




Rotation Characteristics of Three Toric Monofocal Intraocular Lenses

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Purpose: To evaluate the rotational stability of the three monofocal toric intraocular lenses (IOLs) via data from an online toric IOL back-calculator.

Methods: A retrospective data review of an online toric IOL back-calculator, which allows users to input preoperative toric planning information, postoperative lens orientation, and subjective refraction. Inputted data were used to determine the optimal orientation of the toric IOL to minimize residual refractive astigmatism. Aggregate data from 3/11/2019 to 3/10/2020 were extracted and validated. Only data with $\geq 0.5D$ of residual refractive astigmatism were used in the study. Pre-operative intended IOL orientation and post-operative IOL orientation were used to calculate IOL rotation.

Results: After validation, 5397 entries were determined to represent patient eyes, of which 3238 represented the three monofocal IOLs evaluated. The rate of rotation for AcrySof, TECNIS, and enVista Toric IOLs was 72.7%, 83.4%, and 83.0%, respectively, and location only significantly impacted TECNIS IOLs. The magnitude of rotation for rotated IOLs was similar for all models and was significantly more for IOLs initially placed in the oblique axis. All IOL models tended to rotate in a counterclockwise direction (53.2%, 73.0%, 69.7%, respectively; $p < 0.05$), and the tendency was greater for IOLs initially located horizontally.

Conclusion: The AcrySof IQ Toric IOL was more rotationally stable than both the TECNIS and enVista Toric IOLs; there was no significant difference in rotational stability of the latter two.

Keywords: astigmatism, rotation, AcrySof, TECNIS, enVista

Introduction

The majority of patients undergoing cataract surgery have a visually significant amount of anterior corneal astigmatism. In 2010, Hoffman et al published biometry data from 23,239 eyes which showed 73.7% had $\geq 0.5D$ of anterior corneal astigmatism, and over a third (36.05%) had $\geq 1.0D$ of astigmatism.¹ Toric intraocular lenses (IOLs), first approved by the US Food and Drug Administration (FDA) in 1998, are an effective way of reducing corneal astigmatism for these patients at the time of cataract surgery.² A visually significant amount of residual astigmatism after placement of a toric IOL may leave patient and surgeon alike unsatisfied and frustrated.

Residual refractive astigmatism occurs when a toric IOL has the wrong amount of cylinder power or is misaligned. A major cause of toric misalignment is postoperative rotation, which typically occurs soon after surgery.^{3,4} While the earliest models of toric IOLs frequently had significant postoperative rotation,⁵⁻⁸ modern

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models are much more rotationally stable.^{2,4,9–14} However, significant postoperative rotation can still occur.

In 2018, the enVista[®] toric (MX60T; Bausch & Lomb, Rochester, NY) was FDA approved.¹⁵ Initial rotational rates ($>5^\circ$) for this IOL have ranged from 9.5% to 23%.^{11,16,17} One study compared rotational rates of the enVista Toric (n=21) to the AcrySof[®] IQ Toric (n=28) (Alcon Vision LLC, Fort Worth, TX), and Lentis LT (n=14) (Oculentis, Berlin, Germany); rotation $\geq 5^\circ$ occurred in 9.5%, 35.7%, and 35.4%, respectively. The enVista Toric IOL was found to be the most rotationally stable of the three; however, the study was small and statistical significance was not reported for these specific findings.¹⁶

The purpose of the current study was to use a large database to further evaluate and compare rotational characteristics of three monofocal toric IOLs available in the US: enVista, AcrySof IQ, and TECNIS[®] Toric (Johnson & Johnson, New Brunswick, NJ).

Patients and Methods

This analysis was based on data input to an online toric back calculator (www.astigmatismfix.com; hereinafter “AstigmatismFix”) which was designed to assist surgeons in managing residual refractive astigmatism after surgical placement of a toric IOL. The University of North Carolina Office of Human Research Ethics was contacted regarding this study and determined that it did not constitute as human subjects research as defined under federal regulation and further Institutional Review Board approval was unnecessary. No patient identifying data is stored from the website, therefore all data accessed complied with relevant data protection and privacy regulations.

Raw data from AstigmatismFix were collected from 3/11/2019 through 3/10/2020. The start date was determined by the first enVista Toric IOL entry being made on 3/11/2019, and the study lasted 1 year. The data were then validated using data filters listed in **Box 1**. If a user with the same first and last name made multiple entries within a single calendar day, only the first of those entries was used in the final dataset to prevent over representation of a single case. A similar method of data validation was used with the AstigmatismFix data sets in previous studies.^{18–22}

The amount of rotation was calculated by taking the difference of the pre-operative intended IOL orientation and the post-operative IOL orientation. An IOL was said to have rotated if this difference was $\geq 5^\circ$. To determine

Box 1 Validation Criteria

- Patient eye (right eye, left eye)
- Intended IOL axis ($\geq 0^\circ$ to $\leq 180^\circ$)
- IOL types (all types listed on website)
- Current sphere (≥ -6 to ≤ 6)
- Current axis ($\geq 0^\circ$ to $\leq 180^\circ$)
- IOL cylinder power (≥ 0 to ≤ 10)
- Current IOL axis ($\geq 0^\circ$ to $\leq 180^\circ$)
- IOL SE (≥ 5 to ≤ 34)
- Subsequent entries made on the same calendar day with the same first and last name were eliminated.

Abbreviations: IOL, intraocular lens; SE, spherical equivalent.

rotation direction (clockwise vs counterclockwise), it was assumed the IOL rotated $<90^\circ$. A subset analysis was performed by stratifying results based on the intended IOL location. IOLs were said to be with-the-rule (WTR) when located $\geq 60^\circ$ to $<120^\circ$, against-the-rule (ATR) when located $\geq 0^\circ$ to $<30^\circ$ and $\geq 150^\circ$ to $<180^\circ$, and oblique when located $\geq 30^\circ$ to $<60^\circ$ and $\geq 120^\circ$ to $<150^\circ$.

All data validation, calculations, and statistical analyses were performed via Microsoft[®] Excel for Mac (Version 16.35; Microsoft Corporation, Redmond, WA). For rotation frequency, odds ratios were calculated and chi-square tests were performed; for magnitude of rotation, analysis of variance (ANOVA) and equal variance two-tailed Student's *t*-tests were conducted; for rotation direction, a one-proportion *z*-test with the probability of clockwise or counter-clockwise rotation set at 50%. Statistical significance was set at $p < 0.05$.

Results

There was a total of 26,949 AstigmatismFix entries between 3/11/2019 and 3/10/2020. After validation, 5397 entries were determined to represent actual cases. Three monofocal toric IOL models were identified and used in the final dataset: AcrySof IQ Toric, TECNIS Toric, and enVista Toric. Characteristics of this final dataset of 3238 toric IOLs can be seen in **Table 1**.

Rotation Frequency

The rate of rotation $\geq 5^\circ$ was 77.4% (4177/5397) for the entire validated dataset, and 77.7% (2517/3238) when only considering the three monofocal IOLs listed above. The rotation rate for the AcrySof, TECNIS, and enVista toric IOLs was 72.7% (1240/1706), 83.4% (1091/1308), and 83.0% (186/224) respectively. Comparison of rotation rates for the three IOLs can be seen in **Table 2**, where it is shown that the

Table 1 Dataset Characteristics

Laterality	
Right eye	1612 (49.8%)
Left eye	1626 (50.2%)
IOL Model	
AcrySof	1706 (52.7%)
TECNIS	1308 (40.4%)
enVista	224 (6.9%)
Residual Astigmatism	
Mean	1.85D ± 1.05D
Range	0.5–9.0D
Type of Preoperative Astigmatism	
WTR	1390 (42.9%)
ATR	1362 (42.1%)
Oblique	486 (15.0%)

Notes: WTR, with-the-rule (≥60 to <120); ATR, against-the-rule (≥0 to <30 and ≥150 to <180); Oblique, (≥30 to <60 and ≥120 to <150).

Abbreviations: D, diopter; IOL, intraocular lens.

Table 2 Comparison of Toric IOL Rotation (≥5°)

	enVista v. AcrySof (Control)	TECNIS v. AcrySof (Control)	enVista v. TECNIS (Control)
Odds ratio	1.84	1.89	0.97
95% CI	1.28 to 2.65	1.58 to 2.26	0.67 to 1.42
p-value	0.0011	<0.001	0.89

Abbreviation: IOL, intraocular lens.

AcrySof toric IOL rotated significantly less frequently than both the TECNIS (p<0.001) and enVista (p=0.0011) toric IOLs. There was no statistical difference in rotation between the TECNIS and enVista toric models. Rotation rates for each IOL at multiple cutoff points can be seen in Table 3.

Rotation Magnitude

A subset analysis which included the 2517 IOLs that rotated was performed to determine the average magnitude

Table 3 Rotation Rates for Three Toric IOLs at Multiple Cutoff Points

	AcrySof	TECNIS	enVista	Total
Rotation ≥5°	72.7%	83.4%	83.0%	77.7%
Rotation ≥10°	57.7%	71.7%	75.4%	64.6%
Rotation ≥15°	43.6%	57.9%	56.3%	50.2%
Rotation ≥20°	32.6%	47.2%	45.5%	39.4%
Rotation ≥30°	18.8%	27.7%	26.3%	22.9%

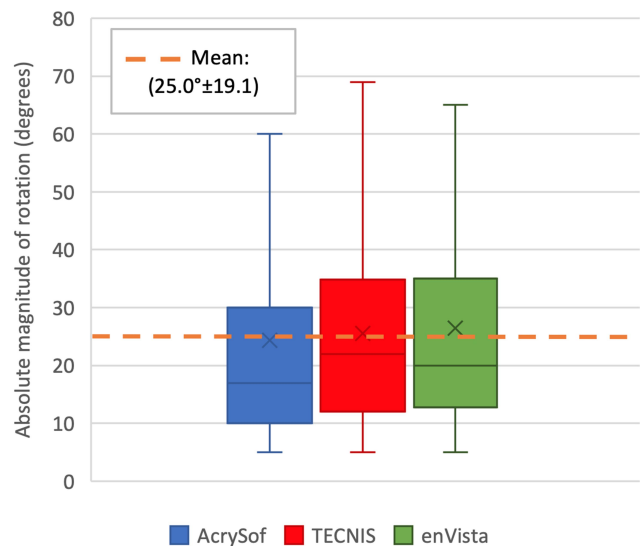


Figure 1 Box and whisker plot of the magnitude of rotation for each IOL model. Only IOLs which rotated ≥5° were considered in this subset analysis. ANOVA showed no statistical difference between the three groups when considered as a whole (p=0.176). A two-tailed, equal variance Student's t-test was performed and showed no difference when comparing the groups head-to-head. (AcrySof v. TECNIS p=0.126; AcrySof v. enVista p=0.191; TECNIS v. enVista p=0.513).

of rotation. There was no statistical difference in magnitude of rotation for the three IOL models (Figure 1).

Rotation Direction

Another subset analysis which excluded IOLs that did not rotate in addition to 15 IOLs located orthogonal from their intended location was performed to determine any bias in rotation direction (n=2502). The AcrySof, TECNIS, and enVista Toric IOLs all had a bias toward counterclockwise (CCW) rotation (53.2%, 73.0%, and 69.7%, respectively) (p<0.05).

Location

The above findings of frequency, magnitude, and direction of IOL rotation were stratified by the intended IOL location and can be seen in Table 4. The major findings were as follows: 1) TECNIS IOLs placed ATR appear to rotate less than those placed WTR or oblique; 2) when IOLs rotate, those placed obliquely rotate at higher magnitudes (Figure 3); 3) when IOLs rotate, those placed ATR favor counterclockwise rotation more so than those placed WTR or obliquely.

Discussion

When considering the results of this study, it is crucial to understand that its population consists solely of cases of residual astigmatism, and therefore the frequency of

Table 4 Effects of IOL Location

	Frequency of Rotation	Magnitude of Rotation	CCW Rotation
AcrySof			
WTR	71.6%	24.4±21.0 ^{ob}	45.3% ^c
ATR	74.5%	23.2±20.0 ^{ob}	60% ^c
Oblique	70.5%	27.6±22.1 ^{ob}	53.7%
TECNIS			
WTR	85.6% ^a	23.8±15.9 ^{ob}	64.9% ^c
ATR	79.7% ^a	26±16.7 ^{ob}	83% ^c
Oblique	86.1% ^a	29.9±20 ^{ob}	74.1% ^c
enVista			
WTR	86.5%	26.2±19.9 ^o	57.9%
ATR	80.7%	25.6±17.1 ^o	80.4% ^c
Oblique	81.0%	32.5±22.9 ^o	64.7%
Total			
WTR	78.7%	24.3±18.7 ^{o b}	55.6% ^c
ATR	76.9%	24.5±18.6 ^{o b}	70.7% ^c
Oblique	77.2%	28.9±21.2 ^{o b}	63.3% ^c

Notes: ^ap<0.05, chi-square test performed on each group individually (ie TECNIS WTR v. ATR v. oblique); ^bp<0.05, ANOVA performed on each group individually (ie AcrySof WTR v. ATR v. oblique); ^cp<0.05, one proportion z-test with expected frequency 50% (performed on each category individually).

Abbreviations: IOL, intraocular lens; CCW, counterclockwise; WTR, with-the-rule; ATR, against-the-rule.

rotation is largely overestimated compared to the population of total implanted toric IOLs. However, this database and method were used previously to compare rotation rates of IOL models,¹⁸ and those findings were later supported by additional publications.^{4,23} Only one known study previously compared the rotation rate of the enVista Toric IOL to others, and the results showed enVista was more

rotationally stable than the AcrySof and Lentis LT IOLs. Although this study was small (n=63, for monofocal toric IOLs) and statistical significance was not reported for rotation frequency. This study found the opposite; both the enVista and TECNIS IOLs were 1.84x and 1.89x more likely to rotate than the AcrySof IOL (p<0.05). The rotational stability of AcrySof IOLs compared to TECNIS IOLs is similar to that found in previous studies,^{4,18,23} and this is the first known comparison of the TECNIS and enVista IOLs, of which there was no statistical difference. Variability in rotational stability among different IOL models is thought to be due to either IOL design or material, although an exact mechanism has yet to be proven. Johnson & Johnson has addressed the rotational instability of the TECNIS IOL by launching the TECNIS Toric II in late 2019, which has squared and frosted edges at the end of the haptic.²⁴ Bausch & Lomb is also in the process of transitioning from the MX60T to the MX60ET. The rotational stability of these newer IOL versions has yet to be published.

The location in which IOLs are placed has also been shown to affect the frequency of rotation.^{4,25} In this study, location only significantly affected the rotation rate in the TECNIS group, which showed IOLs initially placed vertically (WTR) or obliquely rotated more than those placed horizontally (ATR). The anatomy of the capsular bag or gravity may play a role in this slight predisposition.

A tendency to rotate counterclockwise has been described for both TECNIS and enVista IOLs.^{4,16,18,23} This was also found to be true in this study (Figure 2). Regarding AcrySof IOLs, there is no consensus, as clockwise (CW),^{16,25,26}

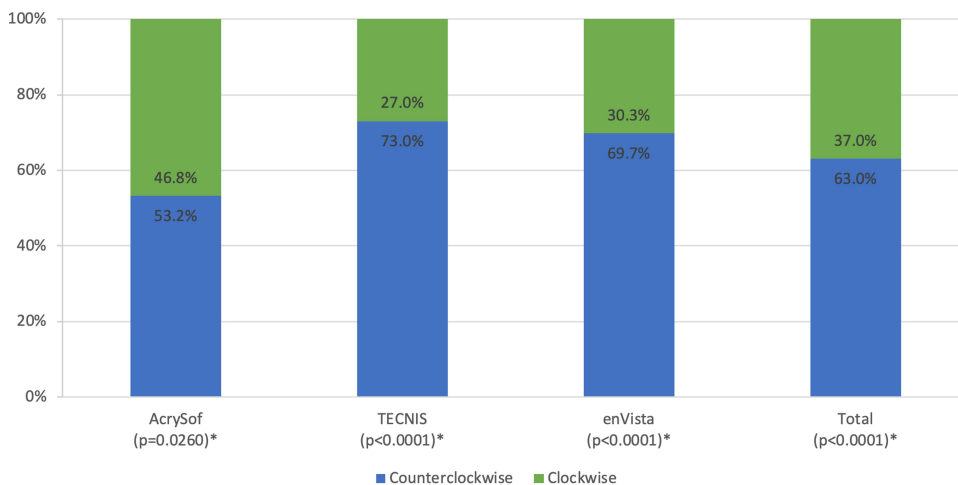


Figure 2 Stacked bar graph of the direction of rotation. A one-proportion z-test was performed with the expected amount of IOLs rotating counterclockwise set at 50%. * denotes groups which were statistically different (p<0.05).

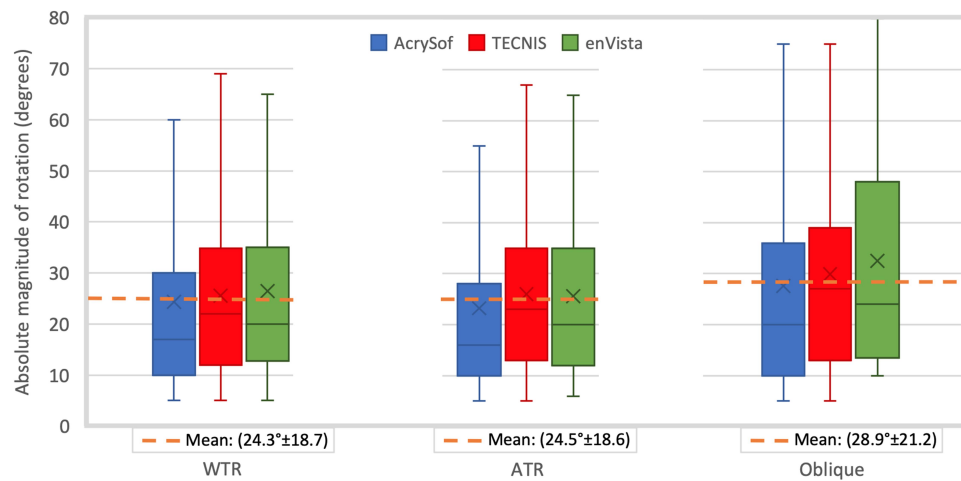


Figure 3 Box and whisker plot of the magnitude of rotation stratified by IOL model and intended IOL location. Via ANOVA, the intended IOL location effected magnitude significantly in the AcrySof ($p=0.0415$) and TECNIS ($p<0.001$) groups, but not the enVista group ($p=0.382$). This was largely due to the increased magnitude of rotation for IOLs located obliquely, and there were only 17 enVista entries in this subset.

CCW,²³ and no direction^{18,27} tendencies have been described. In this study, there was a slight tendency for AcrySof IOLs to rotate CCW (53.2%). When considering the initial location of the IOL, there is a clear tendency for IOLs located horizontally (ATR) to rotate CCW for all IOLs (Table 4). While all locations still had a bias toward CCW rotation for TECNIS and enVista (note: WTR and oblique enVista categories failed to reach statistical significance), for AcrySof each category was different; horizontal (ATR) IOLs tended to rotate CCW, vertical (WTR) CW, and oblique did not have a bias. This may explain the conflicting literature regarding AcrySof IOLs as Miyake et al, who showed a CW tendency, had 100% of IOLs initially located vertically, and Oshika et al, who showed a CCW tendency, had 72% of IOLs initially located horizontally.^{23,25} The tendency for AcrySof IOLs located vertically (WTR) to rotate CW and horizontally (ATR) to rotate CCW seems to support the findings of Lee et al, although a specific statistical analysis regarding this was not performed in their study.⁴

The magnitude of rotation was greater in IOLs initially placed obliquely, which to our knowledge has not been shown before, and was similar for all three IOL models.

Limitations of the study include that AstigmatismFix was not created for the purpose of conducting research, rather it is a freely available tool designed with the primary goal of helping surgeons manage post-operative residual astigmatism in patients who received a toric IOL. Prompts have been added to the website that allows users to label repeat and theoretical entries; however, even with these additions and the rigorous validation criteria described above, there is noise within the data. Regarding

rotation calculations, the assumption was made that the surgeon accurately placed the IOL where they intended to, and therefore any postoperative misalignment was secondary to IOL rotation. It is also possible that postoperative misalignment was due to intraoperative misplacement. However, there is no reason to believe users of any particular toric IOL model would be more or less likely to misplace them, and therefore this unlikely skewed any results. It has also been shown that the majority of postoperative misalignment is in fact due to rotation.³ The enVista group was much smaller than the AcrySof and TECNIS groups. Further controlled studies should be performed to confirm these findings.

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