ARTICLE

Rotational stability and refractive outcomes of a single-piece aspheric toric intraocular lens with 4 fenestrated haptics

Giacomo Savini, MD, Giovanni Alessio, MD, Giuseppe Perone, MD, Scipione Rossi, MD, Domenico Schiano-Lomoriello, MD

Purpose: To assess the outcomes of implantation of a single-piece toric intraocular lens (IOL) with 4 fenestrated haptics.

Setting: IRCCS Fondazione Bietti, Rome, Italy.

Design: Prospective case series.

Methods: All patients who had implantation of the Mini Toric Ready IOL were consecutively enrolled. Intraoperatively, the IOL was aligned using an automated system. Follow-up visits were performed at 1 day, 1 week, and 1, 3, and 6 months. At each visit, retroillumination pictures were taken to assess IOL orientation; visual acuity and refraction were also measured.

Results: The final analysis comprised 63 eyes (63 patients). From the first to the last follow-up, the mean arithmetic rotation was −0.2 degrees ± 3.5 (SD) (range −13 to +10 degrees) and the mean absolute rotation was 1.6 ± 3.1 degrees. Intraocular lens rotation from the first to the last examination was within 5 degrees in 92.1% of eyes and on consecutive visits, within 5 degrees in 98.4% or more of eyes. By 6 months, 10 IOLs (15.9%) had rotated clockwise and 10 counterclockwise. Linear regression did not show a statistically significant relationship between rotational stability and the axis of placement with any preoperative parameter (eg, axial length). The mean magnitude of preexisting corneal astigmatism was 1.9 ± 0.7 diopters (D) (range 0.76 to 3.72 D). At the last follow-up, the mean magnitude of refractive astigmatism was 0.5 ± 0.4 D (range 0.0 to 1.5 D); the difference was statistically significant ($P < .05$).

Conclusion: The toric IOL showed good rotational stability and is an option for correcting corneal astigmatism at the time of cataract surgery.

J Cataract Refract Surg 2019; 45:1275–1279 © 2019 ASCRS and ESCRS

Astigmatism is a common condition, affecting more than 32% of adults in Europe.[1] At the time of cataract surgery, 36% of eyes and 8% of eyes have corneal astigmatism higher than 1.00 diopter (D) and 2.00 D, respectively.[2] Toric intraocular lens (IOL) implantation is the most commonly used method of correcting astigmatism because it offers higher accuracy than other techniques, such as clear corneal incisions in the steep axis and limbal relaxing incisions.[3,4]

However, postoperative residual refractive astigmatism is not uncommon after toric IOL implantation. Several factors can play a role in this, including the architecture of the incision, which influences corneal surgically induced astigmatism (SIA); the measurement of corneal astigmatism, which should take into account the posterior corneal curvature[5,6]; the calculation of the toric power required at the IOL plane, which should take into account the effective lens position[7,8]; and on-axis positioning of the toric IOL, whose flat meridian (usually identified by specific markings) should be aligned with the steep meridian of the cornea. Thus, toric IOLs must have rotational stability in the capsular bag over the long term to achieve successful refractive outcomes.

Recently, a single-piece toric IOL with 4 fenestrated haptics (Mini Toric Ready, SIFI S.p.A.) became commercially available. This IOL was designed to achieve high rotational stability. The 4 haptics were incorporated to increase the area of friction between the IOL and the capsular bag equator, while the fenestrations enable contact between the anterior capsule and posterior capsule.

The current study assessed the rotational stability and refractive outcomes after implantation of the Mini Toric

Submitted: December 31, 2018 | Final revision submitted: March 19, 2019 | Accepted: May 8, 2019

From the GB Bietti Foundation IRCCS (Savini, Schiano-Lomoriello) and the San Carlo di Nancy Hospital (Rossi), Rome, the Unità Operativa Oftalmologia Universitaria (Alessio), Dipartimento di Scienze Mediche di Base, Neuroscienze ed Organi di Senso, University of Bari Aldo Moro, and Poliambulatorio Also Srl (Perone), Saronno, Italy.

Supported by the Italian Ministry of Health and Fondazione Roma, Italy (G.B. Bietti Foundation IRCCS).

Corresponding author: Giacomo Savini, MD, Fondazione G.B. Bietti IRCCS, Via Livenza, 3, Rome, Italy. Email: giacomo.savini@alice.it.

0886-3350/$ - see frontmatter
https://doi.org/10.1016/j.jcrs.2019.05.015

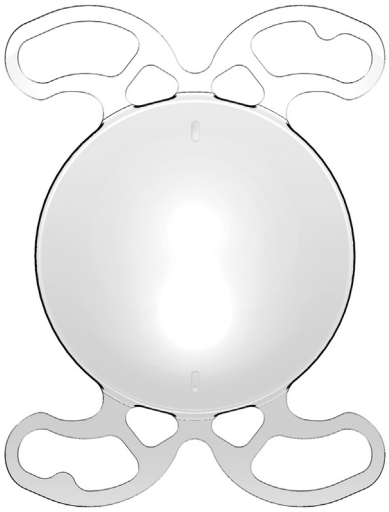

Figure 1. Front view of the toric intraocular lens.

Ready IOL. To our knowledge, no published study has evaluated these parameters with a toric IOL of this design.

PATIENTS AND METHODS

All patients who had implantation of the Mini Toric Ready IOL were consecutively enrolled in this prospective multicenter observational study. The study methods adhered to the tenets of the Declaration of Helsinki for the use of human participants in biomedical research and were approved by the local ethical committees. All patients provided informed consent.

To be included in the study, patients had to have at least 0.75 D of corneal astigmatism. Exclusion criteria were corneal disease (eg, keratoconus, epithelial basal membrane dystrophy, scars) or other ocular comorbidity that could influence postoperative evaluations, previous eye surgery, intraoperative or postoperative complications, and reduced zonular fiber or capsule stability (eg, pseudoexfoliation). In cases of bilateral surgery, only the first eye was included in the study.

Preoperative Measurements

Before surgery, keratometry (K), anterior chamber depth (ACD), and axial length (AL) measurements were acquired using partial coherence interferometry (IOLMaster 500, Carl Zeiss Meditec AG). To identify possible cases of irregular astigmatism, corneal topography and tomography were performed with a rotating Scheimpflug camera–Placido topographer (Sirius, Costruzione Strumenti Oftalmici).

Intraocular Lens

The Mini Toric Ready is a 4-haptic single-piece aspheric IOL with a biconvex hydrophilic–hydrophobic copolymer optic; the optic diameter is 6.0 mm. Each haptic has a large fenestration, and the optic has two markings showing the axis along which the IOL should be aligned (Figure 1). The overall length is 10.75 mm, and the vault is 5 degrees. The front surface of the IOL is aspheric, and the posterior surface is toric. The latter has a double square edge to prevent migration of lens epithelial cells and minimize the incidence of posterior capsule opacification. The IOL provides cylinder correction at the IOL plane ranging from 1.50 to 4.50 D in 0.50 D steps. The magnitude of the IOL cylinder was calculated using the manufacturer's online calculator,[A] which is based on the Assort calculator by Alpins.[9,10] A corneal SIA of 0.2 D was incorporated in the calculator by all investigators. The influence of posterior corneal astigmatism was taken into account by entering the optimized K values as described by Savini et al.[11]

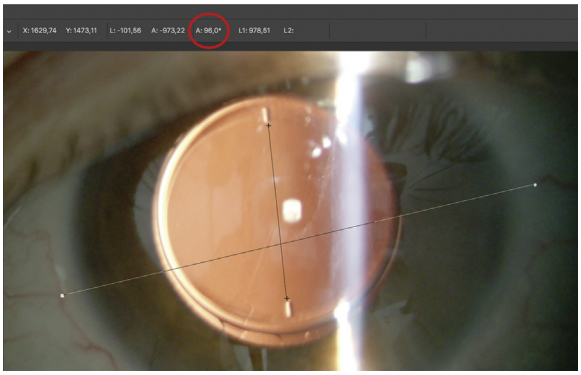

Figure 2. Postoperative photography of the toric intraocular lens. The line connecting the two markings on the toric (*slanted vertical line*) show the intraocular lens is oriented at 96 degrees (*red circle*). A second line connecting two conjunctival vessels on opposite sides of the pupil (*slanted horizontal line*) is used to account for the rotation of the eye on slitlamp examination.

Surgical Technique

The surgeries were performed by 1 of 4 experienced surgeons (G.S., G.A., G.P., S.R.) using the same technique. After a temporal 2.2 near-clear stab incision was created, the anterior chamber was filled with a dispersive ophthalmic viscosurgical device (OVD) (sodium hyaluronate 3.0%–chondroitin sulfate 4.0% [Viscoat]). A continuous curvilinear capsulorhexis with a diameter of approximately 5.0 mm was made. After hydrodissection, standard phacoemulsification, and cortical cleanup, the capsular bag was filled with a cohesive OVD (sodium hyaluronate 1.0% [Provisc]) and the IOL was implanted with the markings oriented along the steep corneal meridian. An automated system (Verion, Alcon Laboratories, Inc.) was used to position the IOL markings on the intended axis of orientation. Finally, the remaining OVD was aspirated from the anterior chamber and from behind the IOL and replaced by a balanced salt solution.

Follow-up

Postoperative follow-up visits were performed at 1 day, 1 week, and 1, 3, and 6 months. At each visit, pupillary mydriasis of at least 6.0 mm was obtained with tropicamide 1.0%. Then, retroillumination photographs were taken with a digital color camera (SL-990, Costruzione Strumenti Oftalmici) to assess the IOL orientation. Care was taken to ensure that the patient's head was in a straight, upright position on the chinrest of the slitlamp; an axial fixation object was used to minimize cyclorotation. The corrected distance visual acuity was also measured at each visit.

Assessment of Intraocular Lens Rotation

Retroillumination pictures were analyzed by a masked operator (D.S.-L.) who imported the image into Photoshop CC software (version 2017.0.0, Adobe Systems, Inc.). The ruler tool was used to draw a line between the two markings on the IOL; based on this, the orientation of the IOL was evaluated (Figure 2). The evaluation was normalized for rotation of the eye in front of the slitlamp between visits by referencing the axis of a line joining two consistent conjunctival vessels or iris features on opposite sides of the pupil margin.[12] The axis was recorded at each visit, and rotation was defined as the difference between the current IOL orientation and the orientation determined at the previous follow-up.

Vector Analysis

Astigmatism analysis was performed according to Naeser's polar value method.[13] The optimized keratometric astigmatism, corneal SIA, IOL cylinder magnitude, IOL orientation, and manifest

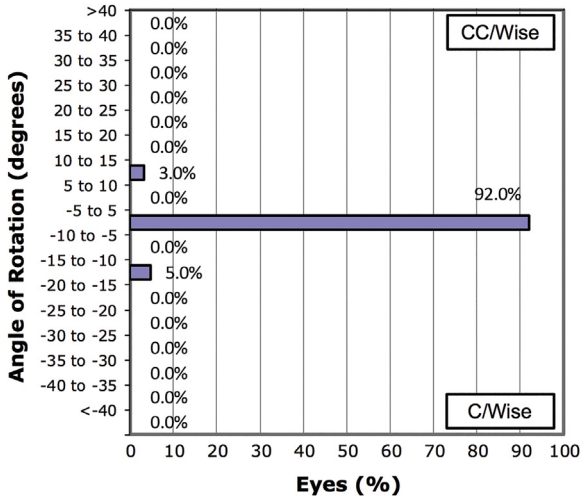

Figure 3. Percentage of eyes with clockwise (C/Wise) or counterclockwise (CC/Wise) rotation at the 6-month follow-up.

refraction at the 6-month follow-up were included in the analysis. The final outcome was the error in refractive astigmatism; that is, the difference between the postoperative refractive astigmatism and the predicted refractive astigmatism.[14]

Statistical Analysis

Statistical analyses were performed using InStat (version 3.1, GraphPad Software, Inc.). The normality of the distribution was assessed with the Kolmogorov-Smirnov test. Comparison of the mean absolute rotational data was performed using the Friedman test for nonparametric data. Comparison of rotation stability between vertically, horizontally, and obliquely implanted IOLs was performed using the Kruskal-Wallis test (nonparametric analysis of variance). Linear regression was used to analyze the relationship between IOL rotation and preoperative parameters (age, K values, ACD, AL, steep corneal meridian).

RESULTS

Analysis of the rotational stability of the IOL was performed in 63 (79.7%) of the 79 eyes included in the study. Analysis could not be performed in the remaining eyes because of loss to follow-up or because the pupil could not be dilated enough postoperatively to obtain a good photograph. Preoperatively, the mean K, ACD, and AL were 43.8 D ±1.4 (SD), 3.1 ± 0.4 mm, and 23.9 ± 1.3 mm, respectively. The AL was greater than 26.0 mm in 5 eyes; no eye had an AL greater than 27.4 mm. There were no intraoperative complications.

Rotational Stability

The toric IOL was implanted vertically (90 ± 15 degrees) in 25 cases, horizontally (0 ± 15 degrees) in 16 cases, and obliquely in 22 cases. The mean difference between the intended axis of IOL orientation and the axis measured at 1 day was 0.1 ± 3.1 degrees (range −10 to +10 degrees); the axis was within ±5 degrees in 59 (93.6%) of 63 cases.

From the first to the last follow-up, the mean arithmetic rotation was −0.2 ± 3.5 degrees (range −13 to +10 degrees) and the mean absolute rotation was 1.6 ± 3.1 degrees. During this period, the rotation was less than 10 degrees in 58 eyes (92.1%) and the rotation in these eyes was always within 5 degrees. Rotation of less than 1 degree was observed in 43 eyes (68.2%). By 6 months, 10 IOLs (15.9%) had rotated clockwise and 10 had rotated counterclockwise (Figure 3).

Table 1. Rotation over time.

Observation Period	Absolute IOL Rotation (°)		Rotation <10° (%)
	Mean ± SD	Range	
1 day to 1 week	0.7 ± 2.0	0, 10	98.4
1 week to 1 month	0.7 ± 1.9	0, 10	98.4
1 month to 3 months	0.7 ± 1.6	0, 6	100.0
3 months to 6 months	0.5 ± 1.4	0, 6	100.0
1 day to 6 months	1.6 ± 3.1	0, 13	92.1

IOL = intraocular lens

No significant correlation between the axis of placement and rotational stability was found. There was no statistically significant difference in the mean final rotation between IOLs implanted vertically (1.8 ± 3.0 degrees), IOLs implanted horizontally (1.2 ± 2.9 degrees), and IOLs implanted obliquely (1.7 ± 3.5 degrees) ($P = .5084$).

Linear regression did not show a statistically significant relationship between the amount of the absolute rotation and the preoperative parameters (age, K value, ACD, AL, and axis of steep corneal meridian; $P > .05$).

Table 1 shows the rotation data over time. There were no statistically significant differences in the mean absolute rotation between each timepoint and the previous timepoint.

Refraction

Preoperatively, the mean magnitude of corneal astigmatism was 1.9 ± 0.7 D (range 0.76 to 3.72 D). At the last follow-up, the mean magnitude of refractive astigmatism was 0.5 ± 0.4 D (range 0 to 1.5 D); the difference was statistically significant ($P < .05$). At the 6-month examination, refractive astigmatism was within ±0.50 D and ±1.00 D in 33 (62.2%) and 42 (79.2%) eyes, respectively. Figure 4 shows the distribution of postoperative refractive astigmatism at the last examination compared with the preoperative corneal astigmatism.

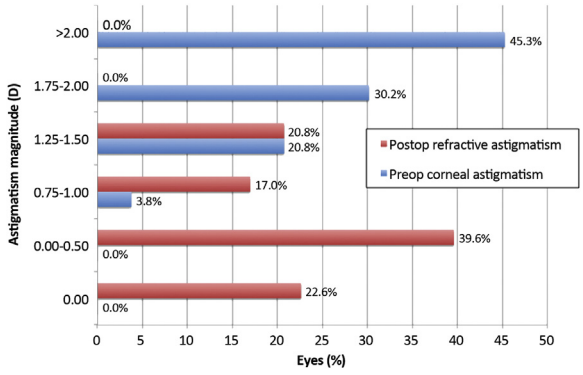

Figure 4. Distribution of preoperative corneal astigmatism and postoperative refractive astigmatism.

On vector analysis, the error in refractive astigmatism was 0.07 D @ 97° in eyes with with-the-rule astigmatism, 0.17 D @ 69° in eyes with against-the-rule astigmatism, and 0.09 D @ 165° in eyes with oblique astigmatism. Slight undercorrection was detected in eyes with with-the-rule astigmatism [KP(φ) = −0.07 ± 0.42 D] and against-the-rule astigmatism [KP(φ) = −0.13 ± 0.33 D], whereas slight overcorrection was observed in eyes with oblique astigmatism [KP(φ) = 0.08 ± 0.23 D], where KP(φ) is the keratometric power of the error in refractive astigmatism along the reference meridian.

At 6 months, the corrected distance visual acuity and uncorrected distance visual acuity (logarithm of the minimum angle of resolution) was 0.02 ± 0.08 and 0.12 ± 0.20, respectively. The back-calculated optimized constants were as follows: Haigis a0 = −2.906, a1 = 0.493, and a2 = 0.270; Hoffer pACD = 5.53; Holladay 1 surgeon factor = 1.71; SRK/T A-constant = 118.81.

Adverse Events

There were no persistent ocular adverse events during the study. No eye required IOL repositioning.

DISCUSSION

Our study found that the recently introduced single-piece aspheric Mini Toric Ready IOL toric IOL with 4 fenestrated haptics had good rotational stability in eyes that have had cataract surgery. The IOL rotation was within 5 degrees from the first to the last follow-up in 92.1% of eyes and within 5 degrees on consecutive visits in 98.4% or more of eyes. These percentages exceed the current American National Standards Institute standard (ANSI Z80.30, 2010),[15] which stipulates a change in rotation of 5 degrees or less in at least 90% of eyes at consecutive visits performed at least 3 months apart.[B]

The good rotational stability can be related to the design of the IOL, which has 4 haptics with large fenestrations; traditional IOLs have 2 haptics. The presence of 4 haptics is intended to increase the area of friction between the IOL and the capsular bag equator. The large fenestration in each haptic enables contact between the anterior capsule and posterior capsule, encouraging capsule fusion.

The mean absolute rotation over the entire follow-up in our study was 1.6 ± 2.1 degrees; this compares favorably with published data for other toric IOLs. Koshy et al.[16] found slightly greater rotation (mean 2.44 ± 1.99 degrees) for a single-piece IOL with 2 open-loop haptics (Acrysof SN60TT, Alcon Laboratories, Inc.). Waltz et al.[17] and Marques et al.[18] found slightly greater rotation (mean 2.70 ± 5.51 degrees and 3.18 ± 3.28 degrees, respectively) for a toric IOL with a similar design (Tecnis models ZCT and ZMT, Johnson & Johnson, Inc.), while Schartmüller et al.[19] found a mean rotation of 1.5 ± 1.2 degrees for another toric IOL with 2 open loops (Vivinex XY1 IOL, Hoya Corp.), a value close to that in our study. Similar values have been reported in other studies of a variety of IOL models.[20–22] Plate-haptic IOLs have slightly worse rotational stability (mean 4.42 ± 4.31 degrees)[23] than the toric IOL we assessed.

Comparison of the mean preoperative corneal astigmatism (1.9 ± 0.7 D) and the mean postoperative refractive astigmatism (0.5 ± 0.4 D) and the results of vector analysis show the high efficacy of the Mini Toric Ready toric IOL. However, residual refractive astigmatism ranging between 0.75 D and 1.50 D was detected in 37% of cases at the last examination. Several factors can play a role in the persistence of this astigmatism, such as the variability in corneal SIA and IOL tilt.

Our study has limitations. First, when we designed the protocol, we followed the method in the majority of previously published studies of toric IOLs, in which rotational stability was assessed 1 day after surgery. We did not measure IOL orientation 1 hour postoperatively, as did Koshy et al.,[16] Hirnschall et al.,[24] and Draschl et al.[25] Although their approach is interesting, such an assessment in our cohort would have provided few additional data because of the small difference between the intended axis of IOL placement and the measured axis at 1 day (mean 0.1 ± 3.1 degrees). Second, our study included few myopic eyes and none with an AL greater than 27.4 mm. Thus, we were not able to draw conclusions about the stability of this IOL in long eyes, which are known to be more susceptible to IOL rotation.[26,27]

In conclusion, the Mini Toric Ready IOL remained stable postoperatively, with a mean absolute rotation of less than 2 degrees over the first 6 months. Vector analysis showed a mean error in refractive astigmatism of less than 0.20 D, indicating that the toric IOL can be effective in correcting astigmatism at the time of cataract surgery.

WHAT WAS KNOWN

- Toric intraocular lenses (IOLs) can be implanted to correct corneal astigmatism at the time of cataract surgery.

WHAT THIS PAPER ADDS

- The recently introduced toric IOL assessed in this study showed good rotational stability and efficacy.

REFERENCES

1. Wolfram C, Höhn R, Kottler U, Wild P, Blettner M, Bühren J, Pfeiffer N, Mirshahi A. Prevalence of refractive errors in the European adult population: the Gutenberg Health Study (GHS). Br J Ophthalmol 2014; 98:857–861
2. Hoffmann PC, Hütz WW. Analysis of biometry and prevalence data for corneal astigmatism in 23 239 eyes. J Cataract Refract Surg 2010; 36:1479–1485
3. Mendicute J, Irigoyen C, Ruiz M, Illarramendi I, Ferrer-Blasco T, Montés-Micó R. Toric intraocular lens versus opposite clear corneal incisions to correct astigmatism in eyes having cataract surgery. J Cataract Refract Surg 2009; 35:451–458
4. Lam DKT, Chow VWS, Ye C, Ng PK-F, Wang Z, Jhanji V. 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
5. Koch DD, Ali SF, Weikert MP, Shirayama M, Jenkins R, Wang L. Contribution of posterior corneal astigmatism to total corneal astigmatism. J Cataract Refract Surg 2012; 38:2080–2087
6. Savini G, Versaci F, Vestri G, Ducoli P, Næser K. Influence of posterior corneal astigmatism on total corneal astigmatism in eyes with moderate to high astigmatism. J Cataract Refract Surg 2014; 40:1645–1653

7. Fam HB, Lim KL. Meridional analysis for calculating the expected spherocylindrical refraction in eyes with toric intraocular lenses. J Cataract Refract Surg 2007; 33:2072–2076
8. Savini G, Hoffer KJ, Carbonelli M, Ducoli P, Barboni P. Influence of axial length and corneal power on the astigmatic power of toric intraocular lenses. J Cataract Refract Surg 2013; 39:1900–1903
9. Alpins NA. A new method of analyzing vectors for changes in astigmatism. J Cataract Refract Surg 1993; 19:524–533
10. Alpins N. Astigmatism analysis by the Alpins method. J Cataract Refract Surg 2001; 27:31–49
11. Savini G, Næser K, Schiano-Lomoriello D, Ducoli P. Optimized keratometry and total corneal astigmatism for toric intraocular lens calculation. J Cataract Refract Surg 2017; 43:1140–1148
12. Wolffsohn JS, Buckhurst PJ. Objective analysis of toric intraocular lens rotation and centration. J Cataract Refract Surg 2010; 36:778–782
13. Naeser K. Assessment and statistics of surgically induced astigmatism. Acta Ophthalmol 2008; 86 (1):1–28
14. Savini G, Næser K. An analysis of the factors influencing the residual refractive astigmatism after cataract surgery with toric intraocular lenses. Invest Ophthalmol Vis Sci 2015; 56:827–835; erratum, 2303
15. American National Standards Institute, Inc. American National Standard for Ophthalmics – Toric Intraocular Lenses. New York, NY, ANSI Z80.30, 2010
16. Koshy JJ, Nishi Y, Hirnschall N, Crnej A, Gangwani V, Maurino V, Findl O. Rotational stability of a single-piece toric acrylic intraocular lens. J Cataract Refract Surg 2010; 36:1665–1670
17. 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
18. Marques EF, Ferreira TB, Simões P. Visual performance and rotational stability of a multifocal toric intraocular lens. J Refract Surg 2016; 32:444–450
19. Schartmüller D, Schriefl S, Schwarzenbacher L, Leydolt C, Menapace R. True rotational stability of a single-piece hydrophobic intraocular lens. Br J Ophthalmol 2019; 103:186–190
20. Entabi M, Harman F, Lee F, Bloom PA. Injectable 1-piece hydrophilic acrylic toric intraocular lens for cataract surgery: efficacy and stability. J Cataract Refract Surg 2011; 37:235–240
21. Seth SA, Bansal RK, Ichhpujani P, Seth NG. Comparative evaluation of two toric intraocular lenses for correcting astigmatism in patients undergoing phacoemulsification. Indian J Ophthalmol 2018; 66:1423–1428
22. Gundersen KG. Rotational stability and visual performance 3 months after bilateral implantation of a new toric extended range of vision intraocular lens. Clin Ophthalmol 2018; 12:1269–1278
23. Bascaran L, Mendicute J, Macias-Murelaga B, Arbelaitz N, Martinez-Soroa I. Efficacy and stability of AT TORBI 709M toric IOL. J Refract Surg 2013; 29:194–199
24. Hirnschall N, Maedel S, Weber M, Findl O. Rotational stability of a single-piece toric intraocular lens: a pilot study. Am J Ophthalmol 2014; 157:405–411
25. Draschl P, Hirnschall N, Luft N, Schuschitz S, Wiesinger J, Rigal K, Findl O. Rotational stability of 2 intraocular lenses with an identical design and different materials. J Cataract Refract Surg 2017; 43:234–238
26. Shah GD, Praveen MR, Vasavada AR, Vasavada VA, Rampal G, Shastry LR. 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
27. 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

OTHER CITED MATERIAL

A. Sifi Medtech Srl. Mini Toric Calculator. Available at: www.minitoriccalculator.com. Accessed June 13, 2019
B. Chang DH. ANSI standards for toric IOLs. Cataract and Refractive Surgery Today. Available at: https://crstoday.com/articles/2013-jun/ansi-standards-for-toric-iols/. Accessed June 13, 2019. 32

Disclosures: *None of the authors has a financial or proprietary interest in any material or method mentioned.*