



Rotational stability and visual performance of aberration-free, hydrophobic acrylic monofocal toric intraocular lens with enhanced material

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Purpose: To evaluate the rotational stability and visual performance of the enVista toric intraocular lens (IOL) (MX60ET) in cataract patients with preexisting astigmatism.

Setting: 6 U.S. sites.

Design: Prospective, multicenter.

Methods: Cataract patients 18 years and older with preexisting astigmatism (0.77 to 4.53 diopters [D]) underwent phacoemulsification and implantation of enVista toric IOL (MX60ET). Outcome measures were the proportion of patients with absolute IOL axis rotation of ≤ 5 degrees, uncorrected and corrected distance visual acuities (UDVA and CDVA) at 4 m, uncorrected intermediate visual acuity (UIVA) at 66 cm, manifest refraction, and adverse events. The patients were followed up on days 1 to 2, 7 to 14, 30 to 60, and 120 to 180.

Results: Mean astigmatism of 101 eyes (101 patients) reduced from 1.47 ± 0.64 D preoperatively to 0.38 ± 0.38 D at days 120 to 180 ($P < .001$), with 88.1% ($N = 89/101$) of eyes achieving astigmatism within 0.75 D. Mean postoperative UDVA and UIVA were 0.10 ± 0.16 and 0.25 ± 0.15 logMAR, respectively. While 79.2% ($N = 80/101$) of patients had postoperative UDVA of 20/32 or better, 63.9% ($N = 62/97$) had UIVA of 20/40 or better. The mean toric IOL rotation from the operative visit to days 30 to 60 was 1.97 ± 2.06 degrees, with 97.4% ($N = 74/76$) of eyes showing toric IOL rotation of 5 degrees or less.

Conclusions: The enhanced enVista toric IOL (MX60ET) demonstrated excellent rotational stability and astigmatic outcomes indicating good efficacy of the IOL for the correction of astigmatism during cataract surgery.

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Toric intraocular lenses (IOLs) are highly effective at correcting astigmatism during cataract surgery. Precise alignment and postoperative rotational stability of the toric IOL are vital to achieving optimal astigmatic outcomes.¹ Toric IOLs may rotate postoperatively because of anatomical or surgical factors such as large capsular bag diameter and incomplete ophthalmic viscosurgical device removal. Furthermore, IOL material and haptic design may affect rotational stability, resulting in toric IOLs being more or less resistant to rotation from such factors.²

The enVista toric IOL (MX60T) is one such IOL that is purposefully designed to be rotationally stable. Its modified C-loop haptics provide a relatively large 110-degree contact angle between the 2 haptics and the circumference of the capsular bag. Clinical data available to date demonstrate

good clinical performance of the MX60T IOL, yielding excellent visual and refractive outcomes along with good rotational stability of the IOL after implantation.^{3–6}

The hydrophobic acrylic material of enVista platform is 25 times harder than traditional hydrophobic lenses. While this surface hardness makes the IOL resistant to scratches and abrasions that may occur during loading and surgical manipulation, the parent MX60/MX60T IOLs required a higher injection force and longer relaxation time. A new version of enVista IOL (MX60E/MX60ET) has been developed with enhanced IOL unfolding, but retaining the other characteristics of the parent IOL platform (including the 110-degree contact angle). A small increase in poly (ethylene glycol) phenyl ether acrylate and a decrease in styrene from the parent IOL model allows better injectability with faster and

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improved unfolding efficiency (4 to 5 times quicker opening) compared with the parent IOL.⁷

This study evaluates the visual and refractive outcomes and rotational stability of the enhanced enVista toric (MX60ET) IOL implanted in cataract surgery patients with preexisting corneal astigmatism.

METHODS

This prospective, multicenter, postmarket study conducted at 6 U.S. sites recruited 103 eyes of 103 cataract patients with preexisting corneal astigmatism desirous of undergoing cataract surgery and toric IOL implantation in 1 or both eyes (NCT05739656). The study adhered to the tenets of the Declaration of Helsinki. The approval was provided by a central Institutional Review Board (IRB) Advarra. Patients meeting the study eligibility criteria were offered enrollment in the study. Patients willing to participate were asked to sign the IRB-approved informed consent form. The patient was considered enrolled in the study after the patient signed the informed consent form.

Only 1 eye of the patient was considered as the study eye. For patients with bilateral cataracts, the eye with the worse corrected distance visual acuity (CDVA) at the preoperative visit was designated as the study eye. If CDVA was same for both eyes, the right eye was designated the study eye. Only the study eye data were collected.

All the enrolled patients attended 6 study visits: preoperative visit (days -90 to -2), operative visit (day 0), and 4 postoperative visits (postoperative days 1 to 2, days 7 to 14, days 30 to 60, and days 120 to 180).

Eligibility Criteria

Patients 18 years and older who met all the following eligibility criteria in at least 1 eye were enrolled. Inclusion criteria were a clinically significant cataract that is considered amenable to treatment with standard phacoemulsification cataract extraction, required toric lens power from 1.25 to 5.75 diopters (D) in the IOL plane/0.90 to 4.03 D in the corneal plane (preoperative against-the-rule [ATR]/with-the-rule [WTR] corneal astigmatism between 0.77 D and 4.53 D), had a projected CDVA of 20/30 or better after toric IOL implantation, required spherical equivalent lens power from 17.0 to 24.0 D, and had a dilated preoperative pupil size ≥ 5.0 mm.

Contact lens wearers were required to demonstrate stable refraction (within ± 0.5 D of mean refraction spherical equivalent [MRSE]) on 2 consecutive examinations at least 7 days apart and discontinue contact lens use at least 2 weeks (for rigid or toric contact lenses) or 3 days (for soft contact lenses) before the first refraction.

Exclusion criteria were any anterior segment pathology that is likely to increase the risk of complications from phacoemulsification cataract surgery, associated ocular conditions that could affect IOL stability, clinically significant irregular corneal astigmatism as determined by the investigator, clinically significant corneal pathology potentially affecting topography of either eye, any ocular condition that could prevent the possibility of a visual outcome better than 20/30 in the study eye, and anterior chamber depth < 2.0 mm as measured by IOLMaster/Lenstar.

Presurgical and Surgical Technique

The Barrett Calculator (<http://ascrs.org/barrett-toric-calculator>) with predicted posterior corneal astigmatism was used for determining toric IOL power using preoperative keratometry (IOLMaster/Lenstar), phacoemulsification incision location, and predicted magnitude of surgically induced astigmatism. All eyes were targeted for emmetropia. Alignment of toric

IOL was performed using preoperatively made corneal ink marks.

Surgery was performed under either local or topical with or without intracameral ophthalmic anesthesia using a standard microsurgical technique. The surgeon's preferred ophthalmic viscosurgical device was used.

After cataract removal, the enhanced enVista 1-piece hydrophobic acrylic toric IOL (MX60ET, Bausch & Lomb, Inc.) was implanted in the study eye of the enrolled patient. It is commercially available in spherical equivalent powers of +17.0 to +24.0 D, with toric cylinder powers of 1.25 D, 2.00 D, 2.75 D, 3.50 D, 4.25 D, 5.00 D, and 5.75 D. The study IOL was not implanted if there was a zonular rupture, if the anterior or posterior capsule was compromised, or if any complication occurred, which, in the investigator's judgment, may cause untoward effects.

Outcome Measures

The study outcome measures included an assessment of the proportion of patients with absolute lens axis rotation of ≤ 5 degrees at postoperative days 30 to 60 from surgical placement. IOL rotation was assessed using a photographic technique. At the time of surgery, baseline photographs of the IOL position were captured through the surgical microscope to document the final position of the IOL postoperatively. At each follow-up visit, pupil-dilated retroilluminated digital slitlamp photographs showing the location of the IOL axis markings, limbal vessels, and iris features were also obtained. These photographs were shared with an independent reading center, where the operative and postoperative photographs were analyzed using ocular landmarks to determine the magnitude and direction of IOL rotation.

IOL rotation from the surgical placement angle was computed as follows.

$$\Delta_{\theta} = \left(\theta_L - \frac{\theta_{R1} + \theta_{R2}}{2} \right) - \left(\theta_T - \frac{\theta_{T1} + \theta_{T2}}{2} \right)$$

Where Δ_{θ} = misalignment from the surgical placement, θ_L = the lens angle at the postoperative visit, θ_{R1} = the angle of the first anatomical reference feature at the postoperative visit, θ_{R2} = the angle of the second reference feature at the postoperative visit, θ_T = the angle of the surgical placement at the operative visit, θ_{T1} = the angle of the first reference feature at the operative visit, and θ_{T2} = the angle of the second reference feature at the operative visit.

Effectiveness outcome variables included measurements of uncorrected and corrected distance visual acuity (UDVA and CDVA, 4 m) and uncorrected intermediate visual acuity (UIVA, 66 cm), change in the magnitude of astigmatism (postoperative refractive astigmatism was compared with preoperative keratometric astigmatism), vector analysis of astigmatic changes, manifest refraction, and adverse events (AEs).

Statistical Analysis

Of the 103 enrolled patients, 2 could not complete the scheduled follow-up visits (one patient moved out of the state and discontinued the study, and the other patient underwent explantation of study IOL and reimplantation of the sulcus IOL because of IOL dislocation and was terminated from the study by the study investigator). As such, all available data of 101 eyes of 101 patients were analyzed.

Statistical analyses were performed using the SPSS program v. 27.0 (SPSS, Inc.). The normality of the sample was evaluated using the Kolmogorov-Smirnov test. Categorical variables were expressed as frequency and percentage; continuous variables were expressed as means, SDs, minimum, and maximum. Visual acuities were presented in logMAR units and Snellen equivalent

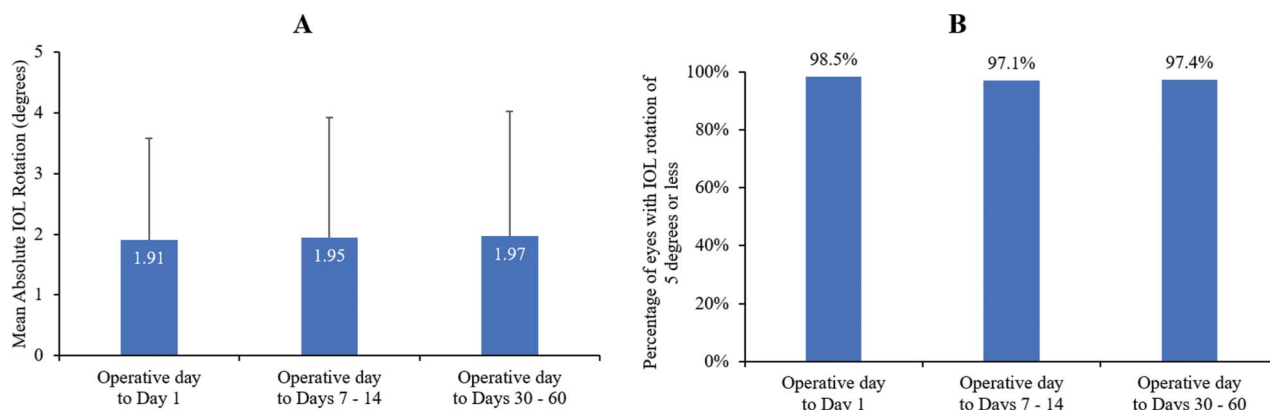


Figure 1. Histogram showing (A) mean absolute IOL rotation (degrees) and (B) percentage of eyes with absolute IOL rotation of 5 degrees or less at different postoperative visits from the operative visit.

where applicable. Normally distributed continuous variables were statistically analyzed using the paired *t* test or Wilcoxon signed-rank test when the data were not normally distributed. Results were considered significant when $P < .05$.

RESULTS

The mean age of the study population was 69.5 ± 8.1 years and comprised of 45.5% male and 54.5% female patients. The study population was primarily White (83.2%).

Rotational Stability

The mean absolute toric IOL rotation from the operative visit to postoperative day 1 was 1.91 degrees, to postoperative days 7 to 14 was 1.95 degrees, and to postoperative days 30 to 60 was 1.97 degrees. A total of 98.5% ($N = 66/67$) of eyes showed toric IOL rotation of 5 degrees or less (from the operative visit) at day 1 and 97.1% ($N = 66/68$) and 97.4% ($N = 74/76$) of eyes at days 7 to 14 and days 30 to 60, respectively (Figure 1, A and B). The direction of rotation from the operative day to day 1 was counter-clockwise in 55.2% ($N = 37/67$) of patients. Within postoperative visits, the mean IOL rotation from day 1 to the postoperative days 30 to 60 visit was 1.70 ± 1.76 degrees and from postoperative days 7 to 14 to days 30 to 60 visit was 1.25 ± 1.07 degrees.

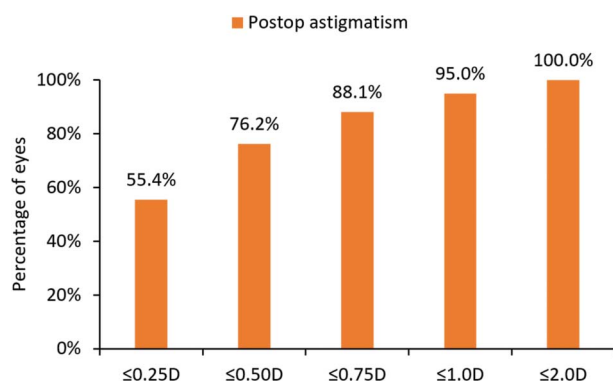


Figure 2. Histogram showing the frequency distribution of postoperative astigmatism in eyes that underwent implantation of en-Vista toric IOLs after cataract surgery.

The correlation analysis revealed that the axial length and anterior chamber depth did not affect the toric IOL rotation.

Astigmatic and Refractive Outcomes

Mean astigmatism reduced significantly from 1.47 ± 0.64 D preoperatively to 0.38 ± 0.38 D ($P < .001$) at postoperative days 120 to 180, with 76.2% ($N = 77/101$) and 88.1% ($N = 89/101$) of eyes achieving residual cylinder within 0.50 D and 0.75 D, respectively (Figure 2). The mean MRSE was -0.12 ± 0.36 D, and 87.1% ($N = 88/101$) of eyes had MRSE within ± 0.50 D.

The vectoral mean of astigmatism decreased from 0.95 D preoperatively to 0.25 D postoperatively (Figure 3). The centroid of postoperative astigmatism was closer to 0.0 D and had a smaller vectoral SD (represented by an ellipse) (Figure 4).

Visual Outcomes

The mean postoperative UDVA was 0.10 ± 0.16 logMAR ($\sim 20/25$ Snellen), and 79.2% ($N = 80/101$) of patients achieved UDVA of 20/32 or better at postoperative days 120 to 180. The mean postoperative CDVA was 0.01 ± 0.12 logMAR ($\sim 20/20.5$ Snellen), with 94.0% ($N = 95/101$) of eyes achieving CDVA of 20/32 or better postoperatively. The mean postoperative UIVA was 0.25 ± 0.15 logMAR ($\sim 20/36$ Snellen), with 63.9% ($N = 62/97$) of patients achieving UIVA of 20/40 or better.

Adverse Events

AEs were assessed in all 103 eyes of 103 patients who were enrolled and underwent surgery. None of the patients reported any AEs related to the study device. No damage in the IOL optic or haptic was noticed during or after implantation, and no glistenings were observed postoperatively. One patient had IOL decentration (due to weak zonular fibers), necessitating IOL explantation and re-implantation of a sulcus IOL.

DISCUSSION

Misalignment of toric IOLs, either because of inaccurate intraoperative alignment or because of postoperative rotation of the IOL, affects the efficacy of toric IOLs, yielding

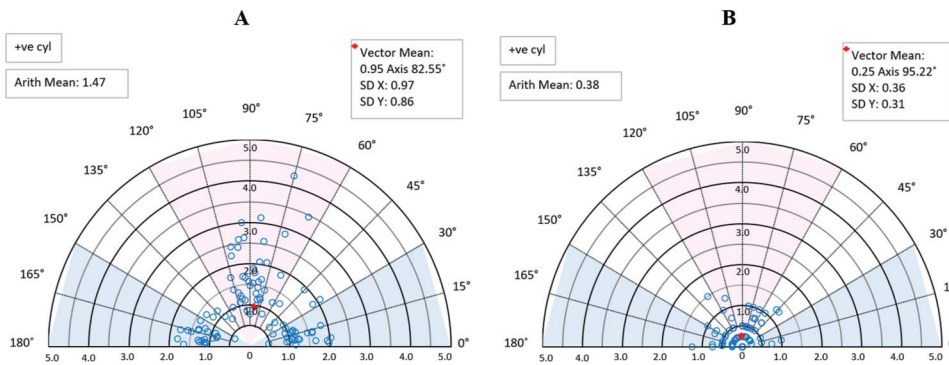


Figure 3. Single-angle polar plots of (A) preoperative astigmatism and (B) postoperative astigmatism.

suboptimal outcomes postoperatively. While many anatomical and surgical factors have been implicated to play a role in IOL rotation, there is increasing evidence in the literature that the characteristics of IOL, including its material, design of haptics, and unfolding speed, affect the rotation rate of IOLs.^{1,8–10}

This study evaluated the rotational stability and astigmatic and visual outcomes of the MX60ET IOL after implantation in astigmatic cataract patients. The mean absolute lens rotation of MX60ET IOL at day 1 was less than 2 degrees, with 98.5% of eyes showing toric IOL rotation of 5 degrees or less from the operative visit. At days 7 to 14 and 30 to 60, over 97% of eyes had toric IOL rotation of 5 degrees or less. The mean absolute rotation of MX60ET achieved in this study is lower than the literature-reported mean absolute rotation of the parent MX60T IOL (range 3.85 to 4.68 degrees; with 75% to 90.5% of eyes showing toric IOL rotation of less than 5 degrees at 1 month postoperatively).^{3–6} It is important to note that this study assessed IOL rotation as the deviation of the IOL axis from

the final position at the conclusion of surgery, whereas in previous publications with MX60T IOL, IOL rotation has been reported from the intended axis (ink marks).^{3–6}

The better rotational stability of enVista MX60ET in comparison with MX60T IOL could be due to the faster unfolding of MX60ET IOL. The IOLs with shorter unfolding times have been postulated to produce earlier and greater contact of haptics with the capsular bag equator, reducing the risk of incomplete unfolding of the haptics at the end of surgery.⁸ The findings of this study are in alignment with the published literature on the topic.^{8,11} The shorter unfolding time complements the rotational stability characteristics of the parent IOL platform. The step-vaulted, modified C haptics of MX60E/MX60ET IOLs vault the haptic posteriorly to form direct contact with the capsular bag. A single haptic of MX60E/MX60ET IOL is designed to make contact of 55 degrees with the capsular bag. This larger contact angle (total coverage of 110 degrees for the 2 haptics in contrast to the contact angle of 88 degrees and 84 degrees with the AcrySof and TECNIS IOL platforms, respectively) with the capsular bag increases the stability of the enVista IOL within the capsule.¹² The haptics also include fenestration holes that help evenly disperse postoperative capsular contractile forces. Zonular integrity and the compression forces of the capsular bag help stabilize the IOL position after implantation.¹³ The broad contact angle of the MX60E/MX60ET IOLs is also complemented by the high haptic compression force (300% higher than the traditional hydrophobic acrylic IOLs) to provide better centration and rotational stability of the IOL.

Literature comparison of the rotational stability of MX60ET with other toric IOL models that encompass C-loop haptics also showed rotation rates of MX60ET to be better than or comparable with other toric IOL models. This comparison included IOL rotation measured using the same methodology, that is, the postoperative position of the IOL at the defined follow-up in reference to IOL orientation at the end of surgery. For comparison, the percentage of eyes showing toric IOL rotation within 5 degrees ranged from 35% to 92% for AcrySof and 82% for TECNIS toric IOLs.^{14,15} The results achieved in this study also corroborate the previously published findings with other recently developed toric IOLs where changes in IOL material/design improved rotational stability of the modified IOLs vs their

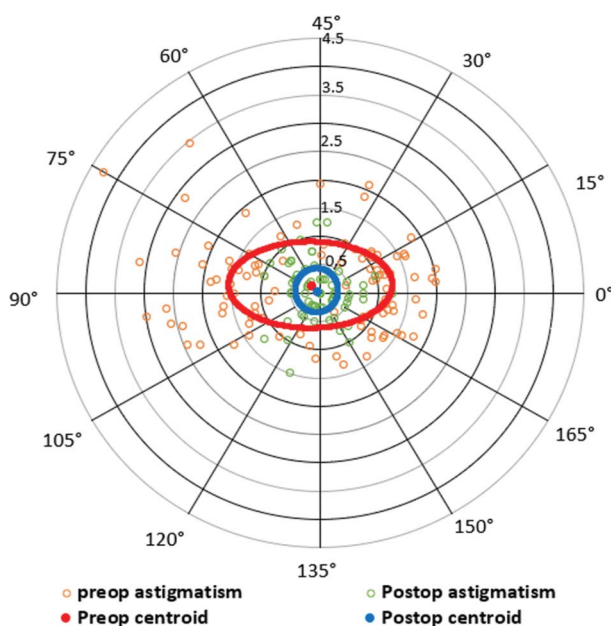


Figure 4. Double-angle vector plots showing preoperative and postoperative astigmatism.

parent IOL models.^{8,11,16–18} For instance, the introduction of frosted haptics in TECNIS toric II IOLs has been found to offer more surface texture and friction between the lens haptics and the capsular bag, improving the rotational stability of the TECNIS toric II IOLs compared with its predecessor.⁸ The rotational stability of enVista MX60ET IOL when compared with the TECNIS Toric II IOL was found to be comparable; the percentage of eyes with IOL rotation within 5 degrees was 97.4% for enVista MX60ET vs 96% to 100% for TECNIS toric II.^{17,18} The enVista MX60ET IOL also had better rotational stability compared with the Clareon toric IOL, with 84.4% of Clareon toric IOL patients showing toric IOL rotation of 5 degrees or less from the end of surgery to 1 month postoperatively vs 97.4% of enVista MX60ET–implanted patients showing toric IOL rotation of 5 degrees or less.¹⁹

In this study, the determination of the lens position at the time of surgery and postoperatively to calculate the rotation of the IOL was performed using the standardized photographic technique that involved the use of iris and scleral landmarks to align the baseline image at the time of implantation and for registration of the images for determination of axis alignment. The use of iris or scleral landmarks and fiducial marks helped control for head tilt, camera rotation, and other anomalies that can affect the perceived orientation of the lens.

Clinically significant IOL rotation may necessitate postoperative IOL repositioning. In this study, none of the MX60ET implanted eyes required toric IOL repositioning surgery. A study presented at ASCRS 2022 that assessed the rotational stability of various toric IOL platforms also showed the lowest rate of clinically significant rotation with enVista toric IOL (only 1.1% of enVista eyes had toric IOL repositioning surgery compared with the repositioning rates of 1.6% with the TECNIS II platform, 2.5% with the AcrySof platform and 5.7% with the TECNIS I platform).²⁰

The excellent rotational stability resulted in excellent astigmatic outcomes, with 76.2% and 88.1% of MX60ET–implanted eyes achieving postoperative residual cylinder within 0.50 D and 0.75 D, respectively. Vector analysis revealed an excellent reduction of astigmatism across WTR, ATR, and oblique orientations. While modern methods of toric IOL axis marking, including digital marking and iris registration, have been reported to be more accurate, the use of manual ink marks in this study also resulted in good astigmatic outcomes, indicating minimal alignment error with manual corneal marks in this study.

The MX60ET IOL also showed good visual outcomes, with 79.2% of eyes achieving a UDVA of 20/32 or better postoperatively. The increased depth of focus provided by the aberration-free optics (that helps maintain positive spherical aberrations of the cornea) of enVista toric IOL also resulted in good intermediate vision, with 64% of MX60ET–implanted eyes achieving UIVA of 20/40 or better postoperatively. The constant power across the entire optic zone results in spherical aberration-free optics that make enVista IOLs more resistant to typical amounts of tilt,

decentration, and defocus, resulting in better image quality compared with negative spherical aberration IOLs.^{21–25}

To conclude, the new MX60ET IOL with enhanced material properties showed excellent rotational stability, low residual cylinder, and good uncorrected visual acuity at distance and intermediate in patients undergoing cataract surgery.

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WHAT WAS KNOWN

- The parent enVista toric IOL (MX60T) has demonstrated good rotational stability and astigmatic outcomes.
- The enhanced MX60E IOL allows better injectability, with faster and improved unfolding efficiency compared with the parent IOL (MX60).

WHAT THIS PAPER ADDS

- This study presents the first clinical data on the enhanced enVista toric MX60ET IOL.
- MX60ET IOL showed excellent rotational stability, with 97.4% of eyes showing toric IOL rotation of 5 degrees or less and mean absolute toric IOL rotation of 1.97 ± 2.06 degrees at days 30 to 60 from the operative visit.
- The use of the MX60ET IOL provided predictable astigmatic outcomes postoperatively. A statistically significant reduction in mean astigmatism was achieved, and 88.1% of eyes had postoperative residual cylinder within 0.75 D.

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