Toric phakic intraocular lens for the correction of hyperopia and astigmatism

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PURPOSE: To evaluate the Artisan toric phakic intraocular lens (pIOL) for the correction of hyperopia and astigmatism.

SETTING: Department of Ophthalmology, Erasmus MC, Rotterdam, The Netherlands, and Department of Ophthalmology, Sint Truiden, Belgium.

METHODS: In this prospective study of 47 eyes of 28 patients with hyperopia and astigmatism, Artisan toric pIOLs were implanted between April 1999 and June 2004. Uncorrected visual acuity (UCVA), best corrected visual acuity, refraction, astigmatism, safety, and predictability were analyzed. Change in astigmatism was analyzed with vector analysis. Refractive cylinders are expressed in minus form.

RESULTS: Mean preoperative spherical equivalent was +4.33 diopters (D) ± 2.26 (SD). Mean follow-up was 11.1 months (range 6 to 36 months). A gain of 1 or more lines in best spectacle-corrected visual acuity (BSCVA) was seen in 36.2%. Safety index and efficacy index after 6 months were 1.06 and 0.87, respectively. The mean postoperative astigmatism at 6 months was 0.19 D at an axis of 144 degrees. At 6 months, about three quarters (76.6%) of the eyes had a UCVA of 20/40 or better. One eye lost 2 lines of BSCVA. In 1 eye, the lens position had to be changed because of a large axis misalignment. No serious complications developed in any of the treated eyes during follow-up.

CONCLUSIONS: Artisan toric pIOLs can correct moderate to high hyperopia combined with astigmatism with good refractive results. In this study, there were no serious complications. However, the predictability of the refractive results appeared to be lower than those in the correction of myopia and astigmatism with toric Artisan lenses.

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Refractive surgery options to treat moderate to high hyperopia and hyperopic astigmatism are limited. Predictability and safety with either laser in situ keratomileusis (LASIK) or photorefractive keratectomy (PRK) are lower compared to the treatment of moderate myopia with or without astigmatism.[1,2] Reported complications are regression, corneal ectasia, epithelial ingrowth, irregular astigmatism, and low predictability, especially in eyes with higher hyperopia or hyperopia combined with astigmatism.[3–6] Clear lens extraction with implantation of a toric intraocular lens (IOL) has the disadvantage of accommodation loss in a younger age group. Phakic IOLs can be an alternative for the correction of hyperopia and hyperopic astigmatism. Over the past few years, studies of diverse phakic IOLs have demonstrated satisfactory results to correct high ametropia.[7–10] Several studies have recently been published on the Artisan toric phakic intraocular lens (pIOL) for the correction of ametropia with astigmatism.[11–13] The Artisan toric IOL is an iris-fixated anterior chamber lens of Perspex CQ-UV poly(methyl methacrylate) with ultraviolet filtration. Its overall diameter is 8.5 mm, and the optical zone diameter is 5.0 mm. Two models of the Artisan lens are available. In model A, the axis runs through the claws at 0 degrees, and in model B, the axis is perpendicular to the line that runs through the claws at 90 degrees. In eyes with

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a preoperative cylinder axis between 0 and 45 degrees or between 135 and 180 degrees, model A is recommended. In eyes with a preoperative cylinder axis between 45 and 135 degrees, model B is recommended.

Studies of the toric Artisan lens have mainly reported the results for the correction of myopia with astigmatism. Differences between hyperopia and myopia that are important for refractive surgery are iris configuration, a shallower anterior chamber depth (ACD), and limited improvement in best spherical corrected visual acuity postoperatively. The third is due to a smaller image size with corrected refraction closer to the eye's nodal point in hyperopic patients. In our opinion, these differences justify a study solely evaluating the results of toric pIOLs for correcting hyperopia and astigmatism. The hyperopic toric Artisan lenses are available in half-diopter increments with a cylindrical power up to 7.5 diopters (D) and a spherical power from +2.0 to +12.0 D. In this article, we report the results of toric pIOL implantation in 47 eyes of 28 patients with hyperopia and astigmatism.

PATIENTS AND METHODS

Forty-seven consecutive eyes of 28 patients were enrolled in this prospective study. Between April 1999 and June 2004, consecutive implantation of toric pIOLs was performed by 2 surgeons (G.L., C.B.) in 2 separate clinics (Erasmus MC Rotterdam, The Netherlands, and Sint Truiden, Belgium). Inclusion criteria consisted of general good health, 18 years of age or older, stable refraction for at least 1 year, astigmatism greater than or equal to 1.5 D combined with hyperopia, absence of ocular pathology, endothelial cell count more than 2000 cells/mm^2, ACD more than 3.0 mm (including corneal thickness), no convex iris configuration, and mesopic pupil size equal or less than 5.0 mm. Informed consent in accordance with the Helsinki Declaration was obtained for each patient.

Preoperative examination included slitlamp biomicroscopy, endothelial cell count (noncontact specular microscopy, Topcon SP-2000-P), keratometry (Topcon KR-7000-P), A-scan biometry (Alcon), applanation tonometry, measurement of mesopic pupil diameter (Colvard pupillometer), indirect ophthalmoscopy, and subjective and objective refraction. Objective refraction with cyclopentolate hydrochlorate 1.0% eyedrops was measured to exclude any accommodative error in subjective refraction. If large differences were found, subjective refraction was performed again. Best spectacle-corrected visual acuity (BSCVA) was also noted (Snellen). All patients were requested to discontinue contact lens wear at least 14 days before preoperative examination.

The power of the Artisan lens and the intended axis of enclavation were calculated based on keratometric readings, ACD, and subjective refraction error according to the Van der Heijde formula.[14] Prior to surgery, the desired axis location was either marked on the limbus with a surgical marker guided by the reflected images of the Javal keratometer on the cornea (G.L.) or the enclavation sites on the iris were marked with an argon laser at least 1 week before surgery (C.B.). Myotic drops (pilocarpine 4%) were administered to prepare the iris for lens fixation. Intervention was performed under general anesthesia (all cases in Sint Truiden and some cases in Erasmus MC) or retrobulbar anesthesia (Erasmus MC). A corneoscleral beveled incision of 5.5 mm was made at the steepest axis for model A and at the flattest axis for model B, and paracenteses were placed at either side 8 mm apart from each other. The anterior chamber was opened and introduced with viscoelastic fluid (Healon [sodium hyaluronate 1%]/Healon GV [sodium hyaluronate 1.4%]) to maintain its depth and to protect the endothelial cell layer. After introduction of the lens into the anterior chamber with the holding forceps, it was positioned on the desired axis and then fixated on the midperipheral iris stroma with a disposable enclavation needle. A slit iridotomy was performed at 12 o'clock to prevent angle-closure glaucoma, whereafter the viscoelastic material was manually irrigated. The incision was closed with a 10-0 nylon running suture. Postoperative treatment included dexamethasone 0.1% or predmycine eyedrops and ketorolac eyedrops 4 times a day for 4 weeks.

Follow-up examinations were scheduled 1 day, 1 week, 1 month, 2 months, 6 months, and 1 year after surgery and on a yearly basis thereafter. Examinations included slitlamp biomicroscopy, endothelial cell count, keratometry, applanation tonometry, subjective and manifest refraction, uncorrected visual acuity (UCVA), and BSCVA. Within the first 2 postoperative months, sutures were removed depending on residual refractive astigmatism and change in topographic astigmatism. Furthermore, patients were asked about subjective complaints of halos and glare. All data were collected prospectively from patient charts during follow-up examination.

Statistical Analysis

Refractive outcomes at 6 months and 1 year were analyzed. All cylinders were expressed in minus form. To analyze BSCVA, UCVA, safety index (mean postoperative BSCVA/mean preoperative BSCVA), and efficacy index (mean postoperative UCVA/mean preoperative BSCVA), Snellen visual acuity was first converted into logMAR to calculate the mean and subsequently transformed back to the geometric mean Snellen visual acuity. All refractive cylinders are expressed in minus form. Change in cylindrical refraction was calculated with vector analysis as described by Holladay et al.[15] using subjective refraction results. To analyze preoperative astigmatism, postoperative astigmatism, and astigmatism induced by the incision, the astigmatism vector computations were calculated using mixed model analysis of variance (SAS software). The model accounts for a possible inclusion of 2 eyes of 1 individual patient. The vector change in keratometric cylinder between preoperative and 6-month postoperative values was considered the astigmatism induced by the incision. For this analysis, eyes that had a second surgical intervention within 6 months after implantation were excluded (n = 1). Continuous variables were described with mean, standard deviation, and range. Comparison of continuous data between preoperative and postoperative periods was performed with the Student *t* test for paired data. A level of significance of $P = .05$ was used.

RESULTS

Forty-seven eyes of 28 patients were included in this study. Preoperatively, all patients had clear lenses and no retinal pathology was noted. A certain degree of amblyopia was observed in 19 eyes, but none of the eyes had a BSCVA less than 20/60. Mean amplitude of the ACD was 3.2 ± 0.2 mm (range 3.0 to 3.8 mm), and mean axial length

was 21.5 ± 1.0 mm (range 19.5 to 23.7 mm). Mean intraocular pressure (IOP) was 15.5 ± 3.5 mm Hg. Mean mesopic pupil diameter was 4.5 ± 0.9 mm (range 3 to 6 mm). Ten patients were men, and 18 patients were women. Mean age (primary eye in bilateral subjects) was 36.7 years (range 19.0 to 65.8 years). Mean preoperative spherical refraction without considering cylindrical refraction was +6.05 ± 2.08 D, and mean absolute refractive astigmatism was −3.46 ± 1.78 D. Mean preoperative endothelial cell count was 3000 ± 378 cells/mm^2 (range 2100 to 3721 cells/mm^2). Follow-up ranged from 6 months to 3 years, with a mean of 11.1 months. All patients attended follow-up at 6 months. At 1 year, complete follow-up data were available for 14 eyes (29.8%).

Preoperative refractive data are presented in Table 1, along with endothelial cell counts and postoperative visual acuity and refractive results. Postoperative data are given at 6 months, otherwise this will be mentioned in the text. A gain of 1 or more lines in BSCVA occurred in 17 eyes (36.2%). About three quarters (76.6%) of the eyes had a UCVA of 20/40 or better. At 1 year, all eyes (n = 14) had a UCVA of 20/40 or better. Of all eyes, 8.5% lost 1 or 2 lines in BSCVA (1 eye lost 2 lines, and 3 eyes lost 1 line). The patient with a loss of 2 lines in BSCVA had severe complaints of halos and glare.

According to vector analysis adjusted for 2 eyes per patient, the mean preoperative astigmatism was −2.29 ± 2.31 D for the horizontal component (x) and −0.17 ± 1.02 D for the vertical component (y), equivalent to a cylinder of 2.30 D at an axis of 92.1 degrees. A double-angle minus cylinder power plot of preoperative data is presented in Figure 1. Six months after implantation, the mean astigmatism was 0.06 ± 0.60 D for x and −0.18 ± 1.02 D for y, equivalent to a cylinder of 0.19 D at an axis of 144 degrees. In the double-angle minus cylinder power plot for postoperative data at 6 months presented in Figure 2, a tendency toward a clearly lower but more against-the-rule astigmatism is seen. The mean spherical equivalent (SE) of the subjective refraction at the 6-month follow-up was −0.05 ± 1.13 D (range −2.00 to 3.00 D) and at 1 year was 0.57 ± 1.24 D (range −1.50 to 3.00 D). Six months after surgery, 76.6% of the eyes were within ±1.00 D of emmetropia and 51.1% of the eyes were within ±0.50 D of emmetropia. The deviation of the achieved SE correction from the attempted SE correction is presented in Figure 3. The safety index after 6 months and 1 year was 1.06 and 1.22, respectively. The efficacy index was 0.87 at 6 months and 1.06 at 1 year. The mean incision-induced corneal astigmatism was 0.60 ± 0.61 D at a mean axis of 177 degrees.

Intervention was uneventful in all patients. No eyes lost more than 2 lines of BSCVA at last follow-up. In 3 eyes (6.4%) of 3 patients, there was a slight decentration of the toric pIOL. However, this did not affect visual acuity. In 1 eye (2.1%), it was necessary to reposition the lens because of a deviation from the intended axis. In this eye with an implanted cylinder of 3.0 D, a deviation of approximately 27 degrees from the intended axis existed, resulting in a residual astigmatism of −2.00 D at an axis of 155 degrees. After the lens position was changed to the correct axis, a residual astigmatism of only −0.50 D at an axis of 163 degrees was left.

Iris pigment depositions on the toric pIOL were observed in 4 eyes of 3 patients. Two of these patients also reported glare and halo symptoms. Complaints of halo and glare were reported in 4 patients. These 4 patients also had the eyes with a loss of 2 lines in BSCVA. No patient reported binocular diplopia after implantation. Intraocular pressure after implantation was not significantly different from preoperative IOP. In 2 eyes, a temporary elevation of IOP over 21 mm Hg was observed in the first month after surgery. A good reaction to topical IOP-lowering medication was seen. The mean postoperative endothelial cell

Table 1. Preoperative and postoperative endothelial cell count and refractive results.

	Preoperative	6 Months (n = 47)	12 Months (n = 14)
ECC (cells/mm^2) mean ± SD (range)	3000 ± 378 (2100 to 3721)	3001 ± 336 (2059 to 3610)	3029 ± 167 (2812 to 3232)
SE (D) mean ± SD, (range)	4.33 ± 2.26 (+.50 to +8.00)	−0.05 ± 1.13 (−2.00 to +3.00)	0.57 ± 1.24 (−1.50 to +3.00)
UCVA ± SD	—	0.59 ± 0.17	0.64 ± 0.11
BSCVA ± SD	0.68 ± 0.15	0.72 ± 0.14	0.74 ± 0.12
± 1.00 D of emmetropia (%)	—	76.6	71.4
± 0.50 D of emmetropia (%)	—	51.1	35.7
UCVA ≥20/40	—	76.6	78.6
Loss ≥2 lines BSCVA (%)	—	2.1	0
Gain ≥1 line BSCVA (%)	—	36.2	57.1
Safety index	—	1.06	1.22
Efficacy index	—	0.87	1.06

BSCVA = best spectacle-corrected visual acuity; ECC = endothelial cell count; SE = spherical equivalent; UCVA = uncorrected visual acuity

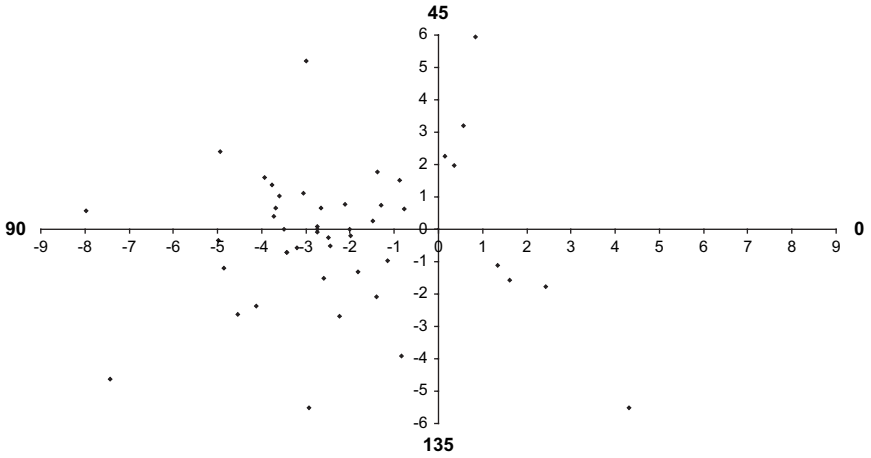

Figure 1. Double angle minus cylinder plot of preoperative refractive cylinders.

count (3001 ± 336 cells/mm^2 at 6 months and 3029 ± 167 cells/mm^2 at 1 year) was not significantly different from mean preoperative cell count. No cataract formation was found during follow-up. No posterior synechias or fibrin membrane formation was observed in any eye. None of the eyes developed other serious sight-threatening complications such as retinal detachment or endophthalmitis during follow-up.

DISCUSSION

Refractive surgery encompasses attention to both the spherical and cylindrical components of refraction. The treatment of hyperopia combined with astigmatism is especially challenging. This study demonstrates that in selected patients, it is possible to correct moderate to high hyperopia combined with astigmatism by Artisan toric pIOL implantation with relatively good refractive results and few complications. Results, however, compare less favorably to those of myopic Artisan toric IOL implantation.

Artisan toric pIOL implantation is a recent alternative to correct ametropia and astigmatism. Several studies have reported on the results of these toric pIOLs.[11–13,16] We have reviewed and summarized the published data on Artisan toric lenses in hyperopic patients. In the European multicenter study by Dick et al.,[11] 22 hyperopic eyes are included. Preoperative SE refraction was +3.25 D. Average magnitude of refractive astigmatism was 3.70 D (no vector analysis). Mean postoperative endothelial cell count, efficacy index, and safety index were given together with the myopic group. All eyes were within ±1.00 D of the intended refraction. Tehrani et al.[13] reported their results in 9 eyes with hyperopia and astigmatism. Mean age in the hyperopic group was somewhat higher (40 years) than in the myopic group (35 years). Mean preoperative SE refraction was +3.8 D, and mean preoperative astigmatism according to vector analysis was 2.9 D. The study reports mainly on the stability of the toric Artisan lens, which was shown to be good. Refractive results were not separately analyzed in the hyperopic group. The last study by Güell et al.[12] included 27 eyes with high myopia or hyperopia and astigmatism. Mean SE refraction was −11.78 D (range +6.00 to −19.50 D). The number of hyperopic eyes included was not given, and data were not analyzed separately for myopic

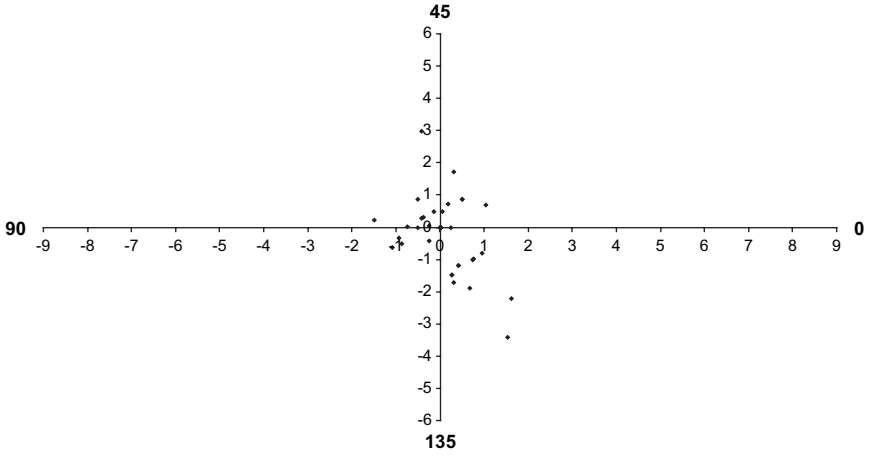

Figure 2. Double angle minus cylinder plot of postoperative refractive cylinders at 6 months.

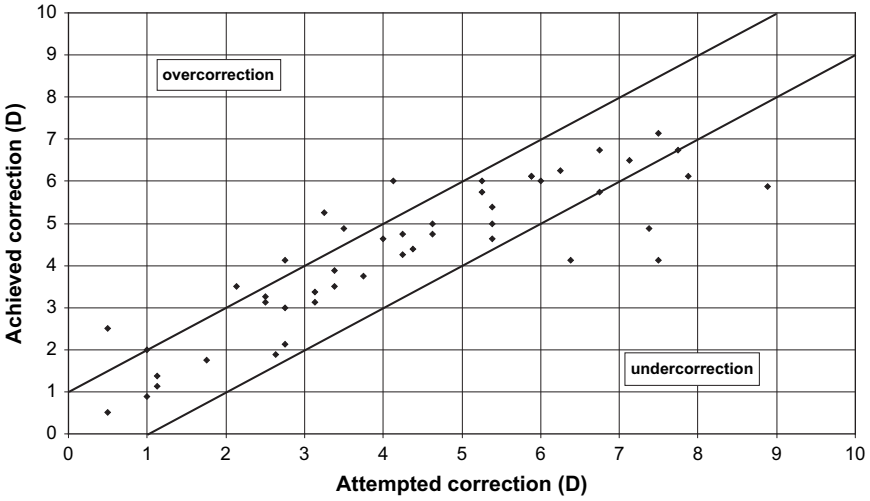

Figure 3. Spread of achieved SE refraction against intended refraction.

and hyperopic eyes. In contrast to the aforementioned studies, the present study reports refractive results after toric Artisan lens implantation including a larger group with solely hyperopia and astigmatism (average SE refraction +4.33D). Hyperopic eyes do not resemble myopic eyes, and in our opinion, a separate analysis of refractive results is more appropriate. Hyperopic eyes tend to be smaller with smaller anterior segments, and a higher frequency of convex irises is seen. Less hyperopic eyes will meet the inclusion criteria for anterior chamber iris-fixated lens implantation compared to myopic eyes. Also, after eyes with an ACD less then 3.00 mm were excluded, mean ACD in this study (3.2 ± 0.2 mm) was clearly lower than in studies including eyes with myopia and astigmatism. Mean ACD in the myopic group reported by the European multicenter study was 3.57 ± 0.26 mm.[11] Mean ACD in patients who had myopic Artisan toric lens implantation at the Erasmus MC was 3.66 ± 0.31 mm (unpublished data). The potential of endothelial cell loss might be higher in hyperopic eyes because a greater cell loss is reported in eyes with shallower anterior chambers and thicker IOLs.[8,17] In this study, we did not observe endothelial cell loss; however, follow-up was only 6 months in all eyes and 1 year in 14 eyes. Longer follow-up is required to assess a potential risk for endothelial cell loss.[17] The serious complication of posterior synechias after toric pIOL implantation is reported mainly in hyperopic eyes.[8] None of the eyes in this study encountered this problem, probably because of the exclusion of convex irises and ACD less than 3.00 mm. Because hyperopia becomes an increasing problem with advancing age, patients treated for hyperopia might on average be older than myopic patients. However, patients in our study group were not older than patients implanted with the myopic toric Artisan lens. To uncover any latent hyperopia, cycloplegic refraction in hyperopic patients is important. Hyperopia is more frequently associated with strabismus and amblyopia than myopia. The percentage of eyes with a postoperative UCVA of 20/40 or better is highly affected by the number of amblyopic eyes included. This could account for the lower percentage of UCVA of 20/40 or better found in this study (19 amblyopic eyes) compared to the European multicenter study.[11] In hyperopic and possibly amblyopic eyes, the evaluation of efficacy using the UCVA parameter is not very meaningful and the efficacy index might be of more value. Correction of the refractive error with toric pIOLs in highly anisometropic patients could exacerbate strabismus or change disparity in retinal image size resulting in diplopic symptoms.[18] Although 2 patients with the high-range astigmatism encountered some trouble in the first few weeks, none encountered permanent problems. In our clinic, we test patients with high anisometropia corrected with spectacles by the Awaya aniseikonia test to prevent problems. This is done both with spectacles and with contact lens correction. Tolerance to postoperatively induced anisophoria might be predicted by this test. Lens implantation was discouraged in patients who did not tolerate full contact lens correction of their ametropia. In comparison to preoperative visual acuity with spectacles in hyperopic eyes, no gain in corrected visual acuity is expected after toric pIOL implantation. This is in contrast to myopic eyes where an increase in the size of the retinal image after correction with a toric pIOL attributes to a gain in visual acuity. This discrepancy can underlie the relatively low safety index found in this study compared to the safety index in myopic patients. In terms of percentages of eyes within ±1.00 or ±0.50 D of emmetropia, predictability in this study was lower compared to the correction of myopic astigmatism with Artisan lenses as shown in Table 2. The position of an IOL in a hyperopic eye is more critical than in a myopic eye because the effect of a miscalculation

Table 2. Predictability of achieved spherical equivalents after implantation of toric pIOLs.

		Number (%)			
		6 Months, Refraction Within		1 Year, Refraction Within	
Study	Preoperative SE (D)	±0.50 D	±1.00 D	±0.50 D	±1.00 D
Dick et al.[11]	−8.90	40/48 (83.3)	48/48 (100)		
Güell et al.[12]	−11.78			17/27 (62.9)	26/27 (96.2)
This study	+4.33	24/47 (51.1)	36/47 (76.6)	5/14 (35.7)	10/14 (71.4)

SE = spherical equivalent

is inversely related to the length of an eye. Calculation of the dioptric power of the lens with the Van der Heijde formula[14] using ACD as a variable might be less accurate in hyperopic eyes.

Accurate axis alignment of the toric pIOL is essential for success, especially in higher astigmatism. Approximately one third of the correction is lost if the lens is rotated 10 degrees off axis. Rotation of the Artisan lens is not likely because of the firm fixation to the midperipheral iris stroma. Off-axis position of an iris-claw lens is most likely caused by incorrect placement of the lens in the axis during surgery. Lens position had to be changed in 1 eye in our study. The technique to change the lens position is relatively simple. The iris is pushed back through the slits of the haptic, and the lens is refixated to the iris at a different part. After the lens position was changed, astigmatism reduced to −0.50 D compared to −2.00 D before.

Alternative surgical options for the correction of hyperopia with astigmatism have their limits. Large treatment zones are necessary to correct astigmatism and hyperopia with LASIK or PRK. Hyperopic PRK appears to be relatively safe and effective for corrections up to +4.00 D.[3,19] In higher corrections, reduced predictability and possible loss of BSCVA are reported.[20] After treatment of hyperopic astigmatism with PRK, a higher percentage of eyes (15.8%) is reported to lose 2 or more lines of BSCVA.[5] In this study, we observed that only 2.1% of the eyes lost 2 or more lines at 6 months. The higher risk for haze or scar formation with PRK in larger hyperopia might underlie this difference. Significant regression, strongly associated with the magnitude of hyperopia, has been reported in LASIK for hyperopia.[20] In comparison to hyperopic PRK and LASIK, hyperopic toric pIOL implantation is expected to achieve an earlier and more stable refraction. It is difficult to compare the results in our study with the results in studies of the treatment of hyperopia and astigmatism with either LASIK or PRK, mainly because of a large variation in the range of preoperative hyperopia. Laser in situ keratomileusis has been shown to be very effective and predictable in lower hyperopia of up to 3 D.[1] However, above approximately 4 to 5 D, efficacy and stability fall off markedly.[21,22] Spherical ametropia and the amount of cylinder were rather high in this study, with only 9 eyes having either an SE below 3 D or a cylinder lower than 4 D. Many patients included in this study were referred to us from other centers to evaluate the possibilities for Artisan lens implantation because LASIK or PRK was not an option. Posterior toric IOL implantation after clear lens extraction is another option for the correction of high astigmatism and hyperopia. Clear lens extraction, however, will result in permanent and complete loss of accommodation in relatively young patients. Furthermore, a greater incidence of intraoperative complications and postoperative retinal detachment is reported and rotational stability might be a problem with toric IOLs in the capsular bag.[23] Other phakic IOL options are posterior chamber (PC) IOLs.[9,10,24] The advantage of a phakic PC IOL lens in hyperopic patients might be a greater distance between the IOL and the endothelial layer. However, other risks are reported with these PC IOLs, such as cataractogenesis and pigment dispersion.[9,25–28] In hyperopic eyes, there might be a significantly higher risk for developing a pupil-block glaucoma.[24] Besides, until now, phakic toric PC IOLs for the correction of both hyperopia and astigmatism in a single procedure have not been commercially available.

The Artisan hyperopic toric pIOL might be a valuable alternative to correct combined hyperopia and astigmatism in carefully selected patients with clear lenses and an ACD of at least 3.00 mm and no convex irises. More patients should be studied to assess whether the formulas used for lens calculation have to be adjusted for hyperopic eyes since the refractive outcome appears to be less accurate than after implantation of myopic Artisan toric lenses. Furthermore, a longer follow-up is needed to evaluate the long-term effect of toric pIOL implantation on endothelial cell loss.

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