA from preoperatively to postoperatively was statistically significant (*P* < .05); however, there were no significant differences between postoperative follow-up visits. The mean SE was -0.61 ± 0.77 D 1 week after surgery and remained stable throughout the follow-up (Figure 3). The mean refractive cylinder was 0.42 ± 0.37 D preoperatively, 0.82 ± 0.53 D 1 week postoperatively, 0.72 ± 0.52 D at 1 month, 0.66 ± 0.49 D at 6 months,

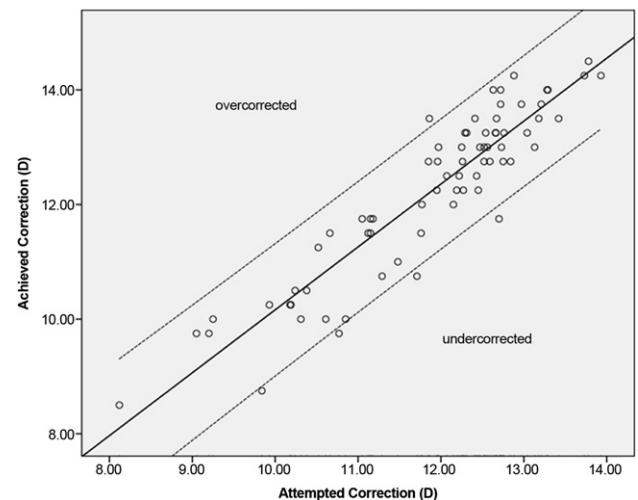


Figure 2. Achieved SE correction versus attempted SE correction 3 years postoperatively.

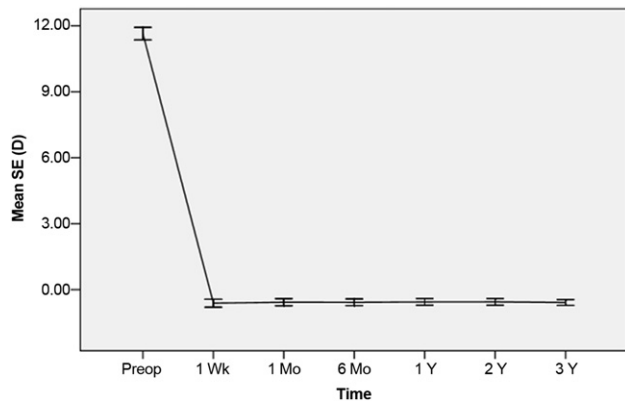


Figure 3. Stability SE over time (SE = spherical equivalent).

0.66 ± 0.48 D at 1 year, 0.64 ± 0.49 D at 2 years, and 0.60 ± 0.46 D at 3 years. The refractive cylinder became stable 6 months postoperatively.

The mean preoperative refractive cylinder was 0.42 D \times 89 degrees. Three years after surgery, the mean refractive cylinder was 0.60 D \times 42 degrees and the mean SIA was 0.52 D \times 58 degrees.

Endothelial Cell Density

The mean postoperative ECD was 2644.24 ± 315.55 cell/mm² (range 2001.2 to 3318.2 cell/mm²) at 1 week, 2596.72 ± 311.10 cell/mm² (range 1988.5 to 3266.7 cell/mm²) at 1 month, 2554.44 ± 308.83 cell/mm² (range 1935.4 to 3218.9 cell/mm²) at 6 months, 2529.61 ± 304.88 cell/mm² (range 1919.5 to 3176.5 cell/mm²) at 1 year, 2506.30 ± 303.47 cell/mm² (range 1908.8 to 3124.7 cell/mm²) at 2 years, and 2484.43 ± 312.75 cell/mm² (range 1903.4 to 3130.8 cell/mm²) at 3 years (Figure 4). The mean postoperative change in ECD was 3.98%, 1.80%, 1.63%, 0.97%, 0.92%, and 0.87%, respectively.

Intraocular Pressure

The mean postoperative IOP was 12.26 ± 2.42 mm Hg (range 7.3 to 18.7 mm Hg) at 1 week, 12.32 ± 1.91 mm Hg (range 7.0 to 16.0 mm Hg) at 1 month, 12.52 ± 1.87 mm Hg (range 9.2 to 18.7 mm Hg) at 6 months, 12.40 ± 2.33 mm Hg (range 7.3 to 18.0 mm Hg) at 1 year, 12.68 ± 2.30 mm Hg (range 7.3 to 17.8 mm Hg) at 2 years, and 12.59 ± 2.43 mm Hg (range 7.3 to 18.0 mm Hg) at 3 years (Figure 5). There were no significant differences in IOP between the follow-up visits ($P > .05$).

Complications

There were no serious intraoperative complications. By the last follow-up, 2 eyes (2.78%) had lost

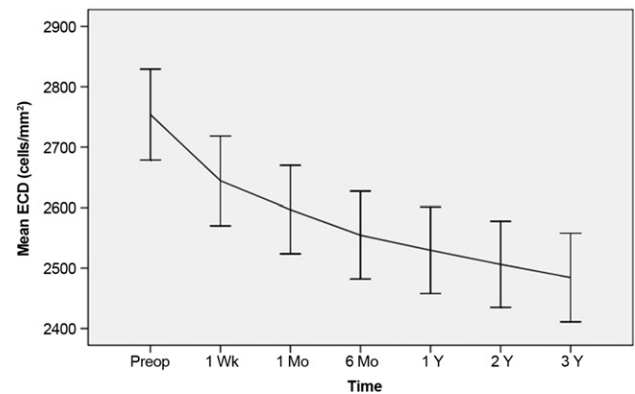


Figure 4. Mean ECD over time (ECD = endothelial cell density).

1 line or more of CDVA. One of the eyes developed retinal detachment 1.5 years after IOL implantation resulting from blunt trauma to the head from a basketball; this eye had a final CDVA of 20/200 after scleral buckling and 2 vitreoretinal procedures to reattach the retina. The other patient developed ischemic optic neuropathy 5 weeks after the surgery and had a final CDVA of 20/32. Pigment precipitates of various densities on the IOL were observed in all eyes 1 day after surgery; most cases were transient and the precipitates were absorbed after the application of a topical corticosteroid. At the last follow-up, pigment precipitates were present in 4 eyes (5.6%) but did not compromise visual acuity. Twelve patients (16.7%) reported glare and halos during night driving, perhaps because the patients' pupil sizes under scotopic conditions were larger than the optic diameter of the IOL. No other serious postoperative complications (eg, iris atrophy, IOL dislocation, cystoid macular edema [CME], irregular pupil, pupillary block, vitreous hemorrhage, corneal decompensation)

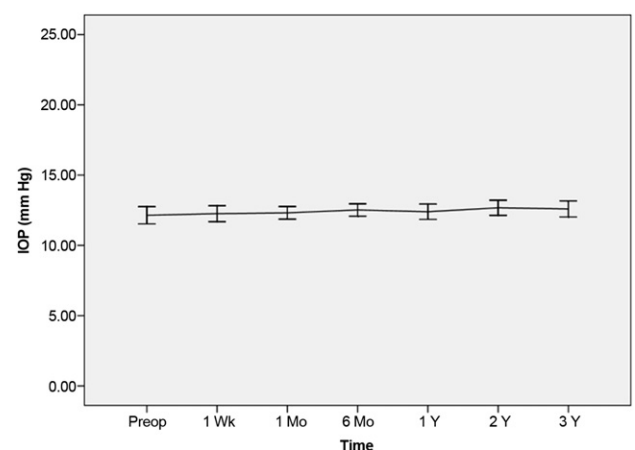


Figure 5. Mean IOP over time (IOP = intraocular pressure).

occurred during the follow-up period. No eye except the 1 with retinal detachment required secondary intervention.

DISCUSSION

Many situations can contribute to aphakia in eyes with insufficient or absent capsule support. These include trauma, crystalline lens subluxation, IOL dislocation, capsule loss during cataract extraction for congenital and juvenile cataract, and complicated phacoemulsification for senile cataract. At present, the main options for secondary IOL implantation include transsclerally sutured PC IOLs,³ angle-supported AC IOLs,⁴ and iris-fixated IOLs.⁵ However, iris-fixated IOLs are preferred because they yield favorable visual outcomes and have a lower incidence of intraoperative and postoperative complications than the other 2 IOL types.^{6,17,18}

The Artisan aphakic, a new-generation iris-fixated IOL, has a biconvex design with ultraviolet light filtration up to approximately 400 nm. The surgeon fixates the IOL to the iris and centers it on the pupil by grasping a fold of midperipheral iris stroma without interfering with vascularization or the trabecular meshwork. These IOLs have been used successfully to correct aphakia and high myopia and their use has been reported in aphakic patients with megalocornea and bullous keratopathy.^{19,20}

In this study, we evaluated secondary implantation of the Artisan aphakic iris-fixated IOL to correct aphakia in eyes with inadequate capsule support. The postoperative UDVA, CDVA, and SE results show the safety, efficacy, predictability, and stability of secondary implantation of this IOL to correct aphakia. Regarding efficacy, the mean CDVA improved from 1.18 ± 0.30 logMAR preoperatively to 0.28 ± 0.18 logMAR 3 years after surgery. In addition, the postoperative UDVA was equal to or better than the preoperative CDVA in 70 eyes (97.2%). The mean SE decreased from 11.65 ± 1.21 D preoperatively to -0.58 ± 0.56 D, with 71 eyes (98.6%) within ± 1.50 D of the target refraction 3 years after surgery; these results suggest that the surgery has good predictability. One week postoperatively, there was no difference in the UDVA and mean SE between any postoperative follow-up intervals, which suggests the stability of the visual acuity and refractive outcomes.

One major concern about Artisan aphakic iris-fixated IOL implantation is corneal endothelial loss.^{12,21} In this study, the mean corneal ECD decreased by 9.78% 3 years after surgery, which is comparable to results in other studies.^{5,22} Moreover, there were no cases of corneal decompensation during

the follow-up. The corneal endothelial cell loss may be primarily the result of mechanical injury during surgery, such as when there is contact between the endothelium and the instruments or the IOL. Using a sufficient amount of OVD during the surgery can protect the endothelium and thus decrease endothelial loss. Baykara et al.²³ suggest that fixating an Artisan aphakic IOL with a scleral tunnel incision will decrease endothelial damage compared with that when a clear corneal incision is used because the scleral incision is placed more posteriorly and causes less endothelial damage during surgery. In traumatic cataract in children, Sminia et al.¹² found that the substantial endothelial loss seemed to be primarily caused by the perforating trauma, not by the presence of the Artisan IOL, and that the cell loss was positively related to the length of the corneal scar. Furthermore, Cruysberg et al.²⁴ found that the distance between the corneal endothelium and the Artisan IOL increased under scotopic conditions, which further decreases the risk for postoperative endothelial loss and contributes to the favorable safety data available on Artisan IOL implantation. However, corneal decompensation after Artisan IOL implantation has been reported and may have been caused by excessive eye rubbing because of itching or by an anterior shift of the IOL due to its loose fixation to the iris surface.^{25,26} Therefore, exact, firm fixation of the IOL in an area with sufficient iris tissue is essential to protect the corneal endothelium. Koss and Kohnen²⁷ found that the postoperative ACD was shallower in smaller eyes than in longer eyes and suggest performing posterior enclavation of iris-fixated IOLs in smaller eyes to ensure a safe distance between the IOL and the corneal endothelium.

Another concern is the potential damage of the Artisan IOL to the iris.²³ In our study, there were various degrees of pigment precipitates on the optic surface or haptics of the IOL in all eyes 1 day after surgery; however, most of the precipitates were transient and absorbed after topical corticosteroid treatment. At the last follow-up, pigment precipitates were present in 4 eyes. There were no cases of iritis or pigment erosion. There is evidence that administering a subconjunctival corticosteroid can significantly decrease the incidence of pigment precipitates.²⁸ Immediate pigment dispersion can occur when the haptics are fixated to the iris during surgery; however, there were no cases of progressive pigment dispersion in our study. The Artisan IOL has a vaulted design and is slightly raised on the iris plane.²⁹ This provides sufficient clearance between the IOL and the iris²⁴ and therefore prevents the IOL from interfering with the normal physiology of the iris as long as the IOL is well fixated to the iris.

Other intraoperative and postoperative complications have been reported with Artisan iris-fixated IOLs. These include positive vitreous pressure, IOL dislocation, pupillary block glaucoma, retinal detachment, pupil ovalization, hyphema, and CME.^{5,22} In our study, there were no serious intraoperative complications. Although no eye had IOL dislocation throughout the follow-up, a relatively high rate of IOL dislocation was reported in earlier series. This phenomenon may be attributed to the rather rigid claws in the earlier generation IOL models, which caused the iris stroma to slide out of the haptic slot.⁸ Most cases of IOL dislocation are not severe and can be corrected by reenclavation. However, severe trauma can cause wound dehiscence, total aniridia, and aphakia with the IOL and iris dislocation into the vitreous cavity.³⁰ Therefore, it is necessary to protect eyes with previous surgery to reduce the incidence of IOL dislocation and wound dehiscence.

A transitory IOP increase resulting from retained OVD was observed in 1 eye; however, there were no cases of a prolonged IOP increase in our study. During surgery, we did not perform a peripheral iridectomy, which is recommended in phakic eyes because of the higher incidence of secondary pupillary block in these cases.²³ One eye developed retinal detachment 1.5 years after IOL implantation from blunt trauma to the head caused by a basketball; the eye had scleral buckling and 2 vitreoretinal procedures to reattach the retina. During the buckling and vitreoretinal procedures, visualization of the peripheral retina was not significantly limited by the IOL. van der Meulen et al.³¹ found that the IOL could be pushed against the corneal endothelium when gas tamponade was used and that injection of OVD into the anterior chamber prevented contact between the IOL and endothelium. One patient developed ischemic optic neuropathy 5 weeks after surgery; the final CDVA was 20/32.

At the last follow-up, 12 patients reported glare and halos during night driving; these symptoms are mainly associated with poor IOL centration or a scotopic pupil diameter larger than the IOL optic diameter.²⁸ Pérez-Torregrosa et al.³² found no serious visual impairment caused by slight IOL decentration with a standard 4.0 mm entrance pupil but that larger pupils could cause visual impairment. No other postoperative complications occurred during the follow-up. The complications in our study varied from those in other studies, which might be attributed to the diversity of previous ocular pathology.

In conclusion, the favorable results and excellent safety, efficacy, predictability, and stability suggest that secondary implantation of an Artisan aphakic iris-fixated IOL is a promising alternative for the

correction of aphakia in eyes with insufficient capsule support; however, a longer follow-up with a larger cohort is necessary to confirm these conclusions.

WHAT WAS KNOWN

- Artisan aphakic iris-fixated IOLs have been successfully used to correct aphakia in eyes with insufficient capsule support in Europe. To our knowledge, there are no studies with long-term results of implantation of the Artisan aphakic IOL in Asian patients.
- In previous studies, peripheral iridectomy was performed in phakic eyes and aphakic eyes.

WHAT THIS PAPER ADDS

- Favorable long-term outcomes with Artisan aphakic iris-fixated IOL implantation were achieved in Asian patients.
- It may not be necessary to perform peripheral iridectomy in aphakic eyes.

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