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

Bryan S. Lee, MD, JD,[1] *David F. Chang, MD*[1,2]

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;■:1−7 © 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 Symfony 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 Verifye+, 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.

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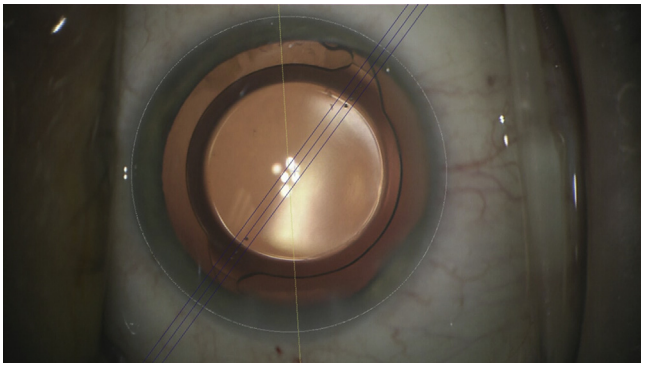

Figure 1. This intraoperative photograph shows the digital marking system used to verify toric intraocular lens position. The *yellow line* shows the 0- to 180-degree axis, and the 3 *blue lines* demonstrate the surgical axis.

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 $\geq$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 $\geq$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