ORIGINAL RESEARCH

Predictability of Residual Postoperative Astigmatism After Implantation of a Toric Intraocular Lens Using Two Different Calculators

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Purpose: To compare predictability of postoperative refractive astigmatism (RA) using the Emmetropic Verifying Optical (EVO) Toric Formula v2.0 to one that accounts only for anterior corneal astigmatism.

Methods: This is a secondary analysis of de-identified data from a clinical trial including 9 sites across the United States. Preoperative biometry was used to predict postoperative RA with the implanted toric IOL using legacy enVista and EVO online calculators. The RA prediction error was computed between back-calculated postoperative RA and predicted residual RA. Outcome measures included vector (centroid) and arithmetic mean RA prediction error.

Results: Comparison of calculators was based on 109 eyes, 97 (89%) of which were implanted with a toric IOL with an effective astigmatism power of 1.4 D or less. Centroid of the RA prediction errors was 0.37 D @ 178 and 0.17 D @ 090 for the legacy and EVO calculators, respectively (p < 0.0001). The proportion of eyes with an absolute RA prediction error ≤0.5 was 47.3% and 49.1% (p = 0.78), while the proportion of eyes ≤1.0 D was 82.7% and 89.1% (p = 0.03). Differences in the proportions ≤0.5 D existed for WTR (p = 0.015) but not ATR (p = 0.75) eyes. The proportion in which orientation of the predicted RA (ATR, WTR, or oblique) matched the actual RA was 62% and 78% for legacy and EVO calculators, respectively (p = 0.0029).

Conclusion: The EVO Toric Formula v2.0 out-performed the legacy calculator with regards to predictions in eyes with low astigmatism.

Keywords: cataract, toric, intraocular lens power, astigmatism, calculators, EVO

Plain Language Summary

Cataract surgery involves removal of the cloudy lens from the eye and replacement with an artificial one. Surgeons choose the power of this artificial lens by taking measurements of the shape of the eye and entering them into a formula. When the lens power is chosen appropriately, it may reduce the need for glasses after surgery. The surgeon's ability to correctly choose the power of this lens depends on accuracy of the measurements and the formula used.

Astigmatism is a defect in the curvature of the eye that results in distorted images. Toric intraocular lenses can be used to correct this. Historically, all of the astigmatism in an eye was assumed to come from the front surface of the eye. It is now understood that other internal interfaces also contribute to total astigmatism. This study sought to investigate the performance of two formulas used for lens power calculations, namely one that accounts for astigmatism measured at the very front of the eye and a second that accounts for additional internal contributors to total astigmatism.

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Results from this study showed that using the new formula resulted in less prediction error than when the older formula was used. Using the new formula to estimate and correct patients' astigmatism is likely to result in fewer patients needing glasses after cataract surgery. It is recommended that surgeons use a modern formula that takes into account all contributors to astigmatism when choosing the power of toric intraocular lenses.

Introduction

Nearly 40% of eyes have clinically significant astigmatism >0.5 D,[1] and its correction has become a common goal of patients seeking spectacle independence after cataract surgery. The most effective treatment option is usually through use of a toric intraocular lens (IOL).[2] For surgeons, the preoperative planning involves reliance upon various calculators for choosing the astigmatic power and axis of alignment of the toric IOL. Historically, these calculators relied upon the assumption that most refractive astigmatism came from the anterior cornea. Outcomes based on these assumptions were fair, with multiple authors reporting mean refractive astigmatism between 0.4 and 0.6 D and proportions with less than 0.5 D residual astigmatism between 50% and 70%.[3,4]

As our understanding of the contribution of astigmatism from the posterior cornea evolved,[5] methods were developed to incorporate its effect. For example, the Baylor toric nomogram adjusts the measured keratometric astigmatism (KA) to account for the posterior corneal astigmatism (PCA) contribution.[6] The Barrett toric calculator (BTC) is another popular formula that uses a proprietary algorithm to not only account for empirically derived PCA but also adjusts the toric power based on the estimated effective lens position (ELP).[7] Several studies have demonstrated the superiority of the BTC over legacy methods that only account for KA. In one such study, Abulafia et al reported centroid errors of predicted astigmatism of ≈ 0.55 D when using two different legacy calculators, compared with only 0.02 D with the BTC.[8]

The enVista Toric Calculator (Bausch & Lomb, Bridgewater, NJ) is a proprietary legacy calculator based upon the vector addition of KA and surgically induced astigmatism (SIA). It does not take into account effective lens position (ELP) of the toric IOL when predicting postoperative residual astigmatism. On the other hand, the Emmetropic Verifying Optical (EVO) formula[9] is a new thick lens formula that takes into account the optical dimensions of the eye and can handle different IOL geometries and powers. Its equivalence to the Barrett

Universal II with regards to spherical equivalent (SE) outcomes has been recently validated in a large retrospective analysis of over 13,000 eyes.[10] The EVO Toric Formula v2.0 adds astigmatism correction capability to the original EVO and combines theoretical posterior corneal astigmatism prediction with thick lens modeling for different types of toric IOLs. A recent study by Kane et al demonstrated near equivalence of the BTC and EVO Toric formulas,[11] but the study made no comparisons to legacy calculators as a point of reference. The Kane study also only studied a single IOL [Alcon Acrysof Toric (SN6ATx)], and there are no studies evaluating the EVO Toric Formula v2.0 on other IOL platforms. For example, the lowest powered enVista toric IOL (MX60ET125, Bausch & Lomb) corrects approximately 0.9 D of astigmatism at the corneal plane, and steps up at different intervals than the Alcon Acrysof Toric IOL (SN6ATx); it is unclear whether a difference between legacy and EVO Toric calculators can still be appreciated when lower levels of astigmatism correction are sought. Thus, the purpose of this study was to investigate the relative predictability of residual refractive astigmatism (RA) using legacy enVista Toric[12] and Emmetropic Verifying Optical (EVO)[9] Toric Formula v2.0 IOL calculators.

Patients and Methods

This was a secondary analysis of de-identified data from a prospective multi-center clinical trial that was designed to evaluate the safety and effectiveness of a one-piece acrylic toric intraocular lens (enVista Toric MX60T, Bausch & Lomb, Bridgewater, NJ). The original study design as well as the description of pre-surgical and surgical technique have been previously published.[13] Keratometric power measurements were taken using an automated optical biometer (IOLMaster, Carl Zeiss Meditec) and consistency and regularity of the astigmatism was confirmed using corneal topography. Visual acuities and refractions were tested at 4 m using the standard Early Treatment Diabetic Retinopathy Study chart at 85 cd/m[2] illumination. All refractions were conducted using 0.25 D steps with a Jackson cross cylinder method for cylinder refinement. The dataset included 112 eyes from 112 subjects with predicted postoperative astigmatism between 0.90 and 2.40 D. During the study, investigators were required to use the legacy enVista toric calculator to calculate the recommended toric IOL cylinder power and axis and predicted postoperative RA. The primary incision was constructed along the steep keratometric axis, and

surgery was completed using a 2.6 mm incision for non-wound assist, in-the-bag placement of the IOL. Actual axis of alignment and postoperative keratometry data were also available in addition to the manifest refraction. The original study was approved by a central Institutional Review Board (The IRB Company, Buena Park, CA); subsequent IRB approval was not required for the present study.

Pre- and postoperative keratometry data were entered into Warren Hill's surgically induced astigmatism (SIA) Calculator,[14] revealing a SIA vector mean (centroid) of 0.25 D @ 39 degrees for the study population. Using this magnitude, and the knowledge that the primary incision was placed along the steep axis, the predicted residual RA for the implanted IOL was calculated with the enVista legacy and EVO Toric Formula v2.0. To compensate for the fact that the two calculators' recommended axis of alignment differed from the actual axis of alignment at the time of surgery, the residual RA predictions from these calculators were compared to theoretically back-calculated postoperative RAs adjusted using the "remove and replace" method previously described by Hill et al.[15] Thus, the RA to which these calculator's predictions were compared was based upon the vector sum of the actual postoperative RA and the difference between the actual and recommended toric IOL powers and orientations (Formula 1).

1. Back-calculated postoperative refractive astigmatism = Actual postoperative refractive astigmatism + (astigmatism induced by the toric IOL at its actual axis of alignment – astigmatism induced by the toric IOL at the calculators' recommended axis)

Back-calculated and predicted RA from the two calculators were converted to the spectacle plane. Residual astigmatism prediction error, defined as the difference between the back-calculated and predicted RAs, was calculated for each calculator (Formula 2).

2. Residual astigmatism prediction error = Back-calculated postoperative refractive astigmatism – predicted postoperative refractive astigmatism.

This was done by converting all calculated and predicted RA vectors to Cartesian coordinates and subtracting corresponding x and y components, as previously described by Holladay.[16] The paired x and y differences were then converted back to polar coordinates to create a clinically

meaningful RA prediction error vector. Primary endpoints included the arithmetic and vector (centroid) means of the RA prediction error. Secondary endpoints included proportion of eyes with a RA prediction error magnitude less than 0.5, 0.75, or 1.0 diopters (D), and proportion of eyes in which the back-calculated RA matched the predicted RA with respect to astigmatism orientation [against-the-rule (ATR), oblique, or with-the-rule (WTR)]. ATR astigmatism was defined as having KA oriented within 30 degrees of the 0–180 meridian, and WTR astigmatism was defined as having KA oriented within 30 degrees of 90.

Statistical analysis was performed using SAS Software v9.4 (SAS Institute Inc., Cary, NC). Differences between RA prediction error centroids were evaluated by splitting them into x- and y-components for each eye and comparing the paired differences between calculators using a Hotelling's T-squared test.[17] Comparison of the RA prediction error arithmetic mean magnitudes (without respect to axis) were made using a repeated measures ANOVA. The proportion of eyes with a RA prediction error magnitude less than 0.5, 0.75, or 1.0 D and proportion of eyes in which the astigmatism orientation from calculated and predicted RA matched were all compared using generalized estimating equation methodology.[18] Results were considered significant at a p-value ≤ 0.05.

Results

The original dataset included 112 eyes from 112 patients. Three eyes were excluded based on a missing anterior chamber depth (1) or postoperative refraction (2), resulting in 109 eyes available for analysis. The demographics for these eyes are displayed in Table 1. The magnitude of KA was not normally distributed, but instead was concentrated towards lower magnitudes, as would be

Table 1 Demographics

Parameter	Mean ± SD (Range)
Age	71 ± 8.9 (40–89)
Gender	63 Females (57.8%), 46 Males (42.2%)
AL (mm)	23.66 ± 0.85 (20.95–26.14)
Keratometric Astigmatism (D)	1.74 ± 0.38 (1.24–2.86)
IOL Power (D)	20.62 ± 2.50 (16–27)
Postoperative Manifest Refraction	
Sphere (D)	−0.30 ± 0.45 (−1.50–1.00)
Cylinder (D)	0.66 ± 0.52 (0–2.50)

Abbreviations: AL, axial length; D, diopters; IOL, intraocular lens; SD, standard deviation.

Table 2 Residual Astigmatism Prediction Errors (Arithmetic and Centroid) by Method of Calculation (n=109)

	enVista	EVO	p-value
Mean ± SD (D)	0.63 ± 0.43	0.57 ± 0.38	0.10
Range (D)	0.03–2.23	0.03–1.84	
Median (D)	0.56	0.51	
Centroid ± SD (D)	0.37 ± 0.66 @ 179	0.17 ± 0.67 @ 090	x-component: p < 0.0001
			y-component: p = 0.8579

Abbreviations: D, diopters; EVO, Emmetropia Verifying Optical toric IOL formula v2.0; SD, standard deviation.

expected in any random sampling of eyes from the population. The orientation of the preoperative KA was as follows: 67 (61.5%) ATR, 38 (34.9%) WTR, and 4 (3.7%) oblique. Of eyes that received a toric IOL, 79 (72.5%) received a MX60T125, 18 (16.5%) received an MX60T200, and 12 (11%) received a MX60T275. These lenses have cylinder powers of 1.25, 2.0 and 2.75 D at the IOL plane and contribute approximately 0.9, 1.40, and 1.93 D of astigmatism correction at the corneal plane, respectively.

The RA prediction error arithmetic mean magnitudes and centroids for the calculators are displayed in Table 2 and Figure 1. When the entire sample was considered, the RA prediction error arithmetic mean magnitude was lower for the EVO calculator, but this difference did not reach significance (p = 0.10). However, the RA prediction error centroid for EVO was lower than that of the legacy calculator (p ≤ 0.0001). The RA prediction error centroid was oriented ATR with the legacy calculator and WTR for EVO. The proportion of eyes that had an arithmetic RA

prediction error magnitude less than or equal to 0.5, 0.75, and 1.0 D are displayed in Figure 2. The EVO had improved proportions within target at all three cut-offs, but this difference was only significant for the proportion within 1.0 D (p = 0.03) when the entire dataset was considered. The proportion of eyes in which the orientation of the predicted RA (ATR, WTR, or oblique) matched the actual RA was 62% and 78% for the legacy and EVO calculators, respectively (p = 0.0029).

Table 3 displays the RA prediction error arithmetic means and centroids for the ATR (n = 67) and WTR (n = 38) sub-groups. Double angle plots of the RA prediction error for each eye are also displayed in Figure 3. RA prediction error arithmetic means for the legacy calculator were higher in WTR than ATR eyes, and this difference approached statistical significance (p = 0.08). Conversely, the arithmetic means for the two different subgroups were similar with the EVO calculator (p = 0.55). The legacy toric calculator produced RA prediction error centroids oriented ATR for both sub-groups,
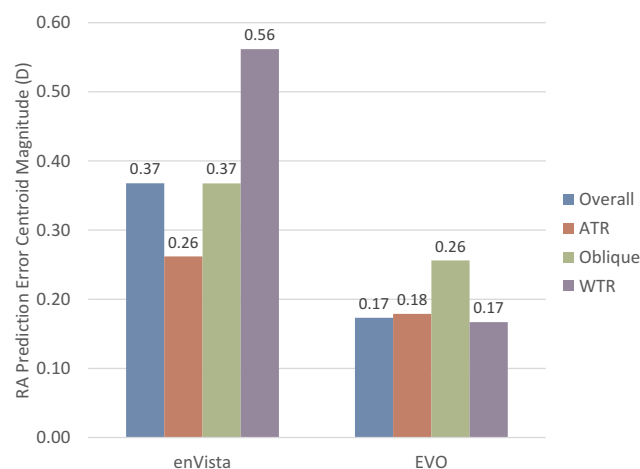
Figure 1 Residual astigmatism prediction error centroid magnitude by method of calculation.
Abbreviations: ATR, against-the-rule; D, diopters; EVO, Emmetropia Verifying Optical toric IOL formula v2.0; RA, refractive astigmatism; WTR, with-the-rule.
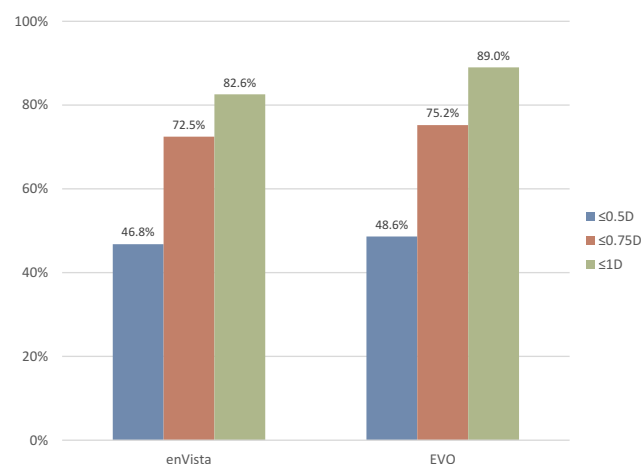
Figure 2 Proportion of eyes with arithmetic residual astigmatism prediction error within 0.5, 0.75, and 1.00 diopters (D).
Abbreviation: EVO, Emmetropia Verifying Optical toric IOL formula v2.0.

Table 3 Residual Astigmatism Prediction Errors by Method of Calculation in Eyes with Against- and with-the-Rule Astigmatism

	enVista	EVO	p-value

Against-the-rule (n = 67)
  Mean ± SD (D)
  Centroid ± SD (D)
	0.58 ± 0.43
	0.27 ± 0.67 @ 175
		0.59 ± 0.39
		0.18 ± 0.69 @ 095
			0.7673
			x-component: p < 0.0001
			y-component: p = 0.6405

With-the-rule (n = 38)
  Mean ± SD (D)
  Centroid ± SD (D)
	0.73 ± 0.42
	0.56 ± 0.64 @ 002
		0.54 ± 0.37
		0.17 ± 0.65 @ 082
			0.0055
			x-component: p = 0.0055
			y-component: p = 0.6189

p-values
  Means
  Centroids
	0.08
	0.0061
		0.55
		0.596	

Abbreviations: D, diopters; EVO, Emmetropia Verifying Optical toric IOL formula v2.0; SD, standard deviation.

while EVO's was oriented WTR. The RA prediction error centroid for the legacy calculator was higher in WTR than in ATR eyes (p = 0.0061), but this was not the case for the EVO calculator (p = 0.596). Comparing sub-groups across methods, the RA prediction error centroid for the legacy calculator was higher in both WTR (p < 0.0001) and ATR (p < 0.0001) eyes than with EVO.

Table 4 displays the RA prediction error for the two calculators, stratified by the toricity of the IOL implanted. Irrespective of toricity, the EVO calculator produced smaller RA prediction error centroids than the legacy calculator. This difference was significant in all three IOL groups (x-component p< 0.0001). Interestingly, there was a trend toward smaller standard deviations as the toricity of the IOL increased, regardless of the calculator used.

Discussion

As our understanding of contributions to corneal astigmatism has increased, so has the number of toric nomograms and calculators available. This complicates the choice for surgeons of which work best. By examining precisely which concepts are incorporated into each, we come away with a greater appreciation for why some calculators perform better than others. This increased understanding may also give surgeons the confidence to move from a calculator of habit to one that incorporates the newest concepts and improves results.

The enVista toric calculator, like the Acrysof iQ Toric (Alcon, Fort Worth, TX) and original Holladay Toric Calculators, may be considered a legacy calculator as total ocular astigmatism is calculated from anterior keratometry and SIA only. Furthermore, the legacy calculators

make no determination on the relationship between effective lens position and effective astigmatism from the toric IOL at the cornea plane. It is thus not surprising that the present study found that the enVista toric calculator resulted in a relatively high RA prediction error centroid magnitude, and that this centroid had an ATR orientation (0.37 @ 179). Note that the RA prediction error vector in the present study is consistent with previously published work from Abulafia et al (0.55 @ 180) on similar legacy calculators.[8,19] The higher RA prediction error vector magnitude and ATR orientation associated with these legacy calculators stem from the now well-established contribution of the posterior cornea. The posterior cornea is known to have its steep axis of curvature oriented vertically in 85–90% of cases, resulting in an optical contribution of ≈ 0.3 D oriented horizontally.[5]

The findings in the present study suggest that the EVO Toric Formula v2.0, which incorporates an empirically estimated posterior corneal astigmatism and effective lens position, performs better than the enVista legacy calculator, which relies only upon anterior corneal astigmatism. Comparison of these two calculators has not been previously reported, yet the results are not entirely surprising, and are consistent with findings in the existing literature. For example, a recent study by Kane et al comparing 6 different modern calculators found that the Barrett and EVO Toric Formulas were nearly equivalent, with 59.9% and 58.9% of eyes, respectively, having a RA prediction error ≤0.5 D.[11] Similar to the RA prediction error centroid reported in the present work (0.17 ± 0.67 D x 090), Kane also reported RA prediction error centroids for the Barrett and EVO Formulas of 0.10 ± 0.64 D x 111 and 0.16 ± 0.63 D x 100.[11] We thus
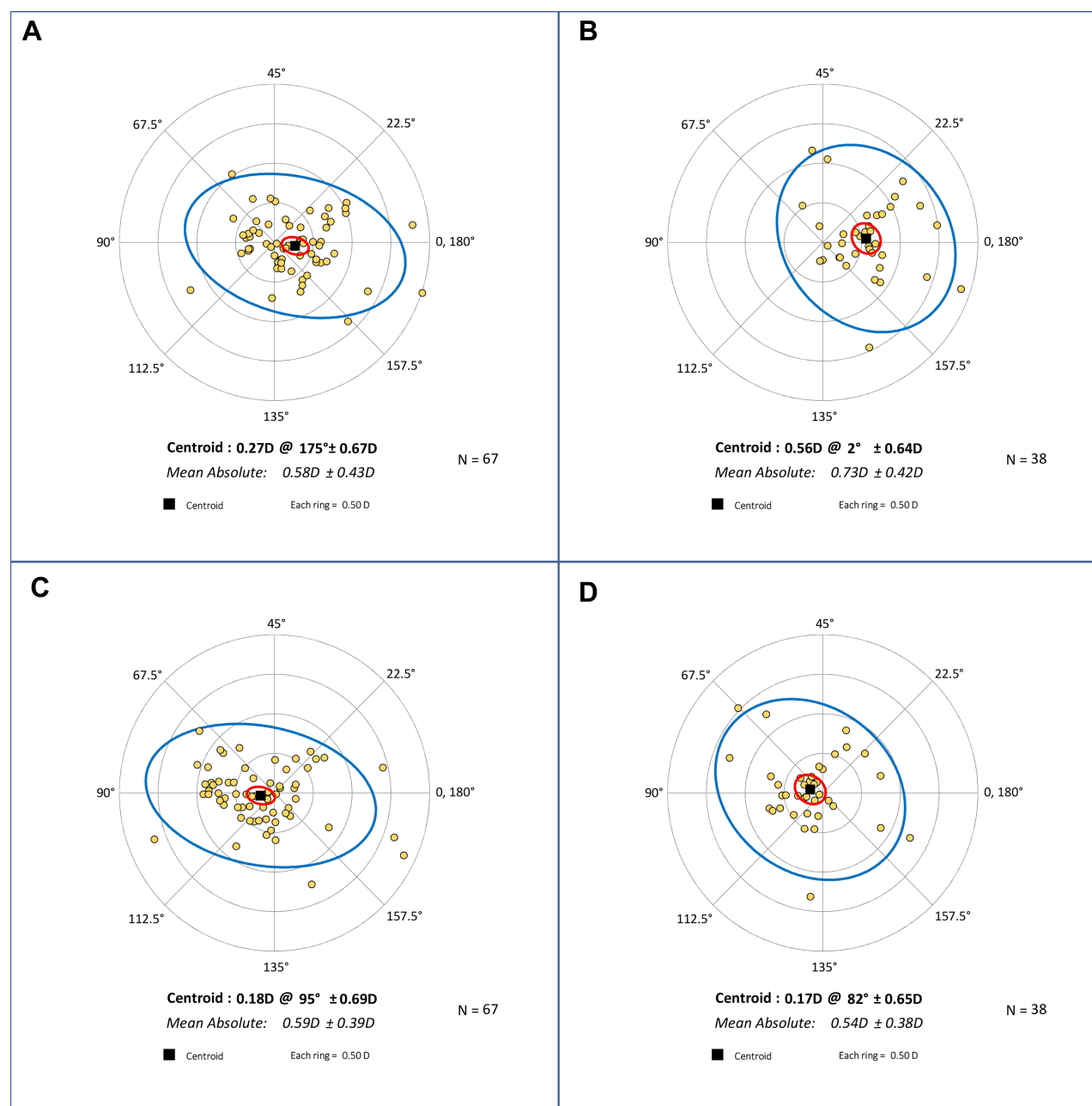
Figure 3 Double angle plots of the residual astigmatism prediction error by method of calculation and sub-group. (**A**) enVista against-the-rule (ATR), (**B**) enVista with-the-rule (WTR), (**C**) EVO ATR and (**D**) EVO WTR.
Abbreviations: D, diopters; EVO, Emmetropia Verifying Optical toric IOL formula v2.0; red circle, 95% confidence ellipse of the centroid; blue circle, 95% confidence ellipse of the dataset.

now have evidence that the EVO Toric Formula v2.0 is not only superior to legacy formulas but is also equivalent to many of the modern toric calculators of present.

It is worth noting that 90% of the eyes in the present study were implanted with a toric IOL with an effective astigmatism power of 1.4 D or less, and no eye had keratometric astigmatism magnitude greater than 2.8 D. This is a dataset with particularly low astigmatism

magnitude. Furthermore, nearly 2/3 of these eyes had preoperative ATR keratometric astigmatism. We know from the results of the present work and others that the performance of modern calculators is best highlighted in eyes with higher-magnitudes, and in those with WTR rather than ATR astigmatism.[6] For example, the "Net Astigmatism" predictions from legacy and modern toric calculators might differ by only 0.3 D in an eye with 1

Table 4 Residual Astigmatism Prediction Errors by Method of Calculation and Intraocular Lens Toricity

Intraocular Lens	enVista	EVO	p-value

MX60T125 (n = 79)
  Mean ± SD (D)
  Centroid ± SD (D)
	
	0.63 ± 0.44
	0.36 ± 0.50 @ 177
		
		0.57 ± 0.39
		0.17 ± 0.47 @ 094
			0.1331
			x-component: p < 0.0001
			y-component: p = 0.1315

MX60T200 (n = 18)
  Mean ± SD (D)
  Centroid ± SD (D)
	
	0.62 ± 0.46
	0.40 ± 0.26 @ 002
		
		0.57 ± 0.38
		0.16 ± 0.23 @ 086
			0.5689
			x-component: p < 0.0001
			y-component: p = 0.6215

MX60T275 (n = 12)
  Mean ± SD (D)
  Centroid ± SD (D)
	
	0.63 ± 0.38
	0.38 ± 0.20 @ 010
		
		0.61 ± 0.36
		0.25 ± 0.19 @ 081
			0.8565
			x-component: p < 0.0001
			y-component: p = 0.0492

p-values
  Means
  Centroids
	
	0.9982
	0.9942
		
		0.9442
		0.9942	

Abbreviations: D, diopters; EVO, Emmetropia Verifying Optical toric IOL formula v2.0.

D of ATR astigmatism, but 1.25 D or more in an eye with 4.0 D of WTR astigmatism. In short, the performance of the EVO Toric Formula v2.0 in eyes with low astigmatism is good and better than that of legacy calculators, but one might expect these differences to be further highlighted in a population that includes higher astigmatism, and a greater proportion with WTR astigmatism.

As mentioned in the results, one additional finding was the trend toward smaller standard deviations in the RA prediction error with increasing IOL toricity. We hypothesize that this is due to the increased variability in axis determination on behalf of the biometer and the investigator performing postoperative manifest refractions when the astigmatism magnitude is low. For example, an optical biometer might register the axis of astigmatism to within 15 degrees when the magnitude is 1.0 D, but would likely register the same to within 5 degrees when the magnitude is 5.0 D. A commonly held belief among surgeons is that increases in prediction error with increasing magnitudes of astigmatism are due to the fact that axial misalignments with IOLs containing higher toricities cause proportionately higher refractive errors. However, in the present study, it is interesting to note that there was no significant increase in the RA prediction error with increasing toricity of the IOL.

The present study has several strengths, which include a relatively large sample size (109 versus 61,[19] 62,[20] and 46[21]) compared to many published works in this domain. It also includes only one eye from each subject (avoiding

paired organ biases) and is also the first study to report upon performance of the EVO Toric Formula v2.0 on an IOL platform other than the Acrysof IQ (Alcon, Fort Worth, TX). On the other hand, limitations of the present work include the relatively high standard deviation of the RA prediction error vector (≈ 0.66 D) in the present study compared to that reported in some other works (≈ 0.33 D).[19] This might be due to variability in surgical technique, axis measurements in eyes with lower magnitudes of astigmatism, and manifest refractions, since the dataset used here came from a multi-center clinical trial. Other works report on outcomes from a single surgeon and include a larger number of eyes with greater keratometric astigmatism. Analysis of data in the present work involved using Hill's "remove and replace" method,[15] which does not take into account ELP of the toric IOL. This may have resulted in an under-representation of the EVO Toric Formula v2.0 performance, which takes into account ELP. Other limitations of this study include the absence of lens thickness (optional factor for both BTC and EVO) and the fact that the dataset included lower-powered torics only. As discussed above, evaluation with a dataset that includes higher-powered torics would have likely further differentiated EVO's performance from that of the legacy calculator. While the methodology for retrospective analysis of toric outcomes has been well established, a prospective comparative case series would be the best test of these calculators' relative performance.

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