Foldable toric intraocular lens for astigmatism correction in cataract patients

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PURPOSE: To evaluate the results of AcrySof toric intraocular lens (IOL) (Alcon) implantation to correct preexisting astigmatism in patients having cataract surgery.

SETTING: Ophthalmology Service, Donostia Hospital, San Sebastián, Spain.

METHODS: This prospective observational study included 30 eyes of 15 consecutive patients with more than 1.00 diopter (D) of preexisting corneal astigmatism having cataract surgery. Bilateral implantation of the AcrySof toric IOL was performed after phacoemulsification. The uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), residual refractive sphere, residual keratometric and refractive cylinders, and toric IOL axis were measured.

RESULTS: The UCVA was 20/40 or better in 93.3% of eyes and 20/25 or better in 66.6%. All eyes achieved 20/25 or better BCVA. The mean refractive cylinder decreased significantly after surgery from −2.34 D ± 1.28 (SD) to −0.72 ± 0.43 D (P<.01). Vector analysis of attempted versus achieved correction showed that 100% of eyes were within ±1.00 D and 80% and 93.9% were within ±0.50 D for J_0 and J_{45}, respectively. The mean toric IOL axis rotation was 3.63 ± 3.11 degrees, with rotation less than 10 degrees in 96.7% of eyes.

CONCLUSIONS: The results indicate that phacoemulsification and posterior chamber AcrySof toric IOL implantation is an effective option to correct preexisting astigmatism in cataract surgery. The AcrySof toric IOL showed good rotational stability.

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Intraocular lens (IOL) technology designs for monochromatic and chromatic aberration correction have undergone important advances.[1] However, low-order optical aberrations should be corrected efficiently to provide the best optical quality, and thus visual quality, for cataract patients. Spherical refractive errors should be managed using accurate keratometry and axial length measurement. In addition to spherical refractive error correction, astigmatism should be corrected to provide postoperative spectacle independence.

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It has been estimated that 15% to 29% of patients with cataract have more than 1.50 diopters (D) of preexisting astigmatism.[2,3] Reducing this preexisting astigmatism may further improve visual outcomes after cataract surgery. Astigmatism can be reduced or eliminated with several techniques, including selective positioning of the phacoemulsification incision, corneal relaxing incisions, limbal relaxing incisions, or excimer laser keratectomy. All these methods have limitations including the degree of astigmatism that can be treated and long-term mechanical instability, and postoperative outcomes are subject to many variables such as age; magnitude; and incision number, depth, and length.[4]

Toric IOL implantation is another valuable option for astigmatism correction in cataract patients. The toric IOL was devised by Shimizu et al.[5] in 1994 and has been used clinically since then. Several studies[6–15] have analyzed the results of implantation of many models of toric IOLs and found this method to be effective in correcting astigmatism. Rotation of the toric IOL after implantation is the main problem associated

with this modality.[16–18] It has been estimated that approximately 1 degree of off-axis rotation results in a loss of up to 3.3% of the lens cylinder power.[19] When the toric IOL rotates 30 degrees, the cylinder power is completely lost.

The purpose of this prospective observational study was to assess the astigmatic reduction and rotational stability of the AcrySof toric IOL (Alcon) in a series of cataract surgery patients with corneal astigmatism greater than 1.00 D.

PATIENTS AND METHODS

This prospective observational study included 30 eyes of 15 consecutive patients with cataract and preexisting regular corneal astigmatism greater than 1.00 D who had bilateral implantation of the AcrySof toric IOL at the Donostia Hospital, Spain, between October 2006 and March 2007. The tenets of the Declaration of Helsinki were followed in the research. Informed consent was obtained from all patients after the nature and possible consequences of the study were explained. Institutional Review Board approval was obtained.

Inclusion criteria included cataract, age between 50 and 85 years, and preoperative regular corneal astigmatism greater than 1.00 D. Exclusion criteria included preoperative astigmatism greater than 5.00 D, history of glaucoma or retinal detachment, corneal disease, previous corneal or intraocular surgery, abnormal iris, pupil deformation, macular degeneration or retinopathy, neuroophthalmic diseases, and history of ocular inflammation.

Before cataract surgery, patients had a complete ophthalmologic examination including manifest and cycloplegic refractions, keratometry, topography (CSO system, Costruzione Strumenti Oftalmici), slitlamp examination, applanation tonometry, and ophthalmoscopy through dilated pupils. Axial length and keratometry were measured with the Zeiss Humphrey IOLMaster (Carl Zeiss Meditec). Calculation of IOL power and axis placement to achieve emmetropia was performed using a program available from the IOL manufacturer (www.acrysoftoriccalculator.com. Accessed January 9, 2008). Preoperative keratometry and biometry data, incision location, and the surgeon's estimated surgically induced corneal astigmatism were used to determine the appropriate AcrySof toric IOL model, spherical equivalent (SE) lens power, and axis of placement in the eye. The SRK/T formula was used for spherical IOL power calculation. The targeted refraction was emmetropia.

All surgery was performed by the same experienced surgeon (J.M.) using topical anesthesia. With the patient seated at the slitlamp and with a coaxial thin slit turned to the 0- to 180-degree axis, the corneal limbus was marked at the 0-degree and 180-degree positions with a sterile marker after vertical alignment of the patient's head. Next, with the patient lying on the surgical table, the steep corneal meridian was identified and marked using a Marquez gauge with the aid of the preplaced reference points. Phacoemulsification was performed through a 2.75 mm temporal corneal incision. In all cases, the target capsulorhexis diameter was 5.50 mm to ensure overlap of the IOL border. After phacoemulsification, a foldable AcrySof toric IOL was inserted in the capsular bag using the Monarch II injector (Alcon Laboratories). The IOL was rotated to align the cylinder axis with the marked steep corneal meridian. The final incision size was 2.75 mm in all cases, and no sutures were used to seal the wound. Cataract surgery was performed in both eyes within 2 weeks.

The AcrySof toric IOL is an open-loop, modified single-piece, acrylic polymer IOL with L-shaped haptics (Figure 1). The IOL's toricity, located on the posterior surface, extends across the entire surface of the spherical optic. The IOL is available in 3 models: SN60T3, SN60T4, and SN60T5. The U.S. Food and Drug Administration (FDA) approved the AcrySof toric IOL in September 2005 for 3 cylindrical powers: 1.50 D, 2.25 D, and 3.00 D at the IOL plane (Available at: http://www.fda.gov/cdrh/pdf/p930014s015.html. Accessed January 9, 2008).

The manufacturer's information indicates that the SN60T3 toric IOL is intended for use when the preexisting corneal astigmatism lies between 0.75 D and 1.50 D. The SN60T4 and SN60T5 toric IOLs are intended for use in eyes with preexisting astigmatism between 1.75 D and 2.00 D and 2.25 D and 2.50 D, respectively. The IOL has a 6.0 mm diameter and an overall length of 13.0 mm. The lens power ranges from +16.00 to +25.00 D.

Monocular uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), refraction, keratometry, and IOL axis were recorded postoperatively in all patients. Intraocular lens rotation was measured at the slitlamp in 1-degree steps using an eyepiece for angle measurement through pupils dilated with tropicamide. A thin coaxial slit was projected in front of the eye and rotated until the thin slit projection overlapped the axis marks of the IOL. Postoperative assessments were performed at 1 week and 1 and 3 months. At 3 months, all examinations were performed by the same ophthalmic technician.

Data analysis was performed using SPSS for Windows (version 13.0, SPSS Inc.). The *t* test was used to compare presurgery and postsurgery refractive and keratometry outcomes. Differences were considered statistically significant when the *P* value was less than 0.01 (ie, at the 1% level).

RESULTS

Thirty eyes of 15 consecutive patients were enrolled in this study. Table 1 shows the patients' demographics. The mean age was 72.1 years ± 8.2 (SD) (range 50 to 85 years). The mean preoperative sphere and preoperative cylinder was +1.26 ± 1.85 D and −2.34 ± 1.28 D, respectively.

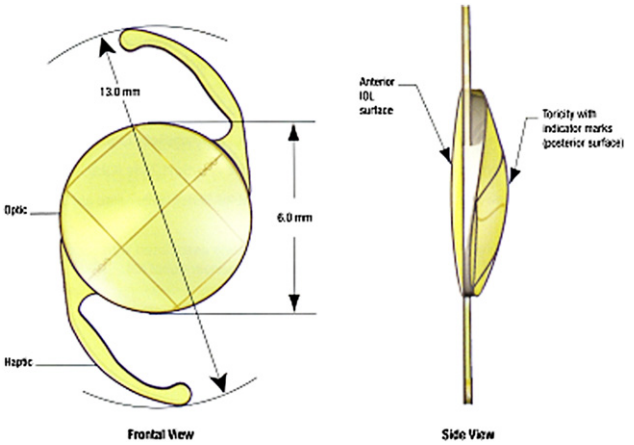

Figure 1. Front and side view of the AcrySof toric IOL.

Table 1. Patient demographics.

Characteristic	Value
Patients (n)	15
Mean age (y) ± SD	72.1 ± 8.2
Sex (male/female)	11/4
Eyes (n)	30
Preoperative sphere (D)	
Mean ± SD	+1.26 ± 1.85
Range	−2.50 to 5.00
Preoperative cylinder (D)	
Mean ± SD	−2.34 ± 1.28
Range	−1.00 to −5.00
Mean preoperative keratometry (D) ± SD	
K1	43.30 ± 1.43
K2	45.65 ± 1.86
Axial length (mm)	
Mean ± SD	23.42 ± 0.88
Range	21.62 to 25.21
Spherical IOL power (D)	
Mean ± SD	20.50 ± 2.35
Range	16.00 to 24.50

IOL = intraocular lens

Visual Outcomes

Table 2 shows the mean preoperative and postoperative UCVA and BCVA. Three months postoperatively, the mean logMAR UCVA was 0.16 ± 0.18 (20/25). The BCVA improved slightly to 0.02 ± 0.05 logMAR (approximately 20/20). The UCVA was 20/40 or better in 93.3% of eyes and 20/25 or better in 66.6%. All eyes achieved 20/25 or better BCVA.

Refractive Outcomes

There was a significant reduction in refractive astigmatism after toric IOL implantation ($P < .01$) (Table 2). Figure 2 shows the astigmatic component of the power vector as represented by the 2-dimensional vector (J_0, J_{45}). The origin in this graph (0, 0) represents an eye free of astigmatism. The spread in the presurgical data is converted into a concentrated data set around the origin after toric IOL implantation.

Figure 3 shows the attempted versus achieved plot for SE (*top*) and for both components of astigmatism: J_0 (*middle*) and J_{45} (*bottom*). For SE, 96.7% of cases were within ±1.00 D and 90% were within ±0.50 D. For J_0, 100% of eyes were within ±1.00 D and 80% were within ±0.50 D. For J_{45}, 100% of eyes were within ±1.00 D and 93.3% were within ±0.50 D.

Figure 4 shows the scatterplot for J_0 and J_{45} calculated with the presurgical and postsurgical keratometry. Refractive changes were not correlated with keratometry changes. The spread of the points before and after toric IOL implantation were similarly distributed. The mean change in keratometric astigmatism was 0.19 ± 0.42 for J_0 and 0.07 ± 0.24 for J_{45}. There were no statistically significant differences between the mean keratometric changes before surgery and after surgery ($P = .27$ for J_0 and $P = .23$ for J_{45}).

Table 2. Visual acuity and manifest refraction before and 3 months after AcrySof toric IOL implantation.

	Mean ± SD	
Parameter	Preoperative	Postperative
UCVA (logMAR)	—	0.16 ± 0.18
BCVA (logMAR)	0.41 ± 0.15	0.02 ± 0.05
Refractive sphere (D)	1.26 ± 1.85	−0.12 ± 0.44
Refractive cylinder (D)	−2.34 ± 1.28	−0.72 ± 0.43

BCVA = best corrected visual acuity; UCVA = uncorrected visual acuity

Rotational Stability

No eye had secondary surgery to reposition the IOL axis within the 3-month postoperative period. No eye had significant IOL rotation (≤20 degrees). The mean toric IOL axis rotation was 3.63 ± 3.11 degrees (range 0 to 12 degrees). One eye (3.3%) had IOL rotation of 12 degrees, and the rest of the eyes (96.7%) had rotation less than 10 degrees (Figure 5, *top*). Figure 5, *bottom*, compares the planned intraoperative toric IOL axis with the toric IOL rotation 3 months after surgery. The figure shows that the planned axis alignment was not a factor in determining the extent of postoperative rotation. There was no statistically significant linear correlation between intraoperative axis alignment and 3-month postoperative rotation ($P > .1$).

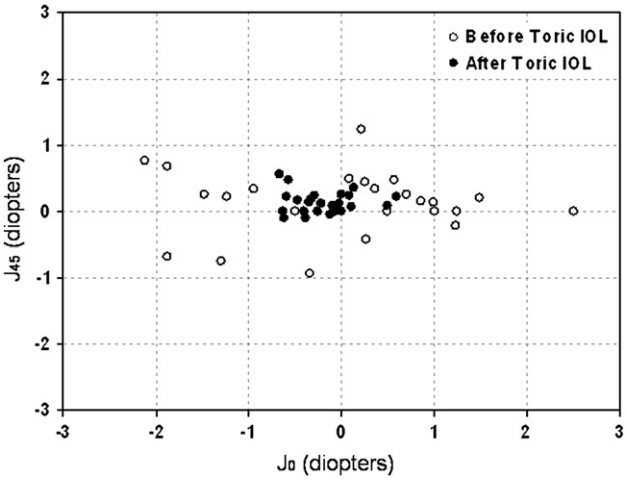

Figure 2. Representation of the astigmatic vector (J_0 and J_{45}) before and 3 months after toric IOL implantation.

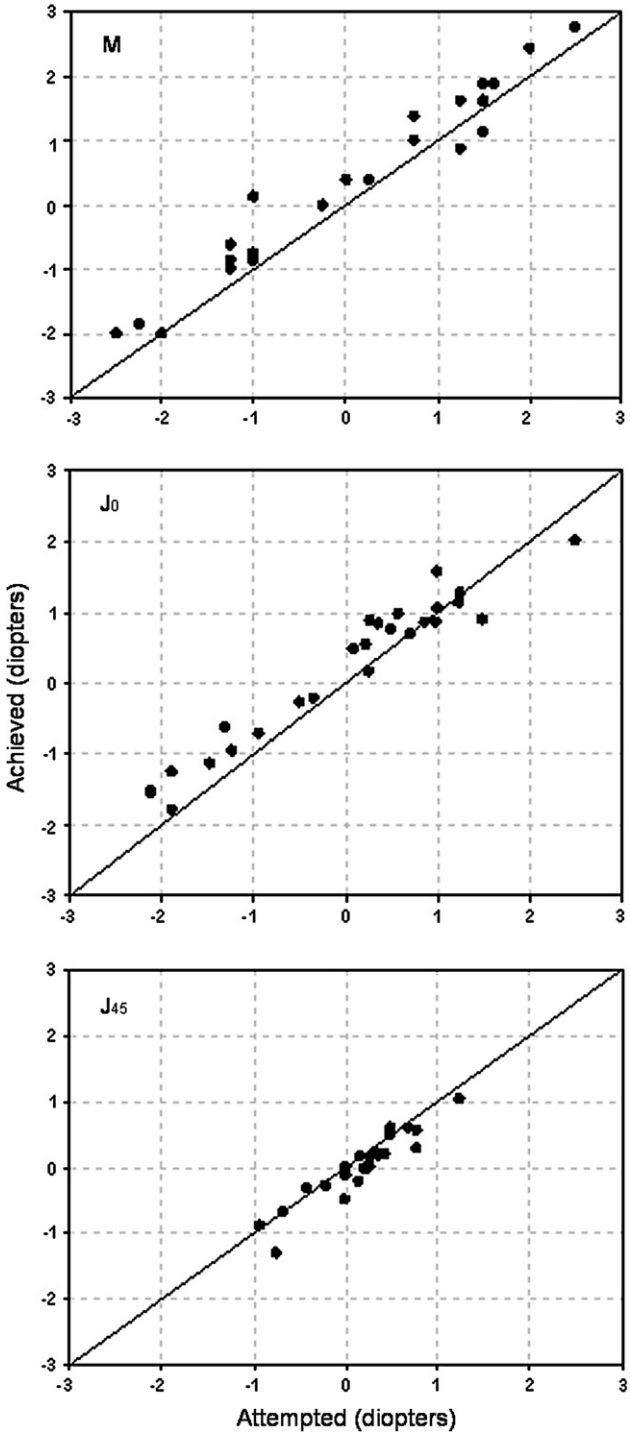

Figure 3. Attempted versus achieved spherical equivalent (M) (top) and the astigmatic components J_0 (*middle*) and J_{45} (*bottom*) of the power vector analysis. Refraction is expressed following the power vector method. Manifest refractions in conventional script notation [S (sphere), C (cylinder) × φ (axis)] were converted to power vector coordinates by the following formulas: $M = S + C/2$; $J_0 = (-C/2)\cos(2\varphi)$; $J_{45} = (-C/2)\sin(2\varphi)$.

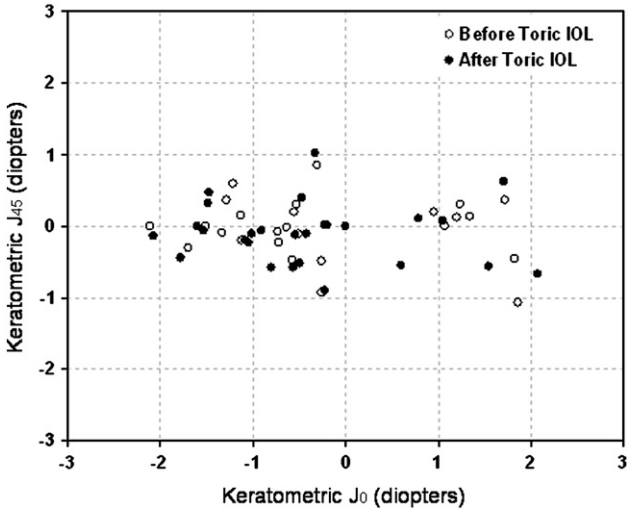

Figure 4. Vector analysis of keratometric data. Scatterplot for J_0 and J_{45} calculated with the presurgical and postsurgical keratometry.

Complications

No eye had intraoperative or postoperative complications or required a secondary intervention. No potentially sight-threatening complications such as persistent corneal edema, pupillary block, retinal detachment, or endophthalmitis were observed during the postoperative period. In addition, as of the last postoperative visit, no eye required neodymium:YAG capsulotomy.

DISCUSSION

Corneal astigmatism can be surgically managed using corneal, relaxing, or limbal incisions and excimer laser keratectomy. Limitations, advantages, and disadvantages have been fully discussed in the literature.[4] The use of toric IOLs to correct corneal astigmatism is one surgical option.

We implanted a foldable toric single-piece IOL in 30 eyes of 15 patients with preexisting corneal astigmatism greater than 1.00 D. To our knowledge, this is the first peer-reviewed article to report the efficacy and rotational stability of this toric IOL in a series of cataract patients. However, the AcrySof toric IOL was tested previously in a randomized prospective multicenter FDA clinical investigation involving 494 patients and 11 investigators (Available at: http://www.fda.gov/cdrh/pdf/p930014s015.html. Accessed January 9, 2008). Follow-up extended to 1 year after IOL implantation in the first eye. Two hundred eleven AcrySof toric IOLs and 210 control spherical IOLs (AcrySof SA60AT) were implanted. The investigators evaluated rotational stability, absolute residual refractive cylinder, and UCVA. The main conclusions of the study were that the AcrySof toric IOL achieved

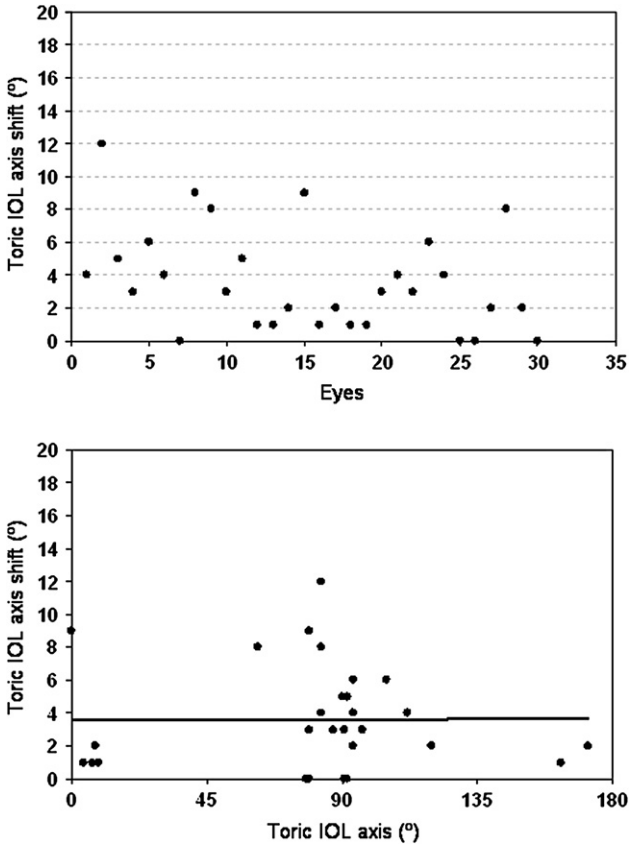

Figure 5. Toric IOL axis shift 3 months after surgery. *Top*: Scattergram of toric IOL axis shift in each eye. *Bottom*: Scatterplot of intraoperative toric intraocular axis versus postoperative toric intraocular axis shift. The continuous line represents the best linear trend equation ($y = 0.0003\ x + 3.6099$; $R = 0.00002$).

excellent rotational stability in the capsular bag. The mean rotational malposition of all AcrySof toric IOL models was less than 4 degrees, with no IOL off axis by more than 15 degrees at 6 months. Rotational malposition was 10 degrees or less in 97% of patients; 81% of patients had less than 5 degrees of misalignment. The study also found a significant reduction in absolute residual refractive cylinder. Patients were 3 times more likely to have 0.50 D or less residual refractive cylinder with a toric IOL than with the control spherical IOL. Overall, 62% of toric IOL patients had 0.50 D or less residual cylinder compared with 20% of control patients. The mean absolute residual effect of cylinder was 0.55 D in the toric group and 1.22 D in the control group. Finally, the improvement in UCVA was significant, with 94% of the AcrySof toric IOL patients achieving a UCVA of 20/40 or better.

In our study, 93.3% of patients achieved 20/40 or better UCVA. In a study by Sun et al.,[9] 84% of eyes achieved 20/40 or better UCVA after Staar TF IOL implantation. Ruhswurm et al.[10] report a lower percentage (67.6%) using the same IOL. Till et al.[13] report that 66% of patients had an UCVA of 20/40 or better after Staar TF or TL IOL implantation. De Silva et al.[15] recently reported that 78.6% of eyes achieved 20/35 or better UCVA after implantation of the MicroSil 6116TU toric IOL (HumanOptics).

Eyes in our study had a 70% reduction in astigmatism after toric IOL implantation. Figure 2 shows how the vectorial components of the astigmatism were reduced and close to 0. Figure 3 shows that astigmatism correction occurred through both components of astigmatism (J_0 and J_{45}). All eyes in our study were within ± 1.00 D and 80% and 93.9% were within ± 0.50 D for J_0 and J_{45}, respectively. Sun et al.[9] found a reduction in astigmatism of approximately 54% after Staar TF IOL implantation (preoperative corneal astigmatism about 2.81 D). Till et al.[13] report a high percentage of reduction (81%) after Staar TF or TL IOL implantation (mean preoperative corneal astigmatism 2.11 $\pm$ 0.90 D). In a series by Chang,[14] the reduction was approximately 75% after Staar TL toric IOL implantation (mean preoperative refractive astigmatism 3.68 $\pm$ 1.38 D). Recently, De Silva et al.[15] found a 65% astigmatic reduction after MicroSil 6116TU toric IOL implantation (mean preoperative corneal astigmatism 3.08 $\pm$ 0.76 D). Differences between IOL models and preoperative astigmatism values are responsible for the variability in the percentage of astigmatism reduction and visual acuity outcomes between toric IOLs.

Figure 4 was plotted to assess whether surgically induced corneal refractive change plays a role in surgically induced refractive change. The figure shows that keratometric astigmatism was distributed randomly before and after toric IOL implantation without significant differences ($P > .1$). Keratometric changes were minimal; thus, the reduction in astigmatism was the result of toric IOL implantation.

Small-incision cataract surgery has shown excellent surgical outcomes[20] and a significant reduction in the degree of induced corneal astigmatism compared with larger incision cataract surgery.[21,22] Usually, selection of the adequate toric IOL is made using a manufacturer IOL program that works on the basis of preoperative corneal astigmatism for the power and axis parameters. Keratometric corneal cylinder is used to calculate the required IOL cylinder. Toric IOL implantation should be performed through small incisions to achieve expected outcomes based on keratometric values. In addition, surgeons may consider a combination of relaxing incisions and toric IOL implantation depending on the astigmatism degree and power availability of the toric IOL.

The major requirement for a toric IOL is rotational stability. Rotation is mainly caused by haptic compression resulting from capsule contraction. One cause of

early postoperative IOL rotation is related to capsular bag size, which correlates with a longer axial length. Chang[14] reports excellent early postoperative rotational stability of the longer (11.2 mm versus 10.8 mm) toric IOL, although he used a plate-haptic IOL design. In our study (3.63 ± 3.11 degree axis rotation), the modified L-shaped haptic design of the AcrySof toric IOL did not induce significant rotation. A previous study[19] suggests that approximately 1 degree of off-axis rotation results in a loss of up to 3.3% of IOL cylinder power. Thus, approximately 12% of IOL cylinder power was lost in our eyes; that is, 0.18 D, 0.27 D, and 0.36 D for the SN60T3, SN60T4, and SN60T5 IOL models, respectively. Considering the 3 models, approximately 0.25 D is lost from axis rotation.

Table 3 compares the rotational stability of different toric IOLs using data from several studies. There is a high variability in IOL rotation as a function of the toric IOL model and haptic design. Toric IOLs with C-loop or plate haptics are prone to rotate from the intended axis postoperatively. C-loop haptic IOLs have the highest rate of postoperative rotation (41% >10 degrees).[5] Early design plate-haptic IOLs rotated less (9% to 38% >10 degrees).[6,7,23] Although the new-generation toric IOLs have increased stability, rotation remains significant (2% to 50% >10 degrees).[13,14] Intraocular lenses with Z-design haptics have good stability, with no IOL rotating more than 5 degrees.[15] Our results are comparable to those found in a recent study by De Silva et al.,[15] who report a low percentage of eyes with IOL rotation. However, in their study, a second surgical procedure to reposition the IOL was necessary. In our series, no IOL required repositioning. It has been reported that rotation of toric IOLs with plate haptics depends on the implantation axis (significantly more rotation when the IOL axis implantation is vertical).[10] This did not occur in any eye in our study, and there was no statistically significant correlation between intraoperative axis alignment and postoperative rotation.

Most IOL rotation happens in the early postoperative period. Once the anterior and posterior capsules fuse, IOL rotation is less frequent. Possible factors influencing the capsule fusion and resultant IOL stability include capsulorhexis size and IOL design and material.[5] Surgeons should consider that repositioning surgery could increase the risk for complications, including cystoid macular edema, capsule tear, and endophthalmitis.[9] In a recent study, Weinand et al.[18] used a high-precision technique to examine rotation control considering cyclorotation of the eye. They found that the spherical AcrySof SA60AT IOL model rotates less than 2 degrees, with 59% of eyes having a rotational angle greater than 1 degree. The mean rotation value 6 months after surgery was 0.7 degree (range 0.1 to 1.8 degrees). The authors recommend this toric IOL model because of its good rotational stability. The toric SN60T model has the same haptics as the spherical SA60AT model. In addition, it has been reported that the SA60AT AcrySof IOL model provides a steady axial position during capsule fusion and shrinkage.[24] The axial IOL position is the major parameter influencing postoperative spherical refractive change. Minimal axial IOL shift will contribute to rotation stability and possible cylindrical refractive change.

In conclusion, the results in our study show that implantation of the AcrySof toric IOL is an effective surgical option to correct preexisting corneal astigmatism during cataract surgery. Future studies with

Table 3. Published peer-reviewed studies of the rotational stability of different toric IOLs.

Study*	Year	IOL	Time (Wk)	Eyes	IOL Rotation	2nd Procedure (%)
Shimizu[5]	1994	C-loop haptic 3-piece	12	47	21% ≥ 30°	—
Grabow[6,7]	1994	Staar 4203T	—	—	4.4% > 33°	—
Werblin[8]	1999	J-loop haptic, 3-piece	Early	12	8% > 30°	—
Sun[9]	2000	Staar TF	12	130	25% > 20°	9.2
Ruhswurm[10]	2000	Staar TF	80	37	19% ≥ 10°	3
Gerten[11]	2001	Custom 3-piece	3	26	26% > 10°	23
Leyland[12]	2001	Staar TF	8	22	10% > 30°	—
Till[13]	2002	Star mixed TF/TL	23	100	14% > 15°	9
Chang[14]	2003	Star TF	4	6	50% ≥ 15°	50
		Staar TL			10% ≥ 10°	0
De Silva[15]	2006	HumanOptics MicroSil 6116TU, 3-piece Z haptics	26	21	0% > 10°	4
Current	2008	Alcon AcrySof SN60T3/ T4/T5 1-piece L haptics	12	30	0% > 12°	0

IOL = intraocular lens
*First author

larger samples and longer follow-ups should continue to evaluate the efficacy and safety of this IOL in cataract surgery.

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