

Simulation of toric intraocular lens results: Manual keratometry versus dual-zone automated keratometry from an integrated biometer

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PURPOSE: To evaluate simulated clinical outcomes in patients with toric intraocular lenses (IOLs) calculated on the basis of dual-zone automated keratometry from an integrated optical biometer, relative to manual keratometry.

SETTING: Private practice, Mesa, Arizona, USA.

DESIGN: Comparative case series.

METHODS: Patient records at 4 clinical sites were reviewed to identify patients who had manual keratometry and biometry with the Lenstar LS 900 recorded before toric IOL implantation and refractive follow-up data after implantation. Preoperative and operative data were extracted from patient charts. Simulated refractive outcomes were calculated based on mathematically removing the actual IOL implanted and then mathematically inserting the IOLs as determined by manual or automated keratometry from the biometry device.

RESULTS: Data for 128 patients were available for analysis. The actual residual astigmatism was comparable between manual keratometry and automated keratometry from the biometry system. Although simulated residual refractive astigmatism was similar between the 2 devices on average, there was variability in results by patient. Simulated residual refractive astigmatism was lower for the biometer when the standard deviation of the angle of astigmatism was low. Site-to-site variability was lower with the biometer than with manual keratometry.

CONCLUSIONS: Simulated outcomes suggest that overall results for a group of patients whose toric IOL surgery planning is performed with the dual-zone automated keratometry data from the biometer will be equivalent to those when manual keratometry is used. The reduced site-to-site variability with the biometer suggests an operational advantage.

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For several years, it has been possible to use toric intraocular lenses (IOLs) to correct existing corneal astigmatism at the time of cataract surgery. Use of a toric IOL was first reported by Shimizu et al. in 1994.¹ The successful use of a toric IOL involves measuring the existing anterior corneal astigmatism, accounting for any astigmatism induced by the surgical incision, and implanting the toric IOL at the appropriate angle to compensate for the combined preoperative and surgically induced astigmatism (SIA). Rotational stability is also important.

There are numerous methods to measure corneal astigmatism. In the case of the Acrysof toric IOL, the

original study conducted for the U.S. Food and Drug Administration approval relied on manual keratometry to determine the corneal astigmatism. As such, manual keratometry has been advocated as a preferred methodology for corneal astigmatism measurement.^A

Early research comparing manual keratometry and automated keratometry suggested that manual keratometry was the gold standard.² Later studies indicated that manual and automated keratometry produce comparable results, although with less variability in the automated results.³ This change is likely related to improvements in the technology of automated keratometers. In the area of cataract surgery,

studies that include consideration of postoperative results for manual methods versus automated methods do not appear in the literature. Several studies evaluate the differences between devices for keratometry measurement; however, they are concerned with calculating the spherical power of the IOL⁴ and 1 study⁵ did not include manual keratometry readings. None of the studies relates the measurements to postoperative results.

The dual-zone autokeratometry feature of the Lenstar LS 900 biometer (Haag-Streit International) uses 32 measuring points arranged in 2 concentric rings of 16 measuring points each. The outer ring has a diameter of 2.3 mm, and the inner ring has a diameter of 1.65 mm. Each displayed keratometry measurement is a composite of the mean of 4 measurements, totaling 128 measuring points. With the recommended 5 scans, the keratometers are derived from a total of 640 measuring points. This is in contrast to manual keratometry, in which 2 perpendicular mires at a diameter of approximately 3.2 mm are the basis of the measurement and generally a single measurement is deemed sufficient. Once the Lenstar LS 900 data are captured, the spherical equivalent radius is calculated for each individual measuring point. The keratometric calculation considers the best-fit ellipsoid built by the reflected points to determine the radii of the circumscribed ellipsoid. Results are then expressed in dioptic or millimeter notation.^B

We performed a retrospective study to determine whether the results of dual-zone automated keratometry for the planning of toric IOLs are equivalent to those from the generally recommended method of manual keratometry.

PATIENTS AND METHODS

Institutional review board approval was requested and granted for a study including retrospective chart review at

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4 clinical sites. The chart review included patients who had toric IOL implantation or for whom a toric IOL was planned who had a biometry measurement with the Lenstar LS 900 biometer and manual keratometry available in the preoperative record as well as a postoperative refraction. Because the interest was in comparing dual-zone automated keratometry and manual keratometry for surgery planning, patients with a known postoperative complication (eg, an IOL known to be positioned incorrectly) were not included in the analysis.

The preoperative manual keratometry and dual-zone automated keratometry were collected, along with autokeratometry data and simulated keratometry from other topography/biometry systems when these measurements were available. Postoperative data included the manifest refraction and the time at which this refraction was obtained (the number of days after surgery). Operative data included the IOL implanted and the axis at which it was implanted, along with the presumed SIA and incision angle for each surgery.

The Acrysof Toric IOL (Alcon Laboratories, Inc.) is available in 3 cylinder powers: the T3 model corrects 1.50 diopters (D) of astigmatism, the T4 model corrects 2.25 D of astigmatism, and the T5 IOL model corrects 3.0 D of astigmatism, all measured at the IOL plane. For a nominal eye, these IOLs provide approximately 1.03 D, 1.55 D, and 2.06 D, respectively, of astigmatism correction at the corneal plane.

Available clinical data were tabulated and de-identified in the Excel program, after which a preliminary analysis was performed using Access software (both Microsoft Corp.). Preliminary analysis included calculating astigmatism from keratometry values, the vector for determining astigmatism differences, and the relative differences between methods. Statistical analyses were performed using the Statistica data-analysis software system (version 9.1, Statsoft, Inc.). Vector analysis was used to evaluate all astigmatic effects. Differences were calculated using analysis of variance (ANOVA) and repeated measures (by eye) ANOVA, with the significance level set at a *P* value of less than 0.05. The ANOVA is equivalent to a *t* test when only 2 groups are involved, as is sometimes the case in the analysis below.

The power of the sample was calculated as follows based on a 2-tailed *t* test of mean differences in the 2 groups: An α level of 0.05 and a power of 0.90 were the desired levels of statistical significance. A difference of 0.125 D was of interest, as half the step size of a standard refraction. Presuming a standard deviation (SD) of 0.25 D for the residual refractive error, independent of measurement method, a minimum sample size of 78 eyes was required to detect the desired difference in results.

The method of analysis was as follows: The magnitude and direction of preoperative corneal astigmatism were calculated for each available preoperative measurement (manual keratometry, Lenstar LS 900). A third category, actual, was also created based on the preoperative measurements used for actual surgery planning; this was indicated in the patient record.

The actual data were categorized to indicate which preoperative method was used to provide the surgery planning data. If the actual data matched the magnitude and direction of astigmatism measured with manual keratometry or dual-zone automated keratometry, it was categorized as such. Otherwise, it was categorized as "other," which included matches to other preoperative measurement devices (eg, IOLMaster, Carl Zeiss Meditec AG) or combination effects

when several preoperative measurements were used to create a composite value for surgery planning. This category also included eyes for which dual-zone automated keratometry or manual keratometry was used with the appropriate lens axis but for which the power of the astigmatism correction was adjusted from that suggested.

Once the data above were tabulated, it was possible to simulate the effects of the manual keratometry and dual-zone automated keratometry on outcomes. For a given eye, each of the 2 keratometry results was used in surgery planning with the appropriate amount of SIA. This yielded a suggested IOL and angle of implantation. The actual IOL implanted and the calculated angle of implantation was known from the surgery planning sheets. Subtracting the actual toric IOL used at the calculated angle of implantation and then adding in the toric IOL suggested by the manual keratometry and dual-zone automated keratometry measurements provided a simulated residual astigmatism.

Figure 1 is a graphic representation of the procedure used. There is no way to quantify the actual corneal astigmatism of the eye (vector 1), the actual SIA that is caused (vector 2), or the random surgical effects, which include misalignment of the IOL (vector 3). Vector 4 is the calculated angle and magnitude of the toric IOL implanted from the surgical planning data. The combination of these 4 vectors yields the residual refractive astigmatism in the eye. To preserve the variability inherent in each surgery, simulated results can be calculated by removing the IOL vector (vector 4) and replacing it with the IOL vector calculated from manual keratometry or dual-zone automated keratometry; the result will be the simulated residual astigmatism in that eye. This mathematic removal of 1 IOL and the insertion of a different IOL yield a different residual refractive astigmatism error, except when the simulated measurement technique was the same as the method actually used for surgery.

The method above meant that minor variations in IOL placement, orientation angle, and effects of posterior corneal astigmatism were appropriately captured in the simulation of surgical results. Most of these factors would be unrelated

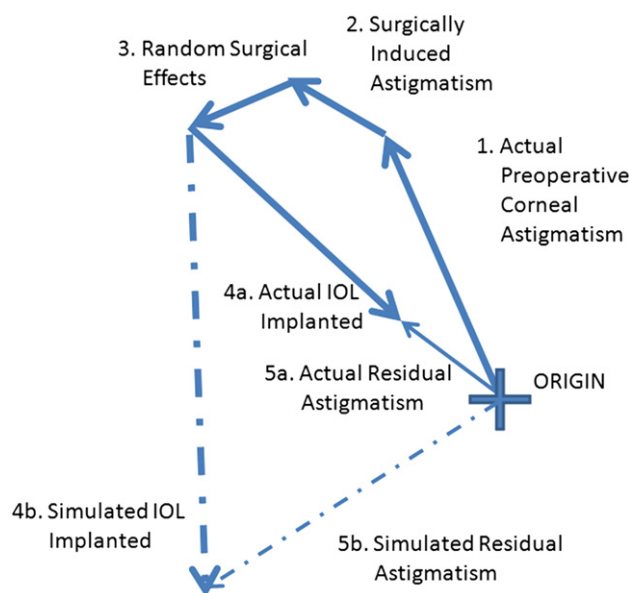


Figure 1. Method of calculating simulated residual refractive astigmatism.

to the IOL power and axis of placement of the toric IOL; they represent surgical variability outside of IOL considerations. As such, this simulated “lens substitution” retained the expected variability from the surgery. The total residual refractive astigmatism of each eye could be determined for the actual case (Figure 1, 5a) and the simulated case (Figure 1, 5b) using the method above.

A final categorization was applied to eyes to provide a proxy measure of the quality of the dual-zone automated keratometry calculation. The SD of the angle of the corneal astigmatism measured was available in the data. Each eye was categorized based on having an angular SD of 3.5 degrees or less or greater than 3.5 degrees. Analyses were performed to determine whether this categorization had an effect on the results.

RESULTS

A review of the available clinical records identified 131 eyes of 98 patients with the relevant preoperative and postoperative data. In 1 case, postoperative notes indicated that the IOL was incorrectly oriented; that eye was removed from the data set. Another patient had concurrent relaxing incisions in both eyes and was also removed. This left 128 eyes of 96 patients for analysis.

A review of the actual method used to calculate the IOL used in surgery was made. Of the 128 eyes, 56 were planned on the basis of manual keratometry readings, 23 on the basis of dual-zone automated keratometry readings, and 49 on results from a different device or consideration of multiple devices. The difference in magnitude of actual postoperative refractive astigmatism between the methods used was not statistically significant ($P = .67$). Figure 2 shows the results of the relevant ANOVA. The mean postoperative refractive astigmatism for all methods was less than 0.50 D. This calculation establishes that the groups of patients treated using the various methods are not

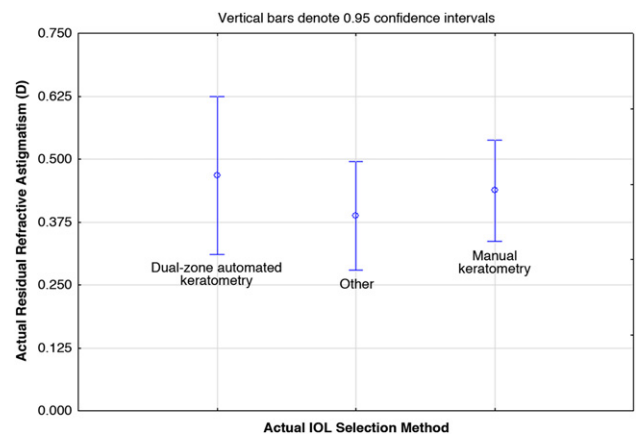


Figure 2. Actual residual refractive astigmatism magnitude by surgical planning input (IOL = intraocular lens).

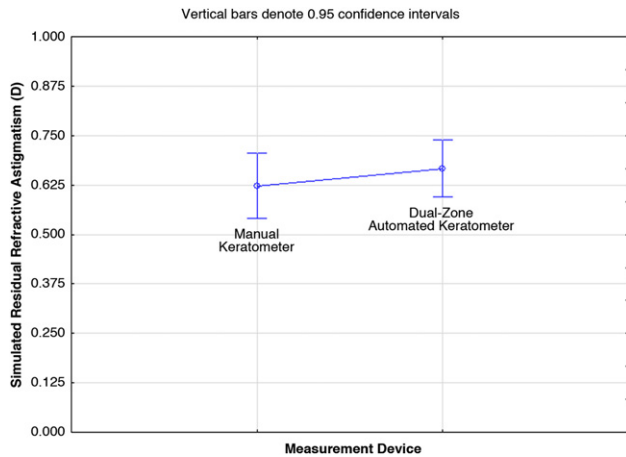


Figure 3. Mean simulated residual refractive astigmatism by device.

materially different; therefore, the simulation that follows would not be biased by the actual method of astigmatism planning used.

The relevant vector calculations were made to provide simulated residual refractive astigmatism errors in all eyes on the basis of substituting the surgical planning data from manual keratometry or dual-zone automated keratometry for the actual data used. The analysis of simulated results was limited to those in which the measured corneal astigmatism was less than 2.50 D for both the manual and automated preoperative data to reduce potential effects from patients with very high cylinder that could not be corrected with an Acrysof T5 IOL; these patients would have high postoperative cylinder, but not as a function of the measurement methodology. Because no adjustment for the actual SIA was possible in the simulated results and no subjective adjustments of IOL choice were permitted, the mean planned residual astigmatism for the dual-zone automated and manual keratometry data was significantly higher than actual astigmatism (0.33 ± 0.26 D for dual-zone automated and 0.33 ± 0.32 for manual versus 0.25 ± 0.25 D actual; $P < .01$).

A repeated-measures ANOVA showed no statistically significant difference in simulated residual refractive astigmatism between the manual keratometry results and the dual-zone automated keratometry results ($P = .55$) in the 111 eyes with measured astigmatism of 2.50 D or less on both devices (Figure 3). The simulated residual refractive astigmatism was 0.50 D or less in 35 eyes (32%) using manual keratometry data and in 32 eyes (29%) using dual-zone automated keratometry data. These numbers were not statistically significantly different ($P = .78$, χ^2 test). In 63 cases, the difference between the simulated residual

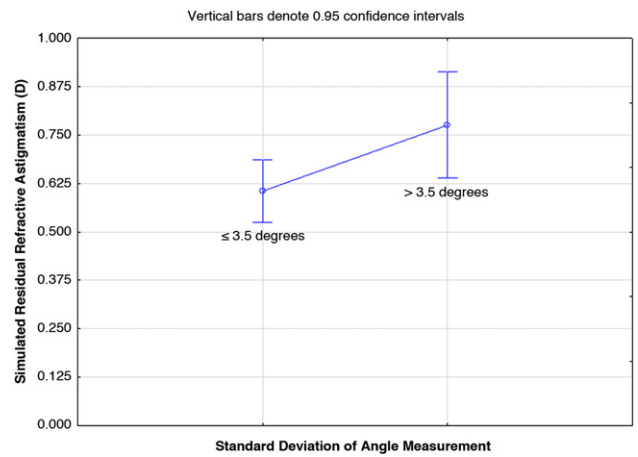


Figure 4. Effect of angle SD on simulated residual refractive astigmatism.

refractive astigmatism from manual keratometry data and dual-zone automated keratometry data was less than 0.25 D. In the remaining 48 cases, 25 simulated results from the dual-zone automated keratometry data were lower than results from the manual keratometry data and 23 were the reverse.

The effect of limiting the dual-zone automated keratometry data through consideration of the SD of the angle measurements had a statistically significant effect on results. Figure 4 shows the ANOVA for the simulated residual refractive astigmatism for dual-zone automated keratometry data categorized by the size of the SD of the angle measurement (3.5 degrees or less or greater than 3.5 degrees). The difference between the means of the 2 groups was 0.17 D ($P < .04$).

Figure 5 shows a cross tabulation of IOL selection by preoperative data. The table includes all patients, even those with high amounts of measured preoperative corneal astigmatism. Of the IOL choices, 55% (71 of 128) were the same for both devices (shaded boxes).

Dual-Zone	Manual			
	Spherical	Acrysof Toric T3	Acrysof Toric T4	Acrysof Toric T5
Spherical	4	5	2	
Acrysof Toric T3	6	40	12	2
Acrysof Toric T4	3	15	12	5
Acrysof Toric T5		3	4	15

Figure 5. Cross tabulation of calculated IOL selection by device. Shaded boxes indicate that the IOL choice was same for both devices (Dual-Zone = intraocular lens chosen with dual-zone automated keratometry; Manual = intraocular lens chosen with manual keratometry).

Table 1. Detailed breakdown of differences IOL selection and astigmatism.

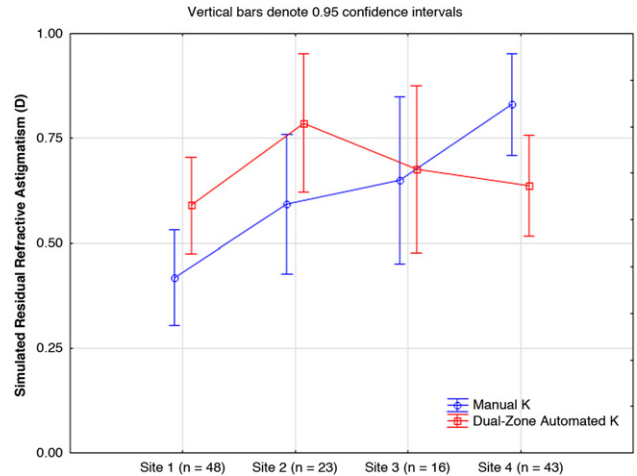
IOL Chosen by Manual K	Simulated Residual Astigmatism		
	Manual Lower	Equal	Manual Higher
Lower than dual-zone automated K	11	4	16
Equal to dual-zone automated K	6	60	5
Higher than dual-zone automated K	10	11	5

IOL = intraocular lens; K = keratometry

Although the astigmatic axis may have varied for these, the magnitude of the correction was at least similar. Table 1 is a more detailed breakdown of these results. It shows the relative effect of choosing a lower cylinder power or higher cylinder power toric IOL. For instance, the last row indicates that when surgical planning with manual keratometry suggested a higher powered IOL than the dual-zone automated keratometry, the simulated residual refractive astigmatism was more than twice as likely to be lower with the manual than with the dual-zone automated keratometry. Values within ± 0.25 D of each other were considered equivalent.

Changes from 1 IOL power to an adjacent IOL power would not be unexpected given the relatively small differences in measured corneal astigmatism that might drive these. However, as Figure 5 shows, there are 10 instances in which a change of more than 1 IOL power occurred (spherical to T4 or T3 to T5). In 7 of the 10 cases, simulated residual refractive astigmatism was lower (mean 0.90 D) when surgical planning was based on dual-zone automated keratometry; in the 3 remaining cases, it was lower when surgical planning was based on manual keratometry (mean 1.20 D). The difference was not statistically significant ($P = .36$, χ^2 test).

Figure 6 shows the ANOVA for the simulated residual refractive astigmatism by device and site. There was a statistically significant effect of site ($P = .01$) and a statistically significant interaction between site and device ($P < .01$). These differences were driven by the variability in results for the simulated residual refractive astigmatism from manual keratometry. The means ranged from 0.41 to 0.83 D for manual keratometry and from 0.59 D to 0.78 D for dual-zone automated keratometry. Separate ANOVAs by site showed no statistically significant difference between sites for simulated residual refractive astigmatism

**Figure 6.** Variability in simulated residual refractive astigmatism by site and device (K = keratometry).

based on dual-zone automated keratometry ($P = .28$) but a statistically significant difference based on manual keratometry ($P < .01$).

DISCUSSION

The overall findings in this simulation suggest that no material difference in the results are to be expected when planning toric IOL surgery with the dual-zone automated keratometry from the Lenstar LS 900 biometer or manual keratometry. No significant difference in actual outcomes was observed in cases when dual-zone automated or manual keratometry data were used for surgery planning, and there was no systematic difference in the calculated simulated residual refractive astigmatism values; individual results would vary by patient; however, there was no systematic overcorrection or undercorrection with 1 method versus the other.

When a difference of more than 1 IOL power was calculated between the 2 methods, the dual-zone automated keratometry data yielded lower simulated residual refractive astigmatism results in 7 of 10 cases. This was not statistically significant but is indicative that the dual-zone automated keratometry is at least as reliable as manual keratometry in terms of results with outliers. However, the difference in the magnitude of the simulated residual refractive astigmatism between methods when there was this level of disagreement between them (approximately 1.00 D) argues for having a second (or third) method of measuring corneal astigmatism to corroborate the primary method in an attempt to avoid these kinds of results. Browne and Osher^C report similar findings and suggest preoperative keratometry from several methods

would be helpful in identifying and avoiding the inadvertent use of clinical outliers.

There are limitations to the approach adopted here. The data are retrospective in nature and simulated. This allowed consideration of real-world surgical variability. However, it did not permit optimization of any particular IOL implantation through use of appropriate incision locations to minimize the planned residual refractive error.

The calculated residual refractive astigmatism error (the expected amount based on the surgical planning output result) in the simulations was higher than for the actual surgical planning because no subjective adjustment of IOL selection was permitted in the simulations. In reality, a surgeon can exercise judgment and consider opting for a T4 IOL when an eye has 1.50 D of astigmatism (below the 1.55 limit suggested for the T4 IOL). Hill and Potvin⁶ showed that the suggested cutoffs for use of the AcrySof toric IOL are relatively conservative. This would affect comparisons between simulated results and actual results; however, it should not affect the relative differences in calculations between the dual-zone automated keratometry data and the manual keratometry data.

Table 1 is of interest because when a lower powered IOL was used, the predicted residual astigmatism was much higher far more often than it was lower (and vice versa). This indicates that the axis of astigmatism is unlikely to have been flipped. If the axis were flipped with a higher powered IOL, a lower power IOL would have reduced or eliminated the power on the flipped axis, reducing the predicted amount of residual astigmatism. This corroborates the notion that the selection of IOLs in this simulation is conservative.

With regard to the dual-zone automated keratometry data, there was a reduction in simulated residual refractive astigmatism when the SD of the measured angle was lower. The difference was on the order of 0.25 D, which is arguably clinically significant. However, it is not clear whether this is a function of measurement variability independent of the eye or an indication of some additional variability in the eye itself. It is important to distinguish correlation and causality in this instance because it has not been determined whether the variability in the measurement is predictive in any fashion. It would be interesting to determine in a future study whether repeated measurements can or would reduce the SD of the angle measured and produce a correspondingly better overall result. Assessment of whether 3.5 degrees is the best cutoff value could also be evaluated. Consideration of the SD of both the amount and angle of measured astigmatism might be helpful.

The variability of measurements by site was much higher for manual keratometry than for dual-zone

automated keratometry. This may be a function of considerations such as different operators, training, and device calibration (which is required for manual keratometry). The ability to use an automated device to achieve the same overall results as a more labor-intensive and operator-dependent device (manual keratometry) has some potential benefit, although this was not been quantified here. In particular, lowering the variability of expected outcomes might allow surgeons to adopt relatively more aggressive treatment strategies because the likelihood of significantly flipping the axis would be reduced. This is likely to improve residual refractive astigmatism results for all patients.⁶

In summary, these simulated results suggest that overall results in a group of patients whose toric IOL surgery planning is performed based on the dual-zone automated keratometry from the Lenstar LS 900 biometer will be equivalent to those based on manual keratometry. However, there will be differences for different patients. The reduced site-to-site variability with dual-zone automated keratometry suggests an operational advantage. A prospective study with random selection of keratometry data (dual-zone automated or manual) in which subjective adjustment of planned IOL power and orientation were permitted would be useful in further investigating this question.

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