The Influence of Incision-Induced Astigmatism and Axial Lens Position on the Correction of Myopic Astigmatism with the Artisan Toric Phakic Intraocular Lens

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Purpose: To evaluate postoperative astigmatism with regard to incision-induced astigmatism and deviation in axial alignment with the use of preoperative limbal marking with the Javal keratometer (Haag Streit, Bern, Switzerland) in eyes implanted with the Artisan toric phakic intraocular lens (IOL) (Ophtec, Groningen, The Netherlands).

Design: Prospective nonrandomized trial.

Participants: Fifty-four eyes of 33 patients with myopia (mean, –9.67 diopters [D]) and astigmatism (mean, –3.44 D).

Intervention: The enclavation site was marked on the limbus using the Javal keratometer. The Artisan toric phakic IOL was implanted according to the axis marked on the limbus. Follow-up was a minimum of 6 months.

Main Outcome Measures: Safety index, efficacy index, predictability, safety, and vector analysis of total refractive correction were determined. The effects of axis misalignment and incision-induced astigmatism on the final refractive error were evaluated.

Results: At 6 months after surgery, the safety index was 1.29±0.29 and the efficacy index was 1.04±0.35. Mean spherical equivalent subjective refraction reduced from −11.39±4.86 D before surgery to −0.38±0.57 D at 6 months. Sixty-seven percent of eyes were within 0.50 D of attempted refraction and 89% were within 1.00 D. Mean preoperative cylinder was 2.92±1.60 D at 91.4°. At 6 months, the mean cylinder was 0.28±0.54 D at 174.3°. No eyes lost 2 or more lines of best-corrected visual acuity at 6 months. Eighty-three percent of eyes achieved uncorrected visual acuity of 20/40 and 28% achieved 20/20. Vector analysis of total surgically induced astigmatism revealed a mean cylindrical change of 3.21±1.71 D. Average axis misalignment was 0.37±5.34°. The mean incision-induced astigmatism was 0.74±0.61 D at 0.2°.

Conclusions: Implantation of the myopic toric IOL leads to safe, efficacious, and predictable results. The level of unpredictability caused by minor axis IOL misalignment has minimal effects on the residual refractive error. The procedure of axis alignment with the Javal keratometer seems to be an accurate method of marking the eye for toric IOL implantation. Incision-induced astigmatism can result in an overcorrection of the cylinder. A systematic undercorrection of −0.50 D for attempted cylindrical outcome could result in an achieved correction closer to emmetropia. *Ophthalmology 2006;113:1110–1117 © 2006 by the American Academy of Ophthalmology.*

Achieving emmetropia or other desired refractions is challenging when spherical ametropia is combined with astigmatism. Keratorefractive procedures with an excimer laser have proven to be accurate for the treatment of mild to moderate myopia combined with astigmatism.[1] Among higher refractive errors, however, such procedures can lead to flap complications and irreversible weakening of the cornea and problems associated with small optical treatment zones.[2,3] Over the last few years, studies on diverse phakic intraocular lenses (IOLs) have demonstrated satisfactory results in the correction of high ametropia.[4–6]

The Artisan toric phakic IOL (Ophtec, Groningen, The Netherlands) can be used for the combination of ametropia and astigmatism. It is an iris-fixated anterior chamber implant of Perspex CQ-UV polymethyl methacrylate with ultraviolet filtration (Ophtec). Its overall diameter is 8.5 mm with an optical zone diameter of 5.00 mm. The myopic toric Artisan IOL is available in half-diopter (D) increments with

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a cylindrical power up to 7.5 D and a spherical power from –3.0 to –23.5 D. Two models of toric phakic IOLs are available to allow lens insertion on the correct axis through a superior or temporal incision, according to the surgeon preference. In models A and B, the axis runs through the claws at 0° and 90°, respectively. Several incision types can be used: corneal, corneoscleral, limbal, or scleral tunnel incisions.[5]

Several studies published recently on the outcome of the toric phakic IOL have demonstrated satisfactory results.[7–10] The Artisan lens also has been shown to be rotationally stable.[8,11] However, a drawback of the lens is that it requires an incision of 5.2 to 5.5 mm. This incision can induce corneal astigmatism.

Precise enclavation of the lens is paramount. Especially in higher degrees of astigmatism, minimal misalignment greatly reduces the corrective value of the lens. Approximately one third of the cylindrical correction is lost if the IOL is rotated 10° off the axis.[12] Some surgeons mark the intended axis of enclavation on the iris with the argon or yytrium–aluminum–garnet laser.[7] Although this procedure seems to be accurate, laser burns can cause inflammatory reactions, iris bleeding, or endothelial cell loss.[13,14] Because laser burns must be placed at least 1 week before lens implantation, they also create logistical problems. Furthermore, laser burns may disappear into the iris folds after enclavation, which preclude the evaluation of accurate lens position. Other surgeons use a digital image system in which the axis is projected on the iris. This image can be used during surgery to find the correct lens position. At our center, the intended position of enclavation is marked on the corneal limbus using the Javal keratometer (Haag Streit, Bern, Switzerland) directly before anesthesia.

In this single-center prospective study, we evaluated the safety, efficacy, and predictability of the toric Artisan myopia phakic IOL. We further assessed the influence of accurate axis lens placement using corneal markings with the Javal keratometer, and studied the effect of astigmatism induced by corneoscleral incisions on the total surgically induced refraction.

Patients and Methods

Fifty-four consecutive eyes of 33 patients receiving toric phakic IOLs were enrolled in this prospective study. Lens implantations were performed by one surgeon (GL) between January, 2000, and January, 2004. Inclusion criteria consisted of the following: (1) general good health, (2) a minimum of 18 years of age; (3) stable refraction for a minimum of 1 year; (4) astigmatism more than 1.5 D combined with myopia; (5) absence of ocular pathological features; (6) endothelial cell count more than 2000 cells/mm^2; (7) anterior chamber depth more than 3.0 mm (including corneal thickness); (8) mesopic pupil size limited to 5.0 mm or less, although larger pupils were included after informing the patients about the increased risk of haloes and glare. Institutional ethics committee approval and informed consent in accordance with the Helsinki Declaration was obtained for each patient.

Before preoperative examination, patients were requested to discontinue contact lens wear for a minimum of 14 days to avoid the possibility of contact lens-induced corneal warpage. The examination included best spectacle-corrected visual acuity (BSCVA) in Snellen notation, slit-lamp biomicroscopy, endothelial cell count (Topcon SP-2000-P), keratometry (autokeratometer, Topcon KR 7000P), A-scan immersion biometry, applanation tonometry, measurement of mesopic pupil diameter (Colvard pupillometer), and indirect ophthalmoscopy. Furthermore, objective refraction was measured with cyclopentolate hydrochlorate 1.0% eyedrops to exclude any accommodative error in subjective refraction. If large differences were found between the 2 refractive errors, subjective refraction was measured again and used to calculate the power of the lens. The power of the IOL, including the intended axis of enclavation, was calculated according to the Van der Heijde formula.[15] Model A was implanted in 53 eyes and model B in 1 eye.

When subjective and corneal astigmatism coincided, intended axes were marked before surgery onto the corneal limbus with a surgical marker guided by the reflected images of the Javal keratometer. If the subjective and corneal astigmatism differed, the cornea was marked on the basis of the subjective measurements, using the reflected image as a reference point. Myotic drops (pilocarpine 4%) were administered to prepare the iris for lens fixation. Surgery was performed with retrobulbar anesthesia (41 eyes of 26 patients) or general anesthesia (13 eyes of 7 patients), according to the patient needs.

A corneoscleral bevelled incision of 5.5 mm was made at the steep meridian and 2 paracenteses were placed 8 mm apart at either side. The anterior chamber was opened and filled with viscoelastic fluid (Healon, AMO, Santa Ana, CA) to maintain its depth and to protect the endothelium. After introduction of the lens into the anterior chamber with holding forceps (Ophtec REF D02-70), it was positioned onto the desired axis and then fixed onto the midperipheral iris stroma with a disposable enclavation needle. A slit iridotomy was performed at approximately 12 o'clock to prevent pupillary block glaucoma; thereafter, the viscoelastic material was irrigated manually.[5] The incision was closed with a 10-0 nylon running suture. Tobramycin 0.3% eye ointment was administered once directly after surgery. Postoperative treatment included ketorolac and dexamethasone 0.1% eyedrops 4 times daily for 4 weeks. If both eyes were to be operated on, the interventions were separated by a minimum of 2 weeks.

Follow-up examinations were scheduled at 1 day, 1 week, 1 month, 2 months, 6 months, and 1 year after surgery, and on a yearly basis thereafter. Postoperative examinations included slit-lamp biomicroscopy, endothelial cell count (from 6 months after surgery), keratometry, applanation tonometry, subjective and objective refraction, uncorrected visual acuity (UCVA) and BSCVA. Within the first 6 postoperative weeks, the suture was dissected or removed if it created undesirable corneal astigmatism. After 6 weeks, the suture was removed if it caused discomfort or had loosened. At the 1-month follow-up, the Javal keratometer was used to determine the postoperative IOL axis alignment. Axis misalignment was defined as the difference between intended and achieved axis. The postoperative IOL position was measured by paraxial illuminating the IOL and projecting the Javal reflections between the claws of the IOL. This was done without prior knowledge of the intended axis of implantation (MB). Furthermore, patients were asked if they experienced haloes or glare. All data were collected prospectively from patient charts.

Statistical Analysis

To analyze BSCVA, UCVA, safety index (mean postoperative BSCVA/mean preoperative BSCVA), and efficacy index (mean postoperative UCVA/mean preoperative BSCVA), Snellen visual acuity first was converted into logarithm of the minimum angle of resolution notation to calculate the mean and then transformed back to the geometric mean Snellen visual acuity. Refractive

cylinders are expressed in minus form. Change in cylindrical refraction was calculated with vector analysis.[12] The astigmatism vector levels were estimated using the mixed model analysis of variance (SAS software; SAS Institute, Cary, NC). The model accounts for a possible inclusion of 2 eyes of 1 patient.

Cylindrical refractions were transformed into double-angle vectors and rectangular coordinates as described by Holladay et al.[12] The double-angle vector plots chart the cylinders horizontally (parallel, x-coordinates) and vertically (orthogonal, y-coordinates). After calculation, the horizontal and vertical components were transformed back to cylindrical notation. Total surgically induced refractive change in astigmatism was calculated with the use of vector analysis using cylindrical subjective refraction results.[12]

Incision-induced astigmatism was defined as the vector of the change that occurred based on preoperative and postoperative keratometry values. This was calculated by first averaging the incision-induced astigmatism of each individual eye after 2 months to correct for measurement errors. In this analysis, eyes in which additional operations were performed after implantation were excluded. Furthermore, the single eye with a model B lens implantation also was excluded, because the incision was on the flat axis.

Comparison of data between preoperative and postoperative periods were performed with the Student t test for paired data using a level of significance of $P = 0.05$. Changes between preoperative and postoperative periods and differences between postoperative periods also were analyzed using mixed-model analysis of variance using a level of significance of $P = 0.05$.

Results

Patient Population

All 54 eyes of 33 patients were followed-up for a minimum of 6 months. At 1 year, follow-up data were available for 45 eyes of 27 patients, and at 2 years, data were available for 20 eyes of 14 patients. Mean follow-up was 17.1±11.4 months. Twenty-three of the 33 patients were female (69.7%). Mean age was 39.5±2.0 years (range, 19–57 years). Average axial length was 27.34±0.27 mm (range, 23.72–32.54 mm), and average anterior chamber depth was 3.66±0.31 mm (range, 3.18–4.32 mm). Mesopic pupil diameter averaged 4.7±0.9 mm (range, 3.0–7.0 mm).

Visual Acuity and Refraction

Preoperative refractive measurements, along with the postoperative spherical equivalent of subjective refraction, UCVA, BSCVA, and percentages of eyes within ±1.00 D or ±0.50 D of emmetropia at 6 months, 1 year, and 2 years are presented in Table 1. The deviation of the achieved spherical equivalent correction from attempted spherical equivalent correction at 6 months is presented in Figure 1. Average BSCVA improved significantly after implantation from 0.71±0.23 before surgery to 0.88±0.23 at 6 months ($P<0.001$). A gain of 1 or more BSCVA lines was seen in 74.1% of the eyes at 6 months. The safety index after 6 months and 1 year was 1.29 and 1.26, respectively. The efficacy index was 1.04 at 6 months and 1.02 at 1 year. Eighty-three percent of eyes achieved a UCVA of 20/40 and 28% achieved 20/20.

Surgical and Incision-Induced Astigmatism

The mean preoperative astigmatism using vector analysis was −2.91±1.66 D for the horizontal component (x-axis) and −0.15±1.54 D for the vertical component (y-axis), equivalent to a cylinder of 2.92±1.60 D at an axis of 91.4°. A double-angle minus cylinder plot of preoperative subjective cylinder is presented in Figure 2. At 6 months, the total surgically induced refractive change was 3.21±1.71 D at an axis of 0.3°. Based on the amount of cylindric correction of the implanted IOL, average attempted cylindric outcome was −0.14 D at 180°. Mean achieved postoperative astigmatism at 6 months was +0.28±0.57 D for the x-axis value and −0.06±0.51 D for the y-axis value, translating to a cylinder of +0.28±0.54 D at a mean axis of 174.3° (Fig 3). There was no significant difference in postoperative astigmatism between follow-up periods ($P = 0.13$ for the x-axis value and $P = 0.84$ for the y-axis value).

Keratometric data did not change significantly after 2 months, even if suture removal took place after this period (Fig 4). The mean incision-induced astigmatism was +0.74±0.61 D at a mean axis of 0.2°. Taking into account incision-induced astigmatism, mean expected cylindrical outcome changed from −0.14 D at 180° to +0.60 D at 180°.

Axis Misalignment

The mean difference between achieved and intended lens axis alignment was 0.37±5.34° (range, −13 to +14°). The mean absolute deviation was 4.15±3.34°. Axis misalignment is presented in Figure 5. An IOL with a −7.0-D cylinder was repositioned owing to a residual cylinder of −1.75 D at 130°, in combination with an axis misalignment of 8°. After IOL realignment, a cylinder of −0.50 D at 65° remained. Two eyes with cylindrical corrections of −2.00 and −3.00 D, respectively, had axis misalignments of more than 10°. No subjective residual astigmatism

Table 1. Preoperative and Postoperative Refractive Results

	Preoperative	Postoperative		
	(54 Eyes, 33 Patients)	*6 mos (54 Eyes, 33 Patients)*	*12 mos (45 Eyes, 27 Patients)*	*24 mos (20 Eyes, 14 Patients)*
SE (mean) ± SD (D), (range)	−11.39±4.86 (−2.13 to −25.63)	−0.38±0.57 (−2.25 to +0.75)	−0.44±0.62 (−2.75 to +0.50)	−0.44±0.51 (−2.13 to 0.00)
Mean vectorial astigmatism (D) × axis	2.92±1.60×91.4°	0.28±0.54×174.3°	0.23±0.54×173.9°	0.26±0.43×175.4°
Mean UCVA±SD		0.72±0.28	0.70±0.28	0.75±0.26
Mean BSCVA±SD	0.71±0.23	0.88±0.23	0.85±0.25	0.94±0.25
±1.00 D of emmetropia (%)	—	88.9	90.7	95.0
±0.50 D of emmetropia (%)	—	66.7	65.1	70.0
Loss ≥2 lines BSCVA	—	0	1 (2.2%)	0
Gain ≥1 line BSCVA	—	40 (74.1%)	33 (73.3%)	14 (70.0%)

BSCVA = best spectacle corrected visual acuity; D = diopters; SE = spherical equivalent refraction; SD = standard deviation; UCVA = uncorrected visual acuity.

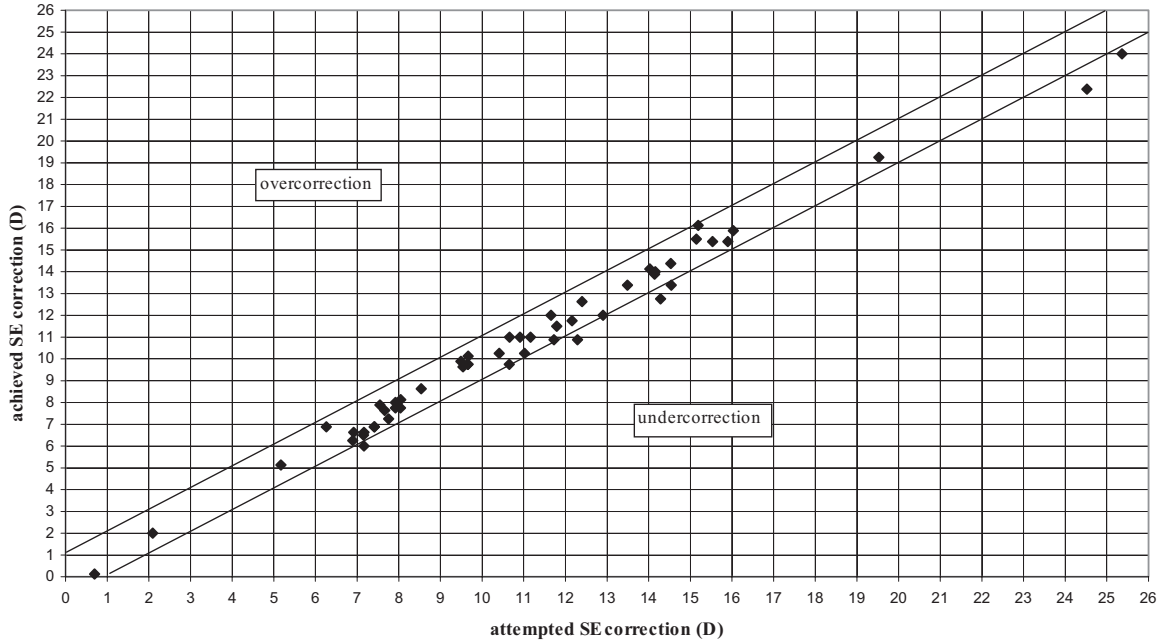

Figure 1. Plot of attempted spherical equivalent versus achieved subjective spherical equivalent at 6 months after surgery. D = diopters; SE = spherical equivalent.

was seen in the first eye, despite an axis deviation of 14°. A deviation of −13° from the target axis in the second eye resulted in a residual subjective cylinder of −1.00 D.

The average (absolute) spectacle cylindrical error as a result of axis misalignment was 0.16±0.12 D. When the known axis deviation for each lens was accounted for, the attempted cylindrical correction of −0.14 D at 180° changed marginally to −0.15 D at 180°.

Endothelial Cell Loss

The mean preoperative endothelial cell count was 2724±388 cells/mm^2 (range, 1577–3463 cells/mm^2). Mean postoperative endothelial cell count was 2779±458 cells/mm^2 (range, 1658–3784 cells/mm^2) at 6 months, 2783±475 cells/mm^2 (range, 1658–3591 cells/mm^2) at 1 year, and 2717±356 cells/mm^2 (range, 2249–3344 cells/mm^2) at

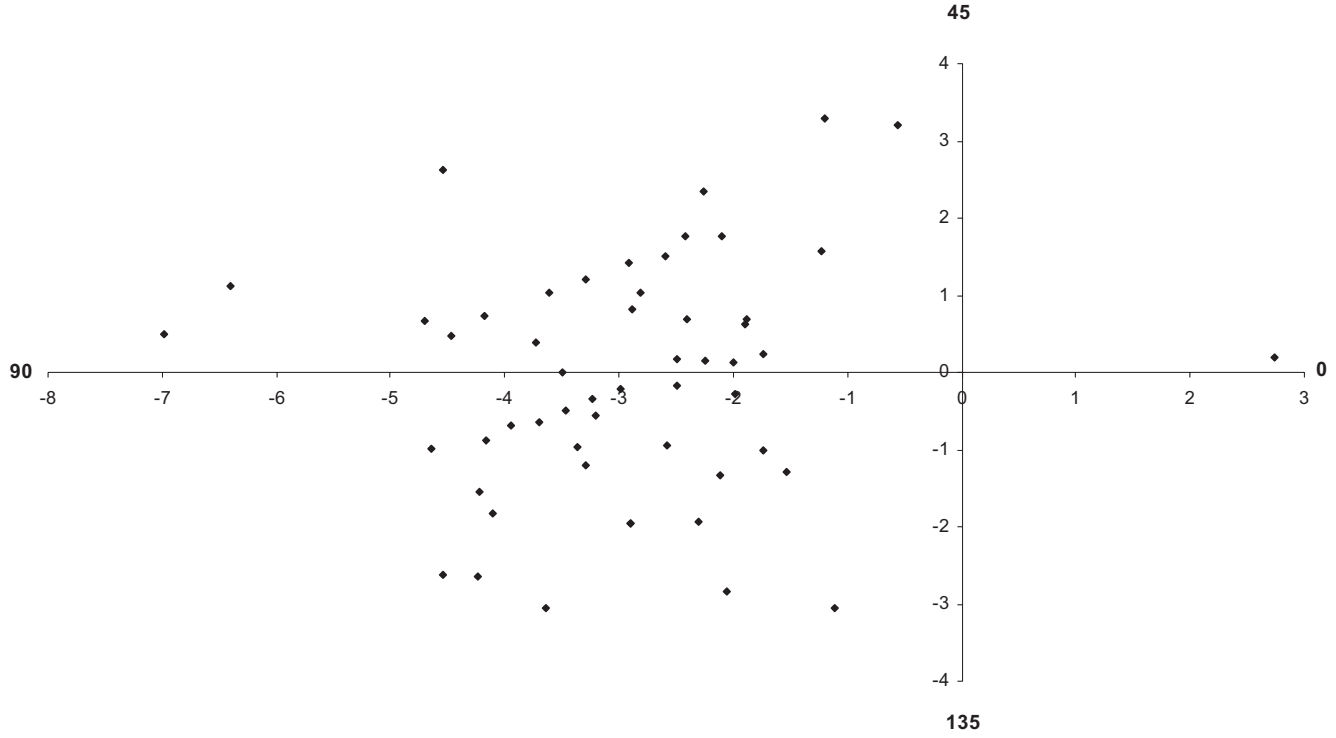

Figure 2. Double-angle plot of minus cylinder of subjective preoperative refraction.

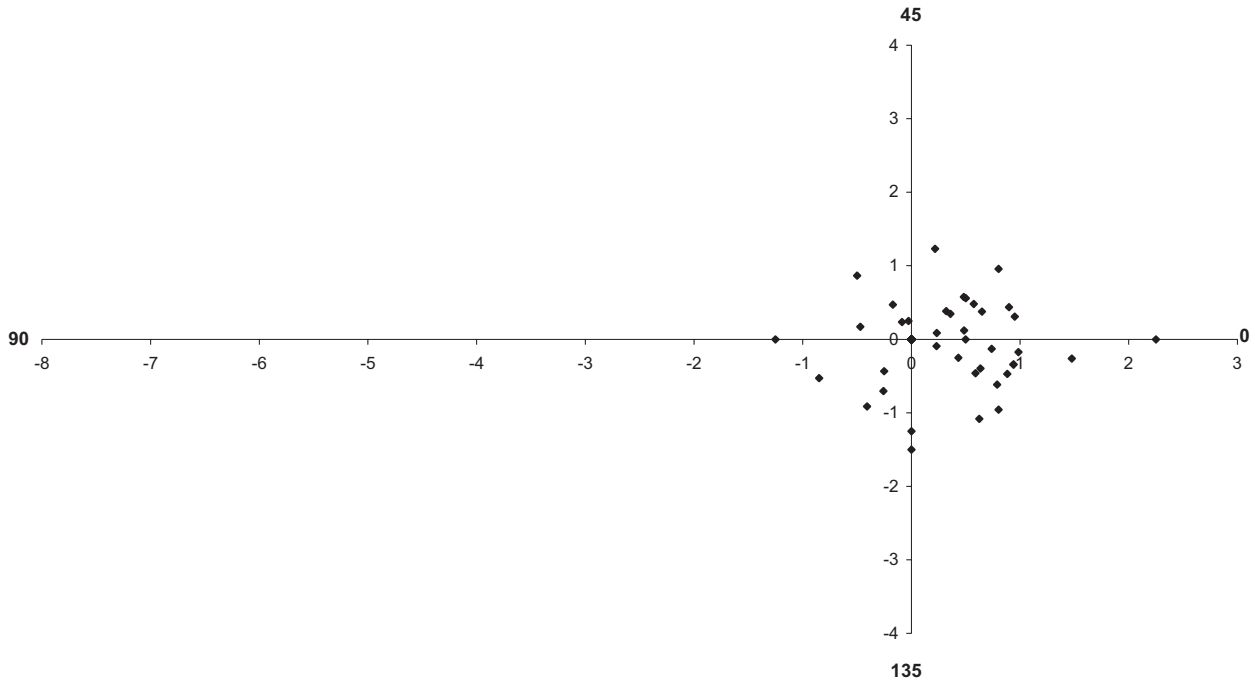

Figure 3. Double-angle plot of minus cylinder of subjective refraction 6 months after surgery.

2 years and did not significantly differ from mean preoperative values ($P>0.45$).

Complications

Intervention was uneventful in al patients. One patient experienced a wound leak after suture removal at 1 week, requiring resuturing of the incision. One patient, with a preoperative asymptomatic retinal break treated with argon laser, experienced a retinal detachment 10 days after surgery. At 1 year of follow-up, the BSCVA in this eye was 0.40, compared to 0.50 before surgery.

The mean preoperative intraocular pressure was 15.3±3.4 mmHg. Seven eyes experienced a temporary intraocular pressure higher than 21 mmHg within the first month of surgery (range, 22–30 mmHg), although this normalized in all eyes after discontinuing topical corticosteroids. The mean postoperative intraocular pressure (15.7±3.4 mmHg) did not differ significantly from preoperative values ($P>0.25$).

One eye in the study experienced a significant loss of line after cataract developed 1 year after surgery. Visual acuity decreased from 0.4 before surgery to 0.2 after surgery. We are not aware of any surgically induced reason for the development of the cataract.

No pigment dispersion or pupillary block occurred in any eye during follow-up. Seven of the 33 patients noted having more difficulty with haloes or glare. One of these patients had a mesopic pupil size larger than 5 mm. All patients were satisfied with the outcome of surgery. No patient considered removal of the lens.

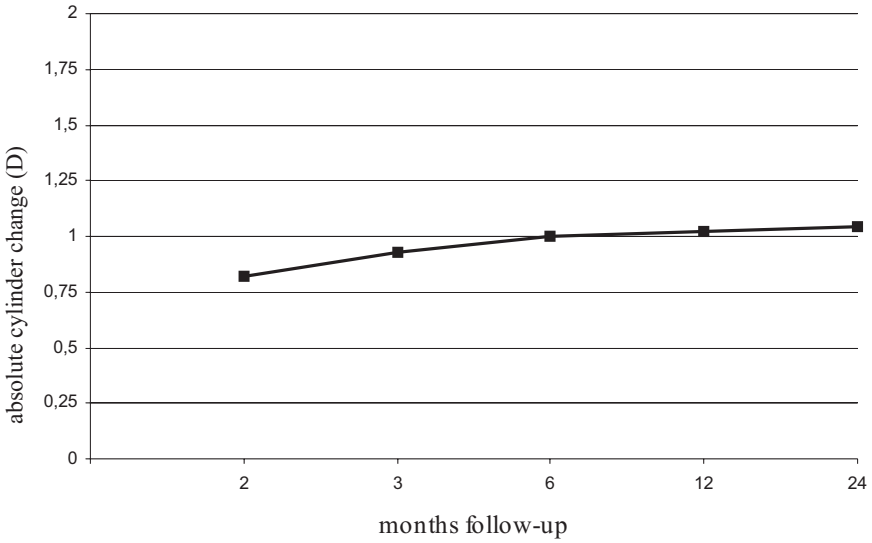

Figure 4. Graph showing the mean absolute incisional-induced astigmatism in diopters (D) at different follow-up periods.

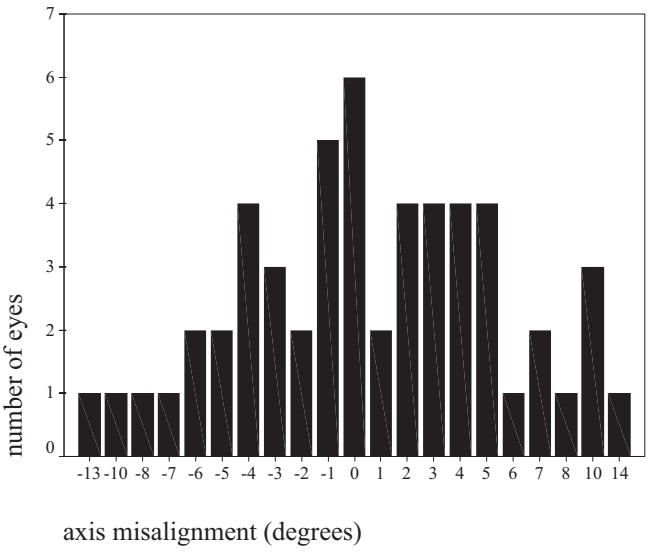

Figure 5. Bar graph showing the postoperative deviation in attempted axis of enclavation per eye.

Discussion

The safety, efficacy, and predictability of phakic toric Artisan lens implantation for the correction of myopia and astigmatism in this study were high. Although the toric Artisan lens was investigated in a large European study, the effect of axis misalignment and incision-induced astigmatism on the final outcome was not analyzed.[7] Based on our calculations, mean intended astigmatism correction ought to have been −0.14 D. However, our study demonstrated a slight overcorrection of +0.28 D. By analyzing the effect of incision-induced astigmatism, we found that an against-the-rule astigmatism of 0.74 D could be introduced by making a 5.5-mm incision on the steep axis. This induced astigmatism also can result after cataract surgery.[16,17] Taking the latter into account, the expected cylinder outcome should have been a 0.60 D overcorrection. Instead, we observed an overcorrection of only 0.28 D. To evaluate if this discrepancy was a result of axis misalignment, we also analyzed its effect on the refractive outcome. We found an absolute axis deviation of 4.15±3.34°, comparable with the results of Tehrani et al.[8] Because rotation of the lens has not been observed as a result of its firm fixation onto the midperipheral iris stroma, axial misplacement of an iris-claw lens must be caused by incorrect alignment of the lens during the surgical procedure. Because proper surgical alignment of the IOL is a prerequisite for the success of toric phakic IOL implantation, a precise method of axis marking is critical. Although most surgeons use preoperative laser iridotomies to mark the axis, we used limbal marking with the Javal keratometer in this study. This method does not incur the risk of intraocular inflammation and also can be practical, because marking can take place immediately before surgery, avoiding extra patient visits. One disadvantage of this method, however, is that the markings can fade or disappear during preoperative preparation of the eye. We encountered this in 1 eye, resulting in an enclavation 14° from the intended axis of implantation. Another lens required realignment after developing a subjective postoperative cylinder of −1.75 D. The effect of the misalignment on the final cylindrical outcome, however, was minimal. The mean attempted cylindrical outcome changed marginally from −0.14 D at 180° to −0.15 D at 180° when the known axis error for each lens was accounted for. Both the incision-induced astigmatism and axis misalignment could not fully explain the discrepancy between the expected and achieved cylindrical corrections. Fixed factors such as the lens only being available in half-diopter increments and a calibration error of ±0.3 D of the lens itself could have influenced the achieved correction. Also, our data are based on subjective refraction only. Our impression is that patients tend to experience less astigmatism than was objectively observed.[10] We do not have a good explanation for this interesting phenomenon.

Refractive results in this study however, were predictable and efficacious and resembled those achieved by LASIK in lower degrees of myopia and astigmatism.[1] Approximately 90% of the eyes in our study were within 1.00 D of emmetropia. These data compare favorably those of LASIK for moderate to high myopia and astigmatism, where studies report 41% to 76% of eyes being within the same range.[1,18–22] LASIK, however, tends to result in lower predictability among higher refractive errors.[23,24] The large amount of stromal tissue ablated with the excimer laser in these higher degrees of myopia and astigmatism also predisposes eyes to corneal ectasia and associated visual problems.[25] Clear lens extraction with toric IOL implantation is another option for such eyes. Studies have shown that clear lens extractions carry a higher risk of retinal detachment and further result in the loss of accommodation in younger patients.[26] Moreover, rotational stability may be a problem with toric IOLs in the capsular bag.[27] Compared with LASIK or clear lens extraction, the correction of moderate to high myopia with astigmatism seems to be safer and more predictable with the implantation of phakic IOLs. Furthermore, unlike excimer laser procedures, the eye is not affected by the amount of refractive correction. Posterior chamber IOL implantation requires a smaller incision (3.2 mm) compared with the toric Artisan lens (5.5 mm).[28–30] However, reports on phakic toric posterior chamber IOLs for the correction of myopia combined with astigmatism currently are limited.[31] The potential for cataractogenesis and pigment dispersion with posterior chamber IOLs is also a crucial long-term concern, as is the potential for postoperative lens rotation.[27,32,33] One patient in this study also experienced a cataract, although it is unclear if this was the result of the intraocular surgery.

In our study, 70% or more of the cases exhibited a gain of 1 or more lines of BSCVA. Such improvements in visual acuity also have been reported in other studies and have been attributed to the increase in the size of the retinal image compared with spectacle correction.[34–36]

Successful correction of myopia and astigmatism with a

toric phakic IOL depends on several variables. In this study, we report not only the accuracy of the refractive results, but also the refractive contribution of the deviation between intended and achieved axis of implantation and the input of incision-induced astigmatism. We believe that understanding these parameters will allow greater insight into toric phakic IOL implantation.

In conclusion, toric myopic Artisan lens implantation leads to highly predictable, effective, and safe results. Marking the enclavation site for toric phakic IOL implantation with the use of the Javal keratometer seems to be a safe and reliable method. Accounting for incision-induced astigmatism could increase predictability further. To compensate for this, a systematic undercorrection of −0.50 D for attempted cylindric outcome is advised when using a corneoscleral incision of 5.5 mm.

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