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# The AcrySof Toric Intraocular Lens in Subjects with Cataracts and Corneal Astigmatism

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### Abstract

**Purpose:** To compare the AcrySof Toric intraocular lens (IOL) and an AcrySof spherical control IOL and to investigate correction capability of the AcrySof Toric IOL in subjects with cataracts and corneal astigmatism.

Design: Comparative case series.

**Methods:** This retrospective review of clinical records comprised 98 eyes with 1.5 to 4.5 diopters (D) of preoperative corneal astigmatism who had cataract surgery and AcrySof T3/T4/T5 toric or AcrySof IQ spherical monofocal IOL implantation. Surgically induced astigmatism (SIA) was calculated for eyes with postoperative keratometry results. The main outcome measures include visual acuity outcomes, Residual astigmatism, IOL position, patient-reported spectacle use, and safety.

**Results:** One year postoperatively, best spectacle-corrected distance visual acuity of 0.8 was 71% (Toric IOL) versus 67% (control IOL). Uncorrected distance visual acuity of 0.8 or better was 62% (Toric IOL) versus 21% (control IOL; P<0.05). Mean absolute residual refractive cylinder was 0.42 D (Toric IOL) versus 1.36D (control IOL; P<0.01). Mean rotation was  $3.21^{\circ}\pm1.25^{\circ}$  (range,  $0^{\circ}-20^{\circ}$ ) for the Toric IOL. Three-month spectacle freedom was 57.0% (Toric IOL) and 34.1% (control IOL; P<0.01). Complications in both groups were few and were as would be expected with cataract surgery.

**Conclusions:** The mean refractive astigmatism after cataract surgery in patients with 1.5 D to 4.5 D of corneal astigmatism was significantly lower when a toric IOL was implanted. The safety results, efficacy and rotational stability support the use of the AcrySof Toric IOL for patients with cataracts and high degree of corneal astigmatism.

In the past decades, cataract surgery has become a safe and no pain surgery with excellent visual quality results for patients. Phacoemulsification and the development of new devices have shortened the surgical procedure down to a few minutes with minimum aggression for the patient eye and a comfortable post-surgery period. However, the continuous development of innovations and technical improvements is accompanied by higher demand for better results by patients as well as surgeons in an ongoing search for excellence for the final visual quality of cataract patients.

The objective is not only to improve the patient's vision but also to achieve emmetropia without added optical correction as far as possible. Traditional spherical monofocal intraocular lenses (IOLs) restore bestcorrected vision and may lessen the postoperative need for spectacles. These IOLs correct only the spherical portion of the total refraction and do not correct corneal astigmatism. Astigmatism has represented a problem for the traditional spherical lens implant, with several solutions being proposed. The uses of arcuate corneal incisions and excimer laser refractive keratectomy have become the best options for resolving these cases for a number of years until the recent appearance of Toric IOLs.

This article reports a restrospective study that compared the safety and efficacy of the AcrySof Toric IOL with those of a spherical control IOL (AcrySof IOL SA60AT; Alcon Laboratories, Inc.) in subjects with cataracts and corneal astigmatism and investigated the correction capability of the AcrySof Toric IOL.

### Method

Ninty-eight patients (98 eyes) cured in our department between July 2009 and March 2010 were included in this study. All these patients were checked by IOL-Master (Carl Zeiss Meditec Inc, Dublin, CA, USA). Their presurgery keratometric astigmatism was  $\geq$ 1.5D and

≤4.5D. Among them forty-six patients were chosen for implantation with Acrysof Toric IOL. The other patients were implanted with Acrysof IQ. The spherical power of the lens was calculated with IOL-Master with constant A optimized for this biometer (118.7), and keratometric values K1 and K2 what put to the Acrysof Toric Calculator software(www. acrysoftoriccalculator.com, Alcon Laboratories Inc, Fort Worth, TX, USA) to determine the cylinder power (IOL model) and the exact presurgery IOL. The SIA (surgically induced astigmatism) is 0.5D [18]. The three lens models implanted were SN60T3, SN60T4 and SN60T5 for IOL plane cylinder correction of -1.50, -2.25 and -3.00 D, equivalent to -1.03, -1.55 and -2.06 D in corneal plane. Following the software IOL selection algorithm, the adequate IOL was determined for each patient and requested from the manufacturer. Before the surgery, the 0°-180° axis was marked with the patient sitting in front of the slitlamp to avoid torsion phenomena. We marked the axis for the IOL calculated by the software using the 0°-180° axis as reference. All surgeries were performed by one experienced surgeon using a standard surgical technique with retrobulbar anesthesia by 2% lidocaine, 2.8 mm corneal

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incision on the steepest meridian, phaco-chop, irrigation/aspiration of cortical material, IOL implantation in the capsular bag with the injector system and no sutures. The IOL implant was performed with the Monarch II injector and the IOL was centered placing its axis as calculated by the software. The irrigation-aspiration was performed softly to avoid lens rotation. Phacoemulsification was performed using an Infiniti (Alcon Surgical) device. The patients were administered a combination of antibiotic and steroid eye drops (TOBRADEX\* sterile ophthalmic suspension) and 0.1% diclofenac sodium postoperatively, initially 4 times per day and then tapered over a 14 day period. The patients were followed up at 30 days, 90days and 180-360 days after surgery [19]. The UCVA (Uncorrected vision acuity) and BCVA (Best corrected vision acuity) were determined at all the returning visiting time, together with the post-op residual astigmatism and the final IOL axis after midriasis with phenylephrine eye drops 10% - tropicamide 1% (Alcon Cusi, El Masnou, Barcelona, Spain). The data were analysed with the SPSS 15.0 software (SPSS Inc, Chicago, IL, USA). Differences between groups were calculated with t tests and analysis of variance. A P value less than 0.05 was considered statistically significant.

# Result

One hundred and eight eyes of 98 patients were included in this study. The mean age was of 65.18 years old (SD: 9.78), in a range of 50-71 years. The distribution by sex was of 43 males (43.9%) and 55 females (56.12%), and in what concerns the laterality of the intervened eyes, 47 were right eyes (47.95%) and 51 were left eyes (52.04%). The average BCVA of all patients was 0.3±0.05. The average corneal astigmatism pre-surgery was 2.5±1.13D. All the included eyes completed the post surgery period without events. Ten patients were excluded due to baseline pathologies involving significant visual limitation: diabetic macular edema, ARMD and venous branch thrombosis. 98 eyes were followed up for three months to twelve months after surgery. As regards the remaining 98 eyes, the results were as follows (Table 2): the mean total UCVA was of 0.83 (SD: 0.14) Snellen, in 71% of cases, it remained equal to or above 0.8, with 31% of the sample reaching the unit (1.0) (Table 1). With optical correction, the mean corrected visual acuity was of 0.94 (SD: 0.10) (Table 1, Figure 1, 2). The mean absolute residual refractive cylinder was 0.42 D for the AcrySof Toric IOL and 1.36D for the control IOL (P<0.01). The residual refractive cylinder was significantly reduced with the AcrySof Toric IOL compared with the control IOL 1 year after surgery. Table 3, Figure 3 shows reduction in absolute residual refractive cylinder. The residual refractive cylinder was  $\leq$  1.00 D in 80.0% of eyes with an AcrySof Toric IOL compared with 35% of those with the control IOL, and was  $\leq$ 1.50 D in 93% of eyes with an AcrySof Toric IOL compared with 70% of those with the control IOL. The mean rotation against the calculated axis was of 3.21±1.25 degrees, without differences against the implanted IOL model.

Three to twelve months after surgery, 57% of subjects with the AcrySof Toric IOL reported spectacle independence for distance vision compared with 34.1% of those with the control IOL (P<0.01).

### Discussion

In a study of 7500 cataract eyes, the mean corneal astigmatism was 1.0 diopters (D) in all eyes; only 4.2% had no corneal astigmatism, 76.8% had 0.25 to 1.50 D, and 19.1% had >1.50 D [1]. Another study of 4540 cataract eyes found no corneal astigmatism in 13.2%, 0.25 to 1.25 D in 64.4%, and >1.50 D in 22.2% [2]. In another study of 480 eyes, mean refractive astigmatism was-1.20 D [3]. Patients with cataracts and corneal astigmatism may benefit from astigmatism correction with

	UCVA(n)/BCVA(n)							
	≤0.5	0.6	0.7	0.8	0.9	1.0		
Toric	3/1	5/2	6/3	9/15	9/9	14/16		
Control	5/1	9/2	12/16	15/16	8/13	3/4		

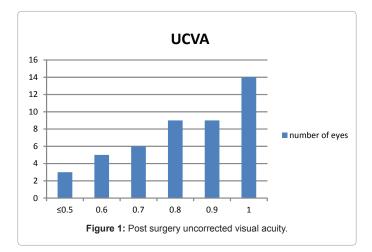
Table 1: Post surgery uncorrected/Best corrected visual acuity.

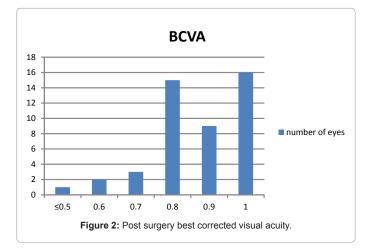
n		moon		UCVA(%)				
	mean	≥1.0	≥0.8	≥0.6	>0.5	≤0.5	- P value	
Toric	46	0.83±0.14	31	71	93	93	6	
control	52	0.65±0.20	19	43	62	84	16	0.0002

Table 2: Uncorrected Distance Visual Acuity 1 Year after Surgery.

	residual	residual refractive cylinder(D)							
	0	≤0.5	≤1.0	≤1.5	≤2.0	>2.0			
Toric	20%	53%	80%	93%	98%	1%			
control	6%	20%	35%	70%	90%	9%			

Table 3: Cumulative absolute residual refractive cylinder 1 year postoperatively.





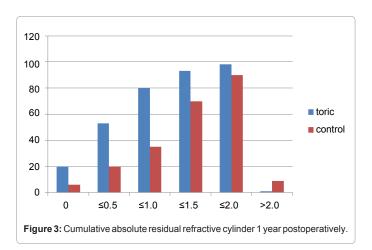
toric IOLs. Limbal relaxing incisions are commonly performed with success but are also associated with potential disadvantages, such as lack of precision [4,5] varied healing responses [4] limited cylinder correction [4] under correction [6,7] overcorrection [4,7] perforation, wound gape [4] egression, infection [7] and loss of best pectacle corrected visual acuity. Extensive corneal refractive surgery or long incisions may distort or denervate the cornea [7,8].

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Toric IOLs have been designed to replace lenses of cataract, reduce postoperative astigmatism, and lessen the need for spectacle use. Toric IOLs may provide greater adjustability than some keratorefractive procedures [9-11]. Plate haptic and loop haptic toric IOLs have been considered for about a decade but have been associated with postoperative rotational instability. Rotation of a toric lens from its intended orientation degrades its corrective power, with approximately 3.3% loss of cylindrical power for every degree off axis [12]. A misorientation of approximately 30° negates the effectiveness of astigmatic correction, and a  $>30^{\circ}$  misorientation may induce additional astigmatism. Some patients complain about blurred or distorted vision, headache, fatigue, eyestrain, squinting, or eye discomfort [13]. The AcrySof Toric IOL (Alcon Laboratories, Inc., Fort Worth, TX) has the same design as the AcrySof Single-Piece IOL (Alcon Laboratories, Inc.), with a toric component on the posterior optic surface and axis indentations indicating the flat meridian of the optic. AcrySof single piece IOLs, including the AcrySof Toric IOL, has been designed to achieve maximum IOL stability. The biomaterial of this lens has demonstrated adhesive properties that support adherence to the capsular bag [19]. The haptics are also intended to enhance IOL stability by supporting maximal adherence of the IOL to the capsule.

Implantation of a toric IOL is one way to manage astigmatism in patients with cataract and corneal astigmatism. 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. It is important to obtain accurate corneal astigmatism measurements to determine the actual amount of cylinder requiring correction and the appropriate spherical power for the IOL. In our study, we used IOL-master to calculator the IOL cylinder power and alignment axis. We believe that any method could be the best way for measuring the amount and axis of astigmatism depending on the clinical settings. Therefore, toric IOL implantation should be performed through small incisions to achieve expected outcomes based on keratometric values. In previous studies of the AcrySof toric IOL, the incision size for cataract surgery has ranged from 2.75 to 3.0 mm. In our study, a 2.8 mm corneal incision was performed. No complications related to the micro incision cataract surgery were observed. Thus, surgeons may consider a combination of micro incision cataract surgery and toric IOL implantation to correct astigmatism in cataract patients.

The major requirement for toric IOLs is rotational stability. Zuberbuhler et al. [14] reported in a series of 44 AcrySof toric IOLs that the postoperative rotation was within 5 degrees in 95% of cases and



within 2 degrees in 68% of eyes after 3 months postoperatively. In 30 eyes, Mendicute et al. [15] demonstrated a mean toric IOL axis rotation of 3.63±3.11 degrees, with rotation less than 10 degrees in 96.7% of eyes using the AcrySof toric IOL. In our study, the mean axis rotation was 3.21±1.25 degrees at 3 months postoperatively. In addition, after longer follow-up of more than 6 months, the mean rotation of the IOL was 3.2±1.05 degrees and was not significantly different from early follow up results. The largest rotation was 9 degrees and was seen in only one eye. The mean rotation of the toric IOLs was 2.91±1.04 degrees at 1 day postoperatively, 3.21±1.25 degrees at 3 months postoperatively, and 3.2±1.05 degrees at final follow-up. Most IOL rotation happened in the early postoperative period. Once the anterior and posterior capsules fuse, IOL rotation was less frequent at long-term follow-up. Ruhswurm et al. [16] found IOL rotation to be associated with increasing capsular bag diameter as well as with axial length. The initial IOL position could affect how gravity influences early rotation. To evaluate multiple possible factors on IOL rotation, further prospective comparative study is warranted.

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In our study, 93% of eyes showed 0.5 or better UCVA and 71% of eyes showed 0.8 or better UCVA at final follow-up. This compares favorably with results in the initial FDA clinical trial in which approximately 66% of patients with unilateral implantation of the toric IOL achieved a UCVA of 0.8 or better and 41% of the unilateral control subjects achieved a UCVA of 0.8 or better in 6-months data [17]. The FDA trial was originally designed to follow for 1 year. Eyes in our study had an 84% reduction in astigmatism after AcrySof toric IOL implantation. 80% of the eyes in our study were within 1.0 D. Mendicute et al. [15] reported a reduction in astigmatism of 70% after AcrySof toric IOL implantation.

### Conclusion

In conclusion, the results from our study show that micro incision cataract surgery with implantation of the AcrySof toric IOL is a safe, predictable, and effective surgical option for correcting preexisting astigmatism during cataract surgery. The AcrySof toric IOL demonstrated no significant rotation during the long-term follow-up period of one year. The toric IOL will play an increasingly important role in the future. Decreasing spectacle dependence improves patient quality of life and should be pursued.

#### **Ethical Approval**

The research was carried out according to the principles of the Declaration of Helsinki; informed consent was obtained and Shanghai Ninth People's Hospital Ethics Committee approved the study. The patient data, which are contained in this article, were taken by a hospital-based doctor at Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine. Permission to use these data in this report has been obtained from all the subjects who participated in this study [20].

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