

Comparison of the Rotational Stability of Two Toric Intraocular Lenses in 1273 Consecutive Eyes

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Purpose: To compare the rotational stability of the 2 most commonly used toric intraocular lenses (TIOLs).

Design: Retrospective cohort study in a single private practice.

Subjects: The study included all patients receiving an Acrysof ($n = 626$) or Tecnis TIOL ($n = 647$) over an 18-month period from April 2015 to September 2016. Patients were only excluded if their surgery could not be performed using a digital marking system.

Methods: All patients had cataract surgery performed in the same surgical center with a similar technique. A digital marking system with limbal vessel registration was used to record the axis of the TIOL at the conclusion of surgery. A dilated examination was performed either later on the day of surgery or the next morning, and the postoperative rotation of the 2 TIOL models was compared. Patients who required a return to the operating room for TIOL repositioning were examined to determine risk factors for reoperation and subsequent outcomes.

Main Outcome Measures: The primary outcome measure was the percentage of eyes with TIOL rotation >5 and >10 degrees. The second main outcome was likelihood of requiring return to the operating room to reposition a rotated TIOL.

Results: The Acrysof TIOL was less likely to rotate postoperatively, with 91.9% of eyes rotated ≤ 5 degrees at the first postoperative check compared with 81.8% of Tecnis TIOL eyes ($P < 0.0001$). This difference persisted for rotation ≤ 10 degrees (97.8% Acrysof vs. 93.2% Tecnis, $P = 0.0002$) and ≤ 15 degrees (98.6% Acrysof vs. 96.4% Tecnis, $P = 0.02$). The mean rotation was 2.72 degrees (95% confidence interval 2.35–3.08 degrees) for Acrysof and 3.79 degrees (95% confidence interval 3.36–4.22 degrees) for Tecnis TIOLs ($P < 0.05$). The Tecnis TIOL showed a strong predisposition to rotate counterclockwise, unlike the Acrysof. More Tecnis TIOL patients required repositioning (3.1% vs. 1.6%), but this did not reach statistical significance ($P = 0.10$). Refractive outcomes were similar between the 2 groups.

Conclusions: The Acrysof TIOL showed significantly greater rotational stability than the Tecnis TIOL. *Ophthalmology* 2018;125:1325–1331 © 2018 by the American Academy of Ophthalmology

Optimal astigmatism correction with a toric intraocular lens (TIOL) requires both accurate surgical alignment and rotational stability. Every degree of misalignment reduces a TIOL's effectiveness by 3%.¹ In the United States, the 2 most commonly implanted monofocal TIOLs are the Acrysof (Alcon, Fort Worth, TX) and the Tecnis (Johnson & Johnson Vision, Santa Ana, CA). These same design platforms are used for each company's toric presbyopia-correcting intraocular lenses (IOLs), such as the Tecnis toric Symphony and the Acrysof toric ReSTOR +3.0 and +2.5 models. Although both monofocal TIOLs showed rotational stability during premarketing clinical trials, those studies looked at rotation after the first postoperative visit. In addition, a recent study has shown that 28% of the mean TIOL axis misalignment measured postoperatively was caused by intraoperative misalignment rather than postoperative rotation.²

Noting the absence of large, published comparison studies, we performed a retrospective study to compare rotational stability of these 2 monofocal TIOL designs in a

high-volume, 2-surgeon practice. This setting provided uniformity in the preoperative, intraoperative, and postoperative diagnostic and surgical protocols, including use of intraoperative wavefront aberrometry (ORA Verifeye+, Alcon), and a digital marking system (Callisto, Carl Zeiss Meditec, Jena, Germany) to minimize any component of intraoperative misalignment. To our knowledge, it is the largest study to compare the rotational stability of these 2 IOLs head-to-head with the assistance of digital marking.

Methods

This retrospective cohort study examined the frequency and amount of TIOL rotation from patients in a single 2-surgeon private practice (Los Altos, CA). A digital intraoperative marking system was installed at the practice's surgery center in late March of 2015. All patients receiving a TIOL over an 18-month period between April 1, 2015 and September 30, 2016 were eligible for the study and had their records reviewed. Patients were excluded from the study if digital marking could not be obtained preoperatively or was not able to be used intraoperatively.

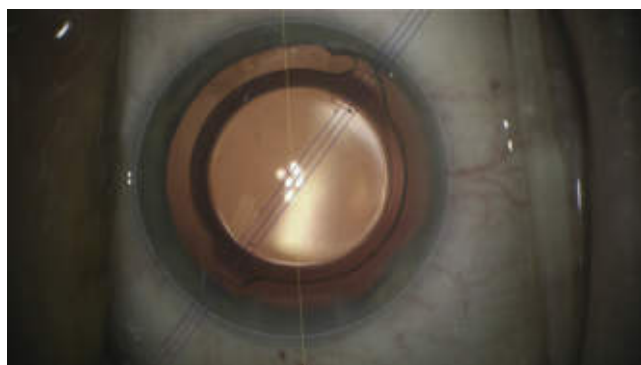


Figure 1. This intraoperative photograph shows the digital marking system used to verify toric intraocular lens position. The yellow line shows the 0- to 180-degree axis, and the 3 blue lines demonstrate the surgical axis.

This digital marking system utilizes preoperative photography taken at the time of biometry (IOLMaster, Carl Zeiss Meditec) to image nasal and temporal limbal vascular landmarks. At the time of surgery, this stored image is digitally registered to the live microscope camera image (Lumera 700, Carl Zeiss Meditec) to adjust for any cyclotorsion associated with the supine position.³ The display unit in the operating microscope then provides a streaming overlay to the surgeon's oculars that shows the 0- to 180-degree reference axis as well as the intended axis of correction (Fig 1). Previous research has suggested that use of the digital overlay system results in lower postoperative astigmatism than traditional manual marking.⁴⁻⁶

Both surgeons operate solely at a private, multisurgeon, ophthalmology-only ambulatory surgery center (ASC). Because of consignment and volume purchasing considerations, more Tecnis monofocal TIOLs were implanted during the initial study period. When this arrangement changed, most of the monofocal TIOL volume at the ASC shifted to the Acrysof platform. The surgeons could always choose either TIOL model for each case based on individual preference and were not blinded to the IOL type.

Surgical Technique

The surgeons based TIOL selection and placement on a combination of autokeratometry (Topcon Corporation, Tokyo, Japan), the IOLMaster 500 (Carl Zeiss Meditec), and topography with ray tracing (iTrace, Tracey Technologies, Houston, TX). The estimated surgically induced astigmatism was 0, and all incisions were made temporally using a 2.5-mm diamond keratome (Accutome, Malvern, PA). All surgeries began with registration of the operative eye using the digital marking system, followed by orientation of the reticle of the intraoperative aberrometer so that the 180 axis of the reticle was parallel to the 180 axis on the Callisto overlay.

After the cataract was removed, there was no anterior capsule polishing performed. The eye was inflated with an ophthalmic viscosurgical device (OVD). For 1258 of the cases, the OVD used was Amvisc Plus (Bausch & Lomb, Rochester, NY), with the rest being Viscoat (Alcon) or Endocoat (Johnson & Johnson). A Barraquer-Terry tonometer (Ocular Instruments, Bellevue, WA) verified that the intraocular pressure was approximately 25 mmHg. Aphakic aberrometry was performed to assist in confirming or modifying the IOL spherical power and toricity. Next, the TIOL was implanted into the capsular bag and dialed into the planned position with the guidance of the digital marking system. The TIOL's axis was then adjusted, if warranted, with the assistance of a pseudophakic aberrometry measurement. If applicable, the digital overlay toric positioning line was changed at this point to align

with the new preferred, post-aberrometry TIOL axis. Thorough irrigation-aspiration was used to remove all OVD, including within the capsular fornices, around the haptics, and behind the TIOL optic. Following OVD removal, to avoid capsular bag distension, the anterior chamber (AC) was inflated and formed with balanced salt solution, but the eye was deliberately left soft, with an intraocular pressure in single digits as estimated by palpation. At the conclusion of the case, the TIOL markings were confirmed to be aligned with the Callisto toric positioning lines. This ensured that the final position of the TIOL was on the intended axis, and this was recorded as the final surgical axis.

Patients received a dilated examination either later on the day of surgery (at least 1 hour postoperatively) or the next morning. When examining the patient at the slit lamp, the examiner took care to ensure that the patient's head was level regardless of any habitual head tilt. The same level head position was used for all preoperative biometry and topography. After the pupil was dilated, Haag-Streit (Köniz, Switzerland) slit lamps with axis alignment markings were used to check the TIOL axis, which was recorded to the nearest degree.

On subsequent postoperative visits, a manifest refraction was performed. Almost all of Dr. Chang's refractions were performed by 1 optometrist, and almost all of Dr. Lee's refractions were performed by the surgeon himself. These took place in a standard examination lane in the usual fashion, starting with spherical equivalent, then refining the cylinder axis and then power using a Jackson crossed cylinder. The TIOL position was rechecked with a dilated examination if the residual astigmatism was ≥ 0.75 diopter (D) or if recheck was judged to be clinically warranted, such as the presence of a significant degree of misalignment on the initial postoperative visit.

Patients were generally offered repositioning surgery if they had a misaligned toric IOL, refractive cylinder ≥ 0.75 D, and uncorrected visual acuity 20/30 or worse. Those with significant misalignment (>10 degrees) were usually offered repositioning even with lesser amounts of refractive cylinder. Patients consenting to TIOL repositioning were taken back to the operating room (OR), and the original paracenteses were reopened. Instead of OVD, balanced salt solution on a cannula was used to keep the AC formed as the TIOL was rotated to the new position with the cannula tip. The target rotation axis was calculated using a combination of manifest refraction, topography, and vector analysis available on the website www.astigmatismfix.org.

Data Collection

This study was approved by Salus institutional review board. Patients receiving a TIOL during the study period were identified from operative logs. Recorded variables included age at the time of surgery, sex, and surgeon. The keratometry, AC depth, axial length, and horizontal white-to-white diameter were recorded from the IOLMaster measurements. Immersion A-scan was used when the IOLMaster could not obtain an axial length measurement. Additional variables included the brand of TIOL used, spherical and cylindrical IOL power, surgical axis, and targeted spherical equivalent, as well as intraoperative use of a capsular tension ring (CTR) or use of an OVD other than Amvisc Plus.

Measured outcomes included TIOL axis at the first postoperative visit (day 0 or day 1), whether a return to the OR was required and why, and best-corrected distance visual acuity (BCDVA) and refraction on the final postoperative visit if it was at least 2 weeks after surgery.

All patients were included in the rotational stability analysis. Patients were excluded from the visual acuity analysis if they had vision-limiting ocular comorbidities such as amblyopia, retinal disease (e.g., macular degeneration, epiretinal membrane, diabetic

retinopathy, retinal vein occlusion, or myopic degeneration), corneal disease (e.g., keratoconus, scar, or Fuchs dystrophy), optic nerve disease, or glaucoma. Patients were excluded from the manifest refraction postoperative cylinder analysis if the BCDVA was worse than 20/40.

Statistical Analysis

The preoperative astigmatism was calculated for each brand as well as mean TIOL rotation and 95% confidence intervals using a 2-sample *t* test. The percentage of eyes that rotated ≤ 5 , ≤ 10 , ≤ 15 , ≤ 20 , ≤ 30 , and >30 degrees at the first postoperative visit was compared using logistic regressions. The direction and amount of rotation was graphed for each TIOL to look for patterns, including dividing the surgical axis into against-the-rule (ATR) (0–30 degrees and 150–180 degrees), with-the-rule (WTR) (60–120 degrees), and oblique (30–60 and 120–150 degrees).

The postoperative astigmatism based on manifest refraction and the percentage of eyes achieving different levels of BCDVA again were compared using a logistic regression. For those requiring repositioning, the refraction and acuity were from the last examination before repositioning. A stepwise multiple regression analysis was performed to test the effect of age, sex, surgeon, AC depth, white-to-white diameter, axial length, keratometry (IOL-Master Ks), and intended axis on the likelihood of IOL rotation >5 and >10 degrees.

Patients who required a return trip to the operating room because of TIOL rotation were examined additionally. The likelihood of needing operative repositioning was compared by a logistic regression test. The identical stepwise multiple regression analysis was performed to see which variables correlated with need to reposition the TIOL. Fisher exact test was used to measure the impact of individual variables such as surgeon, CTR, and viscoelastic type on rotation >5 degrees, rotation >10 degrees, and surgical repositioning.

Results

A total of 626 Acrysof and 647 Tecnis eyes met the study criteria (Table 1). Although patients were not randomized, the patient groups were highly similar. The median patient age was 72 years in both groups, and 56% of Acrysof and 60% of Tecnis patients were female. The most common toric power implanted was the lowest-power model, with 1.5 D cylinder in the IOL plane (48.3% of Acrysof, 51.1% of Tecnis). The toric power distribution was similar between the 2 TIOLs ($P = 0.85$ by logistic regression), although the Acrysof group had a higher percentage of patients with toric powers ≥ 3.00 D (Acrysof T6–T9 or Tecnis ZCT 400–600), 10.7% vs. 6.0%. The preoperative mean amount of astigmatism based on IOLMaster keratometry was slightly higher in the Acrysof group (1.69 [95% confidence interval (CI) 1.61–1.76 D] vs. 1.53 D [95% CI 1.47–1.59 D], $P < 0.05$). Both groups had 55% of patients with ATR astigmatism and 38% with WTR astigmatism.

Rotation

TIOL rotation was defined as the difference between the TIOL's axis at the first postoperative visit and the axis of correction measured by the digital marking system at the conclusion of surgery. The mean absolute value of rotation was 2.72 degrees (95% CI 2.35–3.08 degrees) for Acrysof TIOLs and 3.79 degrees (95% CI 3.36–4.22 degrees) for Tecnis TIOLs ($P < 0.05$) (Table 2).

For the primary study outcome, the Acrysof TIOL group showed significantly better rotational stability, with 91.9% of eyes aligned ≤ 5 degrees from the target axis at the first postoperative check, compared with 81.8% of Tecnis TIOL eyes ($P < 0.0001$).

Table 1. Baseline Demographic Statistics of Eyes Receiving the Acrysof and Tecnis Toric Intraocular Lens

	Acrysof Toric	Tecnis Toric
Median age (years)	72	72
Female %	56	60
Total n	626	647
Preoperative cylinder (95% CI)	1.69 D (1.62–1.76 D)*	1.53 D (1.47–1.59 D)*
Against-the-rule cylinder, n (%)	342 (54.5%)	354 (54.7%)
Oblique cylinder, n (%)	47 (7.5%)	46 (7.1%)
With-the-rule cylinder, n (%)	237 (37.9%)	247 (38.2%)
IOL with 1.5 D cylinder (IOL plane), n (%)	303 (48.3%)	331 (51.1%)
IOL with 2.25 D cylinder, n (%)	165 (26.3%)	184 (28.4%)
IOL with 3.0 D cylinder, n (%)	91 (14.7%)	93 (14.4%)
IOL with ≥ 3.00 D cylinder, n (%)	67 (10.7%)	39 (6.0%)

CI = confidence interval; D = diopter; IOL = intraocular lens.

* $P < 0.05$.

The Acrysof group also had statistically significantly more eyes ≤ 10 degrees from the target axis (97.8% vs. 93.2%, $P = 0.0002$) and ≤ 15 degrees (98.6% vs. 96.4%, $P = 0.02$) from the target axis.

The direction of rotation also differed between the 2 models. The Tecnis TIOL showed a tendency toward counterclockwise (CCW) rotation (mean 2.15 degrees CCW, 95% CI 1.66–2.65 degrees CCW) no matter the intended axis (Fig 2). Large Tecnis rotations were usually CCW. By contrast, the Acrysof TIOL did not show the same tendency (mean 0.38 degrees CCW, 95% CI 0.04 degrees clockwise to 0.80 degrees CCW, $P < 0.05$). The Acrysof TIOL had several large clockwise rotations in eyes with WTR astigmatism. However, for WTR eyes, the Acrysof's stability remained superior (≤ 5 degrees, 91.2% Acrysof vs. 81.4% Tecnis, $P = 0.002$; ≤ 10 degrees, 96.7% vs. 91.2%, $P = 0.013$).

The mean refractive outcomes were equivalent between the 2 groups, with mean postoperative refractive cylinder of 0.30 D for the Acrysof TIOL (standard deviation [SD] 0.35, 95% CI 0.27–0.33) and 0.31 D for the Tecnis TIOL (SD, 0.36; 95% CI, 0.28–0.34), $P = 0.85$. The median was 0.25 D for both IOL groups, and 85.2% of Acrysof TIOL and 85.4% of Tecnis TIOL eyes had postoperative manifest cylinder ≤ 0.5 D ($P = 0.85$). Manifest cylinder was eliminated (0 D) in 40.0% of Acrysof TIOL and 40.6% of Tecnis TIOL eyes (Table 3). The BCDVA was 20/20 or better in 74.2% of Acrysof eyes and 75.5% of Tecnis eyes with good visual potential, with 99.2% of Acrysof and 99.8% of Tecnis eyes at least 20/40 or better ($P = 0.57$).

Table 2. Toric Intraocular Lens Rotation: Percentage of Eyes Demonstrating Rotational Stability

	Acrysof Toric	Tecnis Toric
IOL rotation, degrees (95% CI)	2.72 (2.35–3.08)*	3.79 (3.36–4.22)*
Rotation ≤ 5 degrees	91.9%*	81.8%*
Rotation ≤ 10 degrees	97.8%*	93.2%*
Rotation ≤ 15 degrees	98.6%*	96.4%*
Rotation ≤ 20 degrees	98.9%	97.4%
Rotation ≤ 30 degrees	99.5%	99.4%
Rotation >30 degrees	0.50%	0.60%

CI = confidence interval; IOL = intraocular lens.

* $P < 0.05$.

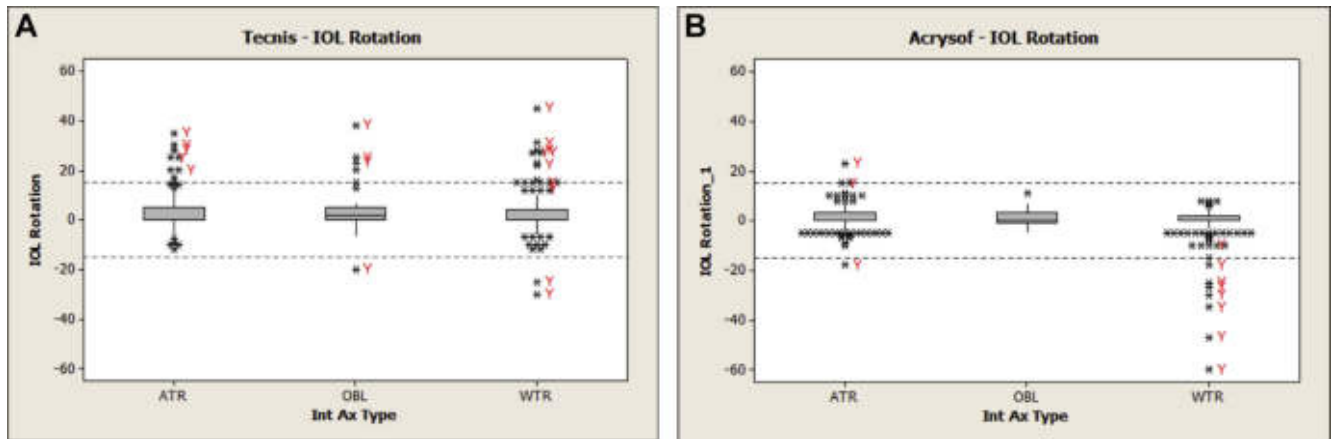


Figure 2. These charts show whether the toric intraocular lens (IOL) rotated counterclockwise (positive) or clockwise (negative) on the first postoperative visit. Eyes were divided into against-the-rule (ATR; 0–30, 150–180 degrees), oblique (OBL; 30–60, 120–150 degrees), and with-the-rule (WTR; 60–120 degrees) astigmatism. Eyes with a Y required return to the operating room for repositioning of a malrotated IOL.

The mean absolute error was 0.34 ± 0.36 D for Alcon and 0.35 ± 0.36 D for Tecnis eyes ($P = 0.40$).

A stepwise regression analysis showed that only lower IOL spherical equivalent power was associated with IOL rotation of >5 degrees ($P = 0.011$). Both greater axial length ($P = 0.023$) and toric axis ($P = 0.005$) were associated with IOL rotation of >10 degrees, as WTR eyes were more likely to rotate. The mean axial length of the Acrysof group (24.70 mm; SD, 1.75) was greater than that of the Tecnis group (24.40 mm; SD, 1.66), which was statistically significant ($P = 0.004$). Adjusting for the difference in axial length slightly increased the difference in IOL stability: ≤ 5 degrees, 92.1% Acrysof vs. 81.5% Tecnis; ≤ 10 degrees, 97.9% Acrysof vs. 93.0% Tecnis; ≤ 15 degrees, 98.7% Acrysof vs. 96.3% Tecnis (all $P < 0.05$).

Repositioning

Eleven Acrysof and 21 Tecnis eyes returned to the OR for surgical IOL rotation. However, 1 eye in each group was repositioned based

on postoperative manifest refraction instead of rotation away from the intended axis and was excluded. There was a non-statistically significant trend toward higher a repositioning rate in Tecnis TIOL eyes (3.1% vs. 1.6%, $P = 0.10$). Four of the 10 Acrysof TIOLs that were surgically repositioned rotated after the initial postoperative visit, whereas none of the Tecnis TIOLs did. However, 1 Tecnis TIOL eye had a 16-degree postoperative rotation at the first postoperative visit that increased to 33 degrees at the second postoperative visit. This patient declined return to the OR because of the eye's poor visual potential, which became apparent postoperatively after refraction.

The results of IOL repositioning were excellent for both groups. The mean deviation from the intended axis of repositioning was 3.2 degrees (SD, 3.8 degrees) for the Acrysof group, with mean residual cylinder of 0.4 D (SD, 0.40 D) afterward. The mean deviation from intended axis of repositioning was 2.1 degrees (SD, 2.5 degrees) for the Tecnis group, with mean residual cylinder of 0.17 D (SD, 0.21 D). The Acrysof repositioning surgeries occurred a mean of 20.8 days after phaco (range, 9–58 days), whereas the Tecnis surgeries occurred 18.7 days after phaco (range, 2–103 days). The stepwise regression analysis on rate of return to the operating room showed only greater axial length to be a significant predictor. For Acrysof TIOLs, the variables with significant differences between rotated and nonrotated eyes were AC depth (3.61 vs. 3.21 mm, $P < 0.01$) and axial length (26.43 vs. 24.67 mm, $P < 0.01$). For the Tecnis TIOLs, only axial length was significantly different (25.41 vs. 24.40 mm, $P < 0.01$).

Other Potential Factors

There was no difference in either repositioning rate or amount of IOL rotation between surgeons ($P > 0.1$). A CTR was used at the surgeon's discretion. Twenty-one Acrysof cases had a CTR, with 1 rotation >10 degrees and 0 repositionings. Thirty-five Tecnis cases received a CTR, with 2 rotations >10 degrees and 0 repositionings. Therefore, use of a CTR did not show any statistical benefit in preventing rotation >10 degrees for either model (Acrysof $P = 0.31$, Tecnis $P = 0.28$).

Six Acrysof TIOL eyes received dispersive OVD during the case, with 0 rotations >10 degrees and 0 repositionings ($P = 1$). Eleven Tecnis TIOL eyes had dispersive OVD, with 2 rotations >10 degrees ($P = 0.16$) and 1 repositioning ($P = 0.29$). There was no difference between patients whose first postoperative visit was on the day of surgery compared with postoperative day (POD) 1.

Table 3. Refractive Outcomes of Toric Intraocular Lenses

	Acrysof Toric	Tecnis Toric
Corrected visual acuity		
$\geq 20/20$	77.6	75.5
$\geq 20/25$	93.1	94.0
$\geq 20/30$	99.0	98.2
$\geq 20/40$	99.2	99.8
$\geq 20/50$	99.8	100.0
$\geq 20/60$	100.0	100.0
Manifest refraction cylinder		
0 D	40.0	40.6
≤ 0.25 D	65.5	63.3
≤ 0.50 D	85.2	85.4
≤ 0.75 D	94.7	93.9
≤ 1.00 D	98.4	96.1
≤ 1.25 D	99.0	98.6
≤ 1.50 D	99.8	99.0
≤ 1.75 D	99.8	99.8
≤ 2.00 D	99.8	99.8
> 2.00 D	0.2	0.2

D = diopter.

All P values > 0.05 .

Twenty-one percent of Acrysof TIOLs had a POD 0 visit, compared with 33% of Tecnis TIOLs. The likelihood of being within ≤ 5 degrees of target was 86.9% for POD 0 eyes vs. 86.8% for POD 1 ($P = 1$); for ≤ 10 degrees, it was 95.3% for day 0 vs. 95.5% for day 1 ($P = 0.88$). There was also no difference when looking at each IOL separately.

Discussion

The Acrysof toric IOL U.S. Food and Drug Administration label compares a POD 0 visit with a POD 120–180 visit, and the Tecnis toric IOL FDA label compares POD 1 and postoperative months 1, 3, and 6.^{7–11} However, no study to date has compared the rotational stability of these 2 TIOLs from the moment surgery concludes. This is important to establish because a recent study of 72 eyes showed that the most likely time for TIOLs to rotate is within the first postoperative hour.² This study also found that rotation between 1 hour and 1 day postoperatively was rare. Using slit-lamp photography, Inoue and associates² examined the TIOL axis immediately after surgery in the recovery area and during successive visits at 1 hour, 1 day, 1 month, 3 months, and 1 year postoperatively. At 1 year postoperative, the mean TIOL axis misalignment was 6.67 degrees, of which 1.87 degrees was caused by surgical misalignment and 4.80 degrees was caused by TIOL rotation. Nearly all of the rotation (mean 4.09 degrees) occurred within the first hour after surgery. Our results, which showed no difference between eyes checked on the day of surgery vs. the day after, are consistent with Inoue's observations. Moreover, the Tecnis TIOL had a higher percentage of POD 0 checks than the Acrysof TIOL, so even if there were an increased risk of rotation on POD 1, that would have benefited the Tecnis TIOL group.

Studies have demonstrated a range of TIOL misalignment, with most reporting less than 5 degrees of misalignment for both the Acrysof and Tecnis TIOL.^{7–9,11–36} One study of 30 Tecnis TIOL eyes reported 7.7 degrees mean misalignment,³⁷ and Inoue reported 6.67 degrees with the Tecnis.² Other exceptions include the Lentis L-312T, which was withdrawn from the market because of mean misalignment of 20 degrees,³⁸ and the Staar plate haptic TIOL.^{15,39,40}

Digital intraoperative marking systems that utilize anatomic landmarks such as limbal blood vessels improve surgical toric axis alignment compared with manual marking methods.^{4–6,20} However, digital marking was not available or not used in most prior clinical studies or comparisons of TIOL rotational stability.^{15,25–32,39–44} For this reason, it is impossible to know how much of any postoperative axis misalignment was due to TIOL rotation or to surgical misalignment in these previously published studies.

Our study compares relatively equal numbers and toric power distributions of the 2 main monofocal TIOL brands used in the United States. The single-practice setting provided uniformity of preoperative and postoperative testing as well as surgical equipment, OVD, and technique. In addition to the large sample size, an important strength of our study was the use of intraoperative aberrometry and digital marking to refine and confirm surgical alignment along the optimal axis. The Callisto digital marker

confirmed the TIOL position at the moment surgery was concluded without requiring an immediate slit-lamp examination in the recovery area.

Although the mean and median amounts of IOL rotation were similar between the 2 platforms, the Acrysof toric platform provided significantly better overall rotational stability because the Tecnis group had more eyes with large amounts of rotation. The Tecnis TIOL predominantly rotated CCW no matter the TIOL's axis.

It is unclear what underlying factors cause the Tecnis TIOL to rotate more frequently. Intraoperatively, we have noted that compared with the Acrysof, the Tecnis TIOL often shifts CCW during OVD removal with the irrigation/aspiration handpiece and is very easy to rotate CCW even after OVD removal. This could arise from characteristics of the acrylic material itself, such as its stiffness or the stickiness of its interaction with the capsular bag. Another possibility could be the width, angulation, or design of the haptics. For instance, the optic-haptic junction appears to be more rigid with the Tecnis than with the Acrysof. The Acrysof haptic is softer and has a terminal bulb, which might affect stability.

Given the difference in rotational stability, it is not surprising that twice as many Tecnis TIOLs required surgical repositioning, although the overall rate was still low. In our practice, TIOL repositioning is usually delayed for 2 to 4 weeks, with the expectation being that capsular bag contraction will prevent re-rotation.⁴⁵ The decision to recommend or offer surgical repositioning is affected by many variables, however, such as the cylinder power of the TIOL and the expected refractive improvement from realignment. Even when it is offered, patients may not elect this option based on factors such as inconvenience or fear. We believe that intraoperative digital marking along with dilated slit-lamp measurement of the TIOL axis postoperatively is therefore the most accurate measure of rotational stability.

This study is better able to answer the question of relative toric IOL stability than previous papers that have examined this question.⁴⁶ The Potvin study relied on anonymous internet reporting without the benefit of preoperative data or a known sample size. By contrast, this study's large sample size and single-practice setting provided uniformity of equipment, preoperative and postoperative testing, and surgical technique, including digital marking to assure accurate axis alignment at the conclusion of surgery.

The weaknesses of this study include the fact that it was retrospective and without randomization to reduce the impact of potential confounding patient or surgeon variables. However, we believe that having a single high-volume, 2-surgeon practice perform a large and equivalent number of cases with each type of TIOL over a relatively short period of time using standard surgical techniques may have reduced potential covariables. The postoperative alignment examinations were all performed by the surgeon and not blinded, but the same technique for TIOL axis determination was used for all patients.

Interestingly, we did not find any statistical evidence that a CTR improved rotational stability, despite anecdotal impressions expressed by others to the contrary.⁴⁷ CTR implantation was at the surgeon's discretion and was for zonulopathy in most cases. In some cases, it was for concern that the patient

might be at high risk of TIOL rotation. A larger, prospective study could better answer the question of whether a CTR reduces the risk of postoperative TIOL rotation.

The predictors of larger amounts of TIOL rotation included greater axial length and its equivalent, lower spherical IOL power. Both are presumably a proxy for size of the capsular bag, which is not currently measurable. Future imaging techniques may potentially allow more accurate TIOL rotation risk assessment based on anatomic factors. WTR axis was also associated with rotation >10 degrees, which could reflect the effect of gravity or haptic position for vertically oriented TIOLs.

The Acrysof toric platform is now being used for the toric ReSTOR multifocal, whereas the Tecnis toric platform is used for the toric Symfony extended depth of focus lens. Because these new presbyopia-correcting TIOL models were not available during the time of our study, we did not specifically assess or compare their rotational stability. However, aside from the diffractive optic, they each retain the same single-piece, hydrophobic acrylic design as their monofocal TIOL counterpart. It would be valuable to compare rotational stability of these diffractive TIOLs in a future study because accurate astigmatism correction and centration are especially important for the functioning of these IOLs.

The interesting finding by Inoue and associates that the majority of postoperative TIOL rotation occurs within the first hour suggests that limiting patient activity immediately after surgery could be helpful. Our study did not examine the timing of rotation, but the fact that the results for patients seen on POD 0 (>1 hour) and POD 1 were identical also suggests that any postoperative rotation happens very soon after surgery.

In conclusion, large amounts of postoperative TIOL misalignment are fortunately rare, but even smaller degrees of misalignment can undermine the refractive success of the procedure. Intraoperative aberrometry and digital marking can improve TIOL surgical alignment accuracy but do not prevent postoperative rotation. Advances in TIOL material and design may reduce the risk of rotation further, but ultimately, adjustable IOLs may provide the best solution because postoperative cylindrical IOL adjustment would occur after the IOL can no longer rotate.

References

- Sanders DR, Grabow HB, Shepherd J. The toric IOL. In: Gills JP, Martin RB, Sanders DR, eds. *Sutureless Cataract Surgery: An Evolution Toward Minimally Invasive Technique*. Thorofare, NJ: Slack Inc.; 1992.
- Inoue Y, Takehara H, Oshika T. Axis misalignment of toric intraocular lens: placement error and postoperative rotation. *Ophthalmology*. 2017;124:1424–1425.
- Swami AU, Steinert RF, Osborne WE, White AA. Rotational malposition during laser in situ keratomileusis. *Am J Ophthalmol*. 2002;133:561–562.
- Black D. Evaluation of markerless alignment system for toric IOLs. ASCRS Annual Meeting (San Diego, CA) 2015. Available at: <https://ascrs.confex.com/ascrs/15am/webprogram/Paper15226.html>.
- Mayer WJ, Kreutzer T, Dirisamer M, et al. Comparison of visual outcomes, alignment accuracy, and surgical time between 2 methods of corneal marking for toric intraocular lens implantation. *J Cataract Refract Surg*. 2017;43:1281–1286.
- Solomon JD, Ladas J. Toric outcomes: computer-assisted registration versus intraoperative aberrometry. *J Cataract Refract Surg*. 2017;43:498–504.
- Waltz KL, Featherstone K, Tsai L, Trentacost D. Clinical outcomes of TECNIS toric intraocular lens implantation after cataract removal in patients with corneal astigmatism. *Ophthalmology*. 2015;122:39–47.
- Alcon Acrysof IQ Toric Directions for Use. https://p.widenedcdn.net/tkts9w/40-500-143_us_en. Accessed February 22, 2018.
- Holland E, Lane S, Horn JD, et al. The AcrySof Toric intraocular lens in subjects with cataracts and corneal astigmatism: a randomized, subject-masked, parallel-group, 1-year study. *Ophthalmology*. 2010;117:2104–2111.
- Alcon Summary of Safety and Effective Data. http://www.accessdata.fda.gov/cdrh_docs/pdf/P930014S015b.pdf; 2005. Accessed February 22, 2018.
- Tecnis Toric 1-piece IOL Directions for Use. <http://www.precisionlens.net/Websites/precisionlens/images/IJ%20Tecnis%20ZCT%20DFU.pdf>. Accessed February 22, 2018.
- Ahmed II, Rocha G, Slomovic AR, et al. Visual function and patient experience after bilateral implantation of toric intraocular lenses. *J Cataract Refract Surg*. 2010;36:609–616.
- Kessel L, Andresen J, Tendal B, et al. Toric intraocular lenses in the correction of astigmatism during cataract surgery: a systematic review and meta-analysis. *Ophthalmology*. 2016;123:275–286.
- Cervantes-Coste G, Garcia-Ramirez L, Mendoza-Schuster E, Velasco-Barona C. High-cylinder acrylic toric intraocular lenses: a case series of eyes with cataracts and large amounts of corneal astigmatism. *J Refract Surg*. 2012;28:302–304.
- Chang DF. Comparative rotational stability of single-piece open-loop acrylic and plate-haptic silicone toric intraocular lenses. *J Cataract Refract Surg*. 2008;34:1842–1847.
- Dardzhikova A, Shah CR, Gimbel HV. Early experience with the AcrySof toric IOL for the correction of astigmatism in cataract surgery. *Can J Ophthalmol*. 2009;44:269–273.
- Farooqui JH, Koul A, Dutta R, Shroff NM. Comparison of two different methods of preoperative marking for toric intraocular lens implantation: bubble marker versus pendulum marker. *Int J Ophthalmol*. 2016;9:703–706.
- Hoffmann PC, Auel S, Hutz WW. Results of higher power toric intraocular lens implantation. *J Cataract Refract Surg*. 2011;37:1411–1418.
- Klamann MK, Von Sonnleithner C, Gonnermann J, et al. Influence of biometric parameters on rotational stability of toric IOLs. *Eur J Ophthalmol*. 2013;23:836–840.
- Webers VSC, Bauer NJC, Visser N, et al. Image-guided system versus manual marking for toric intraocular lens alignment in cataract surgery. *J Cataract Refract Surg*. 2017;43:781–788.
- Weinand F, Jung A, Stein A, et al. Rotational stability of a single-piece hydrophobic acrylic intraocular lens: new method for high-precision rotation control. *J Cataract Refract Surg*. 2007;33:800–803.
- Tsinopoulos IT, Tsalousis KT, Tsakpinis D, et al. Acrylic toric intraocular lens implantation: a single center experience concerning clinical outcomes and postoperative rotation. *Clin Ophthalmol*. 2010;4:137–142.
- Mendicute J, Irigoyen C, Aramberri J, et al. Foldable toric intraocular lens for astigmatism correction in cataract patients. *J Cataract Refract Surg*. 2008;34:601–607.

24. Mazzini C. Visual and refractive outcomes after cataract surgery with implantation of a new toric intraocular lens. *Case Rep Ophthalmol*. 2013;4:48–56.
25. Hirschall N, Maedel S, Weber M, Findl O. Rotational stability of a single-piece toric acrylic intraocular lens: a pilot study. *Am J Ophthalmol*. 2014;157:405–411.e1.
26. Kim MH, Chung TY, Chung ES. Long-term efficacy and rotational stability of AcrySof toric intraocular lens implantation in cataract surgery. *Korean J Ophthalmol*. 2010;24:207–212.
27. Koshy JJ, Nishi Y, Hirschall N, et al. Rotational stability of a single-piece toric acrylic intraocular lens. *J Cataract Refract Surg*. 2010;36:1665–1670.
28. Miyake T, Kamiya K, Amano R, et al. Long-term clinical outcomes of toric intraocular lens implantation in cataract cases with preexisting astigmatism. *J Cataract Refract Surg*. 2014;40:1654–1660.
29. Scialdone A, De Gaetano F, Monaco G. Visual performance of 2 aspheric toric intraocular lenses: comparative study. *J Cataract Refract Surg*. 2013;39:906–914.
30. Shah GD, Praveen MR, Vasavada AR, et al. Rotational stability of a toric intraocular lens: influence of axial length and alignment in the capsular bag. *J Cataract Refract Surg*. 2012;38:54–59.
31. Zhu X, He W, Zhang K, Lu Y. Factors influencing 1-year rotational stability of AcrySof Toric intraocular lenses. *Br J Ophthalmol*. 2016;100:263–268.
32. Zuberhuhler B, Signer T, Gale R, Haefliger E. Rotational stability of the AcrySof SA60TT toric intraocular lenses: a cohort study. *BMC Ophthalmol*. 2008;8:8.
33. Mingo-Botin D, Munoz-Negrete FJ, Won Kim HR, et al. Comparison of toric intraocular lenses and peripheral corneal relaxing incisions to treat astigmatism during cataract surgery. *J Cataract Refract Surg*. 2010;36:1700–1708.
34. Gangwani V, Hirschall N, Findl O, Maurino V. Multifocal toric intraocular lenses versus multifocal intraocular lenses combined with peripheral corneal relaxing incisions to correct moderate astigmatism. *J Cataract Refract Surg*. 2014;40:1625–1632.
35. Titiyal JS, Khatik M, Sharma N, et al. Toric intraocular lens implantation versus astigmatic keratotomy to correct astigmatism during phacoemulsification. *J Cataract Refract Surg*. 2014;40:741–747.
36. Visser N, Beckers HJ, Bauer NJ, et al. Toric vs aspherical control intraocular lenses in patients with cataract and corneal astigmatism: a randomized clinical trial. *JAMA Ophthalmol*. 2014;132:1462–1468.
37. Lam DK, Chow VW, Ye C, et al. Comparative evaluation of aspheric toric intraocular lens implantation and limbal relaxing incisions in eyes with cataracts and ≤ 3 dioptres of astigmatism. *Br J Ophthalmol*. 2016;100:258–262.
38. Maedel S, Hirschall N, Chen YA, Findl O. Rotational performance and corneal astigmatism correction during cataract surgery: aspheric toric intraocular lens versus aspheric nontoric intraocular lens with opposite clear corneal incision. *J Cataract Refract Surg*. 2014;40:1355–1362.
39. Chang DF. Early rotational stability of the longer Staar toric intraocular lens: fifty consecutive cases. *J Cataract Refract Surg*. 2003;29:935–940.
40. Chua WH, Yuen LH, Chua J, et al. Matched comparison of rotational stability of 1-piece acrylic and plate-haptic silicone toric intraocular lenses in Asian eyes. *J Cataract Refract Surg*. 2012;38:620–624.
41. Garzon N, Poyales F, de Zarate BO, et al. Evaluation of rotation and visual outcomes after implantation of monofocal and multifocal toric intraocular lenses. *J Refract Surg*. 2015;31:90–97.
42. Kwartz J, Edwards K. Evaluation of the long-term rotational stability of single-piece, acrylic intraocular lenses. *Br J Ophthalmol*. 2010;94:1003–1006.
43. Lehmann R, Modi S, Fisher B, et al. Bilateral implantation of +3.0 D multifocal toric intraocular lenses: results of a US Food and Drug Administration clinical trial. *Clin Ophthalmol*. 2017;11:1321–1331.
44. Mencucci R, Favuzza E, Guerra F, et al. Clinical outcomes and rotational stability of a 4-haptic toric intraocular lens in myopic eyes. *J Cataract Refract Surg*. 2014;40:1479–1487.
45. Oshika T, Inamura M, Inoue Y, et al. Incidence and outcomes of repositioning surgery to correct misalignment of toric intraocular lenses. *Ophthalmology*. 2018;125:31–35.
46. Potvin R, Kramer BA, Hardten DR, Berdahl JP. Toric intraocular lens orientation and residual refractive astigmatism: an analysis. *Clin Ophthalmol*. 2016;10:1829–1836.
47. Zhao Y, Li J, Yang K, et al. Combined special capsular tension ring and toric IOL implantation for management of astigmatism and high axial myopia with cataracts. *Semin Ophthalmol*. 2016;1–6.

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Abbreviations and Acronyms:

AC = anterior chamber; ASC = ambulatory surgery center; ATR = against-the-rule; BCDVA = best-corrected distance visual acuity; CCW = counterclockwise; CI = confidence interval; CTR = capsular tension ring; D = diopter; IOL = intraocular lens; OR = operating room; OVD = ophthalmic viscosurgical device; POD = postoperative day; SD = standard deviation; TIOL = toric intraocular lens; WTR = with-the-rule.

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