

Rotational stability of a single-piece toric acrylic intraocular lens

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PURPOSE: To assess the rotational stability of a single-piece toric hydrophobic acrylic intraocular lens (IOL) during the first 6 postoperative months.

SETTING: Moorfields Eye Hospital NHS Foundation Trust, London, United Kingdom.

DESIGN: Prospective case series.

METHOD: Eyes with age-related cataract and corneal astigmatism (1.00 to 3.00 D diopter [D]) were measured by partial coherence interferometry (IOLMaster). Preoperatively, the horizontal axis was marked. Surgical technique included a standardized temporal clear corneal incision, phacoemulsification, and in-the-bag implantation of a toric IOL (AcrySof SN60TT). Rotational stability of the IOL was assessed using retroillumination photographs postoperatively at 1 hour and at 1 and 6 months. Uncorrected (UDVA) and corrected distance visual acuities, residual refractive error, and keratometric and refractive cylinders were measured.

RESULTS: The study enrolled 30 eyes (30 patients). The mean absolute IOL rotation was 2.44 degrees $\pm$ 1.84 (SD) at 1 month and 2.66 $\pm$ 1.99 degrees at 6 months. The photographic technique had high reproducibility of axis measurement, with consecutive measurements varying by less than 2.0 degrees. The mean UDVA was 0.16 logMAR (range 0.42 to -0.18 logMAR) at 1 month and 0.20 logMAR (range 0.60 to -0.20 logMAR) at 6 months. The residual refractive cylinder by autorefraction was -0.84 D (range -2.00 to 0.00 D) and -0.80 D (range -1.75 to 0.00 D), respectively.

CONCLUSIONS: The acrylic toric IOL was rotationally stable within the first 6 months postoperatively. The photographic and axis analysis method to evaluate stability had high reproducibility and detected small changes in rotation.

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Toric intraocular lens (IOL) implantation during cataract surgery should result in less spectacle dependence postoperatively in patients with preexisting corneal astigmatism. However, precise alignment of the cylindrical axis of the toric IOL with the astigmatic axis of the cornea is key to success. Imprecise alignment results in residual astigmatism with an axis different from that before surgery. In cases of significant misalignment, it can result in higher astigmatism than preoperatively as well as flipping of the orientation of the axis of astigmatism in the entire eye.

Errors in alignment can occur at several stages during the cataract surgery procedure. Preoperatively, the defined location of the corneal astigmatic axis may be incorrect because of inaccurate measurements; this can

occur when keratometry does not measure in the center of the cornea or when the posterior corneal surface is not assessed and in cases of irregular astigmatism. In addition, the corneal astigmatic power, axis, or both can change to a greater or lesser degree than anticipated after the corneal incision is created during surgery. This can be addressed by adding corneal topography or tomography to the keratometric measurements. Intraoperatively, axis misalignment can occur as a result of cyclotorsion of the eye caused when the patient changes position from sitting to supine, cyclotorsion induced by peribulbar anesthesia, or imprecise positioning of the IOL on the planned axis. Intraoperative axis misalignment errors can be minimized by accurate preoperative marking of the

eye with the patient sitting and by meticulous IOL positioning during surgery.

However, postoperative change in the IOL axis caused by rotational movement is primarily dependent on IOL design. It can occur when there is a mismatch between the overall size of the IOL and the size of the capsular bag or when the capsule shrinks during fibrotic contraction of the bag postoperatively. Because most current IOLs are oversized in relation to capsular bag size, a mismatch is rarely observed and is more likely to occur in long eyes, which tend to have a larger capsular bag diameter.^{1,2} A 1-piece hydrophobic acrylic IOL (AcrySof Toric, Alcon, Inc.) was shown to have good haptic memory,³ better than that observed with poly(methyl methacrylate) or polyvinylidene fluoride haptics in 3-piece IOLs. In addition, the haptics of the 1-piece toric IOL are more bulky than those of the 3-piece IOLs, which may result in better adherence to the capsule at the end of surgery and thus little rotation postoperatively. A recent study⁴ reports that the 1-piece toric IOL has good rotational stability. However, measurements in previous studies used the slitlamp to assess stability, and the slitlamp does not have the resolution required for accurate assessment of the IOL axis because the rotational position of the IOL can be measured in 5-degree steps only. In addition, this method of assessment has questionable reproducibility between and within examiners, can introduce bias because of the subjective nature of the assessment by the examiner, and does not allow objective documentation of findings.

The aim of this study was to establish a reproducible retroillumination photographic technique to follow

the axis position of the 1-piece hydrophobic acrylic toric IOL over time and to assess its rotational stability.

PATIENTS AND METHODS

The trial was approved by the local ethics committee and adhered to the guidelines of the tenets of the Declaration of Helsinki. Inclusion criteria were corneal astigmatism between 1.00 diopter (D) and 3.00 D using partial coherence interferometry (PCI) (IOLMaster, Carl Zeiss Meditec) and cataract. Exclusion criteria were irregular astigmatism or forme fruste keratoconus on corneal tomography using a Scheimpflug scanning-slit imaging device (Pentacam HR, Oculus, Inc.), a difference in astigmatism axis between the PCI keratometry reading (K) and the simulated K reading axes of tomography of more than 10.0 degrees, corneal scarring, phacodonesis, pseudoexfoliation syndrome, traumatic cataract, and other ophthalmic pathology that could have a significant impact on postoperative visual function.

On the day of preoperative assessment, patients had a full ophthalmic examination, PCI biometry, and corneal tomography. Online toric calculator software^A (Alcon, Inc.) was used to calculate the toric power and the axis for IOL alignment. Surgically induced astigmatism (SIA) of 0.50 D for a temporal limbal incision was entered into the calculation. The spherical IOL power was calculated on the PCI device using the SRK/T formula.

Preoperatively, the horizontal meridian was marked with the patient sitting at the slitlamp and the patient's head straight in the chinrest. The slit beam was positioned in the retroillumination position and the slit oriented horizontally. Small superficial incisions were made using an insulin needle at the limbus at the 3 o'clock and 9 o'clock positions and at the 12 o'clock meridian with the slit in the vertical position. Care was taken to center the slit beam on the center of the pupil for alignment. Methylene blue was added to the 3 incisions for easier recognition intraoperatively. Finally, the surgeon verified the correct position at the slitlamp. If a marking was slightly off axis, this was recorded on the case report form to aid the surgeon when positioning the corneal marker intraoperatively.

Surgery was performed using topical anesthesia in most cases; the exception was patients who did not speak English to prevent a lack of communication during surgery. A temporal self-sealing incision was created with a 3.0 mm single-beveled steel blade to provide uniformity of the incision axis. This was followed by injection of an ophthalmic viscosurgical device (OVD), capsulorhexis, phacoemulsification, irrigation/aspiration (I/A) of cortical material, and injection of a cohesive OVD into the capsular bag as standard procedure. After the corneal marking ring was aligned to the 3 preoperative markings, blue pen dots were made on the planned axis. The toric IOL was implanted in the capsular bag using a Monarch II injector. The toric axis was then positioned approximately 20 degrees counterclockwise from the planned axis by rotating the IOL, after which the OVD was aspirated thoroughly using a bimanual I/A set. Care was taken to completely remove the OVD from behind the IOL by slightly displacing and tilting it and reaching behind the optic with the aspiration cannula. Thereafter, the axis of the toric IOL was aligned to the marks. A final check was made after the anterior chamber was filled and the incisions were hydrated. Final alignment was performed using the corneal ring and a 30-gauge cannula through a paracentesis.

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The contralateral eye received the toric IOL or an on-axis incision with a limbal relaxing incision combined with a non-toric IOL (AcrySof SN60AT) to prevent too much asymmetry in postoperative astigmatism between the eyes.

Evaluation Methods

The main outcome measure was the IOL toric axis assessed using retroillumination photography performed 1 hour, 1 month, and 6 months after surgery. Additional examinations at 1 month and 6 months included uncorrected distance visual acuity (UDVA) and corrected distance visual acuity using a backlit Early Treatment Diabetic Retinopathy Study (ETDRS) chart (Precision Vision) at 4 m, autorefractometry in IOL mode (Topcon Corp.), subjective refraction using the cross-cylinder method, keratometry using the PCI device, wavefront measurements using a Hartmann-Shack sensor (WASCA, Carl Zeiss Meditec), corneal topography using the Scheimpflug scanning-slit imaging device, and a full slitlamp evaluation. Astigmatism vector analysis was performed using power vector notation.⁵ The axis orientation was assessed using standardized retroillumination photography and dedicated image-analysis software.

Intraocular lens axis measurements were assessed from photographs attained with a high-resolution digital retroillumination imaging system comprising a Zeiss 120 slitlamp for observation and imaging. A retrolux illumination module was supplied with illumination provided by an anterior segment flashpack (Zeiss) through a fiber-optic cable. A color digital camera (Canon D5) was used for image acquisition; the camera has a large charge-coupled device chip with high light sensitivity, resulting in a high signal-to-noise ratio of the acquired images.

The images were directly transferred to a personal computer and saved to a hard disk. The axis marks were identified with a cursor, and the axis of the IOL was registered. To ensure consistent alignment of the patient's head at each follow-up, the head was positioned as straight as possible based on the examiner's subjective impression.

Rotational stability was analyzed using Keynote software (version 5.0.2, Apple, Inc.). All retroillumination images were imported into the software system. Images on which the marking on the IOL was not visible were not analyzed; this occurred in cases of small pupil or in which 1 Purkinje reflex overlapped the toric marking on the IOL. To avoid bias resulting from the observer's knowledge of IOL orientation gained from previous follow-up photographs, all 90 images were imported in random order to ensure that the images of each patient were not analyzed consecutively. Two thin (0.25 pixel), straight lines were adjusted to the marking on the IOL; the IOL marking consisted of 6 dots upon magnification of the images. Each line touched the 6 dots on each side; therefore, the 2 lines were parallel with the dots in between the lines (Figure 1). The axis of both lines was entered into an Excel spreadsheet (Microsoft Corp.), and the difference and the average of the 2 values were calculated. The average of both lines was used for further statistical analysis. The maximum axis difference in the same eye between the 2 lines in each eye was assessed in 25 photographs taken randomly from the data set and analyzed twice.

In a pilot study, the short-term reproducibility of the photographic technique, including the analysis process for axis assessment in 10 eyes, was evaluated. In the analysis, the same examiner took 2 images approximately 10 minutes apart with new positioning of the patient's head in the chinrest.

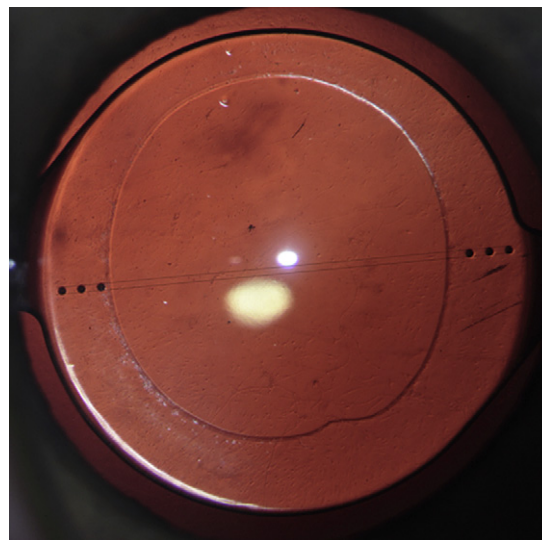


Figure 1. Example of an image from the software used to assess the axis stability of the toric IOL. The dots on the IOL are connected with 2 lines. Each line touches the 6 dots, making the 2 lines parallel.

RESULTS

The study included 30 eyes (22 left, 8 right) of 30 patients. The mean age of the 16 women and 14 men age was 71.5 years (range 51 to 86 years).

Three AcrySof toric IOL models were used: SN60T5 ($n = 17$), SN60T4 ($n = 8$), and SN60T3 ($n = 5$). The mean spherical power of the 3 IOL models was $20.2 \text{ D} \pm 4.7$ (SD) (range 11.0 to 29.5 D). The toric IOL was implanted vertically (90 ± 15 degrees) in 12 cases, horizontally (0 ± 15 degrees) in 9 cases, and obliquely in 9 cases (Figure 2). The mean postoperative IOL rotation was 2.44 ± 1.84 degrees (range 0.1 to 7.8 degrees) at 1 month and 2.66 ± 1.99 degrees (range 0.0 to 7.6 degrees) at 6 months (Figure 3). The mean absolute difference between the intended IOL axis and the observed IOL axis at 6 months was 8.9 ± 8.2 degrees; in 8 cases, the absolute difference was greater than 10.0 degrees.

No significant correlation between the axis of placement and rotational stability was found. However, on average, IOLs implanted on the oblique axis had slightly less rotation (mean 2.12 ± 1.42 degrees) at 6 months than IOLs implanted vertically (mean 2.90 ± 2.04 degrees) and IOLs implanted horizontally (mean 3.21 ± 2.41 degrees).

The IOL was rotated clockwise (mean 4.0 ± 1.8 degrees) in 10 cases and counterclockwise (mean 4.0 ± 0.8 degrees) in 8 cases. The rotation was less than 2.0 degrees in 12 cases.

The mean preoperative astigmatism measured with the PCI device was $-1.97 \pm 0.58 \text{ D}$ (range -3.77 to -0.39 D), with a mean Jackson cross-cylinder at the

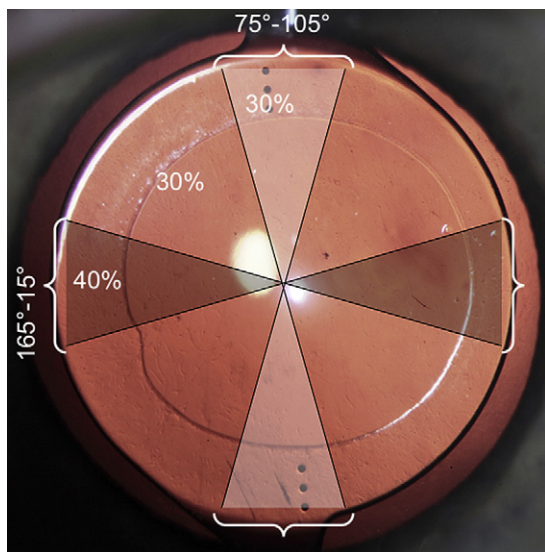


Figure 2. Distribution of axis placement of the IOLs .

0-degree meridian (J0) of -0.05 ± 0.91 D and a mean Jackson cross-cylinder at the 45-degree meridian (J45) of 0.17 ± 0.45 D. The mean corneal astigmatism measured by the Scheimpflug scanning-slit device was -1.84 ± 0.79 D. One eye with more than 2.00 D of corneal astigmatism was unintentionally included in the study; all other eyes met the inclusion criterion for the amount of astigmatism. At 1 month, the mean astigmatism by autorefractometry was -0.80 ± 0.39 D (range -1.75 to 0.00 D), with a mean J0 of -0.25 ± 0.38 D and a mean J45 of 0.17 ± 0.45 D. At 6 months, the mean astigmatism by autorefractometry was -0.84 ± 0.41 D (range -1.75 to 0.00 D), with a mean J0 of -0.25 ± 0.12 D and a mean J45 of 0.12 ± 0.24 D. The difference between the mean predicted residual astigmatism (-0.32 ± 0.29 D; range -1.27 to 0 D) and the final outcome 6 months after surgery was -0.52 D (Figure 4). The power vector difference between 6 months and preoperatively was -0.19 ± 0.89 D for J0 and -0.05 ± 0.48 D for J45. Similar results were found with subjective refraction.

The refractive outcomes were verified 6 months after surgery using wavefront analysis. The astigmatism magnitude value on wavefront analysis (mean -0.92 ± 0.43 D; range -1.90 to -0.19 D) was similar to the autorefractometry value.

The absolute mean difference between the planned IOL axis and the immediate postoperative (1 hour) IOL axis was 2.1 ± 5.6 degrees. In 19 of 30 cases, the rotation was clockwise.

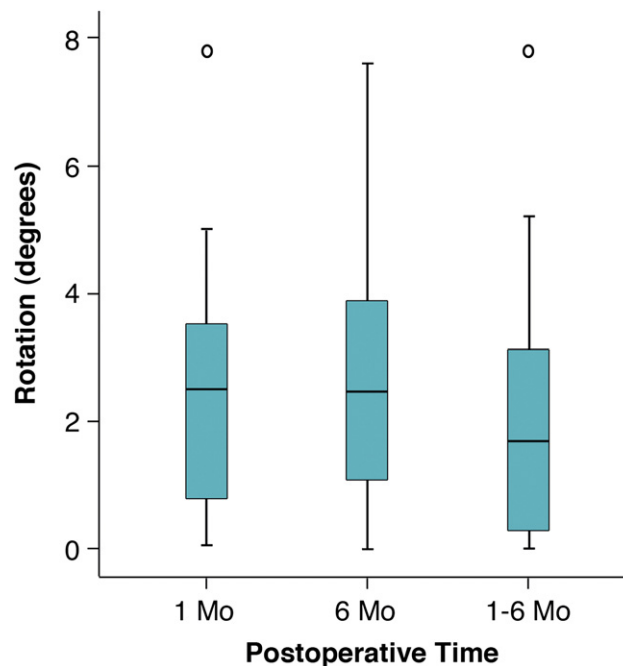


Figure 3. Axis rotation of the toric IOL between follow-ups in all 30 eyes.

The mean postoperative UDVA was 0.16 logMAR (range 0.42 to -0.18 logMAR) at 1 month and 0.20 logMAR (range 0.60 to -0.20 logMAR) at 6 months.

The reproducibility of the method of axis positioning analysis on the photographs was 0.0 degree (maximum difference 0.1 degree). The photographic technique, including the analysis process, showed a high reproducibility of axis measurement with consecutive measurements in the same eye within 1.9 ± 0.8 degrees.

On slitlamp biomicroscopy, there was slight posterior capsule opacification in 1 eye. The eye did not require neodymium:YAG laser capsulotomy because neither visual acuity nor contrast sensitivity was affected.

DISCUSSION

The mean rotation of the toric IOL in our study was similar to the short-term reproducibility of our photographic technique, including the software analysis of the axis. Therefore, the rotational stability results of the evaluated IOL were in the range of the noise of our measurement method. The mean absolute rotation was slight (2.4 degrees from 1 hour after surgery to 1 month; 2.7 degrees to 6 months); the maximum rotation was less than 8 degrees. There was clockwise rotation and counterclockwise rotation in a similar number of eyes, suggesting that there was no IOL movement in most cases and that the low values

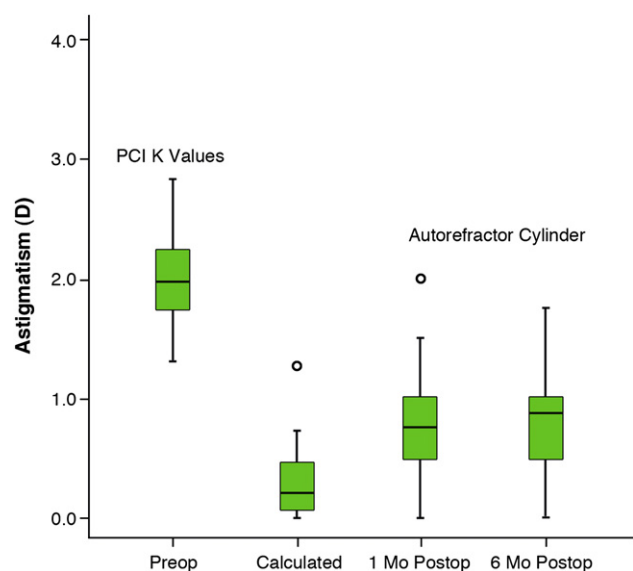


Figure 4. Corneal astigmatism before surgery measured by PCI keratometry, predicted residual astigmatism, and magnitude of astigmatism from autorefraction postoperative (N = 30) (K = keratometry; PCI = partial coherence interferometry).

were the result of the “noise” of the examination and the analysis method. If haptic compression caused by capsule collapse and fibrosis were to induce rotation, we would expect primarily clockwise rotation because of the open-loop design of the haptics. However, there is no universally accepted method to align the patient’s head before taking retroillumination images. Although we tried to adjust the position of the head as carefully as possible at every follow-up, it is not possible to avoid slight rotational bias every time the head is adjusted on the chinrest in front of the camera.

Our results compare well with those in other studies of the same toric IOL design. The rotational stability of the AcrySof SN60TT IOL in our study compares well with findings in the U.S. Food and Drug Administration (FDA) AcrySof Toric IOL clinical trial. The mean rotation in the FDA study^B was less than 4.0 degrees. However, to our knowledge, the axis was assessed by slitlamp grading, which is not as precise as the documentation and analysis method we used. Bauer et al.⁶ report similar rotational stability results using the same 3 AcrySof toric IOL models (SN60T3, SN60T4, SN60T5). Although Bauer et al. found a difference between the SN60T3 group and the SN60T5 group, we did not. It is also not clear why the toric power would have an influence on rotational stability. Zuberhuhler et al.⁷ report a mean absolute rotation of 2.2 degrees in a retrospective cohort study of the SA60TT IOL. They also assessed rotation by slitlamp evaluation and used the intended axis for comparison rather than the immediate intraoperative or postoperative axis.

In a study of 21 MicroSil 6116TU toric IOLs with Z-haptics (HumanOptics AG), De Silva et al.⁸ observed a mean rotation of 5.2 degrees and a maximum rotation of 15 degrees. In a study of 37 foldable toric 1-piece plate-haptic silicone IOLs, Ruhswurm et al.² found a maximum rotation of 25 degrees. In a study of 50 plate-haptic toric IOLs (Staar Surgical Co.), Chang⁹ found a maximum rotation of 20 degrees; 72% of the IOLs were within ± 5 degrees of the intended axis. The reproducibility of the IOL rotation assessment in our study was 1.9 degrees. Several methods to evaluate rotational changes using retroillumination images have been developed. Nguyen and Miller¹⁰ used a digital-overlay imaging technique. Rozema et al.¹¹ used 3 lines and the resulting triangle between a scleral blood vessel, IOL haptic, and IOL optic center. In a similar study, Weinand et al.¹² used 2 characteristic points of the conjunctiva and the IOL to assess the rotational axis, whereas Shah et al.¹³ used an overlay and the angle of the blood vessels. The reproducibility of these methods of consecutive images appears to be similar to that in our study.

In our study, IOL power and toric power had no effect on rotational stability; however, our study had too few cases to reach sufficient power for such analysis. Intraocular lenses in eyes with against-the-rule astigmatism and a horizontal axis position had a tendency toward greater rotation than vertically or obliquely placed IOLs. This could be a result of the larger horizontal capsular bag diameter¹⁴ or differential zonular tensions. However, our sample size was not large enough to detect significant correlations between the axis of placement and the stability of rotation. A larger trial should be performed to compare vertical axis and horizontal axis placement in myopic eyes and hyperopic eyes with a higher probability of a large capsular bag diameter or small capsular bag diameter, respectively.

We found a mean residual astigmatic refractive error of 0.84 D 6 months after surgery. This finding is partly the result of the nature of the algorithm in the online toric IOL calculator,^A which undercorrects the toric power to avoid the axis flips seen in overcorrected eyes. Therefore, the deviation of the final astigmatism from the planned correction calculated preoperatively should be analyzed; in our study, the planned undercorrection was 0.50 D of astigmatism. There are many reasons for the planned undercorrection. These include inaccurate preoperative marking; inaccurate axis placement during surgery; unplanned SIA; postoperative IOL rotation; a decrease in toric power caused by IOL decentration, IOL tilt, or both; and inaccurate assessment of corneal astigmatism by autokeratometry or from a failure to assess the posterior corneal surface.

The mean astigmatism of -2.00 D preoperatively decreased to -0.80 D postoperatively in our study. This finding agrees with that in a study by Dardzhikova et al.,¹⁵ although the mean preoperative astigmatism in our study was higher. We verified our autorefraction values using wavefront measurements.

In conclusion, the Alcon SN60TT IOL remained stable postoperatively, with little rotation over the first 6 months.

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