

Toric Phakic Intraocular Lens

European Multicenter Study

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Objective: To evaluate safety, efficacy, predictability, stability, complications, and patient satisfaction after implantation of Artisan toric phakic intraocular lenses (TPIOLs) for the correction of myopia or hyperopia with astigmatism.

Design: Prospective, nonrandomized, comparative (self-controlled) multicenter trial.

Participants: Seventy eyes of 53 patients (mean, 35 years; range, 22–59 years) with preoperative spherical equivalent between +6.50 and –21.25 diopters (D) and cylinder between 1.50 and 7.25 D.

Methods: Seventy eyes underwent implantation of a TPIOL with an optical zone of 5.0 mm (Artisan, Ophtec, Groningen, The Netherlands). The dioptric power of the intraocular lens was calculated by considering refraction, keratometry, and anterior chamber depth. The follow-up was 6 months in all cases. Lenses were available in powers ranging from +12.0 D to –23.5 D (spherical equivalent) in 0.5-D increments, with additional cylinder from 1.0 D to 7.0 D, also in 0.5-D increments.

Main Outcome Measures: The main parameters assessed were best spectacle-corrected visual acuity (BSCVA), uncorrected visual acuity (UCVA), refraction, endothelial cell count (ECC), intraocular pressure, slit-lamp biomicroscopy, indirect ophthalmoscopy, subjective complaints, and patient satisfaction.

Results: Eyes were divided into group A, myopia (n = 48), with an average preoperative spherical equivalent of -8.90 ± 4.52 D, and group B, hyperopia (n = 22), with an average preoperative spherical equivalent of $+3.25 \pm 1.98$ D. No eyes in either group experienced a loss in BSCVA, and 46 eyes gained 1 or more lines of their preoperative BSCVA. In 62 eyes (88.6%), UCVA was 20/40 or better. There was a significant reduction in spherical errors and astigmatism in all cases after surgery. All eyes of both groups were within ± 1.00 D of target refraction, and 51 eyes (72.9%) were within ± 0.50 D of target refraction. There was a 4.5% mean total loss of ECC during the first 6 months. No serious complications were observed. Overall patient satisfaction was very high.

Conclusions: Six-month clinical trial results demonstrate that implantation of the Artisan TPIOL safely, predictably, and effectively reduced or eliminated high ametropia and astigmatism with one procedure. The refractive effect was stable at 6 months after surgery. *Ophthalmology* 2003;110:150–162 © 2003 by the American Academy of Ophthalmology.

Currently favored surgical techniques for treating ametropia with astigmatism include keratorefractive procedures, such

as laser in situ keratomileusis (LASIK), and photorefractive keratectomy.^{1,2} The complications that have been reported for laser correction of high refractive errors include low predictability, regression, corneal ectasia, and, mainly, poor quality of vision under dim illumination; these are likely

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related to the change of the corneal contour and the small optical treatment zone.^{3,4}

Intraocular procedures capable of correcting the refractive error include phakic intraocular lens (pIOL) implantation, which permits optical correction of the refractive error while maintaining accommodation,⁵ and clear lens exchange (CLE), which must be considered with caution, especially in myopic eyes, because of the potentially higher risk of retinal detachment and loss of accommodation in young patients, among other complications.^{6,7} Similar to corneal refractive surgery, pIOLs use a smaller optical zone to treat higher ametropia.⁸

Over the last few years, phakic anterior chamber lenses for correction of high ametropia have been implanted with satisfactory results. In 1986, Fechner and Worst⁹ modified the existing iris claw lens for aphakia into a negatively biconcave lens to correct high myopia. To increase the safety of this pIOL, the optic design was changed into a convex-concave shape in 1991, and the optic diameter was increased to 5.0 mm to reduce photic phenomena. This lens, called the Worst myopia claw lens, has been implanted successfully since then. In 1998, the name of the lens was changed to the Artisan lens (Ophtec, Groningen, The Netherlands), without a change in lens design. In 2002, AMO (Santa Ana, CA) acquired the global distribution rights and will market its own brand of the Artisan, known as the Verisyse, in the United States and other new markets.

With the introduction of the new Artisan toric phakic intraocular lens (TPIOL), theoretically, the need for combining pIOL implantation with keratorefractive procedures is significantly reduced, avoiding possible complications or problems (e.g., flap striae, haze, reduction in contrast sensitivity under low-light conditions) of any additional keratorefractive procedure. Both spherical and cylindrical correction are combined in the Artisan TPIOL, which aims to correct the total refractive error and spherical and astigmatic error (e.g., corneal astigmatism, lens astigmatism).

To our knowledge, there have been no previous reports on surgical outcome after implantation of a TPIOL. This prospective study was designed to evaluate the clinical and refractive results of this new iris-supported TPIOL model for the correction of ametropia and astigmatism.

Patients and Methods

Patients

Patients older than 18 years, with stable refraction for at least 1 year and astigmatism greater than 1.50 diopters (D), and who also had an otherwise normal ophthalmologic examination and unsatisfactory correction with spectacles or contact lenses for medical, professional, or personal requirements were included. Investigators considering implantation in such patients had to explore the use of alternative methods of refractive correction and consider lens implantation only if the alternatives were deemed unsatisfactory to meet the needs of the patient. Preoperative counseling took place at the time of the initial consultation, and patients were also given a pamphlet to take home and read before committing to undergo surgery. It was emphasized that the objective of the surgery was to achieve reduced spectacle use, realizing that correction might still be required in certain situations such as when

reading or in low ambient lighting. Potential complications of intraocular surgery were also outlined, together with alternative refractive techniques and their respective benefits and risks. All patients were fully informed about the details and possible risks of the specific procedure. Written, informed consent was obtained in all patients before surgery in accordance with the Declaration of Helsinki, and the study was approved by the local ethics committee.

Exclusion criteria were anisometropia, anterior segment pathology, inadequate eyelid closure, endothelial cell count of <2000/mm², anterior chamber depth (ACD) <3 mm, abnormal iris or abnormal pupil function, fixed pupil size >4.5 mm, recurrent or chronic uveitis, any form of cataract, previous corneal or intraocular surgery, intraocular pressure (IOP) >21 mmHg, glaucoma or family history of glaucoma, retinal detachment or family history of retinal detachment, preexisting macular degeneration or macular pathology, systemic diseases (e.g., autoimmune disorder connective tissue disease, atopia, diabetes mellitus), chronic treatment with corticosteroids or any immunosuppressive treatment or state, and pregnancy.

Preoperative and Postoperative Examination

Preoperative and postoperative visits at 1 week, 1 month, 3 months, and 6 months included determination or calculation of uncorrected visual acuity (UCVA), determination of best spectacle-corrected visual acuity (BSCVA), keratometry and/or computerized corneal topography, measurement of the pupil diameter under mesopic and/or scotopic conditions, manifest and cycloplegic refraction (45 minutes after two drops of 1% cyclopentolate) to calculate the spherical equivalent (SE), slit-lamp biomicroscopy to evaluate any lens changes after mydriasis and to determine TPIOL position and axis (axis of enclavation of the slit when passing in the center of the haptics' bridges and the center of the TPIOL's optic), applanation tonometry, evaluation of the central corneal endothelial cell count by using specular microscopy, measurement of the ACD (measured by ultrasound or optical biometry), and indirect ophthalmoscopy. Before the examinations, contact lens wearers were required to leave the lenses out for at least 2 weeks if using hard contacts and for at least 1 week if using soft contact lenses.

The subjective response for postoperative satisfaction was rated on a scale from 1 to 10 (1 for very poor and 10 for excellent). All examinations were performed by the investigator or by an optometrist trained and supervised by the clinical investigator. For the evaluation of the corneal endothelium, the photograph with the largest selectable region of interest for cell counting was selected. The cell count was performed with the method of Waring et al.¹⁰ Patients with a preoperative cell count <2000/mm² or striking non-age-related pleomorphism or polymorphism were excluded from the study. Endothelial cell loss (ECL) was defined as follows:

$$ECL (\%) = \frac{(\text{preop} - \text{postop})}{\text{preop}},$$

where *preop* is the preoperative cell count and *postop* is the postoperative cell count.

Standardized case-report forms were used to collect data at each site and were then relayed to the principal study investigator (HBD).

The TPIOL

The biomaterial of this one-piece compression molded Artisan TPIOL consists of Perspex CQ-UV polymethylmethacrylate (ICI, United Kingdom) with Tinuvin 326 (Ciba Speciality Chemicals, Basel, Switzerland), a benzotriazole, which exhibits effective ul-

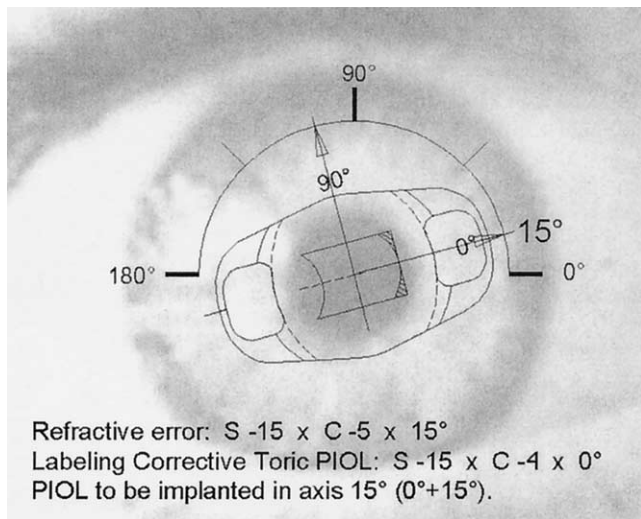


Figure 1. Model A (the cylinder axis is equal to the axis, which runs through the claws) to correct a myopic refractive error of $-15 \times -5 \times 15^\circ$: correct placement of the toric phakic intraocular lens (TPIOL) (label shows $-15 \times C -4 \times 0^\circ$).

traviolet filtration up to approximately 400 nm. The optic diameter is 5.0 mm, and the overall length is 8.5 mm.¹¹ Total height values did not exceed 1.04 mm. The two diametrically opposed haptics fixated the lens on the iris by enclavation of midperipheral iris stroma.

Available TPIOL powers were from -3 to -23.5 D for myopia and from $+2$ to $+12$ D for hyperopia, with a cylindrical correction from 1.0 to 7.0 D. The dioptric power of the TPIOLs was calculated with the Van der Heijde formula,¹² which uses the corneal curvature (K), adjusted ACD, and manifest SE of the patient's subjective refractive error:

$$\text{Power} = \frac{n}{(n/k + P_s)} + \frac{n}{(n/k) - d}$$

where k is the keratometric value of the cornea (D), P_s is the equivalent spectacle power of the corneal plane (D), d is the

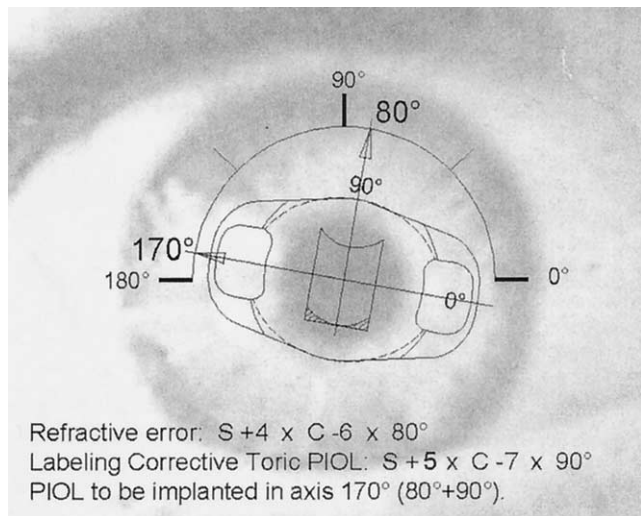


Figure 2. Model B (the cylinder axis is perpendicular to the axis, which runs through the claws) to correct a hyperopic refractive error of $+4 \times -6 \times 80^\circ$: correct placement of the toric phakic intraocular lens (TPIOL) (label shows $+5 \times C -7 \times 90^\circ$).

Table 1. Summary of Preoperative Data for Patients Undergoing Implantation of Toric Phakic Intraocular Lenses

Variable	Group A (SE <0)	Group B (SE ≥0)
Average age (yrs)	35	35
Range of age (yrs)	22-59	26-50
Total no. of eyes	48	22
Right eyes	27	10
Left eyes	21	12
Mean sphere ± SD (D)	-7.03 ± 4.65	5.2 ± 1.93
Range of sphere (D)	-19.0 to 1.75	$2-8$
Mean cylinder ± SD (D)	-3.74 ± 1.09	-3.7 ± 1.05
Range of cylinder (D)	-7.25 to -1.75	-6 to -1.5
Mean spherical equivalent ± SD (D)	-8.9 ± 4.52	3.35 ± 1.98
Range of SE (D)	-21.25 to -1.25	$0-6.5$
Mean corneal power ± SD (D)	44.11 ± 3.2	43.11 ± 2.57
Mean anterior chamber depth (mm)	3.57 ± 0.26	3.36 ± 0.28
Range of anterior chamber depth (mm)	$3.2-4.1$	$2.95-3.84$
Mean axial length ± SD (mm)	26.84 ± 1.87	21.99 ± 0.72
Range of axial length	$23.15-30.25$	$20.69-22.80$

D = diopters; SD = standard deviation; SE = spherical equivalent.

distance (mm) between the intraocular lens (IOL) plane and the corneal plane, and n is the refractive index of aqueous (1.336). Because the distance between the crystalline lens and the TPIOL is 0.8 mm, the d value was corrected with this number.

Required data for the lens power calculation were the following.

1. Manifest objective refraction (autorefractor).
2. Manifest subjective refractive correction at a vertex distance of 12 mm, determined with a phoropter (cross-cylinder technique).
3. ACD (anterior corneal surface to anterior curvature of the crystalline lens).
4. k values (computerized corneal topography, autokeratometer, Javal).
5. Total subjective cylindrical power and axis.

All power calculations were performed by Ophtec BV Groningen, The Netherlands. Most surgeons implanting the Artisan nontoric pIOL prefer to position the IOL horizontally (or oblique, if the surgeon intends to correct some astigmatism by choosing the incision site in the steepest meridian). To allow surgeons to implant the TPIOL in the position they are accustomed to, two models of TPIOLs are available (Figs 1 and 2). In model A (TPIOL-0), the torus axis runs through the claws 0° compared with the torus axis in model B, which is perpendicular to the line that runs through the claws (TPIOL-90). For reference, if the preoper-

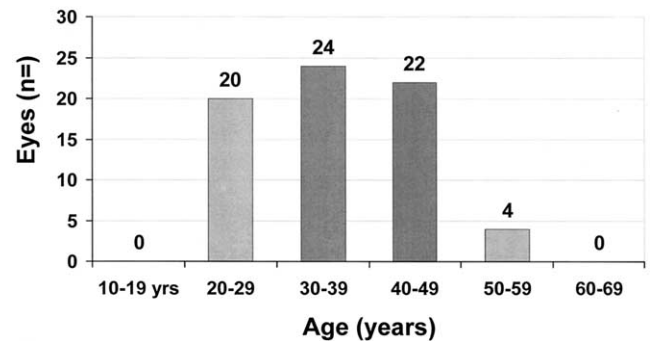


Figure 3. Age distribution of the patients.

ative cylinder axis was between 0° and 45° or between 135° and 180°, a TPIOL with the torus axis at 0° was recommended (model A). In a model A TPIOL, the torus axis is identical to the target enclavation axis, which is equal to the refractive cylinder axis of the patient's eye. When eyes had a cylinder axis between 45° and 135°, a TPIOL with the torus at 90° was recommended (model B). In model B, the correct implantation axis was equal to the refractive cylinder axis of the patient's eye plus 90°.

For a proper placement of the Artisan TPIOL in the cylindrical axis (or perpendicular to the axis) and to avoid placement errors, the surgeon received an illustration of the correct TPIOL position in situ. In accordance with European laws, the Artisan TPIOL had the regulatory status of a custom-made device and did not carry the CE (Conformité Européenne) mark during this clinical investigation.

The CE (Conformité Européenne) mark appears on products that meet safety standards that apply to all countries of the European Union (EU). It was created under the Single European Act and introduced to facilitate the free movement of goods (and services) within the European Union.

Surgical Procedure

The surgical technique is basically the same as that used with standard Artisan refractive IOLs. All surgeons had at least 1 year of experience with the implantation of Artisan myopia/hyperopia pIOLs. There were some differences in the type of surgery among the several surgeons involved in this study. Most surgeons had at least 3 years' experience with the Artisan IOL. Several minor variations of the surgical technique were used to implant the TPIOL. Before surgery, patients were prepared as for standard cataract surgery, but with the addition of miotic drops (pilocarpine 1% to 2%) to prepare the iris for lens fixation, reduce the risk of lens touch during implantation, and facilitate centration of the lens.

Ocular anesthesia was general, retrobulbar, or peribulbar, depending on patient needs and surgeon preference. Povidone-iodine solution (Betadine) was used to prepare and clean the eye and was instilled into the conjunctival sac. Its antiseptic effect continued during the few minutes it took to position and drape the patient before surgery began.

Typically, a 5.3-mm (range, 5–6 mm) primary incision was made, and two paracenteses were made (for instrument access to fixate the lens). The site of the approach depended on the predetermined implant location and cylindrical axis. Several incision types were used by the surgeons: a clear corneal incision in 19 eyes (27%), a limbal incision in 22 eyes (31%), a corneoscleral incision in 26 eyes (37%), and a scleral incision in 3 eyes (4%). In two eyes, a temporal approach was chosen (one TPIOL-90 was implanted at 105°, and one TPIOL-0 was implanted at 100°).

Instillation of a cohesive hyaluronic acid-based ophthalmic viscosurgical device (OVD) through the paracenteses and primary incision was mandatory to maintain sufficient ACD, protect the corneal endothelium, and facilitate adjusting the lens within the eye during fixation. No hydroxypropylmethylcellulose or chondroitin sulfate-containing OVD was used. All OVD was removed by irrigation at the end of the procedure. The closed-system approach using the spreader device introduced by Krumeich et al¹³ was used in four eyes, and a needle was used in the other eyes for safe implantation of the TPIOL. In all eyes, we attempted to achieve a watertight self-sealing tunnel incision without the need to suture.

If simultaneous bilateral surgery was undertaken, the surgeon's gown and gloves were changed, and a separate set of surgical instruments was used. Povidone-iodine solution was instilled before surgery for a second time. On discharge, patients were prescribed a steroid/antibiotic combination for at least 5 days.

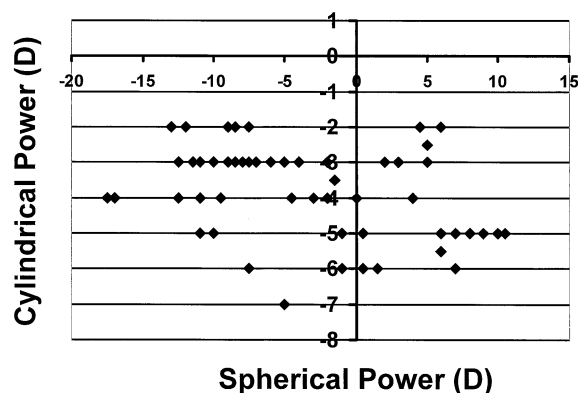


Figure 4. Power distribution of implanted Artisan toric phakic intraocular lenses. D = diopters.

Marking the Enclavation Sites

The enclavation of the claws had to be precisely in the cylindrical axis (or perpendicular to the axis, depending on the lens used). Marking the enclavation sites on the iris with an argon laser before surgery or marking the limbus at the site of the incisions to allow introduction of the enclavation forceps was recommended (with the patient in the sitting position). Alternatively, two surgeons (HBD and OS) used the iris structure (e.g., crypts, pigment, vessels) as a natural marker for the correct positioning of the lens, with the exception of brown irides.

Precise Placement with Enclavation Forceps

To achieve precise placement of the TPIOL in the cylinder axis (or perpendicular to the axis, depending on the lens used), the use of the enclavation forceps was recommended. The paracenteses (side ports) were made accordingly.

Follow-up

Patients were evaluated after surgery at 1 day, 1 week, 4 weeks, 3 months, and 6 months.

Statistical Analysis

Data were collected on standardized case-report forms and then entered into a central database for analysis. Except for one follow-up form in the myopia group at the 3-month examination, there were no missing data in the analysis. For statistical analysis, the logarithm of the minimum angle of resolution values of the visual acuity were converted to decimal notation, and vice versa,

Table 2. Gains and Losses of BSCVA after implantation of Toric Phakic Intraocular Lenses

BSCVA	Group A (n = 48)	Group B (n = 22)
Lost one line	0 (0%)	0 (0%)
No change	15 (31%)	9 (41%)
Gained one line	17 (35%)	10 (45%)
Gained two lines	7 (15%)	2 (9%)
Gained two or more lines	9 (19%)	1 (5%)

BSCVA = best spectacle-corrected visual acuity.

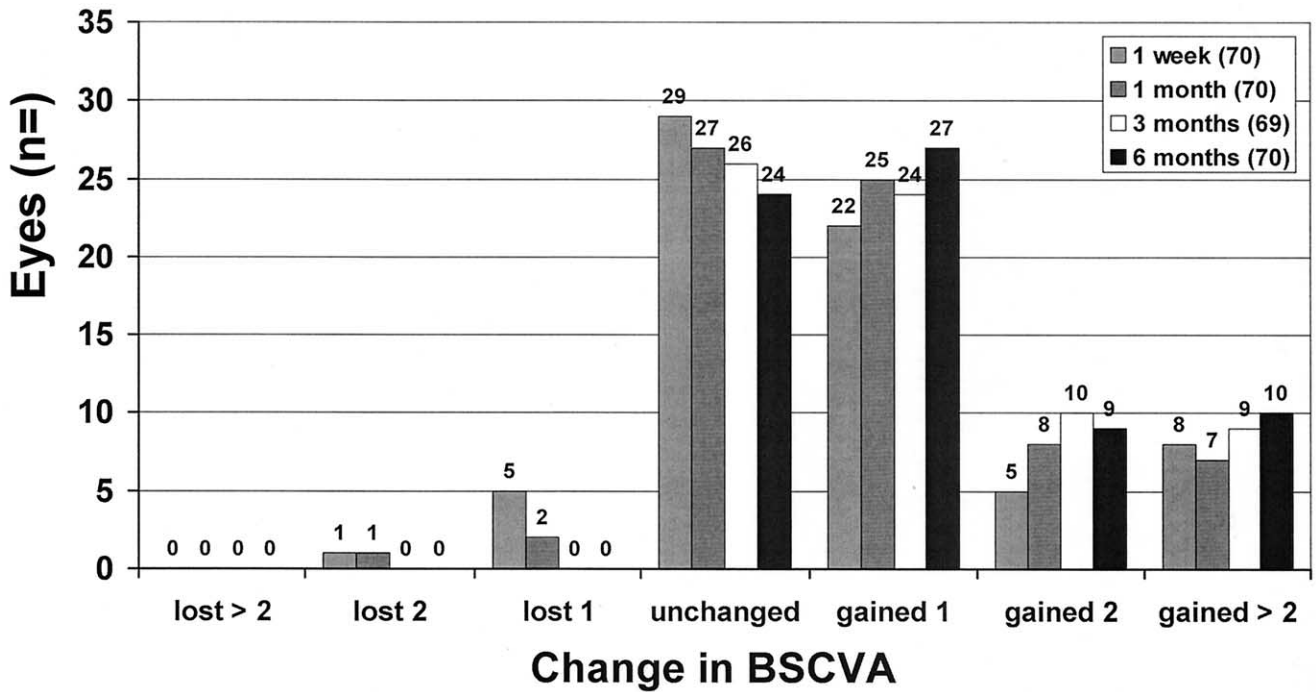


Figure 5. Change in best spectacle-corrected visual acuity (BSCVA) after implantation of toric phakic intraocular lenses.

as described by Westheimer.¹⁴ Descriptive statistics, multivariate analysis, and correlation analysis were conducted with StatView for Macintosh (release 4.51; Abacus Concepts, Berkeley, CA). Continuous variables were described with mean, standard variation, median, minimum, and maximum values. The paired Student's *t* test was used to evaluate the significance of within-group differences. A *P* value of <0.05 was considered significant.

Results

Between January 2000 and June 2001, 70 eyes of 53 patients (34 female, 19 male) received an Artisan TPIOL (Table 1). All eyes were available for analysis at 6 months. The final examination

results, which in all cases was 6 months after surgery, are reported. The mean age was 35.4 ± 9.7 years (standard deviation) (range, 22–59 years; Fig 3). Eyes were divided into group A, myopia ($n = 48$), with an average preoperative SE of -8.9 ± 4.52 D, and group B, hyperopia ($n = 22$), with an average preoperative SE of $+3.25 \pm 1.98$ D.

The mean ACD was 3.57 ± 0.26 mm (range, 3.20–4.10 mm) in group A and 3.26 ± 0.27 mm (range, 3.0–3.84 mm) in group B. Mean axial length was 26.84 ± 1.87 mm (range, 23.16–30.25 mm) in group A and 21.99 ± 0.72 mm (range, 20.69–22.80 mm) in group B. Figure 4 shows the distribution of the TPIOL power range. The torus was manufactured in steps of 0.50 D. 61 model A TPIOLs (or TPIOL-0) and nine model B TPIOLs (or TPIOL-90) were implanted.

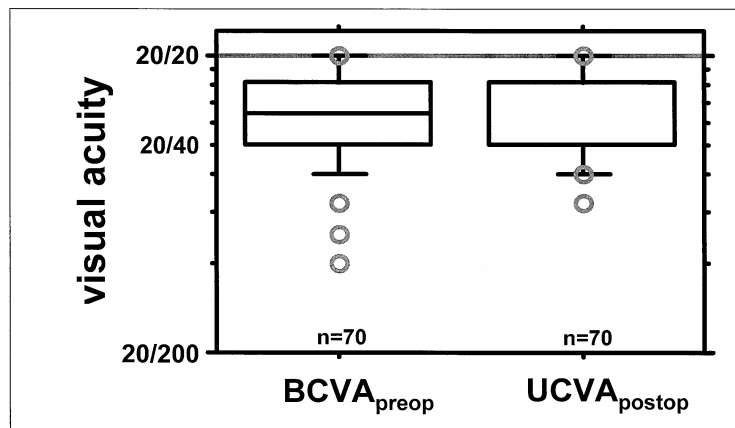


Figure 6. Boxplots for the overall efficacy index (mean postoperative UCVA/mean preoperative BCVA) at the latest visit (horizontal lines indicate medians and 1st and 3rd quartiles; vertical extensions indicate minimum/maximum values and circles outlier values). BCVA = best-corrected visual acuity; UCVA = uncorrected visual acuity.

Table 3. Postoperative Uncorrected Visual Acuity after implantation of Toric Phakic Intraocular Lenses (Visual Acuity in Decimals Shown in Parentheses)

UCVA	20/20 (1.0) or Better	20/30 (0.63) or Better	20/40 (0.5) or Better	20/50 (0.32) or Better
Group A (n = 48)	3 (6.3%)	33 (68.8%)	41 (85.4%)	47 (97.9%)
Group B (n = 22)	4 (18.2%)	18 (81.8%)	21 (95.5%)	22 (100%)

UCVA = uncorrected visual acuity.

We adopted the standardized format for reporting refractive surgery results as described by Koch et al,¹⁵ which assesses various criteria, including safety, efficacy, predictability, stability, secondary procedures, and complications, as described in the following section.

Safety

The mean preoperative BSCVA for all eyes was 0.68 ± 0.23 (range, 0.25–1). After 6 months, the mean postoperative BSCVA was 0.85 ± 0.16 (range, 0.5–1) for all eyes. A BSCVA of 20/40 or better was reported in all eyes at 6 months. The overall refractive safety index of the procedure (ratio of mean postoperative BSCVA to mean preoperative BSCVA) assessed at the latest postoperative visit was 125.1%. The number of eyes gaining and losing lines of BSCVA over time is shown in Table 2. No eye sustained any loss in BSCVA. In 24 eyes, BSCVA remained unchanged; 27 eyes gained 1 line, 9 eyes gained 2 lines, and 10 eyes gained >2 lines of BSCVA (Fig 5). Forty-six eyes (65.7%) gained one or more lines compared with preoperative BSCVA.

Efficacy

Six months after surgery, the mean UCVA was 0.70 ± 0.19 . All eyes in the study had an improvement in UCVA. The overall

efficacy index (mean postoperative UCVA/mean preoperative BSCVA) at the latest visit was 103.3% (Fig 6). In most cases, a small amount of residual myopia was targeted. Table 3 shows the postoperative UCVA achieved for both groups. In 62 (88.6%) of 70 eyes, UCVA was 20/40 or better (Fig 7). Postoperative improvements in UCVA and BSCVA were statistically significant.

Predictability—SE

The deviation of the achieved SE correction from the calculated refractive SE correction was calculated. After 6 months, all eyes of group A (Fig 8) and group B (Fig 9) were within ± 1 D of the desired refraction.

In group A, the mean latest postoperative SE was -0.50 ± 0.56 D, with a range of +0.75 to -1.75 D. In group B, the mean latest postoperative SE was -0.24 ± 0.42 D, with range of +0.38 to -1.63 D.

Figures 8 and 9 show the spread of achieved refraction (SE) against intended refraction (SE). The number of eyes within ± 0.25 D, ± 0.5 D, ± 1.0 D, and ± 2 D of the intended refraction are shown in Table 4.

Predictability—Astigmatic Correction

In group A, the average magnitude of the refractive astigmatism was 3.74 ± 1.09 D (range, 7.25–1.75) before surgery and 0.63 ± 0.53 D (range, 2.0–0.0) after surgery. In group B, the average magnitude of the refractive astigmatism was 3.70 ± 1.05 D (range, 6.0–1.5) before surgery and 0.77 ± 0.64 D (range, 2.0–0.0) after surgery.

Double-angle formulas and plots are necessary to compute and display astigmatic data accurately because astigmatism completes a cycle in 180° rather than the normal 360° . The doubled-angle scatterplot described by Holladay et al^{16,17} of the preoperative (Fig 10) and 6-month-postoperative (Fig 11) astigmatism data, using the value of the cylinder for the magnitude and the axis of the astigmatism for the angle, shows the reduction in astigmatism.

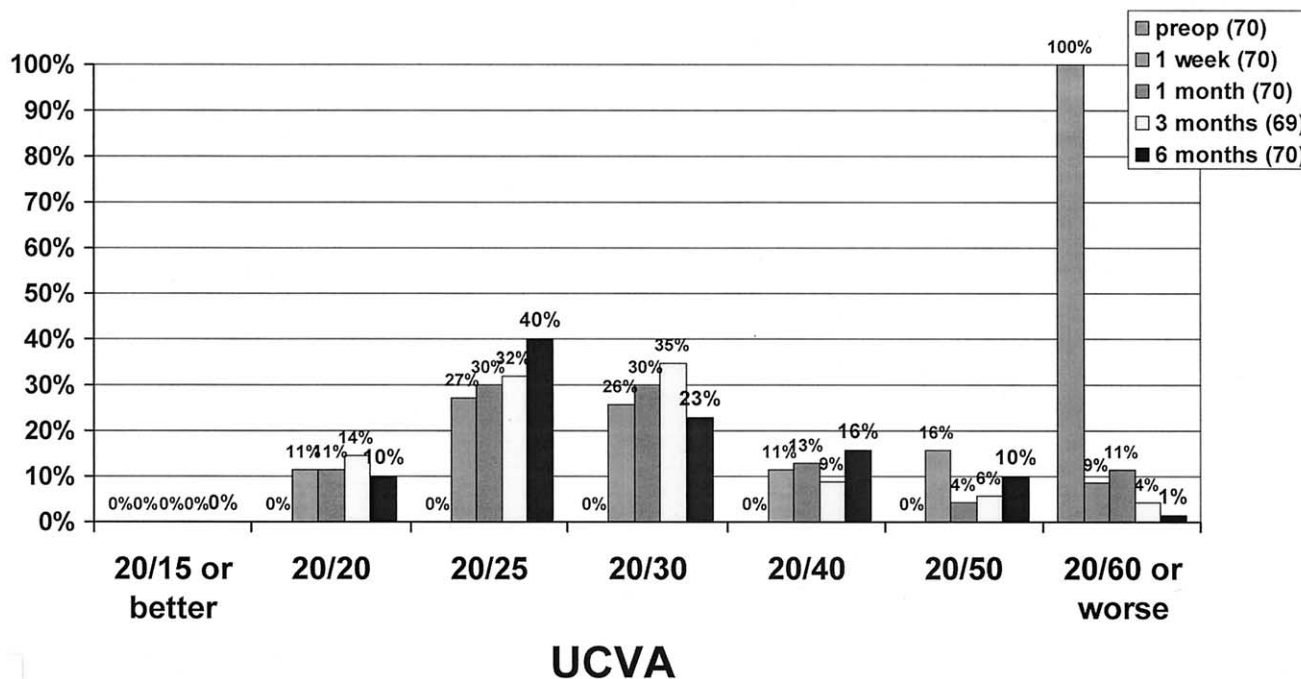


Figure 7. Change in uncorrected visual acuity after implantation of toric phakic intraocular lenses. UCVA = uncorrected visual acuity.

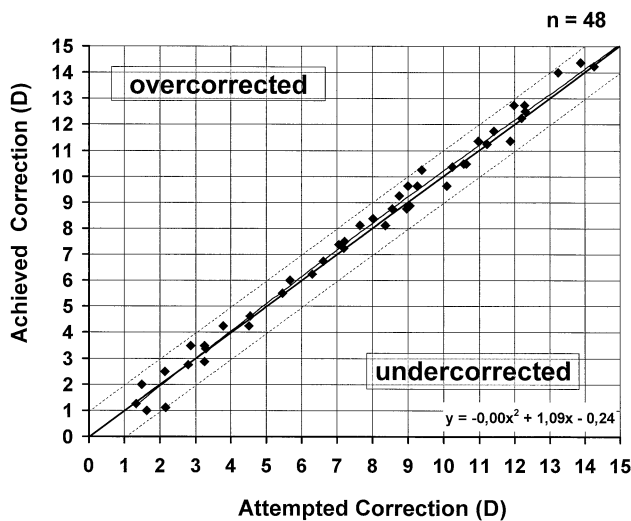


Figure 8. Spread of achieved refraction (SE) against intended refraction (SE) in group A. D = diopters; SE = spherical equivalent.

Stability (Study of Change in SE over Time)

The change in refraction (SE) between the first postoperative visit at week 1 and the latest postoperative examination was low in group A (Fig 12), with a mean SE of -0.50 D after 6 months, as well as in group B (Fig 13), with a mean SE of -0.24 D. The change in refraction between 1 week and 6 months after surgery is shown in Table 5.

Both UCVA and BSCVA stabilized rapidly after surgery, with little change during follow-up. There was no statistically significant difference in UCVA or BSCVA between the individual follow-up intervals after surgery, confirming the stability of visual acuity after surgery.

Corneal ECL

The mean preoperative endothelial cell count was $2983 \pm 505/\text{mm}^2$ (range, 2000–4600). Among all patients, the mean cell loss

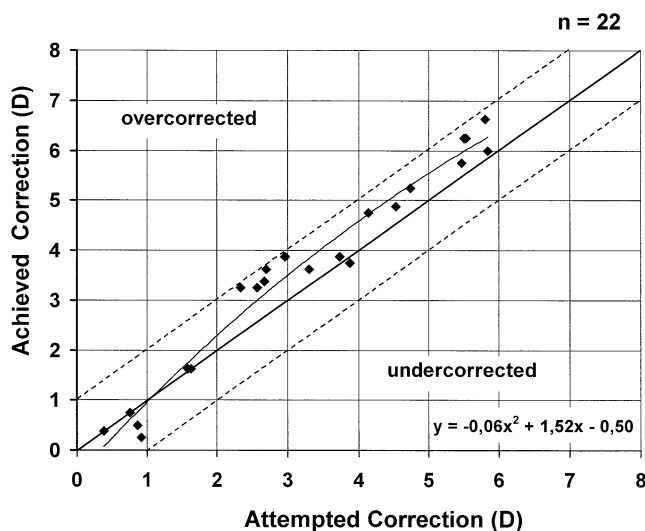


Figure 9. Spread of achieved refraction (SE) against intended refraction (SE) in group B. D = diopters; SE = spherical equivalent.

Table 4. Predictability of Achieved Spherical Equivalents after Implantation of Toric Phakic Intraocular Lenses

Group	Refraction Within		
	± 0.25 D	± 0.5 D	± 1.0 D
Group A (n = 48)	21 (43.8%)	40 (83.3%)	48 (100%)
Group B (n = 22)	7 (31.8%)	11 (50%)	22 (100%)

D = diopters.

was 4.6% at 1 week after surgery, 4.8% after 1 month, 4.9% at 3 months, and 4.5% after 6 months. Changes in endothelial cell density over the entire follow-up period are shown in Table 6. Differences in mean cell density at all postoperative consecutive visits were not statistically significant ($P > 0.05$; Fig 14). No correlation was observed between cell loss and the axial length of the globes.

Complications/Secondary Surgical Intervention

The mean preoperative IOP was 14.8 ± 3.0 mmHg (range, 8–24). Six months after surgery, the mean IOP was 14.7 ± 2.7 mmHg (range, 7–17). IOP at 1 week, 1 month, 3 months, and 6 months after surgery was not statistically significant different from preoperative IOP. Table 7 and Figure 15 show the course of IOP over time.

Two eyes required a secondary intervention. In one eye, a postoperative wound leak occurred, with low IOP (4–8 mmHg) and flattening of the anterior chamber, and required a suture closure of the corneoscleral tunnel incision. In a left hyperopic eye with an implant torus of 3 D, a reposition of the lens was performed after 1 week because of a deviation of approximately 15° from the target axis of 175° . After surgery, deviation of the implant torus from the target axis in this eye was 1° , resulting in an

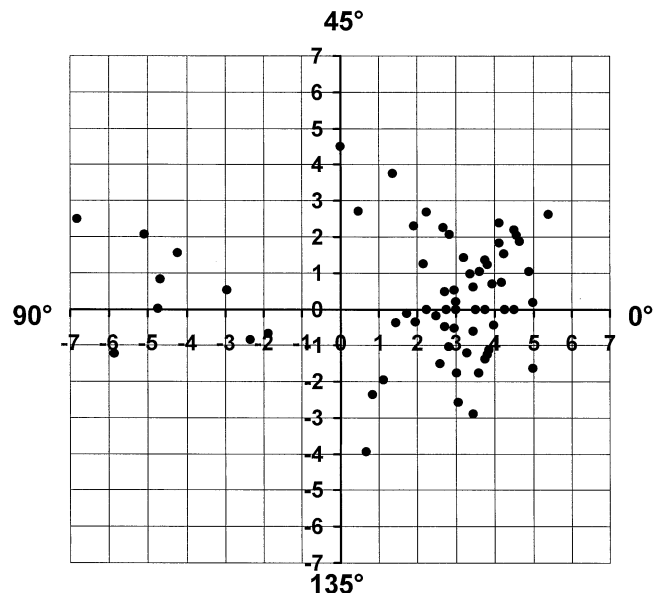


Figure 10. Doubled-angle scatterplot showing a polar plot of the preoperative spectacle plane refractive astigmatism at a vertex of 12 mm by using the value of the plus cylinder for the magnitude and the axis of the astigmatism for the angle. The 0° and 180° locations are the same, just as 0° and 180° are the same for the axis of refraction.

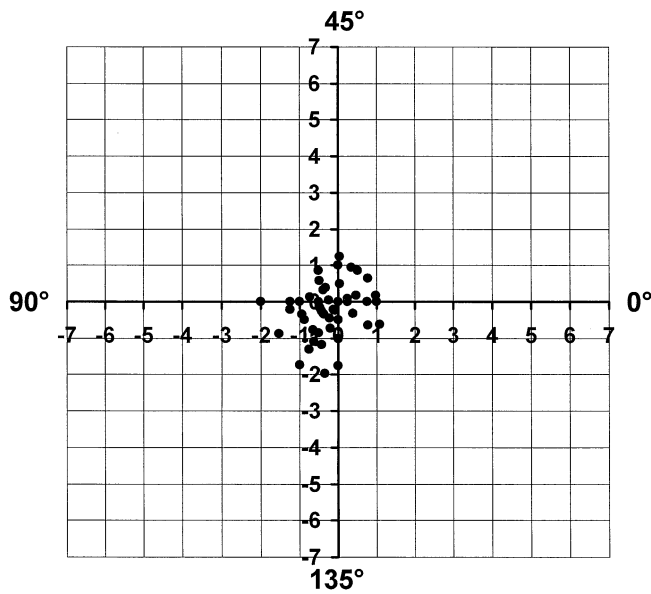


Figure 11. Doubled-angle scatterplot showing a polar plot of the 6-month-postoperative spectacle plane refractive astigmatism at a vertex of 12 mm by using the value of the plus cylinder for the magnitude and the axis of the astigmatism for the angle (see Fig 10 caption). The postoperative data are located at the center of the plot, which illustrates the great reduction of preoperative astigmatism by the implantation of the toric phakic intraocular lenses.

emmetropic refraction. In another eye, pronounced iris pigment precipitates on the optic of the TPIOL were observed.

No potentially sight-threatening complications, such as iris prolapse, iris atrophy, touch of the anterior capsule, persistent corneal edema, pupillary block, cataract formation, retinal detachment, endophthalmitis, or serofibrinous reaction, were reported during the 6-month postoperative period.

Three patients (4.3%) reported mild photic phenomena after surgery, one patient (1.4%) reported moderate glare, and no patient had severe photic phenomena. One patient of these four was slightly bothered by photic phenomena under dark lightning conditions, whereas the other three patients were not bothered by the

photic phenomena. No patient asked for TPIOL explantation or exchange.

Patient Satisfaction

After 6 months, the mean subjective overall patient satisfaction (on a scale from 1 to 10: 1 for very poor and 10 for excellent) was rated 8.98 ± 1.25 (range, 6–10) under bright light conditions, 9.19 ± 1.20 (range, 5–10) under normal light conditions, and 8.89 ± 1.29 (range, 6–10) under dark light conditions (Table 8).

Discussion

In this prospective study of 70 eyes undergoing a new surgical option in refractive surgery, the adherence to postoperative visits was relevant for investigating the evolution of complications such as ECL, described as a possible complication of iris-fixated IOLs in phakic eyes for high ametropia correction. The toric version of the Artisan pIOL measures 8.5 mm in overall length, features a 5-mm convex-concave optic, and is similar to the models for treating myopia or hyperopia, except the toric optic features a spherical anterior surface and a spherocylindrical posterior surface. In this 6-month experience with the Artisan TPIOL in 70 eyes, postoperative uncorrected and corrected visual acuity results demonstrate the safety, efficacy, predictability, and stability of the Artisan TPIOL to correct high ametropia and astigmatism. Six months after surgery, all eyes were within ± 1.00 D of the predicted correction, and 51 eyes (73%) were within ± 0.50 D of predicted correction. Budo et al¹⁸ and Pérez-Santonja et al,¹⁹ whose results resemble ours, have reported a postoperative SE refraction within ± 1.00 D in 79% and 91% of the eyes they operated on, respectively. Power increments are available in 0.5-D steps now, which is very helpful for targeting the individual's refraction and achieving good results. The mean preoperative cylinder was reduced in all eyes from 3.7 D to 0.7 D at 6 months, and the reduction achieved in preoperative astigmatism was also demonstrated by comparing the preoperative and postoperative double-angle plots.

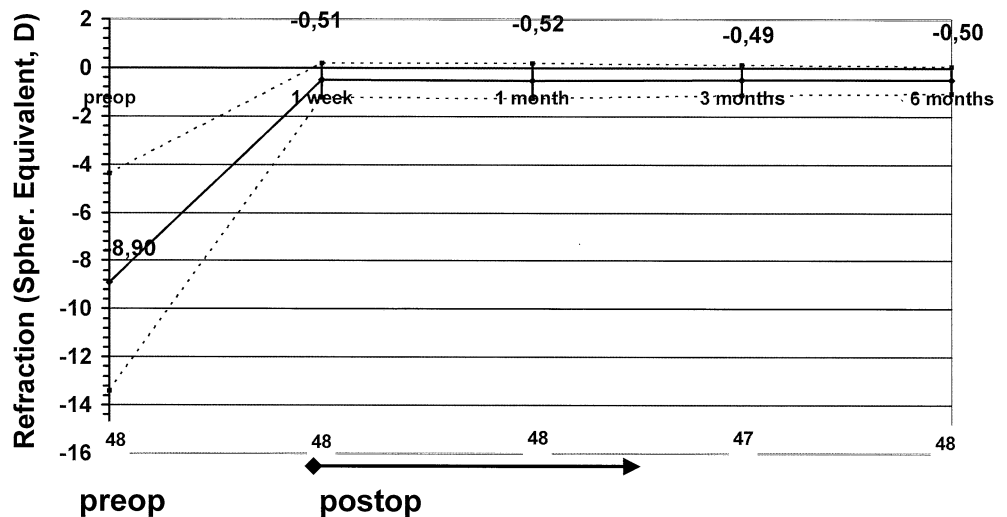


Figure 12. Change in refraction for the myopic eyes (group A) during the follow-up period. D = diopters. ---- = Standard deviation of the respective mean value.

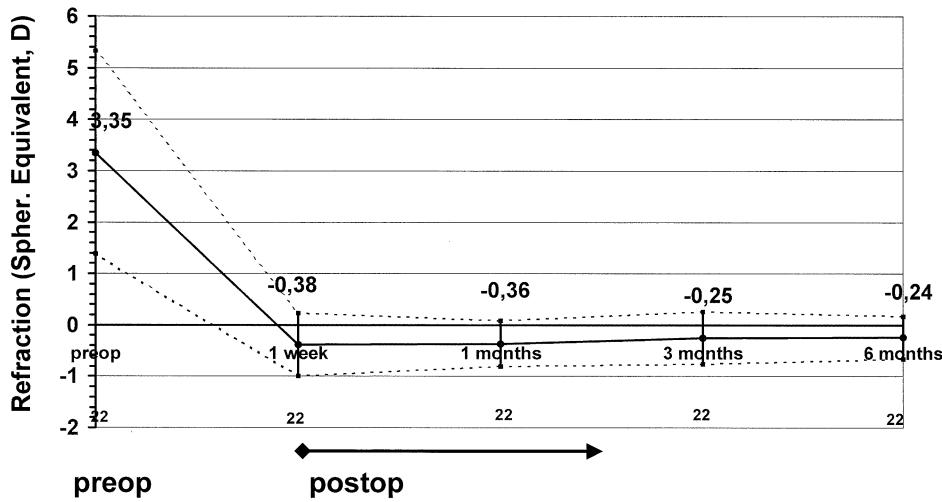


Figure 13. Change in refraction for the hyperopic eyes (group B) during the follow-up period. D = diopters and those instances in which ---- = Standard deviation of the respective mean value.

There are a variety of surgical procedures to treat ametropia and astigmatism. The correction of high ametropia is controversial. Corneal refractive surgery alone cannot adequately correct high ametropia in all cases. All refractive corneal surgical procedures change corneal curvature: radial keratotomy, photorefractive keratectomy, and LASIK convert the cornea from a normal prolate shape with a positive asphericity that is steeper centrally than paracentrally to an oblate shape with a negative asphericity that is flatter centrally than paracentrally. Maintenance of prolate asphericity may be optically beneficial. Although these three procedures are adjustable, none is reversible. In the authors' opinion, intraocular refractive surgery, like lens extraction with IOL implantation²⁰ or pIOL implantation, is a more suitable option for the correction of high ametropia.^{21,22}

Correcting high ametropia with pIOL offers predictable and stable refractive results, especially for patients with moderate and high myopia.^{23,24} In comparison with keratorefractive procedures, predictability is more accurate with pIOLs, especially for myopia of more than -10.00 D.²⁵

The adjustable refractive surgery approach consists of performing the lamellar cut before the Artisan pIOL implantation.²⁶ This alternative method was used to avoid any

possible contact between the corneal endothelium and the anterior chamber IOL during microkeratome pass. Laser treatment was performed as the second procedure after implantation of a 6-mm-optical-zone Artisan lens to correct residual myopia. Possible disadvantages are the risk of flap-related complications, including epithelial ingrowth.²⁷

The bioptics approach involves the combination of LASIK and IOL implantation in eyes with SEs of -18.00 D or greater, subjects with high levels of preoperative astigmatism (greater than -2.00 D), and those instances in which a high lens power availability was a problem. In 67 myopic eyes that underwent this procedure, 85% (57 eyes) achieved an SE refraction within ± 1.00 D, and 67% (45 eyes) achieved an SE refraction within ± 0.5 D of emmetropia.²⁸

Safety of the surgical procedure and long-term biocompatibility have been the primary concerns about the use of pIOLs. In a 3-year multicenter study of the Artisan pIOL conducted by Budo et al,¹⁸ intraoperative problems were minimal and were typically related to the short learning curve required to master the special implantation technique for the Artisan lens. A high level of experience with this lens technology, various modifications in implantation instruments, better training, and refinement of individual technique will help to decrease the slope of surgeons' learning curves. The good refractive efficacy of the Artisan TPIOL in this study translated into improved functional results. The UCVA was 20/40 or better in 88.6% of eyes. BSCVA improved in 65.7% of eyes and was maintained in the rest.

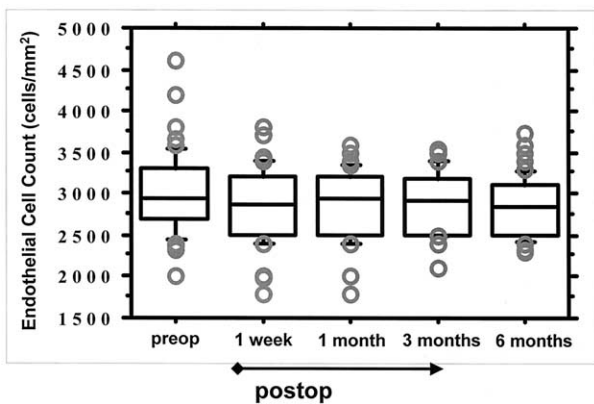


Figure 14. Endothelial cell counts before and after surgery.

Table 5. Change in Spherical Equivalent During Follow-up (Change in Refraction 1 Week to 6 Months)

Group	Change in Refraction		
	± 0.5 D	± 1.0 D	± 2.0 D
Group A (n = 48)	40 (83.3%)	48 (100%)	48 (100%)
Group B (n = 22)	11 (50%)	14 (63.6%)	22 (100%)

D = diopters.

Table 6. Endothelial Cell Count Changes after TPIOL Implantation

ECC (cells/mm ²)	Before Surgery	1 wk	1 mo	3 mos	6 mos
Mean	2983	2845	2841	2838	2849
SD	505	479	424	436	362
Minimum	2000	1500	1800	1500	2294
Maximum	4600	3800	3600	3550	3733
Median	2930	2850	2925	2900	2838
P value		0.42	0.46	0.7	0.17

ECC = endothelial cell count; SD = standard deviation; TPIOL = toric phakic intraocular lens.

Several authors have already reported this gain in corrected visual acuity caused by the increase in the size of the retinal image.^{18,29} Gains in UCVA and BSCVA were statistically significant. The efficacy index, calculated as postoperative UCVA/BSCVA, was 1.03.

An alternative surgical option to pIOL implantation for eyes with high ametropia is CLE. CLE is less predictable, and the risk of retinal detachment increases, especially in myopic eyes. Colin et al⁶ reported that 59.1% of patients with preoperative myopia greater than -12.00 D who underwent CLE were within ± 1.00 D of emmetropia and that 85.7% were within ± 2.00 D at the 7-year follow-up. The incidence of retinal detachment after CLE was nearly double that estimated for people with myopia greater than -10.00 D without surgery. Preservation of accommodation in young patients, quality of vision in dim illumination, predictability, and safety should be considered when evaluating the options for subjects with ametropia and astigmatism.³⁰ The TPIOL seems to be a suitable option for subjects with myopia greater than -10.00 D, hyperopia greater than $+4$ D, and astigmatism greater than 2 D. The refractive effect produced by the TPIOL was stable, with 62 eyes (89%) changing refraction by 1.00 D or less between 1 week and 6 months.

Removability is an important consideration for both the surgeon and the patient, especially in comparison with other refractive corneal surgical procedures, which permanently alter the cornea. Patients seeking a long-term alternative to glasses and contact lenses, but uncomfortable with the finality of permanent changes to their vision, may be amenable to a removable or replaceable alternative.

The use of TPIOLs in high ametropia has some further advantages over corneal procedures, e.g., predictability and stability of the refractive outcome. Therefore, interest in pIOLs for the correction of moderate to high refractive errors has increased. The fact that the Artisan TPIOL does not touch the lens may reduce the risk of late cataract formation.

However, some potential risks of these lenses do exist. The Artisan TPIOL has some limitations. Cyclotorsion of the eye should be accounted for before anesthesia. Because the lens consists of rigid polymethylmethacrylate, the incision has to be enlarged to 5.2 mm for forceps implantation. In a small subgroup analysis of 31 eyes operated on with the TPIOL via a superior sclerocorneal incision of 5.3 mm at the University Eye Hospital in Mainz, Germany, the mean surgically induced corneal astigmatism after 6 months was

0.53 D (unpublished data).³¹ This induced corneal astigmatism has to be integrated into the preoperative power calculation, but it is not correct in all cases, especially when a suture for wound closure is rarely necessary. Preoperative endothelial specular microscopy before implantation of an anterior chamber IOL is mandatory. Although Artisan lenses have been well tolerated and their use is currently one of the best methods available to correct high ametropia, the dependency on the availability of an endothelial microscope is a significant limitation of this procedure. Some situations may decrease the ACD and thus result in contact between the TPIOL and the endothelium; i.e., high-power IOLs (because they are thicker), eye rubbing,³² and, conceivably, contact specular microscopy might lead to this contact. To avoid these situations, we encouraged patients not to rub the eye, and we selected patients with sufficient central and peripheral ACD to provide a safe distance between the TPIOL and the endothelium (minimal central ACD, 3.0 mm). Menezo et al³³ found greater cell loss in eyes with shallower anterior chambers and thicker IOLs, probably because of greater intraoperative contact.

Questions remain about the risk of pigment dispersion, because the haptic claws touch the iris. In theory, pigment could lodge in the trabecular meshwork, thereby blocking the normal outflow of aqueous, which could lead to pigmentary glaucoma. In an ultrasound biomicroscopy study conducted by Pop et al,³⁴ the presence of the haptics did not seem to disturb the pigment layer of the iris, except within a small part of the iris entrapment. The iris entrapment did not touch the corneal endothelium, nor did the haptic touch the angle of the anterior chamber. An average of 0.16 mm was measured between the iris and the haptic arm, thus reducing the risk of pigment dispersion. Possible pigment

Table 7. Course of the Intraocular Pressure During Follow-up of Toric Phakic Intraocular Lens Implantation

IOP (mmHg)	Before Surgery	1 wk	1 mo	3 mos	6 mos
Mean	14.8	15.3	15.3	15.0	14.7
SD	3.0	3.7	3.3	3.1	2.7
Minimum	8	4	8	8	7
Maximum	24	20	21	17	17
Median	15	15	15	15	15
P value		0.34	0.32	0.54	0.95

IOP = intraocular pressure; SD = standard deviation.

Table 8. Change in Subjective Mean Overall Patient Satisfaction (\pm SD) During Follow-up after Toric Phakic Intraocular Lens Implantation

Follow-up	Light Condition		
	Bright	Normal	Low
1 wk	8.5 \pm 1.5	8.8 \pm 1.5	8.2 \pm 1.8
1 mo	8.6 \pm 1.9	9.0 \pm 1.3	8.6 \pm 1.6
3 mos	8.9 \pm 1.5	9.2 \pm 1.3	8.7 \pm 1.6
6 mos	9.0 \pm 1.3	9.2 \pm 1.2	8.9 \pm 1.3

SD = standard deviation.

dispersion would be composed of the pigment layer being slightly folded on itself within the iris entrapment.

Complications/Secondary Surgical Intervention

No eye lost any vision permanently as a result of surgical complication in this small series with 6 months of follow-up. The complications reported in the literature with the Artisan lens implantation, but not found in this study, are lens decentration,³⁵ retinal complications,^{11,29,35} Urrets-Zavalía syndrome,³⁵ lens opacity,¹⁹ and ischemic optic neuropathy.³⁶

Postoperative complications such as glare or halos were related to poor centration of the lens during surgery or to implanting the lens in eyes in which the scotopic pupil was larger than the lens optic diameter. Experience increases the ability to accurately center the lens, and postoperative re-centering is always an option, because the fixation is reversible. Pérez-Torregrosa et al³⁷ found decentration of the iris-claw lens of 0.47 ± 0.29 mm (<1 mm) with respect to the pupil in 22 eyes by using a digital measurement system. They concluded that for a standard 4.0-mm-entrance pupil, a slight decentration should not cause serious visual problems. Larger pupils, however, can have serious visual problems such as halos. A longer follow-up is necessary to be

sure about possible fixation problems. We strongly suggest that surgeons include approximately 1 mm of folded iris inside the claw, because poor fixation has probably been the cause of most IOL decentrations or luxations.

For a good outcome, it is crucial that the cylinder axis be marked accurately and that the Artisan TPIOL be implanted in the right axis. With the unique method of fixation, there is a high likelihood that this TPIOL will not rotate off axis over time. Different axis-marking strategies can be used to ensure correct TPIOL alignment. Depending on the surgeons' preference, the enclavation spots on the iris can be marked with a laser, the paracenteses on the limbus may be marked with a pen, or, as favored in Mainz, orientation can be guided by iris structure.

An Artisan model with a 5.0-mm optic was used exclusively during this study. In 1997, a new model with a 6.0-mm optic was introduced to address potential photic phenomena in patients with larger pupils. This model is more forgiving when the lens is somewhat decentrated. Conversely, a 6.5-mm primary incision is needed for this design. In the near future, foldable Artisan pIOLs will reduce the incision size issue.

As with other series, no chronic increased postoperative IOP was found in our patient population, with the exception of a mild transient increase of IOP that disappeared within the first 2 days after surgery. These increased IOPs in the immediate postoperative period might also be caused by incomplete removal of the viscosurgical device used during surgery. No rotation of the TPIOL, pupil ovalization, uveitis, or persistent corneal dystrophy was observed. No cataractous changes of the lens were seen in this series.

One important potential complication associated with pIOLs is retinal detachment. In our study, we did not encounter any retinal detachment, but incidences of 0.8% and 3% have been reported in iris-fixated and angle-supported pIOLs, respectively. There was no change in the retina examination in this study, but longer follow-up is needed.

Halos and glare remain a concern with this type of lens.

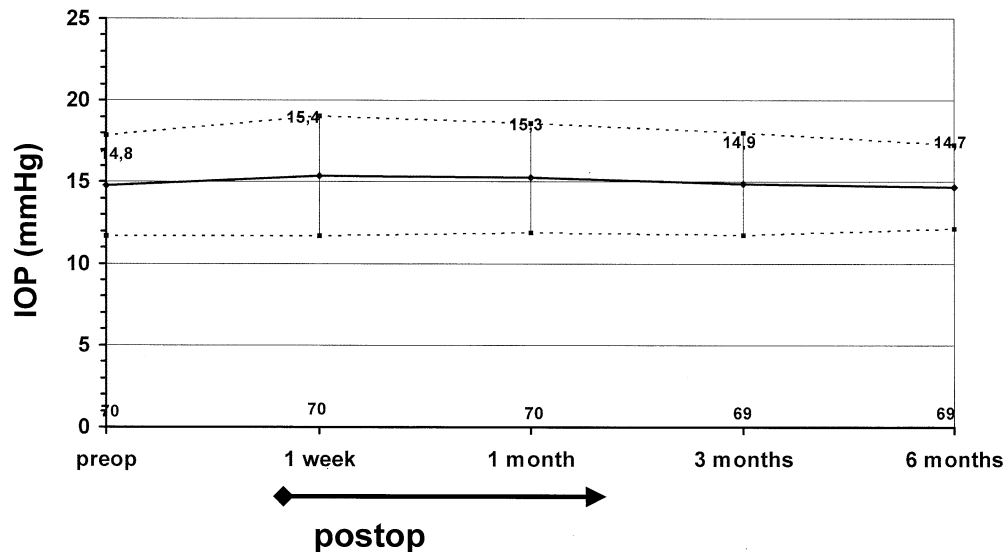


Figure 15. Intraocular pressure (IOP) before and after surgery. ---- = Standard deviation of the respective mean value.

Menezo et al³⁸ found a similar rate of glare (3.2%) with the iris-fixated lens; this rate is comparable to our series (5.7%). Another important cause of halos or glare is the presence of a large iridectomy. Therefore, most eyes in this study received an iridotomy before surgery instead of intraoperative iridectomy.

Patients were asked to rate their satisfaction under normal, bright, and low-light conditions by using a scale of 1 (very poor) to 10 (excellent). At 6 months, the mean rating was approximately 9 or higher in all three settings.

Conclusion

The use of spectacles and contact lenses for the correction of moderate to severe ametropia is well established and is the current standard of care. These modalities incur minimal risk to patients. Contact lenses offer better visual results than spectacles, but some patients cannot tolerate them. Spectacles often result in inferior optical image quality (e.g., aberrations, minification, limitation of the visual field), poor cosmetic appearance, and significant inconvenience. Implantation of the Artisan TPIOL is an acceptable alternative to spectacles and contact lenses; it provides better image quality, reduces reliance on external devices, and has a high level of convenience.

Although there are well-described advantages that favor the use of pIOLs, potential risks must be evaluated before using these lenses. Concerns about damaging anterior chamber structures—especially the corneal endothelium—have been described. Fixation of the Artisan TPIOL on the midperipheral iris tissue did not damage the iris, provided that the enclavation was performed properly, with minimal trauma. No pupil ovalization or iris atrophy was encountered in this study. No TPIOL had to be explanted, whereas with the angle-supported pIOL, an explantation rate of 4.8% has been described because of tissue damage to the iris.²³

Only having 6 months' data on these patients can be considered a limitation to the study. Longer follow-up is required for patients who underwent this procedure. On the basis of the 6-month results of this prospective multicenter clinical investigation of the TPIOL for the correction of high ametropia and astigmatism in phakic eyes, this lens offers a safe and effective method for correcting high spherical refractive errors as well as moderate to high amounts of corneal and/or lenticular astigmatism in both myopic and hyperopic eyes with a single procedure. Data from 70 eyes showed that the iris-fixated Artisan TPIOL reduced preoperative spherical and astigmatic errors with high predictability and good stability and was associated with good visual outcomes and strong patient satisfaction. Complications were minimal and amenable to treatment.

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Historical Image



Apprentice samples. Miniature spectacles were made by prospective members of the Opticians Guild as an examination for admission. If the applicant were talented enough to successfully complete a diminutive pair, or so the rationale went, he could certainly make an adult pair. The spectacles are English and date to 1895. Of the gold pince-nez we know nothing; the fine craftsmanship, however, speaks for itself.

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