

Standardized Analyses of Correction of Astigmatism by Laser Systems That Reshape the Cornea

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ABSTRACT

PURPOSE: To develop a minimum set of analyses and a format for presentation of outcomes of astigmatism correction by laser systems that reshape the cornea.

METHODS: An Astigmatism Project group was created under the auspices of the American National Standards Institute (ANSI) Z80.11 Working Group on Laser Systems for Corneal Reshaping. The Astigmatism Project Group was made up of experts in astigmatism analyses from academia, government, and industry. An extensive literature review was conducted to identify all currently available methodologies for the evaluation of astigmatic outcomes. Project Group members discussed the utility of each method and its specific parameters for evaluating the effectiveness of astigmatism-correcting devices. They gave consideration to unique terminology and analyses required for evaluation of correction of astigmatism by laser systems that reshape the cornea.

RESULTS: The Project Group defined a comprehensive list of analysis variables needed for the evaluation of astigmatism-correcting devices and generated a mathematical definition for each term. They developed a minimum set of analyses needed for evaluation of astigmatism treatments by laser systems that reshape the cornea. They established methods for calculating the refractive error analysis variables and constructed recommended table and graph formats for data presentation.

CONCLUSIONS: This article contains the recommendations of the Astigmatism Project Group of the American National Standards Institute. We propose it as a standard reference for astigmatic refractive error analyses for the evaluation of safety and effectiveness of laser systems that reshape the cornea. [*J Refract Surg.* 2006;22:81-95.]

Many devices for correction of astigmatic refractive errors are currently available in the United States, and numerous other such devices are being developed for potential entry into the marketplace. In the past, scientists and clinicians have used a variety of methodologies¹⁻¹³ to evaluate the effectiveness of astigmatism treatments. Some of these methodologies have been inconsistent with each other or internally inconsistent. These inconsistencies have made it difficult for clinicians and regulatory agencies to evaluate the safety and effectiveness of devices designed to correct astigmatic refractive errors.

As early as 1997, some authors recognized the need for standard methods to assess surgically induced changes in astigmatism.¹³ However, until now there has been no consensus on what these methods should be. To address this problem, the American National Standards Institute (ANSI) Z80.11 Working Group on Laser Systems for Corneal Reshaping formed an Astigmatism Project Group, made up of experts from academia, government, and industry. The group's goal was to identify a common, minimum set of analyses and a presentation format for adequate evaluation of safety and effectiveness of new astigmatism-correcting devices. This article provides the Astigmatism Project Group's recommendations.

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The comments presented here represent the professional opinions of the authors and do not constitute an official document, guidance or policy of the U.S. Government, the Department of Health and Human Services, or the Food and Drug Administration, nor should any official endorsement be inferred.

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TABLE 1
Abbreviations

Term	Acronym
American National Standards Institute	ANSI
Best spectacle-corrected visual acuity	BSCVA
Correction ratio	CR
Defocus equivalent	DEQ
Error of angle	ER
Error of magnitude	EM
Error ratio	ER
Error vector	EV
Intended refractive correction	IRC
Manifest refraction spherical equivalent	MRSE
Normalized error vector	NEV
Normalized intended refractive correction	NIRC
Surgically induced refractive correction	SIRC
Treatment error vector	TEV
Uncorrected visual acuity	UCVA

NON-VECTOR ANALYSES

To obtain adequate data for analyses of a device correcting a refractive error at the corneal plane, the ANSI Z80.11 Working Group developed a comprehensive list of recommended analyses for all refractive indications. Abbreviations used in this article are listed in Table 1.

REFRACTIVE STABILITY ANALYSES

Stability analyses should be performed on eyes evaluated at every follow-up examination (the Consistent Cohort). Additionally, stability needs to be assessed for all sub-sets of eyes examined at consecutive examinations, but not necessarily every follow-up examination.

Recommended stability analyses of manifest refraction spherical equivalent (MRSE), to be performed for the time intervals between all consecutive pairs of scheduled postoperative refractions, are as follows:

- Percentage of eyes that achieve a change of ≤ 1.00 diopter (D) of MRSE between two refractions performed at 1 month and 3 months, and between subsequent refractions performed at least 3 months apart;
- Percentage of eyes that achieve a change of ≤ 0.50 D of MRSE between two refractions performed at 1 month and 3 months, and between subsequent refractions performed at least 3 months apart;
- Mean overall change and change per year in MRSE

between consecutive scheduled visits as determined by a paired analysis; and

- Mean MRSE \pm standard deviation (SD) for the preoperative and each postoperative visit (see Table A2.1).

SAFETY ANALYSES

The following parameters should be calculated for the entire safety cohort:

- Percentage of eyes that lose 2 lines or more of best spectacle-corrected visual acuity (BSCVA);
- Percentage of eyes with BSCVA worse than 20/40 for the subgroup of eyes with BSCVA of 20/20 or better preoperatively;
- Percentage of eyes that have an increase of manifest refractive astigmatism of >2.00 D of manifest cylinder compared to the preoperative refraction;
- Rates of adverse events;
- Contrast sensitivity changes (if studied); and
- Endothelial cell density changes (if studied).

EFFECTIVENESS ANALYSES

The following effectiveness parameters should be calculated:

- Percentage of eyes that achieve predictability (attempted change versus achieved change) of the MRSE of ± 0.50 D, ± 1.00 D, and ± 2.00 D;
- Percentage of eyes that are overcorrected by >1.00 D and >2.00 D;
- Percentage of eyes that are undercorrected by >1.00 D and >2.00 D;
- Percentage of eyes targeted for emmetropia that achieve uncorrected visual acuity (UCVA) of 20/40 or better and 20/20 or better;
- Percentage of eyes not targeted for emmetropia that achieve UCVA of 20/40 or better and 20/20 or better;
- Percentage of eyes that achieve UCVA equal to or better than the preoperative BSCVA for the subgroup of eyes targeted for emmetropia; and
- Percentage of eyes that achieve a difference between postoperative and preoperative BSCVA of: <-2 lines, -2 lines, -1 line, 0 lines, $+1$ line, $+2$ lines, and $>+2$ lines.

ADDITIONAL NON-VECTOR ANALYSES

The Astigmatism Project Group has also recommended additional analyses for evaluation of cylindrical corrections. These include the non-vector analyses listed below in this section as well as the vector analyses presented in the following section.

It has been our experience that consistent data presentation formats allow for easy and efficient interpretation

of such data. We have, therefore, included reference table formats in Appendix 2 for presentation of these data.

Additional non-vector analyses are as follows:

- Accuracy of cylinder to target (see Table A2.1 for suggested format);
- *Defocus equivalent* (DEQ)¹⁴ (DEQ combines the errors in spherical equivalent and astigmatic correction into a single number that is related to the eye's visual acuity). It is the magnitude of the MRSE plus one half the magnitude of the cylinder—independent of sign—in the spectacle plane. Prior to calculation, compensation for chart working distance should be made. For example, when working with a chart at 4 meters, 0.25 D should be subtracted from the sphere for all refractions (see Table A2.2 for suggested format);
- Reduction of non-vector cylinder at stability time point (see Table A2.3 for format). Increases in cylinder are reported as negative numbers;
- Absolute shift in axis at stability time point (see Table A2.4 for format.);
- Cylinder stability, both vector and non-vector (see Tables A2.5a and A2.5b for format). This is done in addition to assessment of MRSE stability. Cylinder stability should be evaluated using criteria similar to those used for MRSE; and
- For correction of mixed astigmatism refractive errors, additional accuracy analyses for the hyperopic and myopic components are recommended (see Tables A2.9a and A2.9b and associated calculation instructions).

VECTOR ANALYSES

The analyses recommended above are helpful in the evaluation of clinical outcomes, but they are not sufficient to fully describe how the treatment affects the shape and optical properties of the cornea. Astigmatism, with its cylinder power and axis, is best described mathematically by a vector. This allows combination of magnitude and direction to be expressed in a single mathematical expression. The idea of applying vectors to the analysis of astigmatism was first suggested in the nineteenth century by Stokes.¹⁵ Vector analysis, as discussed previously,^{1-13,15-18} is essential for evaluation of the accuracy of astigmatism treatments.

Consistent vector analysis techniques are particularly important for assessing the safety and effectiveness of laser systems for corneal reshaping during clinical trials. Unfortunately, prior to this publication there has been no consensus on terminology, let alone methodology, for recommended vector analyses. In the discussions below, we assume the readers' familiarity with the fundamental principles of vector analysis. For those in

need of a review of basic vector manipulation, we recommend a recent article by Alpíns and Goggin.¹⁹

INITIAL DATA TRANSFORMATIONS

Prior to beginning any vector analysis of astigmatism treatment outcomes, the following transformations must be performed on the data set:

- Convert all manifest refraction data from the spectacle to the corneal plane (adjusting for vertex distance), as the intended first optical surface is always the cornea.
- Flip the cylinder axes of left eyes around the vertical axis so that errors due to cyclotorsion or anti-symmetrical healing patterns do not tend to cancel out when averaging data from right and left eyes. The correct conversion method is to create a "transformed" refraction for left eyes in which the new axis is equal to 180° minus the original axis. All left eye refractive data (pre- and postoperative) and targeted postoperative refractions should be converted before any further analysis. Left eye axis transformation can obscure certain types of device-related orientation errors, but such errors can be easily revealed by stratifying axis analyses by left and right eyes. Note that left eye axis transformations and conversions to the corneal plane must be done prior to conversion to vectors through doubling of the axis angle.
- Double all axis angles. To find a vector angle, the refractive cylinder axis must be doubled.⁴ The usual plotting convention is to label the polar plot with axes from 0° to 180° (based on axes prior to doubling) instead of 0° to 360°.

VECTOR ANALYSIS TERMINOLOGY

The basic data variables and calculated vector quantities used in astigmatic vector analysis are defined below and illustrated in Figure 1. Consistent with mathematical convention, all vector abbreviations are in bold font.

The *preoperative astigmatic error* vector represents a primary cylindrical error in the optical refractive power of the eye that must be corrected to restore the eye to emmetropia. It is the starting point for any astigmatic refractive treatment, and is shown in Figure 1 for logical completeness, although it does not appear directly in any calculations or outcomes variables.

The *preoperative astigmatic correction* vector is defined as the negative of the preoperative astigmatic error vector (or equivalently, the vector that is equal and opposite). It represents the cylindrical lens that is needed to restore an astigmatic eye to emmetropia. In common clinical usage, it is of-

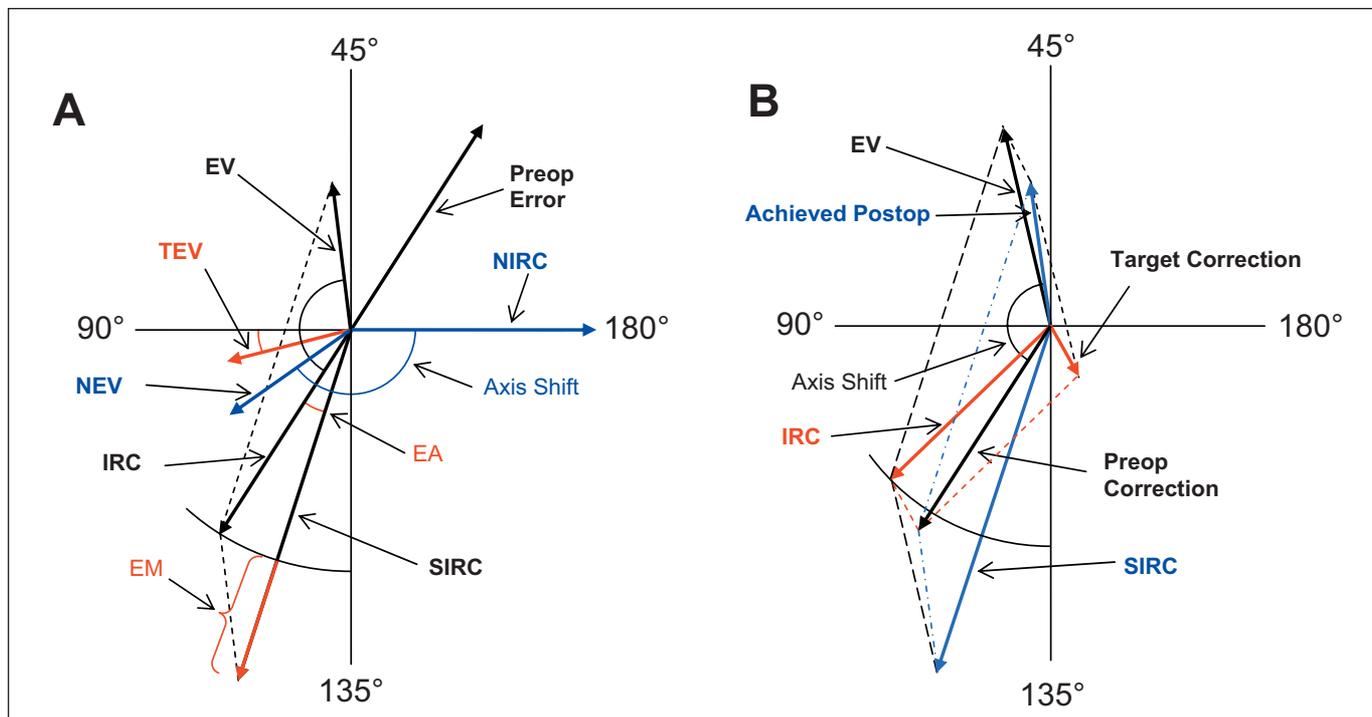


Figure 1. Illustration of basic astigmatic vector quantities and relationships. The following terms are defined in the text: preoperative astigmatic error; intended refractive correction (**IRC**); normalized **IRC** (**NIRC**); surgically induced refractive correction (**SIRC**); error vector (**EV**); normalized **EV** (**NEV**); treatment error vector (**TEV**); error of magnitude (**EM**); error of angle (**EA**); axis shift. **A**) Emmetropic target refraction (**IRC** = preoperative refractive correction). Normalized parameters are shown in blue and **TEV** parameters are shown in red. **B**) Non-emmetropic target refraction (the preoperative astigmatic error and the **NIRC**, **NEV**, and **TEV** are defined as in A, and are not shown for clarity.) Intended treatment vectors are shown in red and achieved treatment vectors are shown in blue.

ten referred to informally as the refraction.* To illustrate the difference between refractive error and correction, a preoperative astigmatic refraction of $+1.00\text{ D} \times 120^\circ$ means that the eye has 1.00 D too little power at axis 120° , requiring a positive cylindrical lens of $+1.00\text{ D} \times 120^\circ$ to correct to emmetropia. (The *postoperative astigmatic correction* vector is defined in an analogous way.)

The *intended refractive correction* (**IRC**) vector is defined as the vector difference between the preoperative astigmatic correction vector and the target postoperative cylinder vector (preoperative* – target*). In other words, it is the refractive correction to be attempted in an astigmatic treatment procedure. If the target refractive state is emmetropia, the **IRC** vector is equal to the preoperative astigmatic correction vector.

The *surgically induced refractive correction* (**SIRC**) vector is the vector difference between the preoperative and postoperative astigmatic correction vectors (preoperative* – postoperative*). It is the achieved correction. In LASIK, it represents the refractive “correcting lens” ablated into the cornea and is analogous to a spectacle lens. Therefore, all analyses attempting

*Converted to the corneal plane.

to determine the accuracy of the correction compare the **IRC** and **SIRC** in various ways.

The *error vector* (**EV**) is defined as the vector difference between the intended refractive correction and the surgically induced refractive correction (**IRC** – **SIRC**). This convention is consistent with the fact that pure undercorrections of astigmatism preserve the original axis, but overcorrections (when applied at the correct meridian) flip the axis (rotate the axis by 90° and the doubled-angle vector by 180°), which is vectorially equivalent to reversing the sign. When the refractive target is emmetropia, the **EV** is identical to the postoperative astigmatic correction vector.

The *normalized intended refractive correction* (**NIRC**) and *normalized error vector* (**NEV**) are equal to the **IRC** and **EV**, respectively, in magnitude, but are rotated so the **IRC** vector axis is zero and the **NEV** axis equals the signed axis shift between **IRC** and **EV**. Normalization of the **EV** allows easy visualization on a double angle plot—undercorrections will plot to the right and most overcorrections plot to the left of the vertical axis. (Overcorrections can plot slightly to the right if the **IRC** and error of angle [see below] are both large.)

The *axis shift* is the angular difference between the postoperative and preoperative manifest cylinder axes.

This is equivalent to half the angular difference between the postoperative astigmatic correction vector and the preoperative astigmatic correction vector. For eyes targeted for emmetropia, these vectors are identical to the **EV** and **IRC** vectors (see Fig 1A), but for eyes not targeted for emmetropia, they are different (see Fig 1B).

The *error ratio* (ER) is the proportion of the intended correction that was not successfully treated ($|EV|/|IRC|$).

The *correction ratio* (CR) is the ratio of the achieved correction magnitude to the required correction ($|SIRC|/|IRC|$). A ratio of 1 is ideal, whereas <1 implies undercorrection and >1 implies excessive application of the treatment.

The *error of magnitude* (EM) is the arithmetic difference of the magnitudes between **SIRC** and **IRC**, ($|IRC| - |SIRC|$). Error of magnitude of 0 is the ideal result. The CR and EM attempt to get at whether the applied treatment is correct in magnitude. Both measures are informative because a larger correction generally tends to have a larger EM but the CR can be relatively constant across all degrees of correction. Note that if the treatment is applied at the correct angle and the EM is negative, then the **EV** is in the opposite direction to the original refraction, and the axis effectively rotates 90° (overcorrection).

The *error of angle* (EA) measures whether the treatment was applied at the correct axis. It is the angular difference between the achieved treatment and the intended treatment. (Mathematically, it is half the angular difference between the **SIRC** and **IRC** vectors, because in vector space, these have doubled angles. The EA is defined always to be an acute angle.) As is conventional mathematically, the EA is negative if the **SIRC** is clockwise from the **IRC** and positive if the **SIRC** is counterclockwise from the **IRC**. The EA is often artificially high for small amounts of astigmatic correction because measurement error tends to be relatively large.

The *treatment error vector* (**TEV**) is defined to have the magnitude of the EM ($|IRC| - |SIRC|$) and the angle of the EA. As such, it is a single vector that contains both aspects of the treatment error. If the EM is negative, the **TEV** angle is equal to the EA + 90° . If the EM is positive, the angle is equal to the EA.

RECOMMENDED VECTOR ANALYSES

The vector analyses listed below are recommended for evaluation of astigmatic correction by lasers that reshape the cornea. These are in addition to the non-vector analyses presented above. Vector analysis should be performed at the time point of stability on all eyes treated for astigmatism. The vector analysis method

should be referenced if a commercial software package is being used. Appendix 1 provides a summary of mathematical definitions for principal vector terms. Appendix 2 provides the suggested reference table formats for presentation of these data:

1. Cylinder Stability (Table A2.5a & b)
2. Intended Refractive Correction (Table A2.6 and Figure 2A).
3. Surgically Induced Refractive Correction (Table A2.6)
4. Correction Ratio ($|SIRC|/|IRC|$) (Table A2.6)
5. Error Vector (Table A2.6 and Figure 2B)
6. Error Ratio (Table A2.6)
7. Error of Magnitude (Table A2.7) (Note: A difference of magnitudes may be positive or negative.)
 - a. Percentage of eyes with error of magnitude $\leq \pm 1.00$ D
 - b. Percentage of eyes with error of magnitude $\leq \pm 0.50$ D
8. Error of Angle (Table A2.8). (See example in Mathematical Definitions for sign convention)
 - a. Percentage of eyes with error of angle $\geq -15^\circ$ and $\leq +15^\circ$
 - b. Percentage of eyes with error of angle $> +15^\circ$
 - c. Percentage of eyes with error of angle $< -15^\circ$

Note: Mean error of angle should be calculated for left and right eyes separately. Any significant difference could indicate a device-related bias and should be further investigated.

For a visual representation of the astigmatic data from all eyes, we recommend plotting the **IRC**, **EV**, **NEV**, and **TEV** vectors on doubled-angle polar coordinates along with the centroid and “standard deviation ellipse” for each data distribution. Holladay et al⁴ provide details for creating such plots. Their general format is illustrated in Figure 2 with a small representative cohort of 20 eyes. The centroid represents the “center of gravity” of the distribution, and is plotted at the “mean x-component” and “mean y-component” position. The ellipse for each plot is centered on the centroid with major and minor axes horizontal and vertical. The horizontal semi-axis is equal to the standard deviation of the x-components, and the vertical semi-axis is equal to the standard deviation of the y-components. (The ellipse in each plot is not a pure depiction of a cross-section of the bivariate distribution, which would be at an oblique angle if there was a correlation between the x and y values. We note that in most cases there is little correlation between the two components.) The ellipse provides a useful visual portrayal of the variability in the x- and y-components to give a quick comparison of the two and to assist in locating outliers.

Figure 2A depicts **IRC** vectors for all 20 eyes along

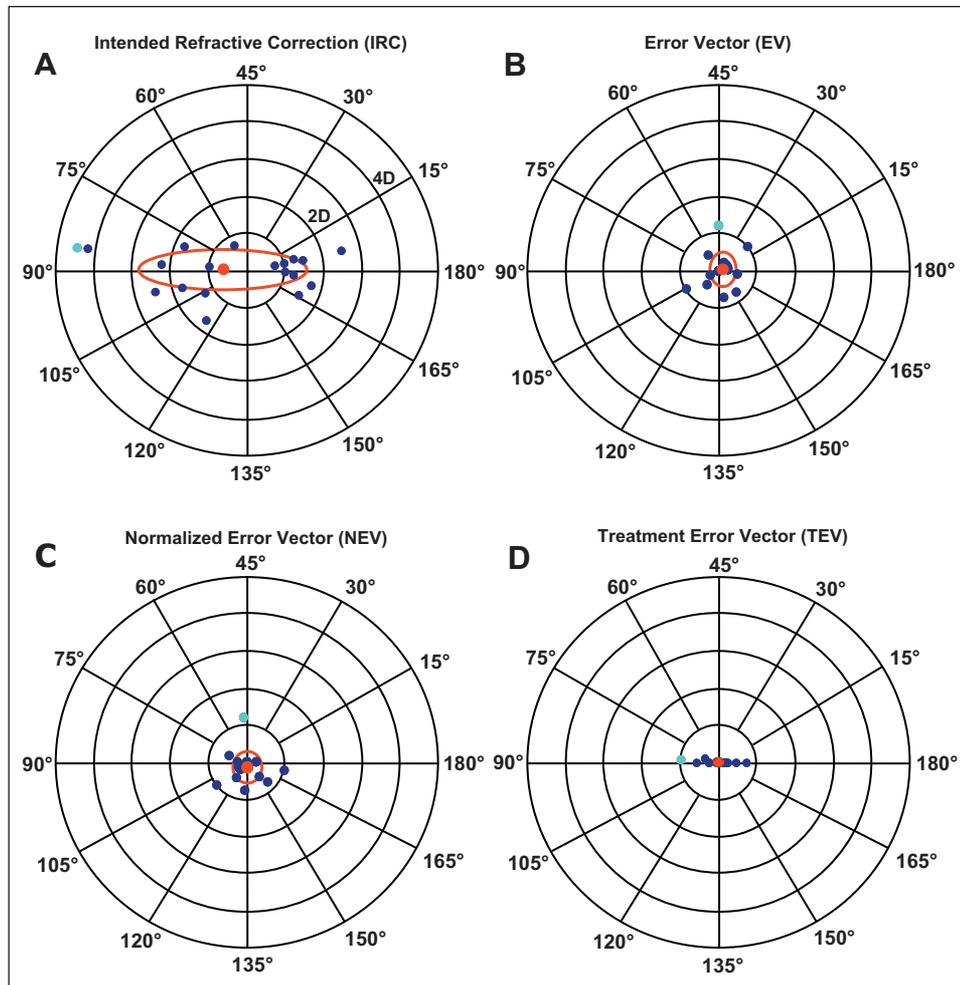


Figure 2. Doubled-angle formats recommended for summary scatterplot display of astigmatism treatment outcomes, illustrated with a cohort of 20 eyes. Color key for data symbols: dark blue=main distribution; light blue=outliers (one point, ie, 5% of the 20 points, is arbitrarily designated as an outlier for illustrative purposes); red=centroid. **A)** Intended refractive correction (**IRC**). **B)** Error vector (**EV**). **C)** Normalized error vector (**NEV**). **D)** Treatment error vector (**TEV**). Standard deviations of the **IRC**, **EV**, and **NEV** data distributions are shown as red ellipses. A standard deviation ellipse can also be plotted for the **TEV** distribution, but the vertical component of the **TEV** standard deviation is 0.02 D for the cohort shown, too small to appear as an ellipse in the plot.

the centroid and standard deviation ellipse. Recall that for eyes targeted for emmetropia, the **IRC** vector is identical to the preoperative astigmatic refraction. In this representation based on plus cylinder convention, eyes having “with-the-rule” astigmatism will tend to lie near the left horizontal axis, whereas eyes with “against-the-rule” astigmatism will tend to lie along the right horizontal axis, with “oblique astigmatism” falling closer to the vertical axes [0].

Figure 2B shows the **EVs** for the eyes in Figure 2A. These vectors are identical to the postoperative astigmatic refractions of eyes targeted for emmetropia. An **EV** scatterplot ideally should show a tight symmetrical cluster of points around the origin. A systematic asymmetry would be an indication of a device-related bias. For example, a malfunctioning microkeratome could consistently cut nonuniform flaps, resulting in a biased biomechanical distortion of the cornea in the direction of the cut.

The **NEVs**, along with the centroid and ellipse, are plotted in Figure 2C. Note that the **NEV** and **EV** magnitudes are identical, but the **NEV** orientation is rotated so that the corresponding **IRC** vector lies on the hori-

zontal axis, ie, its angle is just the angular deviation of the **EV** from the **IRC** vector. Thus, undercorrections lie to the right of the vertical axis and overcorrections tend to lie to the left. An overall tendency towards undercorrection or overcorrection will be readily apparent from the position of the centroid along the horizontal axis. As for the **EV** plot, the desired **NEV** scatterplot result is a tight, symmetrical cluster of points around the origin. Outliers of large magnitude will be readily apparent and can be investigated further.

Figure 2D is a plot of the individual **TEVs**, along with the appropriate centroid. In this plot, undercorrections are again to the right of the vertical axis and overcorrections are to the left (for $EA < 45^\circ$). Data points should generally not be far from the origin or far from the horizontal axis. Any point far from the origin or far from the horizontal axis should be examined closely for possible errors in refractive measurement, treatment procedure, or device calibration. These four sample graphs highlight the usefulness of graphic representation of astigmatic treatment outcomes.

Treatment error vectors can also violate the rule that

undercorrections plot to the right and overcorrections to the left of the vertical axis if axis shifts or errors of angle are very large. The great majority of such exceptions will be related to the difficulty of accurately measuring the axis of small amounts of astigmatism. These vectors will lie close to the origin and are of limited clinical significance. It is possible that a combination of a large measurement error and a large EA (eg, accidentally applying the treatment 90° from the intended meridian) could result in a “double flip” of the plotted vector axis, making an undercorrection look like an overcorrection on the **TEV** plot, but such combinations are expected to occur rarely.

METHODS FOR CALCULATING THE REFRACTIVE ERROR ANALYSIS VARIABLES

Due to the current lack of consistent software packages that can easily perform all of the vector analyses recommended above, we include the following methods for calculations.

The initial data consist of cylinder (C) and axis (A) values, assuming plus cylinder values converted to the corneal plane, and using adjusted axes for the left eye (adjusted axis = 180° – original axis), for:

- the preoperative refractive correction (C_{preop}, A_{preop});
 - the intended astigmatic correction (C_{IRC}, A_{IRC}, which corresponds to the laser input); and
 - the postoperative astigmatic correction (C_{postop}, A_{postop}).
- When the intended outcome is emmetropia, C_{IRC} and A_{IRC} are identical to C_{preop} and A_{preop}.

When the **IRC** cylinder and axis are available for direct input into the laser system, the refractive correction analysis variables are calculated as follows:

1. Convert the preoperative astigmatic correction to X and Y vector components:

$$X_{preop} = C_{preop} * \cos(2 * A_{preop})$$

$$Y_{preop} = C_{preop} * \sin(2 * A_{preop})$$

2. Convert the **IRC** to X and Y vector components:

$$X_{IRC} = C_{IRC} * \cos(2 * A_{preop})$$

$$Y_{IRC} = C_{IRC} * \sin(2 * A_{preop})$$

3. Convert the postoperative astigmatic correction to X and Y vector components:

$$X_{postop} = C_{postop} * \cos(2 * A_{postop})$$

$$Y_{postop} = C_{postop} * \sin(2 * A_{postop})$$

4. Find the magnitude of the **SIRC**.

$$|SIRC| = \sqrt{[(X_{preop} - X_{postop})^2 + (Y_{preop} - Y_{postop})^2]}$$

5. Find the axis of the **SIRC**, A_{SIRC}, using the preoperative and postoperative X and Y components (where Y_{SIRC} = Y_{preop} – Y_{postop} and X_{SIRC} = X_{preop} – X_{postop}).

First find:

$$\theta = 0.5 * \arctan \left(\frac{Y_{SIRC}}{X_{SIRC}} \right)$$

Then, find A_{SIRC} using the X and Y components of **SIRC**:

- If Y ≥ 0 and X > 0 then A_{SIRC} = θ
- If Y < 0 and X > 0 then A_{SIRC} = θ + 180°
- If X < 0 then A_{SIRC} = θ + 90°
- If X = 0 and Y > 0 then A_{SIRC} = 45°
- If X = 0 and Y < 0 then A_{SIRC} = 135°

(Note that the non-vector axis of a cylindrical correction is ½ [angle of the vector].)

Some spreadsheet programs have a four-quadrant arc tangent function available, “atan2,” which can be used in this calculation. Use X_{SIRC} as the X component and Y_{SIRC} as the Y component. These functions generally give results in radians so the answer must be converted to degrees. Then A_{SIRC} = θ, if θ is ≥ 0, and A_{SIRC} = θ + 180°, if θ is < 0.

6. Find EM by subtracting the magnitude of **SIRC** from the magnitude of the **IRC**:

$$EM = |IRC| - |SIRC|$$

Note: EM is a difference of magnitudes and therefore takes on negative values when |SIRC| > |IRC|, ie, in the case of an overcorrection.

7. Find EA by subtracting A_{IRC} from A_{SIRC}.

$$EA = A_{SIRC} - A_{IRC}, \text{ if } |A_{SIRC} - A_{IRC}| < 90^\circ$$

$$EA = A_{SIRC} - A_{IRC} - 180^\circ, \text{ if } A_{SIRC} - A_{IRC} > 90^\circ$$

$$EA = A_{SIRC} - A_{IRC} + 180^\circ, \text{ if } A_{SIRC} - A_{IRC} < -90^\circ$$

$$EA = 0^\circ, \text{ if } A_{SIRC} - A_{IRC} = \pm 90^\circ.$$

TABLE 2

Summary of Vector Analysis Parameters for Three Representative Examples of Surgically Treated Astigmatic Refractive Corrections

Preoperative refraction: 2.00 D cyl, 80° axis **Target refraction:** 0.00 D cyl

Postoperative refraction:

Example A. 1.00 D cyl, 70° axis (undercorrection);

Example B. 1.00 D cyl, 160° axis (overcorrection);

Example C. 0.50 D cyl, 35° axis (axis error only).

Analysis Parameters	Example A	Example B	Example C
Intended refractive correction (IRC)	2.00 D × 80°	2.00 D × 80°	2.00 D × 80°
Surgically induced refractive correction (SIRC)	1.11 D × 89°	2.96 D × 77°	2.06 D × 87°
Error vector (EV)	1.00 D × 70°	1.00 D × 160°	0.50 D × 35°
Normalized error vector (NEV)	1.00 D × 170°	1.00 D × 80°	0.50 D × 135°
Axis shift	−10°	80°	−45°
Error ratio (ER)	0.5	0.5	0.25
Correction ratio (CR)	0.56	1.48	1.03
Error of magnitude (EM)	0.89 D	−0.96 D	−0.062 D
Error of angle (EA)	8.9°	−3.3°	7.0°
Treatment error vector (TEV)	0.89 D × 8.9°	0.96 D × 87°	0.06 D × 97°

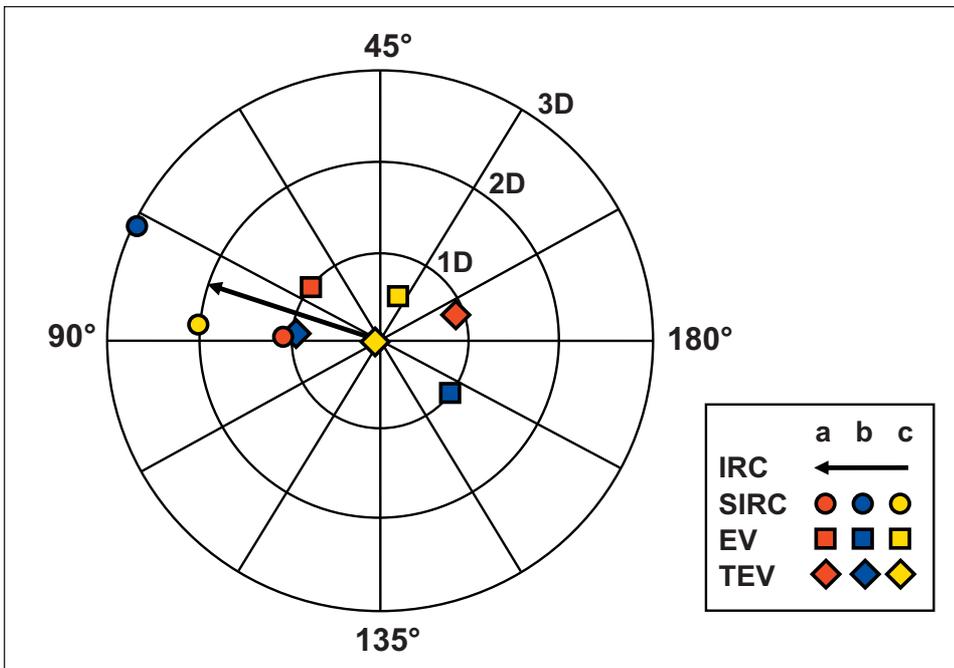


Figure 3. Doubled-angle plot of refractive outcome vectors for the representative examples in Table 2. Note that the **IRC** vector is the same for outcomes a, b, and c.

8. Find the X and Y components of the **EV** in the ophthalmic coordinate system.

$$X_{EV} = X_{IRC} - X_{SIRC}$$

$$Y_{EV} = Y_{IRC} - Y_{SIRC}$$

9. Find the X and Y vector magnitude components of the **NEV**, which is defined for a rotated coordinate system such that $A_{IRC} = 0^\circ$.

$$C_{EV} = \sqrt{(X_{EV}^2 + Y_{EV}^2)}$$

$$X_{NEV} = C_{EV} * (\cos[2 * (A_{EV} - A_{IRC})]), \text{ and}$$

$$Y_{NEV} = C_{EV} * (\sin[2 * (A_{EV} - A_{IRC})]),$$

where A_{EV} is calculated as outlined for A_{SIRC} in step 5 above.

10. Find the components of the **TEV** in a rotated coordinate system such that $A_{IRC} = 0^\circ$.

$$X_{TEV} = EM * \cos(2 * EA)$$

$$Y_{TEV} = EM * \sin(2 * EA)$$

Note: If EM is negative, the effect is to reverse the direction of the **TEV**, or equivalently, to add 90° to the EA. In the case of a “pure” overcorrection with $EA = 0^\circ$, the **TEV** plots as a vector of magnitude EM and angle 180° (axis 90°).

11. Find the centroid values of each plotted vector in the ophthalmic coordinate system.

$$X_{CENTROID} = \frac{\sum_{i=1}^n X_i}{n} \quad \text{and}$$

$$Y_{CENTROID} = \frac{\sum_{i=1}^n Y_i}{n}$$

where n is the number of eyes in the study sample.

12. Find the lengths of the semi-axes for the “standard deviation ellipse” for each plotted vector (except the **TEV**).

Length of ellipse horizontal semi-axis =

$$\text{standard deviation of } X = \sqrt{\frac{\sum_{i=1}^n (X_i - \bar{X})^2}{n - 1}}$$

Length of ellipse in vertical semi-axis =

$$\text{standard deviation of } Y = \sqrt{\frac{\sum_{i=1}^n (Y_i - \bar{Y})^2}{n - 1}}$$

Representative examples of astigmatic refractions illustrating the above calculations are shown in Table 2 and Figure 3. Values are assumed to be at the corneal plane.

CONCLUSIONS

Consistent terminology and analyses of astigmatic data are essential to understanding the results of corrections of spherocylindrical refractive errors. This article presents a comprehensive vector analysis terminol-

ogy. It also provides essential analyses for evaluation of astigmatism corrections by laser systems that reshape the cornea. Methods for calculating the refractive error analysis variables are described.

Use of a standard reference for all astigmatic refractive error analyses will facilitate evaluation of safety and effectiveness of laser systems that reshape the cornea. Analyses and reporting formats presented in this article also can be helpful in evaluation of astigmatic correction by other ophthalmic devices.

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**APPENDIX 1
MATHEMATICAL DEFINITIONS**

(Note. In these vector definitions, “refractive correction” refers only to the cylinder.)

$$\text{Intended Refractive Correction Vector} = \text{IRC} = \text{preop cylinder} - \text{target cylinder}$$

$$\text{Surgically Induced Refractive Correction Vector} = \text{SIRC} = \text{preop cylinder} - \text{postop cylinder}$$

$$\text{Correction Ratio} = \text{SIRC}/\text{IRC} = \frac{|\text{SIRC}|^*}{|\text{IRC}|}$$

$$\text{Error of Magnitude} = |\text{IRC}| - |\text{SIRC}|$$

$$\text{Error Vector} = \text{EV} = \text{IRC} - \text{SIRC}$$

$$\text{Error Ratio} = \frac{|\text{Error Vector}|}{|\text{IRC}|}$$

$$\text{Defocus Equivalent} = |\text{MRSE}| + \left(\frac{1}{2}\right) |\text{cylinder}|$$

$$\text{Error of Angle} = \frac{1}{2} (\text{angle of SIRC} - \text{angle of IRC}), \text{ if } |\frac{1}{2} (\text{angular difference})| < 90^\circ$$

Note that SIRC and IRC are defined based on doubled angles. Therefore,

$$\text{Error of Angle} = \frac{1}{2} (\text{angle of SIRC} - \text{angle of IRC}) - 180, \text{ if } \frac{1}{2} (\text{angular difference}) \text{ is } > 90^\circ;$$

$$\text{Error of Angle} = \frac{1}{2} (\text{angle of SIRC} - \text{angle of IRC}) + 180, \text{ if } \frac{1}{2} (\text{angular difference}) \text{ is } < -90^\circ;$$

$$\text{Error of Angle} = 0, \text{ if } \frac{1}{2} (\text{angular difference}) = \pm 90^\circ, \text{ so that the result is an acute angle.}$$

Error of Angle SIGN should come out as follows:

NEGATIVE if SIRC is clockwise from IRC, and
POSITIVE if counterclockwise.

Treatment Error Vector = TEV = Vector with magnitude of “Error of Magnitude” and angle of “Error of Angle.”

$$\text{Centroid Vector} = \frac{1}{n} \left(\sum_{\text{overall vectors}} \text{Vector}_i \right)$$

Examples for Error of Angle:

Note: SIRC and IRC are vectors based on doubled angles.

- Angle SIRC = 40°. Angle IRC = 10°. $\frac{1}{2} (\text{angular difference}) = \frac{1}{2} (40 - 10) = \frac{1}{2} (30) = 15$.
Error of Angle = +15°.
- Angle SIRC = 0°. Angle IRC = 20°. $\frac{1}{2} (\text{angular difference}) = \frac{1}{2} (0 - 20) = -10$.
Error of Angle = -10°.
- Angle SIRC = 40°. Angle IRC = 280°. $\frac{1}{2} (\text{angular difference}) = \frac{1}{2} (40 - 280) = -120$.
Error of Angle = -120 + 180 = +60°.
- Angle SIRC = 200°. Angle IRC = 20°. $\frac{1}{2} (\text{angular difference}) = \frac{1}{2} (200 - 20) = 90$.
Error of Angle = 0 (assign 0° error, if result is ±90°).

*The mathematical notation “||” indicates the magnitude of a value independent of sign.

APPENDIX 2
TABLE FORMATS FOR ASTIGMATISM TREATMENT OUTCOMES ANALYSIS

Note that stratification by pre- or postoperative cylinder magnitude (Tables A2.3, A2.4, A2.6, A2.7, A2.8, and A2.9) should be performed by cylinder *in the spectacle plane*. In all tables, “N” is the total number of eyes available at a particular time point and “n” denotes the number of eyes in a designated subset.

TABLE A2.1

Accuracy of Cylinder to Target

Cylinder*	Preop	1 Month	3 Months	6 Months
No. Eyes (N)				
Mean±SD				
Attempted change±SD				
Achieved change±SD				
% of eyes within ±0.50 D of target				
% of eyes within ±1.00 D of target				

*Display all refractions in a consistent (either positive or negative) cylinder format.

TABLE A2.2

Defocus Equivalent (DEQ)

$ \text{MRSE} + 0.5 \times \text{Cylinder} $	Preop	1 Month	3 Months	6 Months
No. Eyes (N)				
Mean±SD				
% with DEQ ≤ 1.00 D				
% with DEQ ≤ 0.50 D				

TABLE A2.3

Reduction of Absolute (Non-vector) Cylinder at Stability Time Point

Preoperative Cylinder	n	Percent Reduction of Absolute Cylinder (Mean [range])
All Eyes (N)		
0.0 D to <0.5 D		
>0.5 D to ≤ 1.0 D		
>1.0 D to ≤ 2.0 D		
>2.0 D to ≤ 3.0 D		
>3.0 D to ≤ 4.0 D		
>4.0 D to ≤ 5.0 D		
>5.0 D to ≤ 6.0 D		

TABLE A2.4

Residual Astigmatic Error at Stability Time Point

Residual Cylinder Magnitude	Absolute Shift in Axis*					Total
	≤5° n/N, %, (% CI)	>5° to ≤10° n/N, %, (% CI)	>10° to ≤15° n/N, %, (% CI)	>15° to ≤30° n/N, %, (% CI)	>30° n/N, %, (% CI)	
0.0 D*						
>0.0 D to ≤0.5 D						
>0.5 D to ≤1.0 D						
>1.0 D to ≤2.0 D						
>2.0 D to ≤3.0 D						
>3.0 D to ≤4.0 D						
>4.0 D to ≤5.0 D						
>5.0 D to ≤6.0 D						
>6.0 D						
Total						N

*Shifts are defined to be zero for eyes with zero residual cylinder magnitude.

TABLE A2.5A

Vector Stability of Cylinder¹

Magnitude of Vector Change in Cylinder ²	1 and 3 Months	3 and 6 Months	Subsequent Time Intervals
Eyes with ≤1.0 D magnitude of vector change (n/N, %, [% CI] ³)			
Eyes with ≤0.5 D magnitude of vector change (n/N, %, [% CI] ³)			
Mean magnitude of vector change between visits			
SD			
95% CI			
Mean change per year (change per month×12)			

¹Two separate tables are needed for each stability analysis:

A2.5a(i): Eyes that had two consecutive examinations, but not necessarily every follow-up examination.

A2.5a(ii): Eyes that had every follow-up examination up to the stability time point.

²To calculate this quantity for each eye take the vector difference between the postoperative astigmatic corrections at the two time points defining the interval. Take the mean of the magnitudes of these vectors.

³95% confidence interval around the percentage of eyes meeting the criterion.

TABLE A2.5B

Stability of Absolute (Non-vector) Cylinder¹

Magnitude of Change in Non-vector Cylinder	1 and 3 Months	3 and 6 Months	Subsequent Time Intervals
Eyes with ≤1.0 D change (n/N, %, [% CI] ²)			
Eyes with ≤0.5 D change (n/N, %, [% CI] ²)			
Mean change between visits			
SD			
95% CI			
Mean change per year (change per month×12)			

¹Two separate tables are needed for each stability analysis:

5b(i): Eyes that had two consecutive examinations, but not necessarily every follow-up examination.

5b(ii): Eyes that had every follow-up examination up to the stability time point.

²95% confidence interval around the percentage of eyes meeting the criterion.

TABLE A2.6

Vector Analysis Summary at Stability

Preoperative Cylinder	n	IRC (Mean±SD)	SIRC (Mean±SD)	EV (Mean±SD)	CR (Mean±SD)	ER (Mean±SD)
All Eyes (N)						
0.0 D to ≤0.5 D						
>0.5 D to ≤1.0 D						
>1.0 D to ≤2.0 D						
>2.0 D to ≤3.0 D						
>3.0 D to ≤4.0 D						
>4.0 D to ≤5.0 D						
>5.0 D to ≤6.0 D						

TABLE A2.7

Error of Magnitude (EM) at Stability

Preoperative Cylinder	n	Mean EM±SD (%, n/N)	Mean EM ±SD (%, n/N)	% EM ≤ ±1.00 D	% EM ≤ ±0.50 D
All Eyes (N)					
0.0 to ≤0.5 D					
>0.5 D to ≤1.0 D					
>1.0 D to ≤2.0 D					
>2.0 D to ≤3.0 D					
>3.0 D to ≤4.0 D					
>4.0 D to ≤5.0 D					
>5.0 D to ≤6.0 D					

TABLE A2.8

Error of Angle (EA) at Stability

Preoperative Cylinder	n	Mean EA±SD	% with EA ≤15°	% with EA > +15°	% with EA < -15°
All Eyes (N)					
0.0 D to ≤0.5 D					
>0.5 D to ≤1.0 D					
>1.0 D to ≤2.0 D					
>2.0 D to ≤3.0 D					
>3.0 D to ≤4.0 D					
>4.0 D to ≤5.0 D					
>5.0 D to ≤6.0 D					

TABLE A2.9A

Accuracy of Manifest Refraction in Preoperative Hyperopic Meridian¹

TABLE A2.9B

Accuracy of Manifest Refraction in Preoperative Myopic Meridian¹

Mixed Astigmatism Cohort

Correction Error at Stability Time Point	1 Month (n, % ²)	3 Months (n, % ²)	6 Months (n, % ²)	9 Months (n, % ²)
0.0 D				
Undercorrected				
>0.00 D to 0.50 D				
>0.50 D to 0.99 D				
1.00 D to 1.99 D				
≥2.00 D				
Overcorrected				
>0.00 D to 0.50 D				
>0.50 D to 0.99 D				
1.00 D to 1.99 D				
≥2.00 D				
Total (N)				
Mean Correction Error ± SD				

¹Tables A2.9a and A2.9b have identical layout as shown above (A2.9a summarizes hyperopic meridian and A2.9b myopic meridian).

²Represents percent of column total.

CALCULATION INSTRUCTIONS FOR TABLES A2.9A AND A2.9B

To calculate the under-/overcorrection (assuming full correction was intended).

1. Put preoperative manifest refraction in crossed-cylinder form.
2. Calculate the powers of the postoperative refraction projected onto the preoperative major meridians. To do this:
 - a. Put the postoperative refraction in plus cylinder form.
 - b. Add or subtract 90° to the plus cylinder axis to get the meridian of greatest plus power.
 - c. Calculate the angles between this meridian of postoperative greatest power and the two preoperative major meridians.
 - d. Project the postoperative cylinder power onto the two major preoperative meridians using:
Projected cylinder power = cylinder power \times $|\cos^2(\text{angle from [c]})|$.
 - e. Add the postoperative sphere to both of these meridians to get the total error in the meridian.
3. Look only at the preoperative myopic meridian. The postoperative refractive error in that meridian is the amount under- or overcorrected. If the postoperative refractive error is positive, then it is an overcorrection; if it is negative, then it is an undercorrection.
4. Look only at the preoperative hyperopic meridian. The postoperative refractive error in that meridian is the amount under- or overcorrected. If the postoperative refractive error is negative, then it is an overcorrection; if it is positive then it is an undercorrection.

Example:

1. Preoperative: $+1.00 - 2.25 \times 005$ equals $+1.00 @ 005$ combined with $-1.25 @ 095$.
2. Postoperative: $+0.50 - 0.75 \times 010$.
 - a. Postoperative equals $-0.25 + 0.75 \times 100$.
 - b. Meridian of greatest plus power is $100 - 90 = 10^\circ$.
 - c. Angle between meridian of greatest power and 005° is $10 - 5 = 5^\circ$. Angle between meridian of greatest power and 095 is $95 - 10 = 85^\circ$.
 - d. Projected power in 005 meridian = $0.75 \times \cos^2(5^\circ) = 0.744$ D
 - e. Projected power in the 095 meridian = $0.75 \times \cos^2(85^\circ) = 0.00570$ D
 - f. Total power in the 005 meridian = $0.744 - 0.25 \approx +0.49$ D
 - g. Total power in the 095 meridian = $0.006 - 0.25 \approx -0.24$ D
3. The preoperative myopic meridian was the 095 meridian. It has a 0.24 D undercorrection.
4. The preoperative hyperopic meridian was the 005 meridian. It has a 0.49 D undercorrection.

If an eye was not targeted to emmetropia, look at the intended final refractive error in the two major meridians (crossed-cylinder form) and calculate the difference from the postoperative results calculated in 2(e) to determine the under- or overcorrection.