

Improving toric intraocular lens calculations using total surgically induced astigmatism for a 2.5 mm temporal incision



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Purpose: To determine in cataract surgery the total surgically induced astigmatism (SIA) that accounts for all factors that contribute to the difference between preoperative keratometric and postoperative refractive astigmatism other than any toricity of an intraocular lens (IOL).

Setting: Twenty surgical sites in the United States.

Design: Retrospective case series.

Methods: An analysis was performed of 4 clinical trials involving toric IOLs and nontoric IOLs in standard cataract surgery. Data included preoperative keratometry and manifest refraction measurements at multiple postoperative visits. For each eye with a nontoric IOL, the total SIA vector was calculated as the vector difference between postoperative refractive and preoperative keratometric astigmatism. The relationship between the total SIA vector and meridian of preoperative keratometric astigmatism was determined and used to develop a new calculation algorithm for toric IOL

implantation. The algorithm was tested retrospectively to identify optimum candidate eyes for various cylinder power toric IOLs as well as to compare results with the Barrett toric calculator.

Results: The total SIA vector was a significant contributor to surgically associated astigmatic changes in eyes receiving nontoric IOLs. The total SIA vector was dependent on the preoperative steep meridian in a consistent fashion, allowing development of a new calculation algorithm for toric IOL correction. Retrospectively applying this algorithm to toric IOL cases led to significantly improved differences between toric and nontoric control populations.

Conclusions: Total SIA analysis is a new approach for toric IOL surgery. Because it considers all factors that may influence outcomes, the total SIA is a useful inclusion in toric IOL surgical planning.

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Toric intraocular lens (IOL) implantation has become the most common method to correct corneal astigmatism after cataract removal because of its predictability.^{1–3} Studies^{4,5} have shown that more than 0.5 diopter (D) of residual astigmatism can reduce uncorrected visual performance and patient satisfaction. To achieve good astigmatic outcomes, it is imperative that the toric power of the IOL is correct and that it is placed in the proper orientation. This outcome depends on accurately predicting the final corneal astigmatism and any other factors that affect the ocular astigmatism with cataract surgery and toric IOL implantation.

The most common cataract incision today is a temporal near-clear 2.5 to 2.8 mm with a secondary 1.0 mm incision superiorly. The total surgically induced astigmatism (SIA) with this type of incision, from 4 datasets of control eyes receiving nontoric IOLs, was determined using different techniques and was then applied to the 3 datasets of toric IOL study patients.

PATIENTS AND METHODS

Datasets

Four datasets were available for retrospective analysis. Each dataset was from an Alcon-sponsored trial, approved prospectively by an institutional review board and adhering to the tenets of the Declaration of Helsinki and its statement of ethical principles for medical research involving human subjects. Informed written consent was obtained from all patients. Patients were required to have normal eye examinations with the exception of a cataract and no other history of eye disease. Table 1 shows the abbreviations used in the figures, the actual model, and the toricity for each IOL used in the study. All IOLs were in the Acrysof series (Alcon Research Laboratories, Inc.).

Dataset 1 (Minimal Preoperative Astigmatism) The first dataset was from a study in 2012 of spherical (nontoric) IOLs (SN60WF) for which the average preoperative keratometric astigmatism had to be less than 1.00 D (ClinicalTrials.gov identifier NCT01510717^A). In the study, no attempt was made to enroll a uniform distribution of preoperative keratometric meridians. All patients were required to be seen for follow-up at 1 day, 1 week, 1 month, 3 months, 6 months, and 12 months. Complete measurement data for all visits were available for 222 eyes with temporal

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Table 1. Intraocular lens properties.

Abbreviation	IOL Model	Toricity (D)
T0	SA60AT/SN60WF	0.00
T2	SN6AT2	1.00
T3	SA60T3	1.50
T4	SA60T4	2.25
T5	SA60T5	3.00
T6	SN6AT6	3.75
T7	SN6AT7	4.50
T8	SN6AT8	5.25
T9	SN6AT9	6.00

IOL = intraocular lens

primary surgical incisions. **Figure 1** shows the distribution of preoperative keratometric astigmatism in these eyes, 69 (31%) had against-the-rule (ATR) astigmatism, 57 (26%) with-the-rule (WTR) astigmatism, 51 (23%) oblique astigmatism at 45 degrees, and 45 (20%) oblique astigmatism at 135 degrees. For all plots and analyses in this study, left-eye vectors are mirrored about the x-axis on the double-angle plot to allow direct comparison with right-eye vectors.^{6–8} The mean preoperative keratometric astigmatism magnitude was 0.54 D. With low amounts of astigmatism, the distribution of the meridian of corneal astigmatism was very uniform.

Dataset 2 (Small Preoperative Astigmatism) The second dataset was from a study from 2012 to 2013. It comprised 518 eyes of 518 patients of which 253 (control group) received a spherical monofocal IOL (SN60WF) and 265 (test group) received a toric monofocal IOL with 1.00 D of toricity (SN6AT2). Patients were required to have between 0.50 D and 1.00 D of preoperative keratometric astigmatism; the mean value was 0.72 D. **Figure 2, A**, shows the distribution of preoperative keratometric astigmatism in the control group; 75 (30%) had ATR astigmatism, 45 (18%) oblique astigmatism at 45 degrees, 95 (38%) WTR astigmatism, and 38 (15%) oblique astigmatism at 135 degrees. **Figure 2, B**, shows the distribution of preoperative keratometric astigmatism in the toric group; 82 (31%) had ATR astigmatism, 60 (23%) oblique astigmatism at 45 degrees, 81 (31%) WTR astigmatism, and 42

(16%) oblique astigmatism at 135 degrees. All patients were required to be seen for follow-up at 1 day, 1 week, 1 month, 3 months, and 6 months. Preoperative and postoperative keratometric measurements (only dataset with postoperative keratometry) were taken with the IOLMaster biometer (Carl Zeiss Meditec AG) or the Lenstar biometer (Haag-Streit), and manifest refraction was performed at each visit.

Dataset 3 (Moderate Preoperative Astigmatism) The third dataset was from a study from 2002 to 2005 ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study?term=NCT01214863&rank=1) identifier NCT01214863^B). It comprised 411 eyes, of which 202 (control group) received a spherical monofocal IOL (SA60AT) and 209 (test group) received a toric monofocal IOL (SA60T3, SA60T4, or SA60T5; toricity 1.50 D, 2.25 D, 3.00 D, respectively). These eyes had between 0.75 D and 2.88 D of preoperative keratometric astigmatism as measured by manual keratometry. **Figure 3, A**, shows the distribution of preoperative keratometric astigmatism in the control group; 82 (41%) had ATR astigmatism, 30 (15%) oblique astigmatism at 45 degrees, 75 (37%) WTR astigmatism, and 15 (7%) oblique astigmatism at 135 degrees. **Figure 3, B**, shows the distribution of preoperative keratometric astigmatism in the toric group; 81 (39%) had ATR astigmatism, 21 (10%) oblique astigmatism at 45 degrees, 98 (47%) WTR astigmatism, and 9 (4%) oblique astigmatism at 135 degrees. All patients were required to be seen for follow-up at 1 day, 1 week, 1 month, 3 months, 6 months, and 12 months, and manifest refraction was performed at each visit. In the study, no attempt was made to enroll a uniform distribution of keratometric meridians, and keratometry was performed with a manual keratometer. As a result, the cohort had few eyes with oblique astigmatism.

Dataset 4 (Large Preoperative Astigmatism) The fourth dataset was from a post-approval study from 2012 to 2015 ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study?term=NCT01601665&rank=1) identifier NCT01601665^C). It comprised 233 eyes in the control group (SN60WF) and 226 in the test group (toric monofocal SN6AT6, SN6AT7, SN6AT8, SN6AT9; toricity 3.75 D, 4.50 D, 5.25 D, 6.00 D), respectively. The preoperative keratometric astigmatism ranged from 1.68 D to 8.5 D. **Figure 4, A**, shows the distribution of preoperative keratometric astigmatism in the control group; 58 (25%) had ATR astigmatism, 5 (2%) oblique astigmatism at 45 degrees, 161 (69%) WTR astigmatism, and 9 (4%) oblique astigmatism at 135 degrees. **Figure 4, B**, shows the distribution of preoperative keratometric astigmatism in the toric group; 63 (28%) had ATR astigmatism, 10 (4%) oblique astigmatism at 45 degrees, 142 (63%) WTR astigmatism, and 11 (5%) oblique astigmatism at 135 degrees. All patients were required to be seen for follow-up at 3 months, and manifest refraction (no keratometry) was performed. In the study, no attempt was made to enroll a uniform distribution of preoperative keratometric meridians and the preoperative keratometry was performed with a manual or optical keratometer. Few eyes had oblique astigmatism.

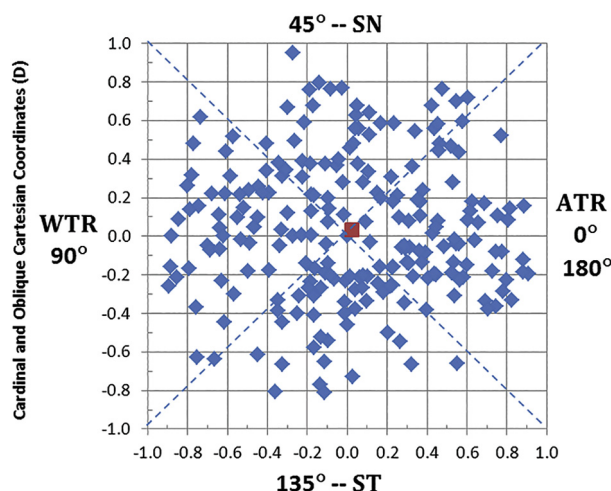


Figure 1. Double-angle vector plot of the preoperative keratometric astigmatism for the first dataset of 222 eyes with the SN60WF intraocular lens. Blue diamonds indicate individual astigmatism measurements. Red squares indicate the centroid of all readings (ATR = against the rule; SN = superonasal; ST = superotemporal; WTR = with the rule). Since all Left eyes are mirrored (see text), 45 degrees is always SN and 135 degrees ST.

SURGICAL TECHNIQUE

Approximately 20 surgeons were involved in each of the 4 studies. All patients received a manual temporal near-clear corneal incision. The incision size decreased over time, starting from an average of approximately 3.1 mm in the earliest trial to approximately 2.5 mm in the latest trial. The surgeons were requested to use their standard technique for orienting the toric IOL.

Determination of Surgically Induced Astigmatism

The second dataset was the most rigorously controlled of the toric IOL studies. It also had the most uniform distribution of corneal meridians. In addition, it had postoperative optical keratometry and manifest refraction at every visit, allowing comparison of 2 methods for determining the SIA. The first method used the classic keratometric method

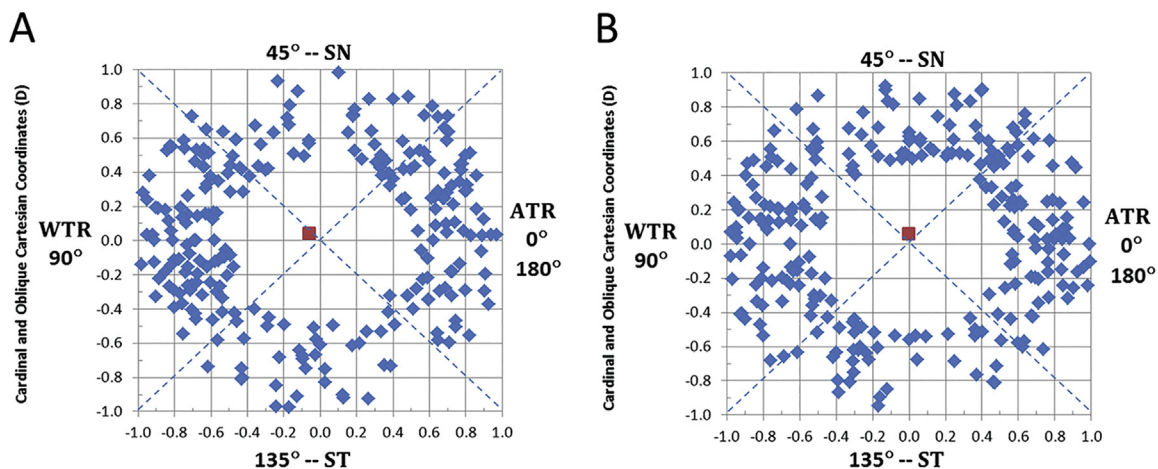


Figure 2. Double-angle vector plots of the preoperative keratometric astigmatism for the second dataset of 253 control eyes using the SN60WF IOL (A) and 265 study eyes using the SN6AT2 toric IOL (B). Blue diamonds indicate individual astigmatism measurements. Red squares indicate the centroids of all readings (ATR = against the rule; IOL = intraocular lens; SN = superonasal; ST = superotemporal; WTR = with the rule).

(vector difference between the postoperative (K_{post}) and preoperative (K_{pre}) keratometric astigmatism) as follows:

$$K_{\text{pre}} + \text{SIA}_k = K_{\text{post}} \quad (1A)$$

$$\text{SIA}_k = K_{\text{post}} - K_{\text{pre}} \quad (1B)$$

where SIA_k is the keratometric SIA.

The second method used the vector difference between the postoperative refractive astigmatism ($\text{REFastig}_{\text{post}}$) at the corneal plane and the preoperative keratometric astigmatism.

$$K_{\text{pre}} + \text{SIA}_{\text{total}} = \text{REFastig}_{\text{post}} \quad (2A)$$

$$\text{SIA}_{\text{total}} = \text{REFastig}_{\text{post}} - K_{\text{pre}} \quad (2B)$$

where $\text{SIA}_{\text{total}}$ is the total SIA.

The total SIA (postoperative refractive astigmatism minus preoperative keratometric astigmatism) method

will include any posterior corneal surface effects and other contributions, such as physiologic IOL tilt or decentration, refractive changes in the anterior and posterior corneal surfaces from the cataract incisions, and systematic differences in measured keratometric versus actual corneal refractive astigmatism.^{9,10,D} A complete discussion of total SIA and the use of double-angle plots to describe outcomes can be found in an editorial by Abulafia et al.⁸ The postoperative refraction should be vertexed to the corneal plane using the cross-cylinder form to determine the exact refractive astigmatism, as previously described.^{7,11} The nominal vertex distance of the phoropter is 13.75 mm when the cornea is aligned properly and was used when a measured value was not available.

The relationship between the total SIA and the meridian of preoperative astigmatism was determined as follows: For each meridian from 0 to 179 degrees, the mean total SIA and keratometric SIA vectors were calculated by averaging all SIA vectors at preoperative keratometric

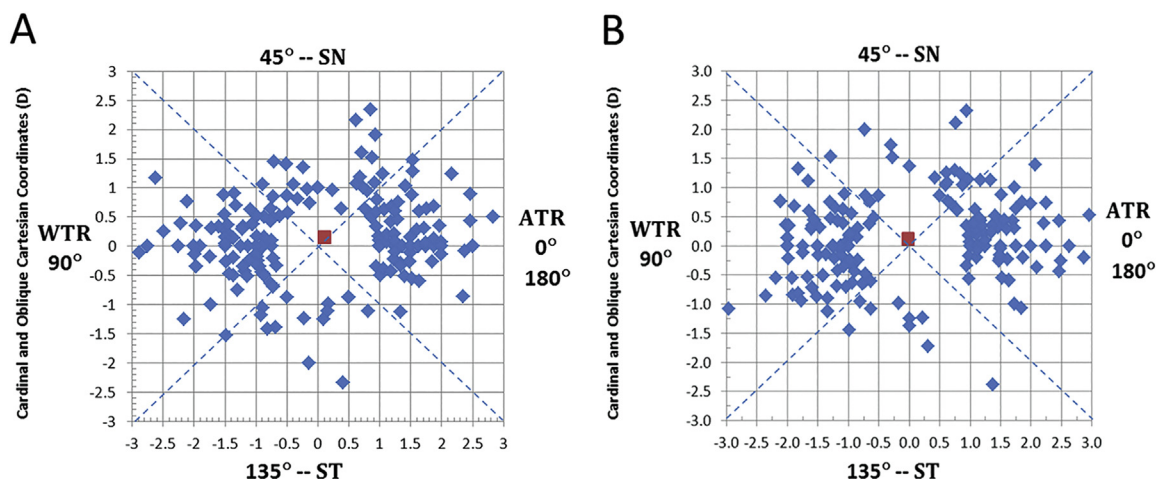


Figure 3. Double-angle vector plots of the preoperative keratometric astigmatism for the third dataset of 202 control eyes using the SA60AT IOL (A) and 209 study eyes using the SA60T3, SA60T4, and SA60T5 toric IOLs (B). Blue diamonds indicate individual astigmatism measurements. The red squares indicate the centroids of all readings (ATR = against the rule; IOL = intraocular lens; SN = superonasal; ST = superotemporal; WTR = with the rule).

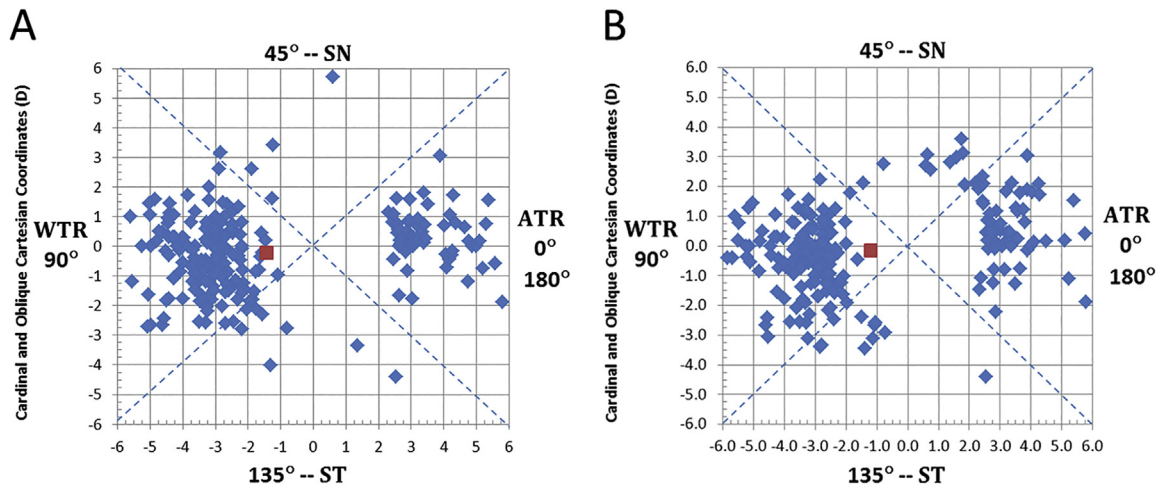


Figure 4. Double-angle vector plots of the preoperative keratometric astigmatism for the fourth dataset of 233 control eyes using the SN60WF IOL (A) and 226 study eyes using the SN6AT6, SN6AT7, SN6AT8, SN6AT9 toric IOLs (B). Blue diamonds indicate individual astigmatism measurements. Red squares indicate the centroids of all readings (ATR = against the rule; IOL = intraocular lens; SN = superonasal; ST = superotemporal; WTR = with the rule).

meridians within ± 20 degrees. For example, for the 45-degree meridian, the mean total SIA vector was computed for all preoperative keratometric measurements between 25 degrees and 65 degrees. This averaging suppressed the noise in the individual measurements. Figure 5 shows the polar meridional frequency plots of the 4 datasets for the controls. The second dataset (ie, small astigmatism group with SN6AT2 toric IOLs and nontoric SN60WF control IOLs) had the most uniform distribution in preoperative keratometric astigmatism meridians and therefore was used as the reference dataset in much of the analysis.

For dataset 2, the keratometric SIA and total SIA values were then plotted on double-angle plots⁸ for comparison (Figure 6). Similarly, for each of the 4 other clinical datasets, the total SIAs using control eyes were determined and plotted on analogous double-angle plots. The total SIA perimeters for each of the 4 control datasets also were determined at every postoperative visit available to determine the change over time (stability).

The following 2 methods were evaluated to provide a continuous function of preoperative keratometry versus total SIA from the 4 datasets: (1) elliptical fits to the total SIAs for the 4 datasets and (2) a scaling equation that enlarged or

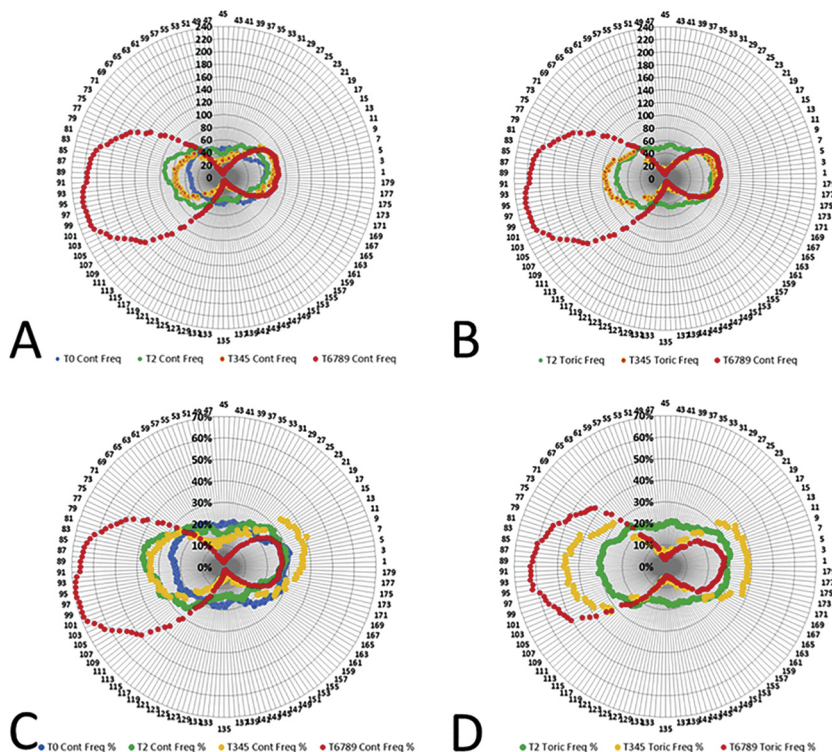


Figure 5. A: Polar frequency plots of the 4 control datasets by meridian with a ± 20 -degree sampling window. B: Polar frequency plot of the 3 toric IOL datasets by meridian with a ± 20 -degree sampling window. C: Plot A with each dataset normalized by percentage of eyes. D: Plot B with each dataset normalized by percentage of eyes (Cont = control; Frq = frequency; IOL = intraocular lens).

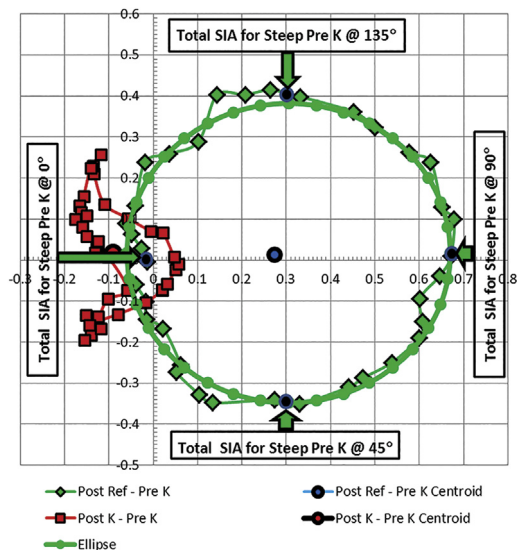


Figure 6. Double-angle vector plot of the keratometric (red squares) and total (green diamonds) SIA for T2 control dataset and least-squares circular fit (green circles) to total SIA (K = keratometry; Post = postoperative; Pre = preoperative; Ref = refractive; SIA = surgically induced astigmatism).

reduced the second dataset perimeter to fit the preoperative keratometric astigmatism versus the average radius of the perimeter of the datasets. For the first method, a least-squares elliptical fit was then determined for each of the 4 datasets at the latest postoperative visit (6 or 12 months) using Table Curve 2D (version 5.01, Systat Software, Inc.). The ellipse for any magnitude of keratometric preoperative astigmatism could be generated for all meridians from 0 to 180 degrees and is called the elliptical total SIA.

The second method used a scaling equation shown in Figure 7 that was determined from the best fit of preoperative keratometric astigmatism versus total SIA radius from the respective global centroid for each of the 4 datasets. The actual total SIAs in Figure 6 (green diamonds from dataset 2) would be used for the 0.72 D preoperative keratometric astigmatism and the perimeter would be enlarged or reduced about the global centroid using the scaling equation.

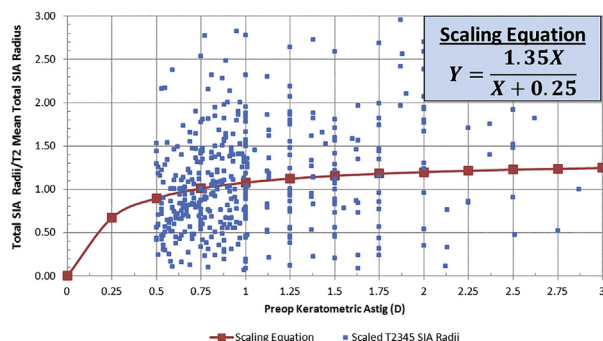


Figure 7. Graph of scaling equation from preoperative keratometric astigmatism versus total SIA radii (see text) ($n = 457$) (Astig = astigmatism; SIA = surgically induced astigmatism).

$$\text{Scaling} = \frac{1.35 \times \text{Pre K Astig}}{\text{Pre K Astig} + 0.25}$$

It can be seen that for 0.00 D preoperative keratometric astigmatism the scaling is 0 and for 0.72 D it is 1.0; the maximum scaling is limited to a value of 1.35. The elliptical total and scaling total SIAs were applied to the 3 toric datasets (ie, 2, 3, and 4) along with zero SIA that was used in the original submissions for comparison. A histogram of the percentage of patients in 0.25 D steps from 0 to 2.0 D was determined when the patient received the same toric IOL that was recommended for (1) zero SIA, (2) the elliptical total, and (3) the scaling total SIAs for each of the 3 toric datasets as well as (4) the keratometric SIA for dataset 2.

The SIAs were used with the Holladay toric calculator^{12,13} to calculate the appropriate toric IOL for each patient. The Holladay calculator uses the generic thin-lens vergence formula^{8,13,14} to determine the exact ideal toric power as the difference between the steep and flat preoperative corneal meridians after vector adjustment of the SIA.

The Barrett toric calculator^E was also used to calculate the appropriate toric IOL for each patient for the 3 toric datasets (ie, 2, 3, and 4). A histogram of the percentage of patients in 0.25 D steps from 0.00 to 2.00 D was determined using the actual postoperative refraction when the patient received the same toric IOL recommended by the Barrett toric calculator.^E

RESULTS

Figure 6 shows the double-angle plot of the actual keratometric SIAs and actual total SIAs at 6 months in the second dataset control group (T0). The global center for the keratometric SIA was WTR at 0.09 @ 84 degrees ($x = -0.09$ D and $y = +0.02$ D), and the shape of the perimeter formed by the meridional keratometric SIAs was very irregular. The center for the total SIA was ATR at 0.27 @ 1.3 degrees ($x = +0.27$ D and $y = +0.01$ D), and perimeter formed by the meridional total SIAs was circular with a radius of 0.37 D. The actual total SIA vector for each meridian is opposite the vector for the preoperative keratometric meridian (eg, for preoperative keratometric WTR the total SIA is ATR and for preoperative keratometric ATR the total SIA is WTR).

The computation of meridional total SIAs for the control eyes in the other 3 datasets (eg, 1, 3, and 4) was performed in the same manner and shown in Figure 8, A, along with the second dataset controls for comparison. The least squares elliptical fits are shown in Figure 8, B, for each of the 4 ellipses and the scaled meridional perimeters in Figure 8, C, from the scaling equation.

In the second dataset, postoperative optical keratometry and manifest refraction were performed at the last visit so the keratometric SIA and total SIA could be compared. Because the original protocol for this dataset used zero for the SIA, it was included in the comparison. Figure 9 shows the histograms of residual astigmatism for the zero, keratometric, elliptical total, and scaling total SIAs and the Barrett toric calculator in the control group and toric

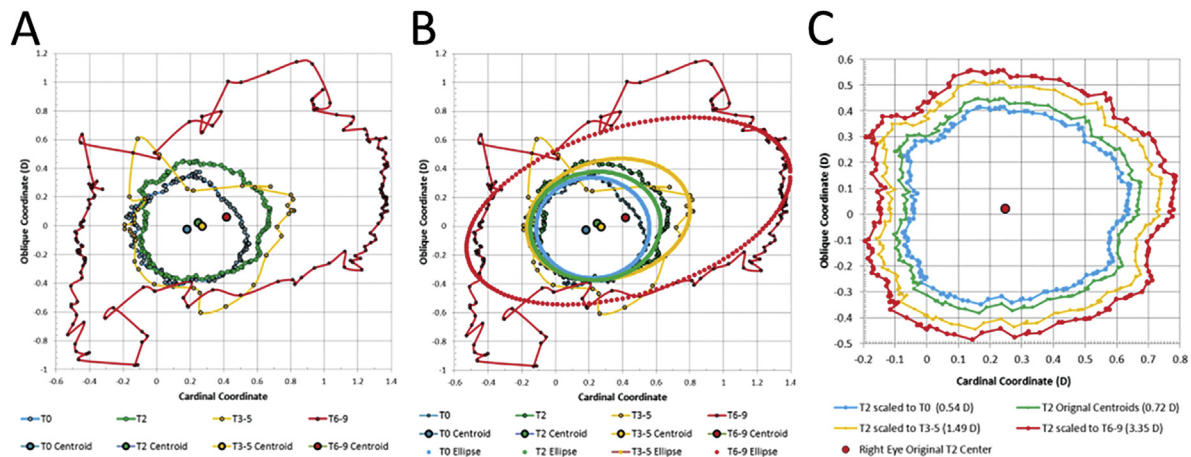


Figure 8. Double-angle vector plots of the A: Actual total SIA for each of the 4 control datasets. B: Best elliptical fits to each of the 4 total SIA datasets. C: Best scaling total SIA plots to the 4 total SIA datasets (SIA = surgically induced astigmatism).

group. For the keratometric SIA, 215 (85%) of the control eyes and 218 (82%) of the toric IOL eyes were calculated to be good candidates for the SN6AT2 IOL; Figure 9, A, shows the results. Because the zero SIA was used in the original protocol for the SN6AT2 IOL group as an inclusion criterion, all 265 eyes with toric IOLs were determined to be good candidates for the T2 IOL using zero SIA. Figure 9, B, shows the residual astigmatism for zero SIA in the control group (253) and toric group (265).

For the elliptical and scaling total SIA, the results were virtually identical to each other, as expected (because the fits were both circles); 134 control eyes (51%) were determined to be appropriate for the SN6AT2 IOL, 116 eyes (44%) had an expected residual astigmatism that would

have been better suited for a spherical IOL, and 3 (1%) eyes had an expected residual astigmatism that would have required an IOL with a higher toricity than the T2. In the SN6AT2 toric IOL group, 147 (55%) of the 265 eyes were appropriate for the SN6AT2 IOL, 110 (42%) were better suited for a spherical IOL, and 8 (3%) would have required an IOL with higher toricity. The results for the elliptical total SIA are shown in Figure 9, C, and the scaling total SIA in Figure 9, D.

For the Barrett toric calculator, 119 (47%) control eyes were found to be appropriate for the SN6AT2 IOL, 39 (15%) were found to be appropriate for a spherical IOL and 95 (38%) would have required an IOL with a higher toricity than the T2. In the SN6AT2 toric IOL group, 117

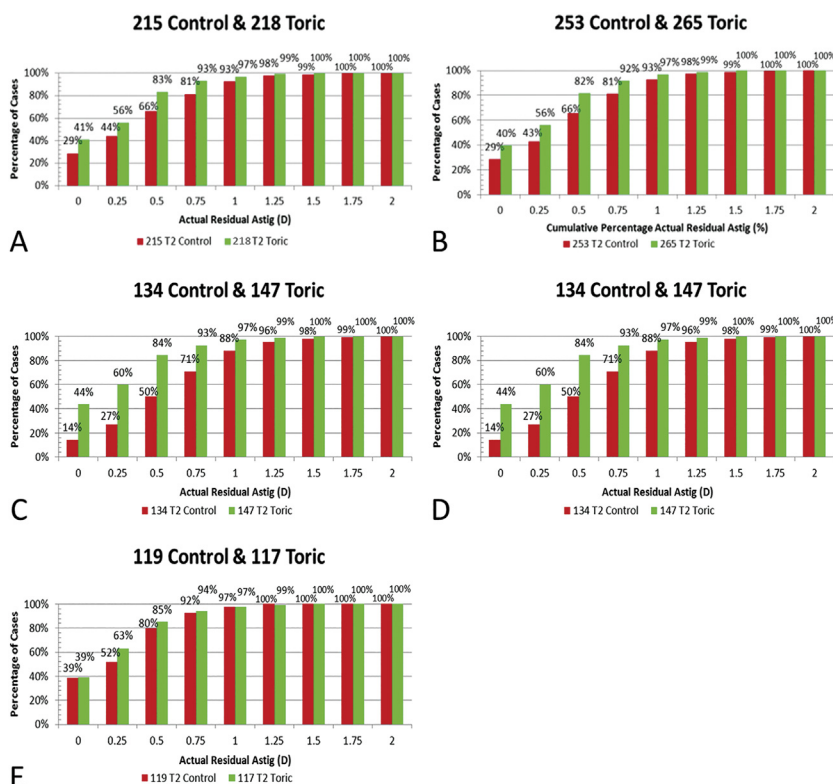


Figure 9. Histogram percentages from 0.0 to 2.0 D of residual astigmatism for the control and toric SN6AT2 IOLs using (A) the keratometric SIA, (B) zero SIA, (C) the elliptical total SIA, (D) the scaling total SIA, and (E) the Barrett toric calculator (Astig = astigmatism; IOLs = intraocular lenses; SIA = surgically induced astigmatism).

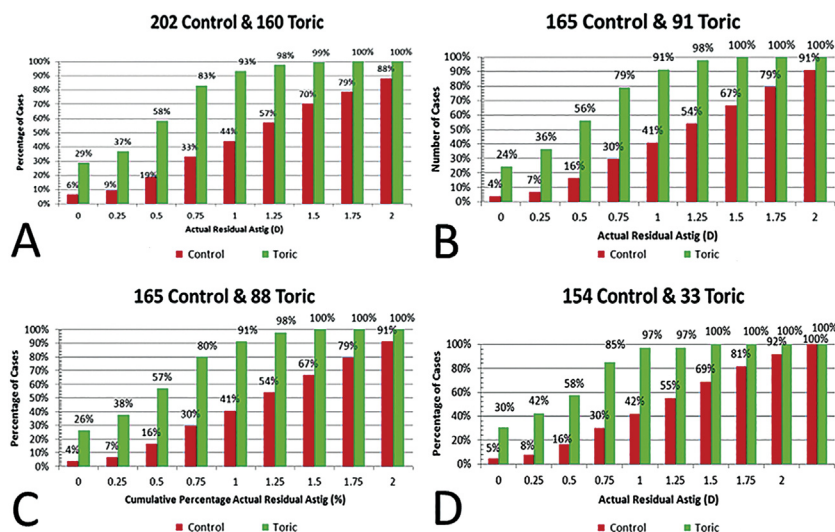


Figure 10. Histogram percentages from 0.0 to 2.0 D of residual astigmatism for the control and toric SA60T3, SA60T4, and SA60T5 IOLs using (A) zero SIA, (B) the elliptical total SIA, (C) the scaling total SIA, and (D) the Barrett toric calculator (Astig = astigmatism; IOLs = intraocular lenses; SIA = surgically induced astigmatism).

(44%) of the of 265 eyes were appropriate for the SN6AT2 IOL, 36 (14%) were better suited for a spherical IOL, and 112 (42%) eyes would have required an IOL with higher toricity. Figure 9, E, shows the results for the Barrett toric calculator.

Using zero SIA, the elliptical, scaling total SIA, and the Barrett toric calculator, the number of eyes appropriate in the third and fourth datasets in the control group and toric group could be determined. Four histograms of the residual astigmatism for the suitable eyes in the third dataset using the zero, elliptical total, scaling total SIAs, and the Barrett toric calculator in the control and toric groups are shown in Figure 10 and for the fourth dataset in Figure 11.

Figure 12 shows the preoperative astigmatism versus residual astigmatism for all toric IOLs. The figure includes only cases that would have been candidates for the toric IOL using zero SIA, the elliptical total SIA, scaling total SIA, and Barrett toric calculator.

The total SIA perimeters and centers were available at all visits from 1 week to 6 or 12 months in 3 of the 4 control groups (datasets 1, 2, and 3), allowing the determination of the stability over time. There was a 0.15 D to 0.20 D ATR shift of the actual total SIA centers from 1 week to 6 months. The left side of the SIA perimeters (preoperative ATR) had the greatest shift of approximately 0.30 D ATR from 1 week to 6 months, whereas the right side (preoperative WTR) shifted by approximately 0.10 D ATR only.

DISCUSSION

Figure 13 shows the prevalence of astigmatism in the cataract age group. The actual data¹⁵ are shown with the least-squares best fit to a log normal (Gaussian) density function and the resulting cumulative log normal function. Seventy-eight percent of cataract patients have keratometric astigmatism of 0.50 D or greater, which is considered the minimum amount that should be corrected to provide good vision and patient satisfaction.^{4,5} The peak keratometric astigmatism in this age group is between 0.25 D and 0.50 D and is the coefficient b in equation 3 (0.3783 D). The

median astigmatism is 0.67 D (50th percentile). Equation 3 is the log normal (Gaussian) formula (Table Curve 2D) and has an R^2 value of 0.99.

Eq # 8174

$$y = a \exp \left[- \frac{\ln(2)}{\ln(d)^2} \ln \left\{ \frac{(x - b)(d^2 - 1)}{cd} + 1 \right\}^2 \right] \quad (3)$$

where \exp stands for exponential, \ln is the natural log; $a = 0.189697$, $b = 0.378300$, $c = 1.066212$, and $d = 2.477521$.

The prevalence of the meridian (ATR, WTR, or oblique) of keratometric astigmatism varies with the magnitude. In Figure 5, C and D, we see that for minimal (blue) and low (green) amounts of astigmatism, WTR and ATR are equal at 30% and only slightly more than oblique at 45 degrees and at 135 degrees, which are near 20%. For moderate amounts of preoperative astigmatism (yellow), the WTR and ATR are almost equal at 40% to 45%, respectively, with both oblique astigmatisms plummeting to less than 10%. For large amounts of astigmatism (red), WTR is predominant at 65% followed by ATR at 30%; there are few cases with oblique astigmatism. This variation in the percentage of WTR, ATR, and oblique astigmatism with magnitude explains the variation in the types of astigmatism in various studies in which the magnitudes are different.

The total SIA is critical for accurately determining the appropriate toric IOL for a specific patient. Many authors have used the keratometric SIA (delta K or the postoperative minus the preoperative keratometry) since Naylor's first description in 1968¹⁶ and 7 years later in the classic article on the pathophysiology of corneal astigmatism after cataract extraction by Jaffe and Clayman in 1975.¹⁷ As first pointed out by Koch et al.,¹⁸ using keratometry neglects to effect of posterior corneal astigmatism, as others have confirmed, and leads to a systematic error of approximately 0.50 D of ATR astigmatism.^{19,20} Another factor that can contribute to the refractive ocular astigmatism that is not accounted for by keratometry is the systematic tilt of the

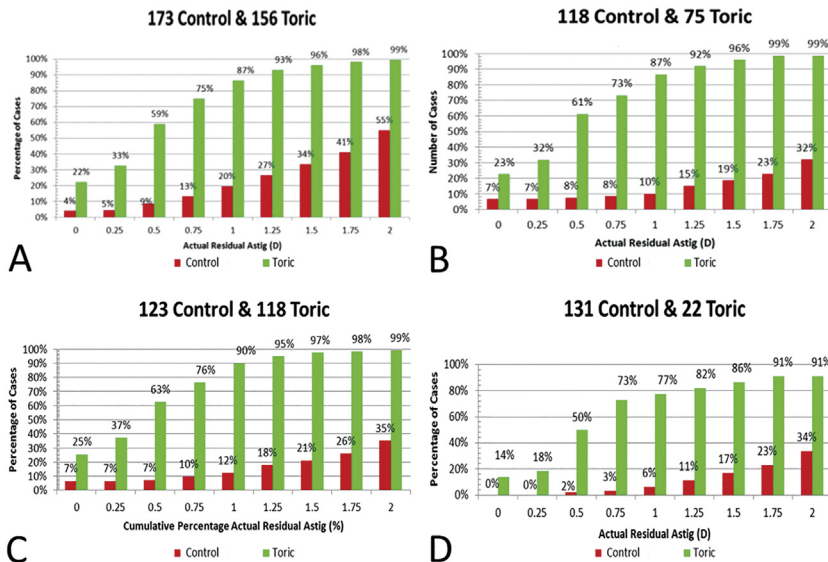


Figure 11. Histogram percentages from 0.0 to 2.0 D of residual astigmatism for the control and toric SN6AT6, SN6AT7, SN6AT8, and SN6AT9 IOLs using (A) zero SIA, (B) the elliptical total SIA, (C) the scaling total SIA, and (D) the Barrett toric calculator (Astig = astigmatism; IOLs = intraocular lenses; SIA = surgically induced astigmatism).

IOL about the vertical axis and temporal decentration, both of which induce ATR astigmatism^{21–23} as a result of the physiologic tilt of the eye (angle $\alpha = 5.2$ degrees and mean temporal decentration = 0.2 mm), resulting in approximately 0.20 D of refractive ATR astigmatism.²⁴ Another limitation of previous studies is the timing of the postoperative measurements. Many studies determine the SIA 1 month postoperatively, and stabilization is not achieved for at least 6 months. The additional change with time is a progressive increase in ATR astigmatism. The use of the postoperative refraction at 6 months and

the preoperative keratometric astigmatism to determine the total SIA accounts for all factors contributing to the refractive postoperative astigmatism and allows for stabilization.

The most common value to use for the total SIA is the centroid of the postoperative prediction error (~ 0.33 – 0.50 D ATR), as was shown by Abulafia et al.^{12,20} This approach shifts the prediction error to the center of a double-angle plot so that the mean error is near zero. This shift, however, has no effect on the spread (variance) of the data but can significantly reduce the prediction error

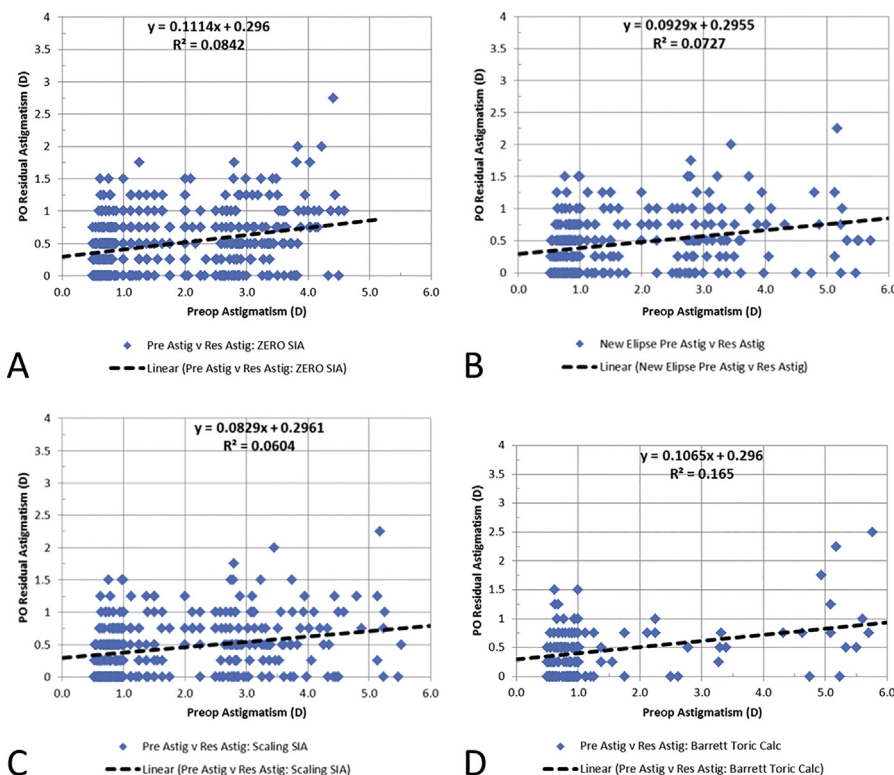


Figure 12. Preoperative astigmatism versus residual astigmatism for (A) zero SIA, (B) the elliptical total SIA, (C) the scaling total SIA, and (D) the Barrett toric calculator (Calc = calculator; Pre = preoperative; Res = residual; SIA = surgically induced astigmatism).

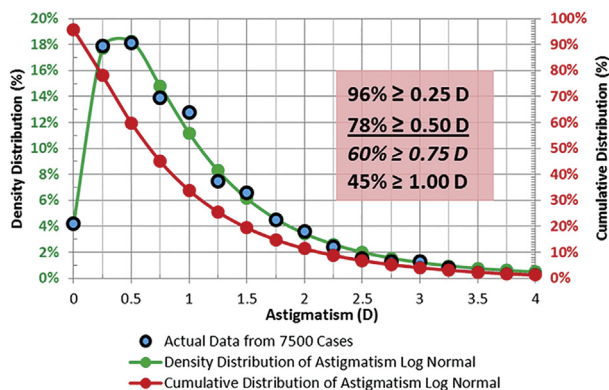


Figure 13. Frequency percentage (green) and cumulative percentage plot (red) of astigmatism in the cataract population. The actual data (blue points) and log normal (Gaussian) equation (green curve) with an R^2 value of 0.99.

for constant effects such as posterior corneal astigmatism and physiologic IOL tilt and decentration.

A second improvement is to treat WTR, ATR, and oblique astigmatism differently. The Baylor nomogram does this for all 3 groups of keratometric astigmatism.²⁵ The results state that preoperative keratometric WTR astigmatism should be reduced, ATR astigmatism increased, and oblique astigmatism neutral. This adjustment would not only shift the centroid of the cluster of data to the center but also reduce the spread (variance) of the data. Our values for the scaling total SIAs at 90 degrees (WTR) and 0 degree (ATR) (Figure 14) are similar to those of the Baylor nomogram.

Our method of determining the total SIA as a function of the magnitude and axis of the preoperative keratometric astigmatism refines the improvement of the Baylor

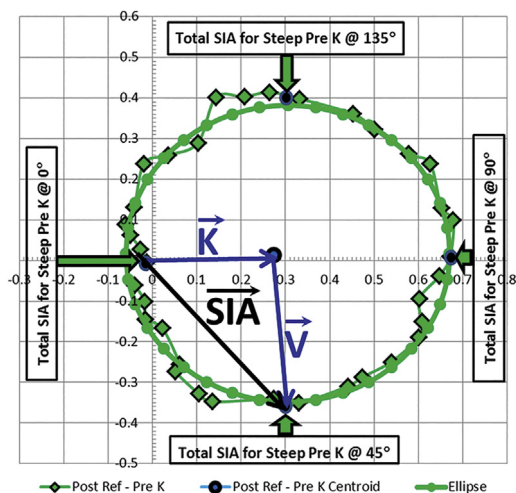


Figure 14. Double-angle vector plot of total SIA (green diamonds) for SN6AT2 IOL control dataset and least squares circular fit (green circles) to total SIA. The total SIA vector for 45 degrees is shown (black vector). The final total SIA vector has 2 components, a constant component (K , blue vector) and a variable component (V , blue vector) (IOL = intraocular lens; K = keratometry; Post = postoperative; Pre = preoperative; Ref = refractive; SIA = surgically induced astigmatism).

nomogram further by providing a more exact value for a specific patient (astigmatic magnitude and axis). Figure 14 shows the perimeter of the total SIA in the control group in the second data dataset (green diamonds). The total SIA vector for 45 degrees is shown (black vector). The total SIA vector has 2 components, a constant component (K , blue vector) and a variable component (V , blue vector). The total SIA is the sum of these 2 vectors. The constant vector component of the total SIA corresponds almost exactly with the posterior corneal astigmatism found by Koch et al.,²⁵ plus the astigmatism induced by the physiologic tilt and decentration of an IOL.^{21–24}

The variable component vector for a specific axis of preoperative keratometric astigmatism goes from the center of the perimeter (centroid) to the point of the keratometric steep meridian of the astigmatism on the perimeter. The variable component vector (V) has a magnitude of approximately 0.39 D and is in the opposite direction of the preoperative astigmatism. For the second dataset, the magnitude is about one half of the mean preoperative keratometric astigmatism (0.39/0.72). This variable vector (V) is unique to the patient's preoperative meridian and magnitude of astigmatism and must be added to the constant centroid (K). The variable component vector always reduces the magnitude of the preoperative keratometric astigmatism. The explanation for why the variable component is always negative and reduces the corneal astigmatism can be explained by current 3-dimensional finite modeling^{26–28} and clinical studies²⁹ that show unpaired orthogonal incisions (temporal and superior) would reduce the astigmatism of the cornea.

In the second dataset (Figure 14), if the preoperative astigmatism were 0.72 D @ 90 degrees (the mean magnitude of the dataset), the constant vector would be 0.27 D ATR and the variable vector 0.40 D ATR for a total SIA of 0.67 D of ATR. The predicted 6-month postoperative refractive residual astigmatism with a nontoric IOL would be 0.05 D @ 90 degrees (0.72 – 0.67 D), which is almost spherical; therefore, a toric IOL is not indicated. In contrast, for the same 0.72 D magnitude of preoperative astigmatism at 180 degrees, the constant vector is still 0.27 D ATR but the variable vector is 0.33 D WTR; the resulting total SIA vector is 0.06 D of WTR (0.33 – 0.27 D). The predicted postoperative astigmatism would be 0.66 D (0.72 – 0.06 D), indicating the eye is a perfect candidate for the SN6AT2 IOL, which nominally corrects 0.69 D of refractive astigmatism. Although the constant component is the same, the variable components are in opposite directions so that the case at 90 degrees adds to the ATR astigmatism whereas the case at 180 degrees subtracts from the ATR astigmatism. The magnitude of the total SIA is significantly different for the same amount of WTR and ATR preoperative keratometric astigmatism.

For any other axes of preoperative astigmatism (not 90 degrees or 180 degrees), the total SIA would be at a different axis than the preoperative astigmatism, with the maximum difference occurring at the oblique meridians of 45 degrees and 135 degrees. For example, in

Figure 14 (preoperative astigmatism of 0.72 D @ 45 degrees) the constant vector is 0.27 D ATR (K) and the variable vector 0.32 D @ 135 degrees (V). The resulting total SIA is 0.42 D @ 152 degrees (black vector). It is necessary to maintain a spherical equivalent (SE) of zero for the SIA (corneal SE power must remain constant³⁰ when adding the SIA); therefore, the resulting total SIA is $-0.21 + 0.42$ @ 152 degrees, a Jackson cross-cylinder.³¹ Adding the total SIA of $+0.42$ D @ 152 degrees to the preoperative keratometric astigmatism of 0.72 D @ 45 degrees yields 0.44 D @ 29 degrees, 16 degrees clockwise to the original steep meridian of 45 degrees. This result is the expected ocular refractive astigmatism predicted with a nontoric IOL and the proper meridian at which to place the toric IOL. The axis change from the preoperative keratometry also decreases with increasing magnitude of preoperative astigmatism because the total SIA vector becomes a smaller percentage of the preoperative magnitude (Figure 7).

In Figure 9, A and B, the keratometric SIA and zero SIA are shown and are not statistically significantly different from each other or the control group, which means there is no benefit. The difference between the control group and the toric group is small and ranges from 11% to 17% for residual astigmatism of 0.00 to 0.75 D.

In contrast, Figure 9, C and D, are both significantly different from the control group up to 0.75 D, with differences ranging from 22% to 34%. The elliptical total and scaling total SIAs are the same because the fits are both circles with an R^2 value of 0.99. They both have the same SIA values for 0.50 to 1.00 D of preoperative astigmatism.

In Figure 9, E, the Barrett toric calculator had small differences between the toric group and control group, with 0% to 11% for residual astigmatism of 0.00 to 0.75 D (Figure 9, E). The differences were not statistically different and much less than the elliptical total and scaling total SIAs.

In Figure 10, all 4 methods, including zero SIA, are significantly better than the control group up to 1.75 D of preoperative keratometric astigmatism. However, there is no statistical difference in the 3 SIAs and the Barrett toric calculator in the toric group (SA60T3, SA60T4, SA60T5), indicating that the 4 different calculation methods are comparable. In Figure 11, the difference between the control group and the toric group (SN6AT6, SN6AT7, SN6AT8, SN6AT9) is even greater, but again there is no difference in the 3 SIAs. The Barrett toric calculator, however, had statistically significant lower percentages and differences from the control group for 0.00 to 0.75 D of residual astigmatism (Figure 11, D).

The reason for no statistical difference in the 3 SIAs at higher toricities (and higher preoperative keratometric astigmatism) can be explained by the findings in Figure 12. There is an increase in the amount of residual astigmatism with an increase in the amount of preoperative astigmatism. The y -intercept for all 3 graphs is essentially the same (\sim approximately 0.296 D), indicating the average limiting residual astigmatism for a preoperative

keratometric spherical cornea. The scaling total SIA had the flattest slope of 0.0829 (Figure 12, C) followed by the ellipse total SIA of 0.0929 (Figure 12, B), the Barrett toric calculator of 0.1065 (Figure 12, D), and finally 0.1114 for zero SIA (Figure 12, A). The slopes show that the overall residual astigmatism is lowest with the scaling total SIA and highest with zero SIA.

The 2 most important factors causing the increase in residual astigmatism with the increasing toricity of the IOL is the reduced accuracy for larger amounts of preoperative keratometric astigmatism and the effect of misalignment of a toric IOL postoperatively. For a given angular misalignment of the toric IOL from ideal (typically 4.9 ± 2.1 degrees),^{32,33} the residual astigmatism is directly proportional to the toricity of the IOL. For a 1.00 D toric IOL, which on average corrects 0.69 D of astigmatism at the corneal plane, 4.9 degrees of misalignment results in approximately 0.12 D of residual astigmatism at the corneal plane versus a residual of approximately 0.72 D for a 6.00 D toric IOL. In short, for the same misalignment in the orientation of the toric IOL, 6.00 D of toricity will have 6 times the residual astigmatism of a 1.00 D toric IOL. The impact of the total SIA on the postoperative residual astigmatism diminishes with increasing preoperative astigmatism and consequent increasing toricity of the toric IOL.

The elliptical total SIAs for the third dataset (SA60T3, SA60T4, SA60T5) and fourth dataset (SN6AT6, SN6AT7, SN6AT8, SN6AT9) become progressively different from the circular scaling total SIAs, with the elliptical fit becoming more eccentric (major and minor axes different in Figure 8, B). The difference from the scaling total SIA is primarily a shortening in the minor axis in the oblique meridians. The shorter minor axis with the elliptical fit might be related to the sparsity of cases in the oblique meridians (45 degrees and 135 degrees) seen in Figures 3 and 4 with the third dataset and fourth dataset. For example, in Figure 3, A, when determining the total SIA for the 45-degree meridian, the ± 20 -degree window would include cases ranging from 25 degrees to 65 degrees. Most of the total SIAs used are near the extremes of 20 degrees and 65 degrees (near the dashed lines) and would artificially result in a much shorter radius than when cases at 45 degrees are available, as in Figures 1 and 2, A.

The scaling total SIA from the first and second control data avoids this sampling problem but extrapolates the results in the oblique meridians for higher amounts of astigmatism using an average radius from the center of the perimeter (Figures 6 and 7). The slope is flatter in Figure 12 for the scaling total SIA, which indicates that the extrapolation technique for scaling is better than the elliptical fit because of the scarcity of oblique data for the larger amounts of preoperative astigmatism.

The determination of the total SIA should not be done until the postoperative refraction is stable. The total SIAs for the control data in all 3 datasets over time clearly show stability does not occur for at least 6 months after

surgery and there is a continuing ATR shift. It is also prudent to target for 0.25 D of WTR astigmatism to compensate for the 0.25 D ATR astigmatism per decade drift after cataract surgery, as found in the 20-year longitudinal study by Hayashi et al.³⁴

It is important to emphasize that the total SIAs found in our datasets were derived specifically with small (~ 2.5 mm), near-clear temporal incisions with the secondary incision usually superiorly. Larger or smaller incisions, a primary incision not temporal or near-clear, or an inferior secondary incision will almost certainly result in different total SIAs.

WHAT WAS KNOWN

- The SIA is an important factor in determining the appropriate toricity for an IOL.
- Keratometry does not account for posterior corneal astigmatism or other sources of astigmatism that are not from the front surface of the cornea.
- The keratometric astigmatism changes approximately 0.25 D ATR per decade beyond 1 year after surgery and is similar to that in control eyes that did not have surgery.

WHAT THIS PAPER ADDS

- The total SIA accounts for all factors that contribute to the postoperative refractive astigmatism, such as posterior corneal astigmatism, IOL tilt and decentration, and any other systematic cause.
- The total SIA can be determined for every magnitude and axis of preoperative keratometric astigmatism to achieve the lowest residual refractive astigmatism for a specific patient.
- The total SIA drifts ATR during the first year after surgery and should not be calculated until stable at 6 months or longer.

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