

Iris-fixated toric phakic intraocular lens: Three-year follow-up

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PURPOSE: To evaluate the 3-year safety, efficacy, predictability, and stability of iris-fixated toric phakic intraocular lens (pIOL) implantation for the correction of myopia or hyperopia with astigmatism.

SETTING: Department of Ophthalmology, Johannes Gutenberg University, Mainz, and Department of Ophthalmology, University Clinic, Bochum, Germany.

METHODS: A prospective clinical trial of 40 eyes of 23 patients with high ametropia and astigmatism was conducted. Best spectacle-corrected visual acuity (BSCVA), uncorrected visual acuity, refraction, astigmatism, intraocular pressure, slitlamp biomicroscopy, and indirect ophthalmoscopy were measured preoperatively and postoperatively.

RESULTS: Of the 40 eyes, 28 were myopic and 12 were hyperopic. Three years postoperatively, 70% of eyes were within ± 1.00 diopter (D) of the targeted refraction. In the myopic group, mean preoperative BSCVA was 20/40 and improved postoperatively to 20/25. Sixty-six percent of eyes gained 1 or more lines from the preoperative BSCVA. The mean cylinder decreased from $-3.58 \text{ D} \pm 1.26$ (SD) preoperatively to -1.15 ± 1.01 D postoperatively. In the hyperopic group, preoperative BSCVA was 20/25 and improved to 20/20 postoperatively. Thirty-six percent of eyes gained 1 or more lines from the preoperative BSCVA. The mean cylinder decreased from -3.37 ± 0.88 D to -1.53 ± 0.69 D postoperatively. The correction was stable in all eyes 3 years after surgery. No potentially sight-threatening complications occurred.

CONCLUSION: The 3-year follow-up showed the iris-fixated toric pIOL was effective in correcting high ametropia and astigmatism.

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Popular, corneal reshaping procedures (laser in situ keratomileusis [LASIK] and photorefractive keratectomy [PRK]) may not fully correct astigmatism associated with ametropia. Toric intraocular lenses (IOLs), therefore, represent a promising alternative. In 1986, Worst and Fechner modified the existing iris-fixated IOL into a negatively biconcave IOL with a convex-concave optic design. Initially called the Worst myopia fixated IOL, it was later named

the Artisan (Ophtec BV),¹⁻³ which then also became known as the Verisyse (Advanced Medical Optics, Inc.). The IOL is reported to give good results.²⁻⁷

The toric Artisan lens has a spherical anterior surface and a toric posterior surface. Two opposed haptics enable fixation on the midperipheral iris. Short-term results after implantation of the toric model were promising.¹ To our knowledge, this is the first report of long-term surgical outcomes with this IOL. This prospective study was designed to evaluate the 3-year postoperative clinical and refractive results of iris-fixated toric phakic IOL (pIOL) implantation for the correction of ametropia and astigmatism.

PATIENTS AND METHODS

Forty eyes of 23 patients had surgery at the University Hospital, Department of Ophthalmology, Mainz, Germany, from February 2000 to September 2001. Eyes were divided into a myopic group and a hyperopic group. All patients were fully informed about the details and risks of the procedure and provided written

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informed consent in accordance with the Declaration of Helsinki. The study was approved by the local ethics committee.

Patients older than 18 years who had a stable refraction for at least 1 year and astigmatism greater than 1.50 diopters (D) with an otherwise normal ophthalmologic examination and unsatisfactory correction with spectacles or contact lenses were included in the study. Exclusion criteria were anisometropia, anterior segment pathology, inadequate eyelid closure, endothelial cell count less than 1800 cells/mm², central anterior chamber depth (ACD) less than 3.0 mm, abnormal iris or pupil function, recurrent or chronic uveitis, any form of cataract, previous corneal or intraocular surgery, intraocular pressure (IOP) greater than 21 mm Hg, glaucoma or family history of glaucoma, retinal detachment or family history of retinal detachment, preexisting macular degeneration or macular pathology, systemic diseases, chronic treatment with corticosteroids or any immunosuppressive treatment or state, and pregnancy.

The biomaterial of the Artisan lens consists of Perspex CQ-UV poly(methyl methacrylate) with Tinuvin 326, a benzotriazole with effective ultraviolet light filtration up to approximately 400 nm. The optic diameter is 5.0 mm, and the overall length is 8.5 mm. Available IOL powers range from -3.0 to -23.5 D for myopia and +2.0 to +12.0 D for hyperopia, with a cylindrical correction from 1.0 to 7.0 D in 0.5 D steps.

The IOL is available in 2 models depending on the axis of astigmatism. In eyes with a preoperative cylinder axis between 0 degree and 45 degrees or between 135 degrees and 180 degrees, an IOL with the torus axis at 0 degree is recommended (model A). In eyes with a preoperative cylinder axis between 45 degrees and 135 degrees, an IOL with the torus at 90 degrees is recommended (model B). Both models can be enclavated in the required position.¹

Intraocular lens calculations were based on the Van der Heijde formula,⁸ which uses the mean corneal curvature (K), the adjusted ACD, and the patient's spherical equivalent (SE) at a vertex distance of 12.0 mm. All power calculations were performed by Ophtec BV.

Preoperative preparation was the same as for typical cataract surgery. In addition, miotic drops (pilocarpine 1% to 2%) were given instead of mydriatic drops to prepare the iris for IOL fixation. In all eyes, a superior sclerocorneal self-sealing 5.1 to 5.3 mm incision and 2 paracenteses were created. A cohesive ophthalmic viscosurgical device (sodium hyaluronate 1% [Healon]) was injected through the paracenteses to maintain ACD and protect endothelial cells. The precise cylindrical axial orientation was ensured with alignment marks on the limbus and with natural structures such as iris crypts, pigments, or vessels identified by photographs attached to the operating room microscope. After correct alignment was ensured, the IOL was enclavated onto the iris.

All eyes were examined 1 week, 1, 3, and 6 months, and 1, 2, and 3 years after surgery. Uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), computerized corneal topography, applanation tonometry, SE, IOL position and axis, ACD, and indirect ophthalmoscopy were measured preoperatively and postoperatively. Manifest and cycloplegic refractions were conducted 45 minutes after instillation of 2 drops of cyclopentolate 1% to calculate the SE. Slitlamp biomicroscopy was used to determine IOL position and axis and to evaluate crystalline lens changes after mydriasis. The IOLMaster (Zeiss) was used to measure the ACD. The standardized format for reporting refractive surgery results described by Koch et al.⁹ was used. Pupil size was evaluated with the Colvard pupillometer (Oasis Medical).

SPSS version 11.0 (SPSS Inc.) was used for descriptive statistical analysis. Continuous variables were described using mean, standard deviation, median, and minimum and maximum values. Images are presented in Datagraph format.

RESULTS

There were 28 eyes in the myopia group and 12 eyes in the hyperopia group. Patient age ranged from 21 to 61 years in the myopic group and from 25 to 49 years in the

Table 1. Preoperative patient data.

Group	Value
All eyes	
Number	40
Age (y)	
Mean	36
Range	21 to 61
Women (eyes)	23
Men (eyes)	17
Right eyes	18
Left eyes	22
Myopic eyes	
Spherical equivalent (D)	
Mean	-9.84 ± 4.98
Range	-2.50 to -21.50
Sphere (D)	
Mean	-8.08 ± 5.09
Range	-0.50 to -19.00
Cylinder (D)	
Mean	-3.58 ± 1.26
Range	-1.75 to -7.00
Pupil size (mm)	
Mean	5.5 ± 1.03
Range	3.0 to 7.0
ACD (mm), range	3.03 to 4.23
Axial length (mm)	23.16 to 31.84
IOL power (D), range	-3.25 to -20.00
Hyperopic eyes	
Spherical equivalent (D)	
Mean	+3.43 ± 1.58
Range	+1.50 to +6.25
Sphere (D)	
Mean	+5.10 ± 1.56
Range	+3.50 to +6.50
Cylinder (D)	
Mean	-3.37 ± 0.88
Range	-1.50 to -4.25
Pupil size (mm)	
Mean	5.3 ± 0.65
Range	4.0 to 6.0
ACD (mm), range	2.99 to 3.84
Axial length (mm)	20.69 to 22.69
IOL power (D), range	+2.00 to +7.50

ACD = axial length; IOL = intraocular lens

hyperopic group. During the 3-year follow-up, 4 eyes in the myopic group and 1 eye in the hyperopic group were excluded. Two patients moved away, and 1 patient did not attend the follow-up visits. Table 1 shows the preoperative data, including refraction, ACD, axial length, and pIOL power, in both groups.

Visual Acuity

Preoperative UCVA in 75% of eyes in the myopic group was 20/400; preoperative UCVA in 75% of eyes in the hyperopic group was 20/60. All eyes had a postoperative improvement in UCVA over preoperative values. After 3 years, 58% of eyes in the myopic group had a postoperative UCVA of 20/40 or better and 17% achieved a postoperative UCVA of 20/25 or better. In the hyperopic group, 73% of eyes had a postoperative UCVA of 20/40 or better and 27% achieved a postoperative UCVA of 20/25 or better (Figure 1).

The mean 3-year postoperative BSCVA was 20/25 in the myopic group and 20/20 in the hyperopic group. In the myopic group, 67% of eyes gained 1 or more Snellen lines and 46% gained 2 or more lines. In the hyperopic group, 36% of eyes gained 1 or more Snellen lines and 9% gained 2 or more lines (Figure 2).

The overall efficacy index (mean postoperative UCVA/mean preoperative BSCVA) was 1.04 ± 0.10 in the myopic group and 1.14 ± 0.13 in the hyperopic group. The overall 3-year postoperative refractive safety index (mean postoperative BSCVA/mean preoperative BSCVA) was 112% in the myopic group and 104% in the hyperopic group. Seventy

percent of eyes in both groups were within ± 1.00 D of the intended refraction 3 years after surgery.

Astigmatism

In the myopic group, the mean postoperative subjective cylinder was -1.15 ± 1.01 D and in the hyperopic group, -1.53 ± 0.69 D. Thus, the mean reduction in astigmatism was -2.43 D in the myopic group and 1.84 D in the hyperopic group. At the last visit, the mean difference between intended and achieved torus orientation was 1.0 ± 3.40 degrees in the myopic group and 0.42 ± 1.27 degrees in the hyperopic group (Figure 3).

Intraocular Pressure

In both groups, there were no statistically significant changes in IOP during the follow-up. After 3 years, the mean IOP was 15 mm Hg (range 10 to 18 mm Hg) in the myopic group and 17 mm Hg (range 14 to 18 mm Hg) in the hyperopic group (Figure 4).

Complications

One eye had transient postoperative corneal edema that resolved after 1 week. Iris pigment precipitates of varying intensity were observed on the lens optic in 7 eyes. Immediately after surgery, 2 eyes had increased IOP (32 mm Hg) that normalized without additional local or systemic therapy. A postoperative wound leak with low IOP (4 to 8 mm Hg) and flattening of the anterior

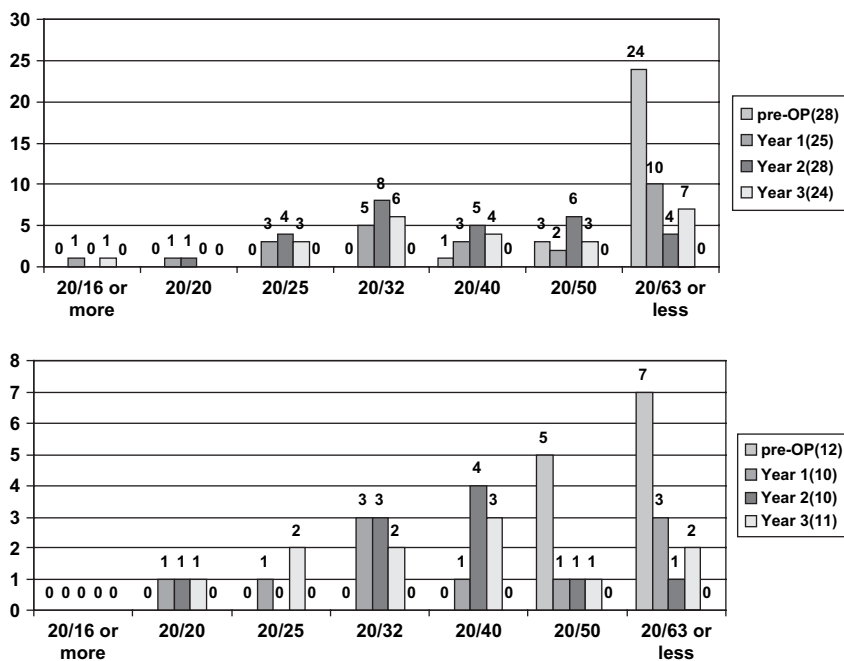


Figure 1. Postoperative UCVA in the myopic (top) and hyperopic (bottom) groups.

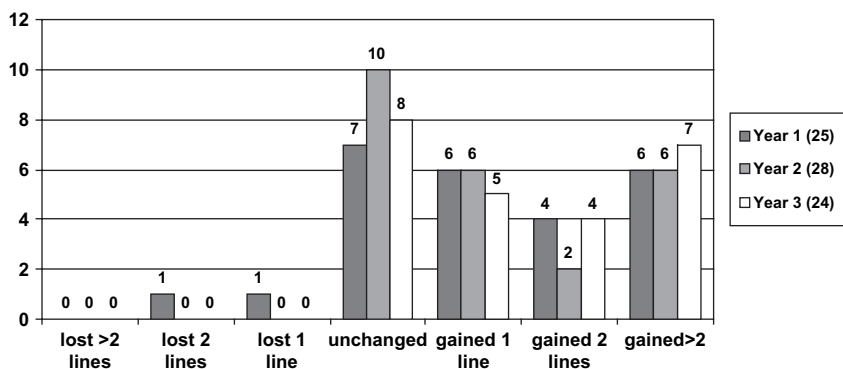
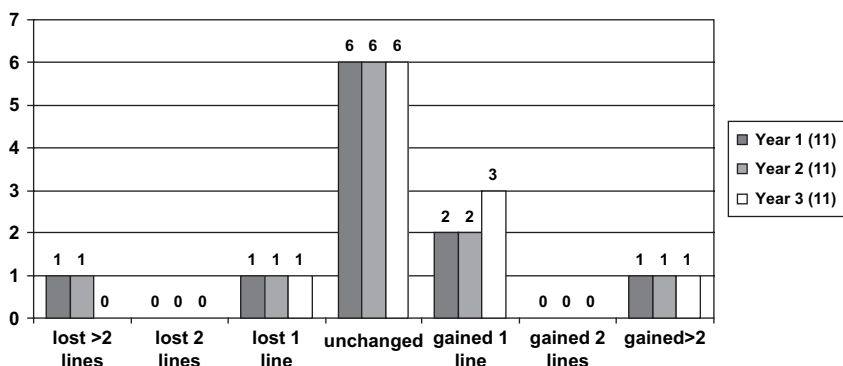


Figure 2. Gains and losses in BSCVA in the myopic (*top*) and hyperopic (*bottom*) groups.



chamber occurred in 1 eye, which required suture closure of the corneoscleral tunnel incision. One week postoperatively, successful repositioning of the pIOL was performed in 1 hyperopic eye because of a 15-degree deviation from the target axis of 175 degrees.

No potentially sight-threatening complications such as iris prolapse, iris atrophy, touch of the anterior lenticular capsule, persistent corneal edema, pupillary block, cataract formation, retinal detachment, or endophthalmitis were observed during the postoperative period.

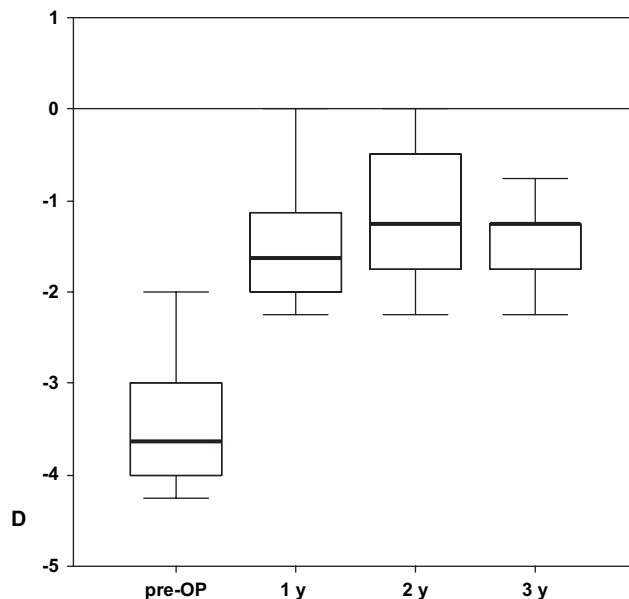
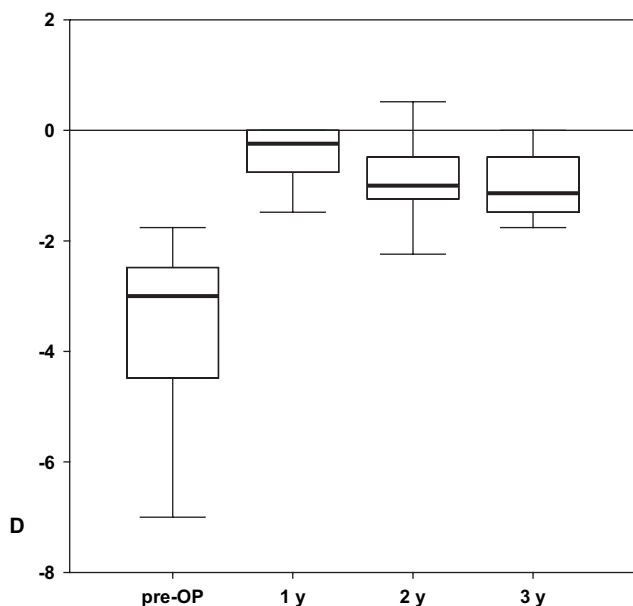


Figure 3. Reduction in total astigmatism during preoperative versus postoperative period. Horizontal lines indicate medians and 1st and 3rd quartiles. Vertical extensions indicate minimum/maximum values, and circles indicate outlier values. *Left:* Myopia group. *Right:* Hyperopia group.

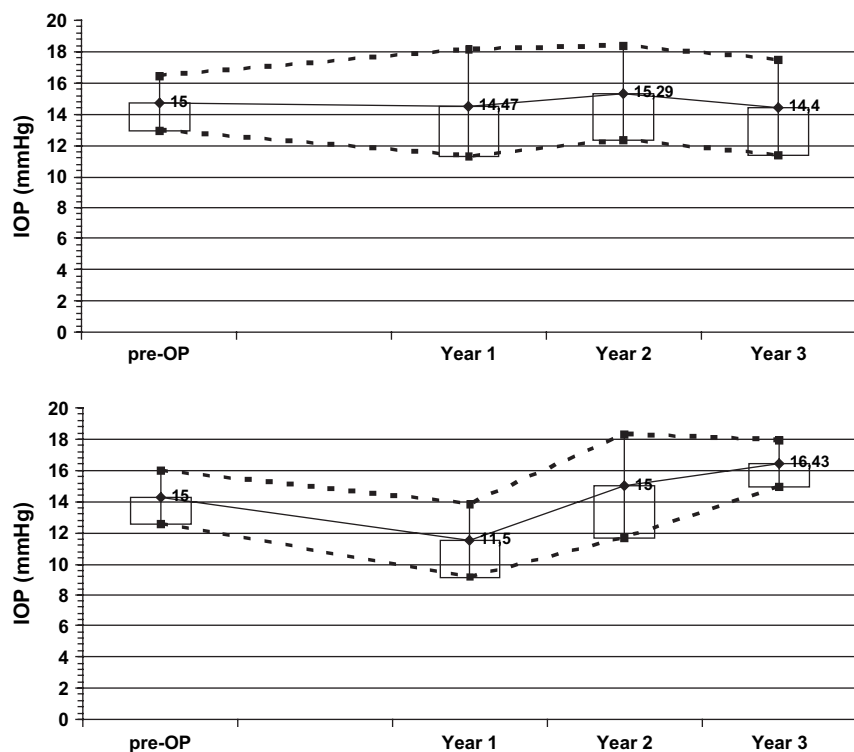


Figure 4. Intraocular pressure in the 1, 2, and 3 years after iris-fixated toric pIOL implantation in the myopic (top) and hyperopic (bottom) groups.

DISCUSSION

To our knowledge, this is the first report of 3-year surgical outcomes after implantation of an iris-fixated toric IOL in phakic eyes. Our data demonstrate that the iris-fixated toric pIOL is an effective surgical option to correct high ametropia and astigmatism in 1 procedure. In the myopic group, mean BSCVA was 20/40 preoperatively and improved to 20/25 postoperatively; in the hyperopic group, mean BSCVA improved from 20/25 preoperatively to 20/20 postoperatively.

Several studies of the iris-fixated toric pIOL have refractive outcomes similar to ours. In a European multicenter clinical study, Dick et al.¹ reported no loss of BSCVA and a gain of 1 or more Snellen lines from the preoperative BSCVA in 46 eyes. In 62 eyes (88.6%), UCVA was 20/40 or better. Spherical errors and astigmatism were significantly reduced in all cases. In the myopic group, the mean refractive astigmatism was reduced from 3.74 ± 1.09 D to 0.63 ± 0.53 D. In the hyperopic group, the mean refractive astigmatism was reduced from 3.70 ± 1.05 D to 0.77 ± 0.64 D.

Güell et al.¹⁰ report that in a study of the Artisan toric IOL, 62.9% of eyes were within ± 0.50 D of emmetropia; 70% gained 1 or more Snellen lines from the preoperative BSCVA, and 11.1% lost 1 Snellen line. The means of the

parallel and orthogonal components of cylindrical correction were 1.97 D and 0.10 D, respectively, of the intended cylinder change.

Surgical options for correcting astigmatism include corneal or limbal relaxing incisions, PRK, and LASIK.^{1,5,10} Although LASIK is the leading refractive technique for correcting refractive errors, it has limited ability to correct higher astigmatism. Keratorefractive procedures irreversibly change the corneal curvature and may change its optical quality by inducing additional visual aberrations.¹ Refractive lens exchange as an alternative procedure is controversial because of the increased incidence of retinal detachment in eyes with high myopia. The rate of retinal detachments ranges from 1.9% to 8.1%¹¹⁻¹⁴ and remains a concern with this procedure. The concomitant loss of accommodation is another disadvantage, especially in younger patients.

Correction of high astigmatism may be achieved with combined procedures such as astigmatic keratectomy and LASIK. However, pIOLs correct lenticular and corneal astigmatism and ametropia in 1 reversible procedure.¹⁵ In addition, compared with keratorefractive options, predictability is more accurate with pIOLs for myopia greater than -10.0 D.^{16,17} The potential risks and complications associated with iris-fixated IOLs must be taken into

consideration. It is crucial that highly trained surgeons familiar with the special implantation technique perform the surgery to reduce intraoperative and postoperative complications.⁵ Surgically related complications including transient corneal edema from endothelial touch, transient IOP elevation, or hyphema can be minimized by accurate surgical training.

Progressive endothelial cell loss, uveitis, pigment dispersion, and the development of glaucoma are major concerns.¹ A preoperative iridotomy or an intraoperative iridectomy is highly recommended, as is an annual examination that includes endothelial photography. Risk factors for progressive endothelial cell loss are age, flat ACD, and a thicker IOL optic.¹⁸

Menezo et al.¹⁹ report a mean endothelial loss of 6.6% at 1 year, 9.2% at 2 years, and 11.7% at 3 years. Pérez-Santonja et al.¹⁸ describe a 13% endothelial cell loss at 1 year and 17.6% 2 years after implantation. Mean endothelial cell loss in this patient population was 3.2% 3 years postoperatively in the myopic group and 2.9% in the hyperopic group (unpublished data). These results represent cell loss values greater than the physiological annual cell loss. However, this decrease is significantly lower than described by Menezo et al. and Pérez-Santonja et al.

Iris-fixated pIOL implantation was an effective, safe, and predictable option for high ametropia and astigmatism in this 3-year follow-up study. Accommodation and corneal curvature preservation are advantages of the procedure. There were no major complications, although further studies of a larger patient population with a longer follow-up are recommended.

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