ARTICLE

Toric outcomes: Computer-assisted registration versus intraoperative aberrometry

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Purpose: To compare refractive outcomes of intraoperative computer-assisted registration and intraoperative aberrometry for the reduction of cylinder during toric intraocular lens (IOL) placement.

Setting: Bowie Vision Institute, Bowie, Maryland, USA.

Design: Prospective randomized case series.

Method: The patients were divided into 2 groups that had toric IOL implantation after phacoemulsification. The intraoperative computer-assisted registration group (Group 1) had preoperative toric calculations. The aberrometry group (Group 2) was guided by a vergence formula and intraoperative pseudophakic cylindrical measurements to determine the final IOL power and intended orientation. The primary outcome measure was the mean postoperative remaining refractive astigmatism, and it was compared with the predicted amount of cylindrical correction with the IOL.

Results: Fifty-two patients (104 eyes) had sequential cataract surgery. The mean amount of cylinder correction was 1.60 diopters (D) ± 0.70 (SD) (range 0.75 to 3.08 D) in Group 1 and 1.74 ± 0.79 D (range 0.72 to 3.08 D) in Group 2. The mean remaining refractive astigmatism was −0.29 ± 0.22 D in Group 1 and −0.46 ± 0.25 D in Group 2 ($P = .0003$). A difference vector of 0.1 @ 87 degrees (0.31 D arithmetic mean) was calculated in Group 1 and 0.0 @ 82 degrees (0.44 D arithmetic mean) in Group 2. The correction index was 1.03 in Group 1 and 0.95 in Group 2.

Conclusion: Intraoperative markerless computer-assisted registration and biometric guidance summarily yielded less remaining refractive cylinder than toric IOL placement guided by intraoperative aberrometry.

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A significant number of patients with cataract have comorbid corneal astigmatism,[1] and cylinder is a cause of reduced uncorrected distance visual acuity (UDVA) after cataract removal. A stated goal of the American Academy of Ophthalmology for cataract surgery is improved visual function with better uncorrected vision and reduced dependency on spectacles.[2] The predictability of intraocular lenses (IOLs) with a toroidal surface in reducing postoperative astigmatism is well documented. Several factors contribute to the precision of a toric IOL and have been studied at length. Accurate identification of corneal astigmatism as part of a biometric evaluation facilitates the neutralization of corneal astigmatism, and the rotational stability of IOLs is supported in the literature.[3]

A recent study[4] showed the usefulness of videokeratography with measurements of corneal astigmatism using optical biometry in combination with specific web-based toric clinical calculators. Furthermore, the effect of cyclorotation can be significant when preparing for refractive surgery[5] and reference marks are frequently used.[6] The application of sophisticated cameras and eye trackers to acquire landmarks on the surface of the eye is a common application for keratorefractive surgery.[7,8] Newer methods of evaluating the cornea, including the limbus and scleral anatomy, with infrared imaging enable registration at the time of corneal biometry. Intraoperative surgical guidance for toric IOL placement with iris registration has been reported to reduce the refractive error better than manual keratometry alone.[9]

Other studies[10] have shown the use of intraoperative aberrometry as an alternative to traditional biometry for toric IOL placement and orientation. This methodology has effectively addressed a much needed indirect assessment of the posterior corneal contribution not evaluated as part of conventional corneal analysis.[11] In addition, a new technique of measuring total corneal power using corneal topographic astigmatism might prove to increase accuracy.[12]

The purpose of the present study was to evaluate the efficacy of the remaining postoperative refractive astigmatism when

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preoperative autokeratometry combined with intraoperative data injection with the surgical microscope was used as part of the surgical planning, and compare the outcomes with intraoperative aberrometry measurements for the purposes of toric IOL alignment in a refractive cataract cohort. Of interest was whether the biometry, without the posterior corneal information and the intraoperative guidance, provided a simple modification to the target-induced astigmatism to address the posterior corneal contribution and is as good as the total ocular aberrometric calculations at reducing the predicted postoperative refractive astigmatism. The secondary endpoint was to evaluate the mean absolute error of the 2 guidance systems in predicting remaining refractive cylinder.

PATIENTS AND METHODS

Patients

This randomized prospective contralateral cohort study was performed in a private practice setting. The study protocol was approved and overseen by the Institutional Review Board of the Bowie Vision Institute, Bowie, Maryland, USA, and it adheres to the tenets of the Declaration of Helsinki and applicable regulatory requirements. Patients provided written informed consent before the study-specific procedures were performed, and consecutive eyes were enrolled that met the inclusion criteria for each eye. The patients who qualified returned for a mandatory preoperative evaluation that included a comprehensive examination.

Group 1 consisted of eyes guided by the Markerless-Callisto Intraoperative Biometric System (Carl Zeiss Meditec AG), whereas Group 2 (contralateral eye) was evaluated for the efficacy of intraoperative aberrometry (Optiwave Refractive Analysis with Verifeye third-generation software, Alcon Surgical, Inc.) when placing a single-piece toric IOL (Tecnis, Abbott Medical Optics, Inc.).

Patients were excluded if they had significant anterior segment pathology that would preclude adequate corneal imaging, preexisting corneal opacity, zonulopathy that would prevent centration of an endocapsular-supported IOL, previous keratorefractive surgery, disease that could limit the visual outcome after cataract surgery, an inability to intraoperatively register the guidance system or acquire the aberrometry during the surgical procedure, or a wavefront analyzer measurement that showed that a nontoric IOL or a toric IOL of cylindrical power greater than the specified range should be implanted.

The assignment for a surgical guidance platform of a toric IOL using either computer-assisted guidance or intraoperative aberrometry was randomly determined for the first eye. The contralateral eye was then performed with the alternate guidance system, 1 to 4 weeks later.

Guidance System and Procedure

Preoperative biometry was performed using partial coherence interferometry (PCI) (IOLMaster 500, Carl Zeiss Meditec AG) along with infrared ocular surface image for eventual registration. Eyes scheduled for implantation of an aspheric toric IOL (models ZCT150, ZCT225, ZCT300, ZCT400, as determined by the online toric calculator[A]) were considered eligible. Sequential corneal analysis with the Galilei G4 dual rotating Scheimpflug–Placido corneal analyzer (Ziemer Ophthalmic Systems AG) and the OPD-III with dynamic sciascopy and Placido imaging (Nidek Co. Ltd.) was performed. The IOL spherical power was determined using standard formulas.

Surgical Technique

All surgical procedures were performed by the same surgeon (J.D.S.). A femtosecond laser–assisted capsulotomy with a 5.25 mm radius centered on the pupil, phacofragmentation, and a 2.85 mm trilamellar clear corneal incision was placed at a 5.5 mm to 5.7 mm radius in the temporal axis.

Incisions were made at the temporal 0- or 180-degree axis. For all eyes, a surgically induced change in corneal astigmatism of 0.0 was used as the surgically induced corneal astigmatism to offset the effect of the posterior cornea power, as has been described for calculating the toric IOL power.[6,7,9]

The Callisto computer-assisted markerless guidance system uses the autokeratometry feature of the IOL Master 500 device, which projects 6 light reflections on the anterior cornea at a diameter of 2.5 mm. Next, a high-quality infrared image of the anterior ocular surface is captured for intraoperative registration, orientation, and alignment guidance. The specific toroidal power was selected based on the online Abbott Medical Optics toric calculator[A] to provide the least absolute remaining predictive cylinder. After the markerless registration was acquired, the alignment was guided through the right ocular, with care taken to center the optic on the visual axis. After the final position was determined, a pseudophakic aberrometric measurement was performed with intraoperative aberrometry software (Verifeye) and recorded after the eye was inflated with a balanced salt solution. Barraquer tonometry (Ocular Instruments, Inc.) was used to confirm an intraocular pressure (IOP) 16 to 18 mm Hg as a crossover measurement.

In Group 2, the IOL toroidal power was provided to the surgeon, who was blinded to the toric calculation, and included the toric platform with 2 IOL powers above and below the IOP crossover measurement to allow for variance based on the intraoperative measurements.

An aphakic power measurement was performed after the anterior chamber was reinflated with sodium hyaluronate 1.0% (Provisc) and an IOP of 16 to 18 mm Hg was confirmed with the Barraquer tonometer. The Optiwave intraoperative aberrometer uses Talbot-Moire interferometry in which the wavefront deflection is generated through analysis of a specific fringe pattern.[13] The toric IOL platform and the IOL spherocylindrical power were determined using the Verifeye system. The surgeon determined the quality of the intraoperative measurement to assess the ocular surface for appropriate hydration, fixation, and avoidance of undue external pressure on the globe. The final IOL position and orientation was guided by serial intraoperative aberrometric measurements in an effort to align the IOL until the "No Rotation Recommended" parameter was achieved, consistent with less than 0.50 diopter (D) of cylinder.

Sequential surgery was performed between 1 to 4 weeks after the first-eye surgery. The contralateral eye was treated with the same surgical technique in accordance with the alternate guidance system for toric IOL placement and orientation.

Postoperative Assessment

Confirmation of the IOL position was performed at the 90-minute postoperative evaluation at the slitlamp. The patients were then examined 1 week and between 4 weeks and 6 weeks postoperatively. The postoperative visual acuity and refraction were evaluated in a masked fashion by a technician or optometric physician.

The UDVA and corrected distance visual acuity (CDVA) using a Snellen acuity chart were recorded at 20 feet. The manifest cylindrical refraction obtained during the CDVA examination was determined as the remaining refractive astigmatism. Changes in the orientation of the axial marks were considered to assess the stability of the IOL alignment. The PCI measurements were repeated at the final postoperative visit to calculate the phaco-induced surgically altered corneal flattening.

Data collection included preoperative and postoperative keratometry values from the PCI device, intraoperative aphakic cylinder values (magnitude and axis) in Group 2, and intraoperative pseudophakia after toric IOL alignment values (magnitude and axis) for both study groups.

Statistical Analysis

Data analysis was performed using SPSS for Windows software (version 19.0, International Business Machines Corp.). The normality

of the data samples was evaluated using the Kolmogorov-Smirnov test. When parametric analysis was possible, the Student *t* test for unpaired data was used for comparisons between groups, whereas the Mann-Whitney test was applied to assess the significance of such differences when parametric analysis was not possible. For all statistical tests, a *P* value less than 0.05 was considered statistically significant. Correlation coefficients (Pearson or Spearman depending on whether the normality condition could be assumed) were used to assess the correlation between different variables. The Alpins vector method was used to analyze the astigmatic changes after surgery.[14–16] The difference vector, which is the median absolute error with median absolute deviation, was calculated. The percentage of eyes that were within ±0.5 D and ±1.0 D of the target cylinder was calculated.

RESULTS

The study comprised 52 patients (104 eyes). Table 1 shows the demographics in the 2 groups. No patient was excluded because of an inability to acquire intraoperative measurements or registration in either group. There was a statistically significant difference in the mean preoperative keratometric astigmatism between Group 1 and Group 2 (Table 2) ($P = .24$). The mean follow-up was 31 days (range 21 to 54 days) and 29 days (range 19 to 58 days), respectively. Group 1 had a correction index of 1.03, whereas Group 2 had a value of 0.95, which is reflective of slight undercorrection (Figure 1). A difference vector of 0.31 D with a vector mean of 0.1 @ 87 degrees was calculated in Group 1 and of 0.44 D with a vector mean of 0.0 @ 82 degrees in Group 2.

An aphakic measurement resulted in a mean difference between the preoperative keratometric astigmatism and the intraoperative aberrometric non-lens astigmatism measurement of 0.30 ±0.28 D (summated vector mean; centroid *x*: 0.03 ± 2.36; centroid *y*: 0.03 ± 1.37) and was comparable across the mean with-the-rule astigmatism measurement of 0.34 ± 0.27 D and the mean against-the-rule (ATR) astigmatism measurement of 0.29 ± 0.26 D subgroups. Further categorical analysis involved classifying eyes with greater or less than 1.25 D total astigmatism, a component that comprises the non-lens ocular residual astigmatism in refractive surprises. The difference between the intraoperative aberrometric aphakic astigmatism approached significance at 0.20 ± 0.14 D (eyes ≤1.25 D, n = 20) ($P = .14$) and at 0.35 ± 0.29 D (eyes >1.25 D, n = 32) ($P = .06$.) The mean corneal flattening effect at the incision at the temporal meridian was 0.51 ± 0.02 D and 0.51 ± 0.08 D in Group 1 and Group 2, respectively.

Table 1. Demographics in Group 1.

Parameter	Number
Age (y)	
Mean ± SD	70.4 ± 9.8
Median	69.7
Range	43.6, 85.4
Age group, n (%)	
<60 y	7 (13.4)
60 to 69 y	21 (40.4)
70 to 79 y	14 (26.9)
>80 y	10 (19.2)
Sex, n (%)	
Female	33 (63.5)
Male	19 (36.5)
Race, n (%)	
White	36 (69.2)
Black	12 (23.1)
Asian	2 (3.8)
Other	2 (3.8)

The mean postoperative remaining refractive astigmatism was 0.29 ± 0.22 D and 0.46 ± 0.25 D in Group 1 and Group 2, respectively. Analysis by *t* test showed better results in Group 1 for the remaining refractive astigmatism ($P = .00039$). Figure 2 shows the cumulative distribution of the remaining refractive astigmatism at the final postoperative evaluation. More than 25% of the patients in Group 1 had no postoperative astigmatism, whereas 4 patients (8%) in Group 2 had no remaining refractive astigmatism. The median absolute error in predicting cylindrical correction by IOL were similar for both guidance systems; that is, 0.35 D and 0.39 D in Groups 1 and 2, respectively ($P = .91$), and irrespective of the axis.

DISCUSSION

Astigmatic correction during cataract removal is increasing.[17,18] Predictability remains a concern despite improvement in measurements because of the difficulty in identifying and orienting the correct axis for toric IOL alignment.[19,20] Accuracy and precision are often predicted using reproducible biometry, which often requires multiple modalities of keratometry and continued refinement of surgeon factors to improve outcomes for each IOL. Despite new-generation IOL formulas, Abulafia et al.[21] concluded that the toric calculators that consider the influence of effective lens position only predict one third of the eyes within ±0.50 D of the residual astigmatism.

With the assistance of intraoperative aberrometry, Hatch et al.[10] increased the likelihood of achieving a remaining refractive astigmatism of 0.50 D or less by 2.4 times compared with standard methods of toric IOL placement. We achieved similar results with aberrometry in 76.5% of eyes with remaining refractive astigmatism of 0.50 D or less using the same software. In comparison, 92.2% of eyes in the intraoperative computer-assisted registration group were within ±0.50 D without the inconsistencies that were highlighted in the study by Stringham et al.,[22] outlining the variability of the surgical process that can affect the accuracy and ultimate efficacy of aberrometric analysis. Furthermore, more than two thirds of eyes that had computer-assisted registration had 0.25 D or less of remaining refractive astigmatism.

One such surgical variable is the corneal flattening effect discussed by Alpins et al.[14] In contrast, surgically induced corneal astigmatism incorporates the torque that rotates the astigmatism.[15] With this in mind, the flattening effect of the incision was consistent between the 2 groups because it was assumed that the effect of the posterior corneal power on the total corneal astigmatism in Group 1 would neutralize the ATR refractive contribution as a simplification of the Baylor nomogram. However, we were careful to calculate the effect of the corneal incision and with the different vector analyses, the results were consistent with those of Koch et al.[11] and Preussner et al.[23] The effect of the posterior cornea and the surgical incisions easier to

Table 2. Preoperative ocular characteristics in the 2 groups.

Parameter	Computer-Assisted Registration			Aberrometry			*P* Value
	Mean ± SD	Median	Range	Mean ± SD	Median	Range	
AL (mm)	24.31 ± 1.19	24.30	20.88, 26.46	24.34 ± 1.31	24.31	21.27, 28.87	.901
K1 (D)	43.29 ± 1.25	43.76	41.01, 46.81	43.23 ± 1.49	42.98	41.06, 46.20	.456
K2 (D)	44.88 ± 1.44	44.96	42.78, 48.08	45.01 ± 1.51	45.08	42.56, 48.08	.931
Corneal astigmatism (D)	1.60 ± 0.66	1.42	0.75, 3.26	1.79 ± 0.78	1.59	0.65, 4.07	.238

ACD = anterior chamber depth; AL = axial length; K1 = flattest keratometry reading; K2 = steepest keratometry reading

understand because of the non-lens ocular residual astigmatism measurements[16] and are reflected in the mean value of 0.30 ± 0.28 D at 179 degrees.

Previous studies that report only the postoperative mean arithmetic refractive cylinder with corrected and uncorrected vision do not assess torque, angle of error, or magnitude of error. The advantage of the Alpins method is the ability to assess the relative propensity for overcorrection and undercorrection. Alió et al.[24] calculated a mean undercorrection of approximately 0.30 D relative to the intended correction, and they attributed this to misalignment.

In a series of 111 eyes treated with a toric IOL and guided by aberrometry, Woodcock et al.[25] calculated a mean centroid of 0.05 ± 0.04 D at 11.77 degrees, indicating a slight trend toward overcorrection. Our results suggested a correction factor of 0.95 in the aberrometry group, or undercorrection, and 1.03 in the computer-assisted registration group, indicating an overcorrection similar to their 0.20 ± 0.45 D at 179 degrees. Twice as many eyes (64%) in their intraoperative aberrometry group than the eyes (31.3%) in our aberrometry group had a postoperative astigmatism of 0.25 D or less. Their aberrometry group results were similar to the results in the eyes (68.6%) with a postoperative astigmatism of 0.25 D or less in our computer-assisted registration group. However, when compared with the number of eyes with a postoperative astigmatism of 0.50 D or less, their study achieved 85.6%, which was similar to but not better than the 76.5% achieved in our aberrometry group. Woodcock et al.[25] used traditional ink markings to show the location of the astigmatic axes in their control group; however, they did not indicate whether reference marks and subsequent axis identification marks were placed. Our study did not have a control group, and the computer-assisted markerless registration superimposes the axis of alignment to within ±1.0 degree. Therefore, the discordance between the results in their intraoperative aberrometry group and our aberrometry group might represent study variance, especially considering that we had fewer patients. The difference between the results might also be explained by software upgrades in the systems evaluated; Woodcock et al. included Verifeye-Plus, which we did not have as part of our evaluation.

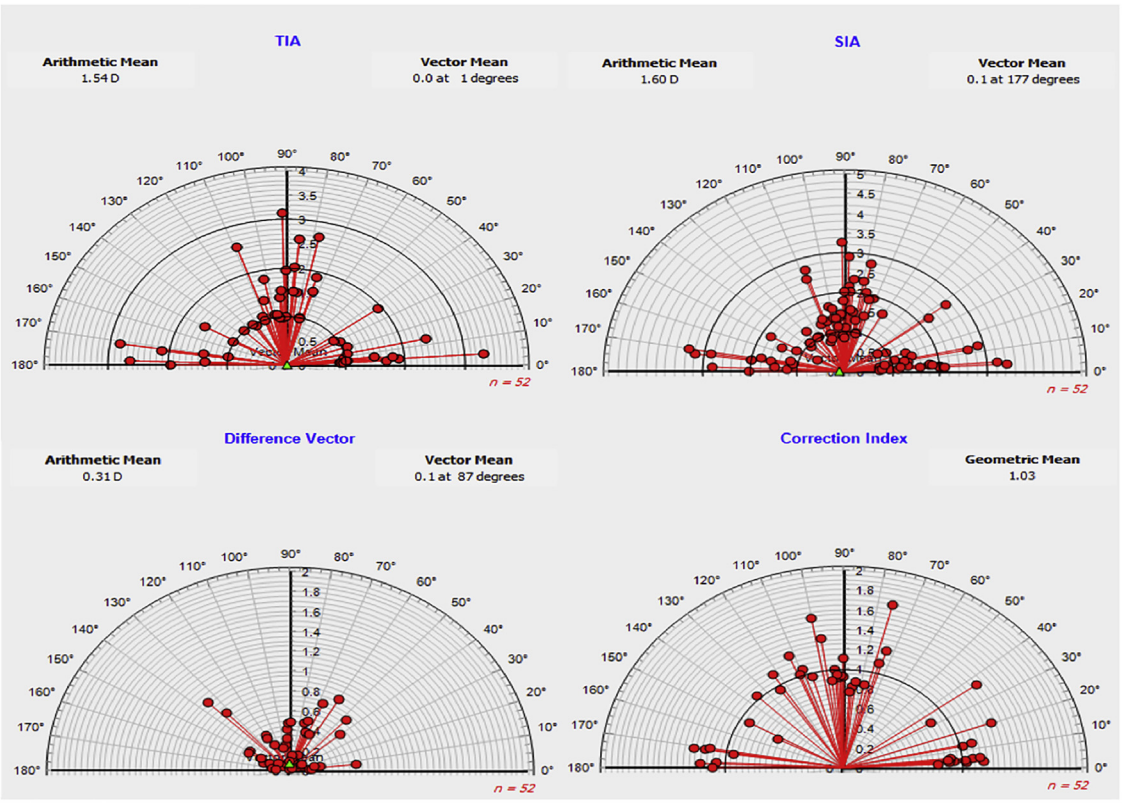
In Hirschall et al.'s review[20] using the same optical biometer, the main source of error influencing the accuracy of a toric IOL was the precision of the preoperative axis identification. By comparison, our study reduced the remaining refractive astigmatism by two thirds in Group 1, presumably because we did not use traditional axis marking.

Another potential limitation stems from the web-based toric-IOL calculators. Goggin et al.[26] pointed out that the Alcon web-based toric IOL calculator[B] does not consider the distance between the corneal and IOL planes and that the cylindrical value is determined by the mean pseudophakic eye based on a fixed ratio. In contrast, our computer-assisted registration group was provided by the Abbott online calculator[A] which does not omit the anterior chamber depth, nor does the Assort calculator,[C] which could have provided another advantage in determining the remaining refractive astigmatism.

For the reduction of remaining astigmatism, the outcomes were better with the use of both intraoperative guidance systems when compared with the published results for traditional toric IOLs for remaining refractive astigmatism.[3,4,9,10,17] However, computer-assisted registration was statistically better than intraoperative aberrometry for achieving remaining refractive astigmatism when a toric IOL was implanted. However, in the intraoperative aberrometry group, the spherical and cylindrical powers were set to change 31% of the time (16 of 52 eyes), which led to a different toric platform than what was recommended by the preoperative IOL spherical power or online toric calculator. Also, 3 of the 16 eyes were treated with a toric IOL when a nontoric IOL would have been suggested by the preoperative biometry. This highlights a limitation in this study, which focused solely on the precision of reducing the refractive cylinder. Clinical studies[26,27] found that intraoperative aberrometry is a reliable method of determining IOL spherical power. However, the spherical equivalent, as part of the IOL calculation/vergence formula, certainly plays a role in a fully integrated system, such as computer-assisted registration and intraoperative aberrometry, and it is worthy of future consideration.

Furthermore, patient selection was based on several clinical factors to ensure reproducibility of astigmatism in magnitude and meridian with 3 devices. One device, the Galilei G4, included posterior corneal contribution/total corneal power. We selected patients who had similar readings with the 3 corneal devices while acknowledging the contribution of the total corneal power. Therefore,

Intraoperative computer-assisted registration group:



Intraoperative aberrometry group:

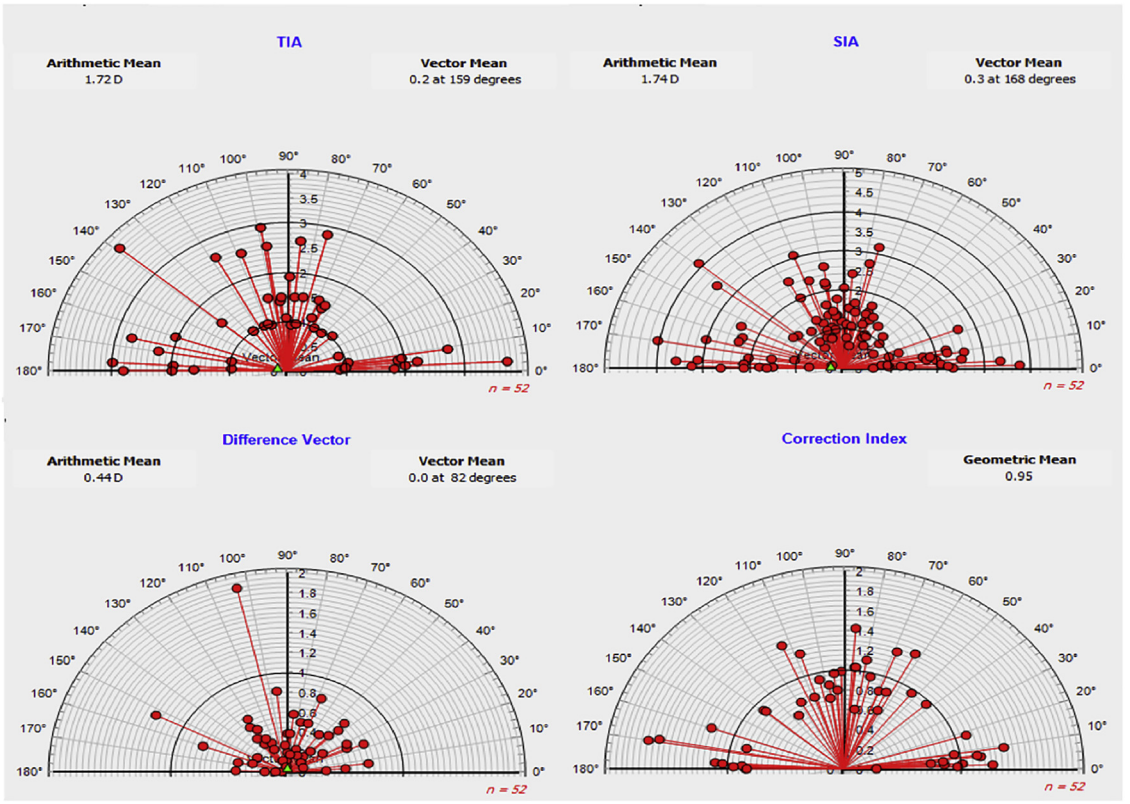


Figure 1. Single-angle polar plots showing the results of an Alpins method analysis to determine the vector indices and correction indices in the 2 groups (SIA = surgically induced astigmatism vector [actual astigmatism correction after consideration of phaco incision]; TIA = target-induced astigmatism vector [intended astigmatism correction after consideration of phaco incision]).

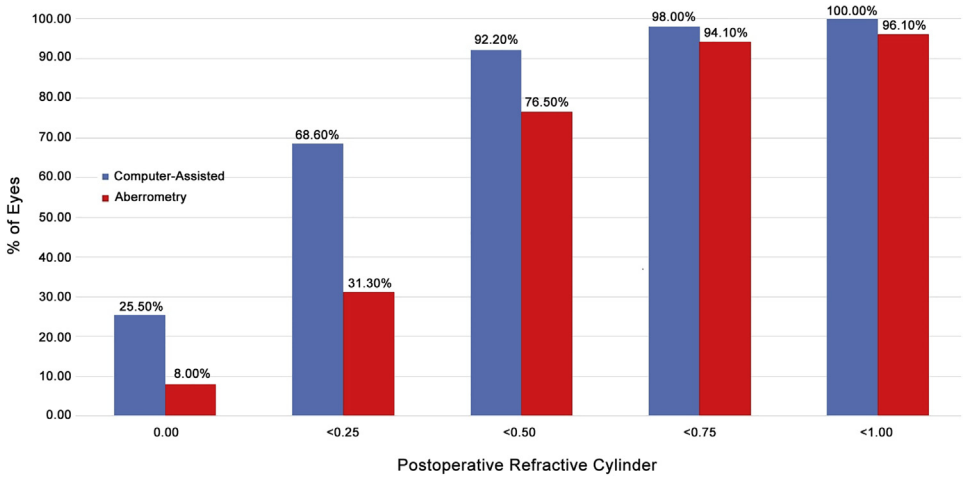


Figure 2. Distribution of postoperative magnitude of refractive cylinder.

reproducible corneal analysis was crucial for inclusion. The study by Klijn et al.,[28] which compared a Scheimpflug imager with a color diode corneal topographer, found the reduced levels of residual cylinder could be achieved when considering the back surface of the cornea as part of the total corneal astigmatism rather than considering the anterior corneal astigmatism alone. However, we used the traditional model of a surgically induced corneal astigmatism of 0.0 temporally to allow for a clinical application to be derived from traditional autokeratometry. The mean non-lens ocular residual astigmatism measurement of 0.30 $\pm$ 0.28 D at 179 degrees and the consistent corneal flattening effect of 0.5 D at the temporal meridian show the potential for nearly 0.25 D of induced residual arithmetic astigmatism before an IOL is placed. Although it might be considered a limitation that we did not include the information from total corneal power, which was readily available and is gaining popularity in clinical practice,[29] other factors that include clinical efficiency have to be explored.

A notable distinction between the 2 guidance systems might explain the differences in remaining refractive astigmatism. With regard to the computer-assisted registration system, the intended residual astigmatism was significantly less than in the intraoperative aberrometry group. Often, the goal was for a "No Rotation Recommended," or a measurement of less than 0.50 D of cylinder in the case of our study group. This created a confirmation bias and served to discourage further refinement that could have driven the refractive astigmatism even lower.

In conclusion, the defocus equivalent is increasingly being addressed by intraoperative guidance systems, and the delivery of reproducible reduction of astigmatism is achieved when computer-assisted registration and aberrometry are incorporated individually. The computer-assisted registration resulted in less remaining refractive astigmatism with toric IOL guidance than intraoperative aberrometry; however, the mean absolute predictabilities were statistically indistinguishable. The microscope might serve as a future hub for the 2 technologies to provide continuous monitoring and deliver vital biometrics during refractive cataract procedures.

WHAT WAS KNOWN

- Intraoperative aberrometry reduces residual refractive astigmatism better than traditional toric markers.

WHAT THIS PAPER ADDS

- The use of computer-assisted registration resulted in less postoperative refractive astigmatism than the use of aberrometry and traditional toric markers.

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