



Intraoperative aberrometry versus standard preoperative biometry and a toric IOL calculator for bilateral toric IOL implantation with a femtosecond laser: One-month results

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PURPOSE: To compare astigmatic outcomes in patients with bilateral cataracts having toric intraocular lens (IOL) implantation with intraoperative aberrometry measurements in 1 eye and standard power calculation and a toric IOL calculator with inked axis marking in the contralateral eye.

SETTING: Twelve sites in the United States.

DESIGN: Prospective cohort study.

METHODS: The eye with the more visually significant cataract was randomized to intraoperative aberrometry measurements (Ocular Response Analyzer with Verifeye) or standard preoperative biometry and use of a toric calculator with the contralateral eye automatically assigned to the other group. The primary effectiveness outcome was the proportion of eyes with a postoperative refractive astigmatism of 0.50 diopter (D) or less at 1 month.

RESULTS: Of the 130 patients (260 eyes) enrolled, 124 (248 eyes) were randomized; 121 (242 eyes) completed the trial. The percentage of eyes with astigmatism of 0.50 D or less at 1 month was higher in the intraoperative aberrometry group than in the standard group (89.2% versus 76.6%) ($P = .006$). The mean postoperative refractive astigmatism was lower in the intraoperative aberrometry group ($0.29 \text{ D} \pm 0.28$ [SD] versus $0.36 \pm 0.35 \text{ D}$) ($P = .041$). Secondary effectiveness endpoints, including manifest refraction spherical equivalent prediction error, uncorrected distance visual acuity, and corrected distance visual acuity, were similar.

CONCLUSIONS: Compared with standard methods, the use of the intraoperative aberrometry system increased the proportion of eyes with postoperative refractive astigmatism of 0.50 D or less and reduced the mean postoperative refractive astigmatism at 1 month. Other efficacy outcomes were similar.

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Implantation of toric intraocular lenses (IOLs) for the treatment of astigmatism and aphakia requires calculation of appropriate cylinder power based on anterior corneal measurements and/or topography and surgically induced astigmatism using a toric calculator and placement in a specific position to achieve the best

refractive results. Spherical IOL power is usually calculated preoperatively using various formulas that are based on the length of the eye, the estimated postoperative position of the IOL, and the corneal curvature/power. In planning surgery, the eye is marked with ink while a patient is sitting upright to show the

location of the astigmatic axis, thus accounting for the effects of cyclotorsion when the patient is supine during surgery. This method, however, is inherently imprecise because it is subject to loss of accuracy if the marks are misaligned or the ink smears.

Many formulas based on anatomic measurements have been developed to predict pseudophakic anterior chamber depth and effective lens position. Intraoperative aberrometry provides real-time IOL spherical and cylinder power calculation information during the aphakic measurement phase and axis positioning for toric IOLs during the pseudophakic phase.^{1,2} In addition, the intraoperative aberrometer measures the total refractive astigmatism in the eye in the aphakic phase, which accounts for the anterior and posterior curvature of the cornea and is particularly important in patients whose anterior corneas have been reshaped by keratorefractive procedures and those for whom toric IOL implantation has been planned.^{3,4}

Wavefront aberrometry is widely used to improve the results of laser vision correction. However, the types of aberrometers used in keratorefractive surgery are too large to use intraoperatively¹ and their dynamic range is not wide enough for the aphakic measurements needed in IOL surgery.³ The Talbot-Moiré measurement system is a miniaturized double-pass system that uses offset gratings called Ronchi gratings to produce a fringe pattern.⁵ Aberrations in the wavefront cause distortions in the fringe pattern, which are translated into a refractive value using a proprietary algorithm.^{3,6} The aberrometer is small enough to mount under the surgical microscope, and the fully integrated system includes an easy-to-operate surgeon interface. The Ocular Response Analyzer biomechanical waveform analyzer with Verifeye (Alcon Surgical, Inc.) is the third-generation version of the intraoperative aberrometry system developed by Wavetec

Vision, and it has undergone significant hardware and software upgrades since the launch of the original system in 2008.⁵ This noninvasive noncontact diagnostic integrated intraoperative wavefront aberrometer system uses real-time intraoperative optical measurements and replaces ink markings by matching the IOL axis with the axis of astigmatism using the refractive data gathered and processed by the system.

In this study, patients with astigmatic bilateral cataract, none of whom had previous keratorefractive surgery, had femtosecond laser-assisted (Lensx, Alcon Surgical, Inc.) cataract surgery and IOL (Acrysof, Alcon Surgical, Inc.) implantation in both eyes. In 1 eye, the third-generation biomechanical waveform analyzer was used to determine the spherical power, cylinder power, and axis of placement of the IOL; the fellow eye had surgery based on standard preoperative measurements. The spherical IOL power was determined using standard formulas, and the cylinder power and axis of placement were determined using the Acrysof IQ toric calculator[^] (Alcon Surgical, Inc.) with traditional ink markings showing the location of the astigmatic axis.

PATIENTS AND METHODS

This prospective randomized observer-masked contralateral eye comparison study enrolled patients with bilateral cataracts scheduled for femtosecond laser-assisted cataract extraction combined with implantation of an Acrysof IQ aspheric toric IOL at 12 sites in the United States. All surgeries were performed by 1 of 14 ophthalmic surgeons, each of who had at least 2 years of experience with this procedure.

This clinical investigation conformed to the requirements of the Declaration of Helsinki and was approved by the Institutional Review Board of each participating institution. All patients provided written informed consent.

Inclusion Criteria

Patients were included if they were in good general health, older than 22 years with bilateral cataract, able to provide written informed consent, and scheduled for laser refractive cataract extraction surgery or femtosecond laser-assisted cataract extraction surgery with implantation of an aspheric toric IOL (Alcon models SN6AT3, SN6AT4, SN6AT5, SN6AT6, and SN6AT7, as determined by the toric calculator[^]) in the posterior chamber. Axial length was to range from 22.01 to 27.00 mm, and preoperative dilated pupil diameter was to be more than 6.0 mm. Patients also had to be willing and able to attend all postoperative examinations and have clear ocular media other than cataract, the potential for a postoperative visual acuity of more than 0.2 logMAR (20/32), and be willing to discontinue use of soft contact lenses or rigid gas-permeable contact lenses for a minimum 2 weeks and 3 weeks before surgery, respectively.

Per protocol, no more than 25% of all IOLs planned to be implanted based on the Acrysof IQ Toric IOL calculator were model SN6AT3. Eyes were included if the third-generation

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biomechanical waveform analyzer measurements showed that a nontoric IOL or an IOL of cylindrical power greater than the specified range should be implanted and that IOL was implanted.

Exclusion Criteria

Patients were excluded from the study if they had limbal relaxing or arcuate incisions created manually or with a femtosecond laser, were currently participating in the trial of another investigational drug or device, had complications during surgery unrelated to the investigational device, or had lens/zonular instability (eg, Marfan syndrome, pseudoexfoliation syndrome) or a history of infectious corneal diseases (eg, herpes simplex, herpes zoster) or other conditions that might result in corneal scarring, significant central opacity/scar, severe dry eye, or irregular astigmatism. Patients were also excluded if they required sedation or another procedure, such as iris hooks or insertion of a capsular tension ring during surgery; were unable to maintain adequate fixation for image capture with the investigational device; had keratopathy/kerectasia (defined as any corneal abnormality other than regular corneal astigmatism, including corneal leukoma and pterygium); or had inflammation or edema (swelling) of the cornea, including keratitis, keratoconjunctivitis, and keratouveitis. In addition, patients were excluded if they could reasonably be expected to require a secondary surgical intervention at any time during the study (other than neodymium:YAG capsulotomy) or had previous corneal refractive surgery.

Additional exclusion criteria were amblyopia or corneal dystrophy (eg, epithelial, stromal, or endothelial dystrophy); a diagnosis of degenerative visual disorders (eg, macular degeneration) predicted by subjective assessment of the retina to cause future acuity losses to worse than 0.2 log-MAR (20/32) and/or to interfere with acquiring images or determining a precise postoperative refraction; shallow anterior chamber not caused by a swollen cataract; microphthalmos; a history of retinal detachment, kerectasia/kerectopathy, corneal transplantation, recurring severe anterior or posterior segment inflammation of unknown etiology, rubella, or traumatic cataract; iris neovascularization; uncontrolled glaucoma or glaucoma with visual field defects; poorly dilating pupil or other defects of the pupil preventing the iris from adequate peripheral retraction; aniridia; optic nerve atrophy; or anisometropia. Patients who had implantation of an IOL other than an aspheric Alcon toric IOL were also excluded except for patients in the test group deemed by intraoperative measurements to not require a toric IOL. Women who were pregnant, nursing, or suspected of being pregnant and patients deemed unsuitable for the study by the investigator or subinvestigator were also excluded.

Randomization and Masking

The eyes were randomized to a test group and a control group. Procedures on test eyes were based on intraoperative aberrometry measurements, whereas procedures on control eyes were based on standard preoperative biometry assessments, conventional IOL power formulas, the Acrysof IQ toric IOL calculator,^A and ink marking for positioning. No eye in the control group was assessed by intraoperative wavefront aberrometry.

The first eye to have surgery, defined as the eye with more visually significant cataract determined by

preoperative corrected distance visual acuity (CDVA), was randomized 1:1 by block randomization to the test group or the control group, with the contralateral eye assigned by default to the other group. If the CDVA was equal in both eyes, the right eye had IOL implantation first. Patients returned for testing 1 day and 1 week after surgery in each eye and 1 month after surgery in the second eye. Patients with visually significant posterior capsule opacification at 1 month were scheduled for a visit at 3 months. The second eye had surgery 7 to 14 days after the first eye.

The postoperative logMAR visual acuity and refraction were evaluated in a masked fashion by a technician or optometrist. Evaluators were not present at randomization during surgery or in the recovery area and did not have access to patients' medical or surgical charts, including the results of intraoperative aberrometry.

Examinations and Devices

Preoperative examinations included 2 consecutive corneal topography maps, measurement of pupil size, and determination of potential postoperative visual acuity. Preoperative and 1-month postoperative examinations included corneal topography (Humphrey Atlas Topographer, Carl Zeiss Meditec AG), optical low-coherence reflectometry (OLCR) keratometry (Lenstar, Haag-Streit AG), and measurements of uncorrected distance visual acuity (UDVA) and CDVA using the 100% contrast, 4 m Early Treatment Diabetic Retinopathy Study acuity charts (charts 1, 2, and R) housed in Vector Vision illumination boxes. Visual acuity tests were performed at the prescribed 4 m testing distance. Axial length was measured preoperatively using the OLCR device. The femtosecond laser-assisted components of the cataract procedure were performed using the Lenx laser. Intraoperative aberrometry measurements were obtained from the test group using the Ocular Response Analyzer with Verifeye third-generation biomechanical waveform analyzer. For control eyes, the Alcon Acrysof IQ calculator^A was used as a guide for cylinder power selection and IOL positioning, with standard IOL formulas used to calculate the spherical power component of the IOL. Vector analysis was performed as described.⁷

Effectiveness Parameters

The primary effectiveness parameter was the proportion of eyes with postoperative refractive astigmatism of 0.50 D or less at 1 month. Secondary efficacy endpoints included the proportions of eyes at 1 month with refractive astigmatism of 0.25 D or less, 0.75 D or less, and 1.00 D or less; the proportion of eyes having manifest refraction spherical equivalent (MRSE) absolute prediction errors of 0.25 D or less, 0.50 D or less, 0.75 D or less, and 1.00 D or less relative to predicted postoperative SE at 1 month; the postoperative UDVA and postoperative CDVA; and the UDVA as a function of the MRSE.

Statistical Analysis

Primary effectiveness was assessed in the full analysis set, which included all patients who successfully had femtosecond laser-assisted refractive cataract surgery in both eyes. Data from patients with postoperative ocular complications at the 1-month visit that were not directly related to the use of the device at the time of surgery were not included in the full

analysis set. Sensitivity analyses were performed to evaluate the impact of patients excluded from the full analysis set.

The study hypothesis was that the proportion of eyes with a postoperative refractive astigmatism of 0.50 D or less at 1 month would be higher ($P < .05$) in eyes having surgery based on intraoperative aberrometry (test group) than on standard preoperative biometry measurements (control group). Because of the paired-eye binary outcomes, the primary effectiveness was analyzed using the McNemar test. The frequencies and proportions of eyes meeting the criteria at 1 month were summarized, as were the subject-level frequencies and proportions describing whether these criteria were met in both eyes, neither eye, or 1 eye. The mean postoperative parameters in the 2 groups, including mean refractive astigmatism, were compared using paired t tests.

Descriptive summaries for proportions of eyes within astigmatism thresholds of 0.25 D or less, 0.50 D or less, 0.75 D or less, and 1.00 D or less were reported, as were the MRSE, UDVA and CDVA, and UDVA as a function of the MRSE. The frequencies and proportions of patients at 1 month with an MRSE within specified threshold levels relative to the predicted postoperative SE levels of 0.25 D or less, 0.50 D or less, 0.75 D or less, and 1.00 D or less were summarized. The predicted postoperative SE was defined as the anticipated residual SE error based on the IOL power selected by intraoperative aberrometry in the test group or by standard IOL power formulas in the control group.

RESULTS

This study enrolled 130 patients (260 eyes); of these, 124 patients (248 eyes) were randomized and 121 (242 eyes) completed the study (Table 1). The baseline demographic characteristics of the full analysis set are shown in Table 2 and the baseline ocular characteristics in Table 3. Thirteen randomized patients were

Table 1. Patient information.

Group	Patients, n (%)	Eyes, n (%)
Total enrolled	130	260
Screening failures	6	12
Safety analysis set	124 (100)	246 (100)*
Full analysis set [†]	111 (89.5)	222 (90.2)
Not in full analysis set	13 (10.5)	26 (10.6)
Improper implementation of IOL power guidance in either eye	6 (4.8)	12 (4.9)
Ocular complication at 1 month (not related to device)	4 (3.2)	8 (3.3)
Fellow-eye surgery not performed	2 (1.6)	4 (1.6)
Missing 1-month postop assessment in either eye	1 (0.8)	2 (0.8)

IOL = intraocular lens

*Total was 246 instead of 248. Two subjects did not have IOL implanted in contralateral eye; their second eyes were therefore excluded from the full safety analysis set.

[†]Prespecified primary analysis set

excluded from the full analysis set. The patients who elected not to have implantation in the second eye did so for reasons unrelated to the procedure (Table 1).

Safety or Adverse Events

No deaths occurred during the study. One patient had a nonfatal nonophthalmic adverse event after enrollment that occurred before surgery in the first eye.

Table 2. Demographic and clinical characteristics of the full analysis set.

Parameter	1st Eye Test Group (n = 52)	1st Eye Control Group (n = 59)	Total Patients (N = 111)
Age y			
Mean \pm SD	66.2 \pm 7.8	68.0 \pm 8.07	67.2 \pm 8.0
Median	65.7	67.8	67.1
Min, max	43.5, 88.2	49.8, 87.2	43.5, 88.2
Age group, n (%)			
<60 years	11 (21.2)	8 (13.6)	19 (17.1)
60 to 69 years	25 (48.1)	31 (52.5)	56 (50.5)
70 to 79 years	15 (28.9)	14 (23.7)	29 (26.1)
\geq 80 years	1 (1.9)	6 (10.2)	7 (6.3)
Sex, n (%)			
Male	19 (36.5)	27 (45.8)	46 (41.4)
Female	33 (63.5)	32 (54.2)	65 (58.6)
Race, n (%)			
White	44 (84.6)	46 (78.0)	90 (81.1)
Black	4 (7.7)	8 (13.6)	12 (10.8)
Asian	2 (3.9)	5 (8.5)	7 (6.3)
Other	2 (3.9)	0	2 (1.8)

Table 3. Ocular characteristics of the full analysis set.

Parameter	All Test Group Eyes (n = 111)	All Control Group Eyes (n = 111)	Total Eyes (N = 222)
Average K (D)			
Mean \pm SD	44.00 \pm 1.32	43.99 \pm 1.36	43.99 \pm 1.34
Median	44.06	44.05	44.06
Min, max	41.10, 47.10	40.85, 47.03	40.85, 47.10
Keratometric astigmatism (D)			
Mean SD	1.92 \pm 0.74	1.92 \pm 0.66	1.92 \pm 0.70
Median	1.79	1.85	1.83
Min, max	0.64, 4.21	0.79, 4.22	0.64, 4.22
Amount, n (%)			
\geq 0.5 to <1.5	35 (31.5)	33 (29.7)	68 (30.6)
\geq 1.5 to <2.5	49 (44.1)	57 (51.4)	106 (47.8)
\geq 2.5 to <3.5	25 (22.5)	20 (18.0)	45 (20.3)
\geq 3.5	2 (1.8)	1 (0.9)	3 (1.4)
Axial length (mm)			
Mean \pm SD	24.32 \pm 1.13	24.34 \pm 1.11	24.33 \pm 1.12
Median	24.19	24.24	24.22
Min, max	22.32, 26.80	22.25, 26.67	22.25, 26.80

Table 4. Summary of paired outcomes in individual study patients.

Test Group ≤ 0.50 D	Control Group ≤ 0.50 D	Number (%)
Yes	Yes	79 (71.2)
Yes	No	20 (18.0)
No	Yes	6 (5.4)
No	No	6 (5.4)

Effectiveness

The proportion of eyes in the full analysis set at 1 month with postoperative refractive astigmatism of 0.50 D or less was higher in the test group than in the control group (99 eyes [89.2%] versus 85 eyes [76.6%]; $P = .006$). The number of patients (14 [53.8%]) falling outside the intended astigmatic target (< 0.50 D) was lower in the test group than in the control group. Table 4 shows the results of an assessment of paired outcomes in individual patients.

The proportions of eyes with postoperative refractive astigmatism of 0.25 D or less, 0.75 D or less, and 1.00 D or less were higher in the test group than in the control group (Figure 1). Similarly, the mean postoperative astigmatism was lower in the test group than in the control group (0.29 D \pm 0.28 [SD] versus 0.36 ± 0.35 D; $P = .041$). Similar results were observed in the safety analysis set (data not shown).

The mean absolute value of the prediction error was slightly lower in the test group than in the control group (0.25 ± 0.19 D versus 0.27 ± 0.21 D; $P = .23$). In addition, the percentages of eyes with an absolute value of the prediction error within specified threshold levels (≤ 0.25 D, ≤ 0.50 D, ≤ 0.75 D, and ≤ 1.00 D) relative

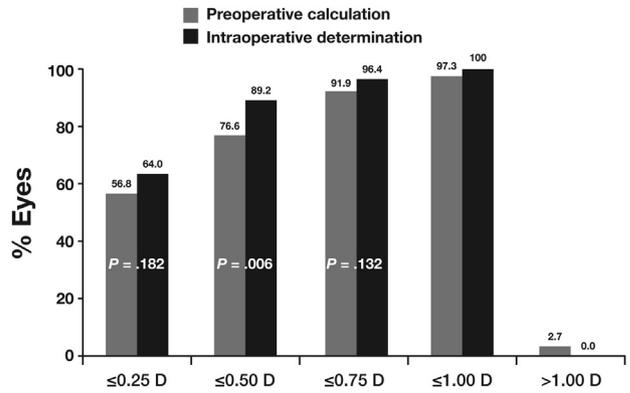


Figure 1. Percentages of eyes with postoperative refractive astigmatism of 0.25 D or less, 0.50 D or less, 0.75 D or less, and 1.00 D or less at 1 month (111 in each group). The P values were calculated using the McNemar test.

to the predicted postoperative SE were slightly higher in the test group than in the control group (Figure 2); however, none of these differences was statistically significant. The mean postoperative UDVA (0.035 ± 0.137 logMAR versus 0.078 ± 0.181 logMAR) and CDVA (-0.47 ± 0.096 logMAR versus -0.045 ± 0.102 logMAR) were also similar in the test group and control group. Figure 3 shows individual postoperative logMAR UDVA results relative to the MRSE for individual eyes in both groups.

Vector Analysis

Vector analysis of the test group showed that the mean centroid was 0.61 ± 1.97 D at 94.43 degrees preoperatively, showing that this group tended toward with-the-rule (WTR) astigmatism (Figure 4). The mean intraoperative aphakic refractive astigmatism in this group was 0.31 ± 1.64 D at 85.78 degrees, which was still WTR but was lower in magnitude. One month postoperatively, the mean centroid was 0.05 ± 0.04 D at 11.77 degrees, or very slightly against the rule (ATR), indicating a trend toward very slight overcorrection.

In the control group, the mean centroid was 0.68 ± 1.92 D at 83.85 degrees preoperatively, again tending toward WTR astigmatism (Figure 5). One month postoperatively, the mean centroid was 0.20 ± 0.45 D at 179.22 degrees, or very slightly ATR, indicating a greater overcorrection in this group. Intraoperative measurements were not taken in the control group; therefore, intraoperative vector analysis could not be performed.

DISCUSSION

In this study, the Ocular Response Analyzer system with Verifeye intraoperative aberrometer was a reliable method for calculating the power and position

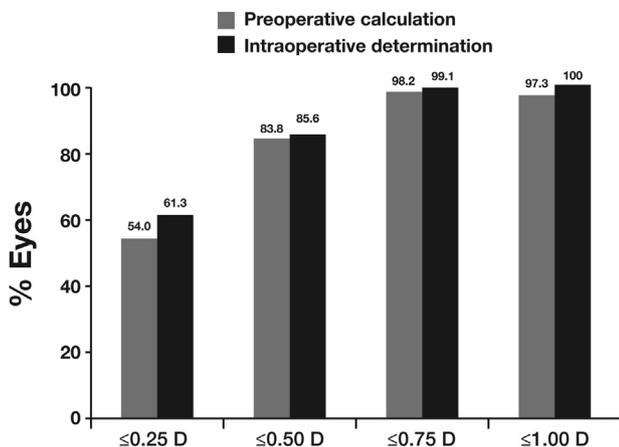


Figure 2. Median absolute value of the prediction error and proportions of eyes with postoperative MRSE at specified threshold levels (111 in each group)

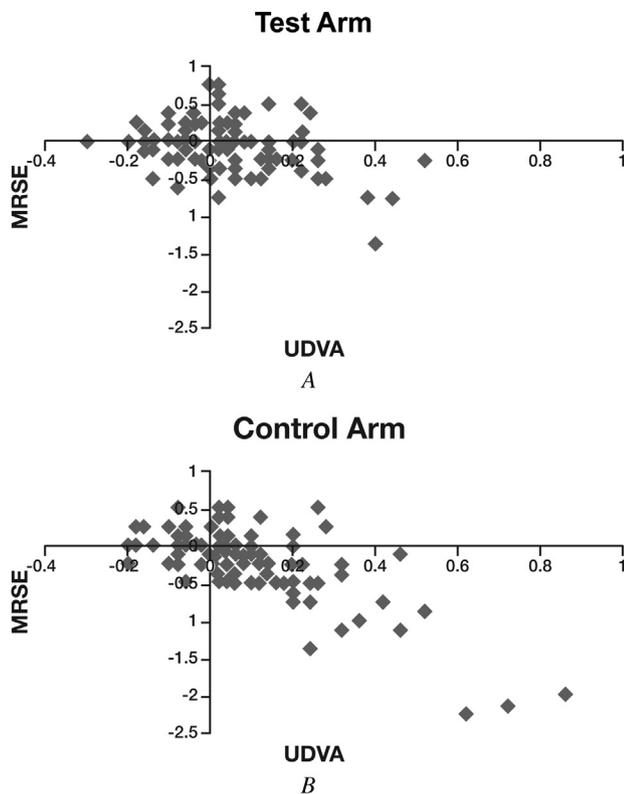


Figure 3. Relationship between MRSE and UDVA in individual eyes implanted using (A) intraoperative aberrometry and (B) preoperative calculations (MRSE = manifest refraction spherical equivalent; UDVA = uncorrected distance visual acuity).

of toric IOLs in astigmatic cataractous eyes that had not had previous refractive surgery. This third-generation biomechanical waveform analyzer performed better than the Acrysof IQ toric calculator in terms of increasing the proportion of astigmatic eyes with postoperative refractive astigmatism of 0.50 D or less. All eyes in the full analysis set achieved

a postoperative refractive astigmatism of 1.00 D or less. This is particularly important because at least 1 study⁸ has reported that more than 1.00 D of residual cylinder was the cutoff point at which patients elected to have an excimer laser enhancement. To our knowledge, this study is the largest prospective randomized observer-masked contralateral-eye comparison study to date to show that compared with standard methods, the use of the intraoperative aberrometry system increased the proportion of eyes with refractive astigmatism of 0.50 D or less ($P = .006$) and reduced the mean refractive astigmatism ($P = .041$) at 1 month.

Although the mean UDVA was slightly better in the test group (aberrometry measurement technique) than the control group (standard measurement technique) (0.035 ± 0.137 logMAR versus 0.078 ± 0.181 logMAR), the difference was not statistically significant. However, the range and distribution of postoperative UDVA differed in the 2 groups. First, the UDVA in the test group ranged from -0.03 logMAR (Snellen equivalent 20/10) to 0.52 logMAR (Snellen equivalent 20/66), with a median UDVA of 0.02 logMAR (Snellen equivalent 20/21). The UDVA in the control group ranged from -0.20 logMAR (Snellen equivalent 20/13) to 0.86 logMAR (Snellen equivalent 20/145), with a median UDVA of 0.04 logMAR (Snellen equivalent 20/22). Further examination of these ranges showed that the number of eyes in the test group was higher than in the control group for each postoperative UDVA cutoff, from 0.00 logMAR to 0.30 logMAR (Figure 6). Conversely, the number of eyes with a UDVA of more than 0.30 logMAR was almost 3 times higher in the test group than in the control group (11 versus 4). Thus, these data show a directional increase in the number of eyes with a UDVA of 0.30 logMAR or better and a decrease in the number

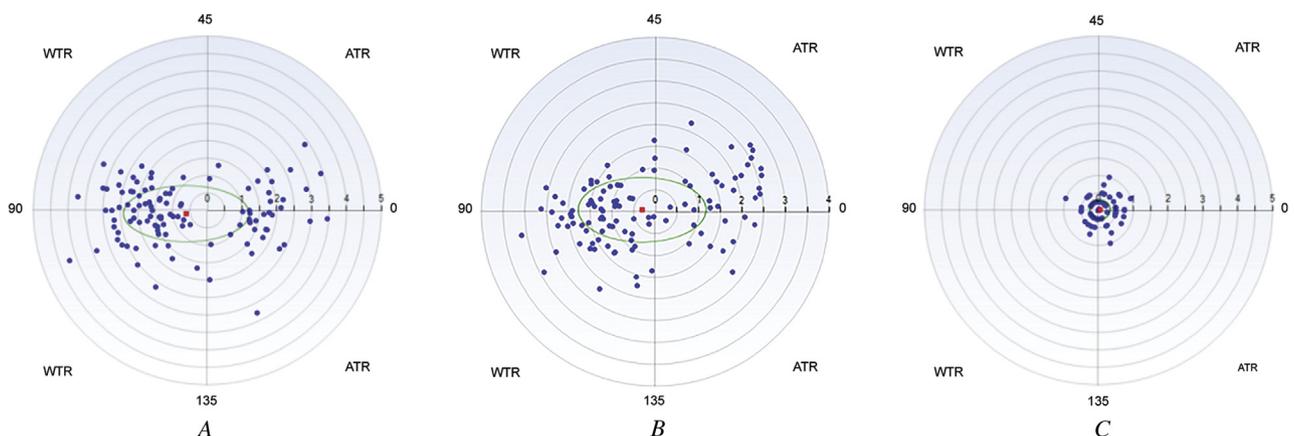


Figure 4. Vector analysis of individual eyes having IOL implantation using intraoperative aberrometry measurement and assessed preoperatively (A), intraoperatively (B), and 1 month postoperatively (C).

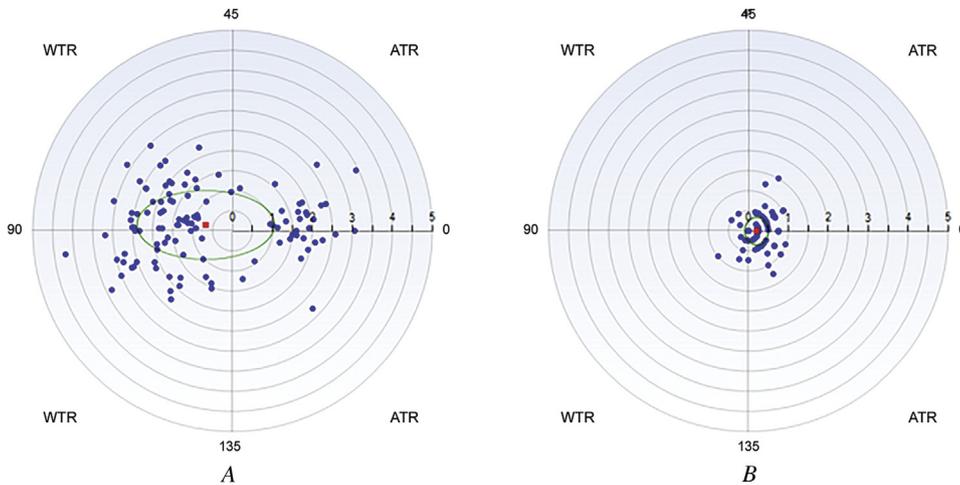


Figure 5. Vector analysis of individual eyes implanted using preoperative calculations and assessed preoperatively (A) and 1 month postoperatively (B) (ATR = against the rule; WTR = with the rule).

of outliers (ie, eyes with a UDVA worse than 0.30 logMAR) in the test group.

The computer-assisted markerless toric alignment system might provide an advantage over manual eye markings in determining the axis of placement; however, at present this system does not provide guidance on whether the correct cylinder power was calculated based on preoperative measurements. Before surgery, the system measures anterior corneal astigmatism and estimates the effects of incisions as well as the effects of the toric IOL on postoperative refractive astigmatism. During surgery, the digital marker superimposes the preoperative patient information and custom plan on the digital image of the eye, providing a toric alignment guide. This system superimposes the axis of alignment to within ± 1 degree, as determined by the preoperative plan. In contrast to this system, manual markings can be several degrees wide, off center, or a little higher or lower than intended, thus partially negating the effects of treatment. An error of 1 degree has been shown to reduce the treatment effect by approximately 3%; therefore, errors of several degrees

can substantially reduce the effects of treatment.⁹ In this study, however, alignment was apparently not responsible for the difference in postoperative astigmatism between the 2 groups. In the intraoperative aberrometry group, the IOL cylinder power was changed by more than 0.75 D in 22% of eyes.

Few previous studies have evaluated the performance of intraoperative aberrometry. A recent retrospective study³ compared refractive predictability of IOL power recommendations in the second-generation Ocular Response Analyzer system with 3 conventional methods in 245 eyes of 215 patients; all eyes had previous keratorefractive surgery for the treatment of myopia. That study found that use of the biomechanical waveform analyzer resulted in a significantly lower mean absolute value of the prediction error than the other methods (all $P < .0001$), with 67% of eyes analyzed with the biomechanical waveform system being within ± 0.50 D of the predicted outcome and 94% within ± 1.00 D. The results in these eyes were comparable with those in eyes without previous refractive surgery in which conventional methods were used. Although 6% of eyes had an IOL power prediction error more than 1.00 D, the biomechanical waveform analyzer had a significantly greater predictive accuracy ($P < .0001$). A retrospective case-control analysis assessed only 67 eyes,⁸ whereas a third assessed 46 eyes that had previous keratorefractive surgery.⁶ A small prospective study of 28 eyes found that an early version Wavetec intraoperative aberrometry system (Orange) yielded results equivalent to those of the IOLMaster (Carl Zeiss Meditec AG).⁵

One study,¹⁰ although it did not actually use an intraoperative aberrometry system, hypothesized that intraoperative aberrometry cannot be relied on for toric IOL placement and power calculations. That study proposed that among the intraoperative

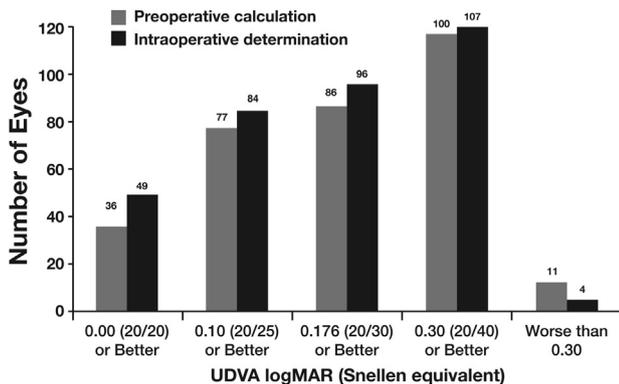


Figure 6. Number of eyes in the intraoperative determination and preoperative calculation groups meeting each postoperative UDVA cutoff (UDVA = uncorrected distance visual acuity).

variables that might contribute to unreliable results, there are erratic differences in cylinder readings caused by speculum tightness and patient eye squeezing, compounded by surgery-induced changes in cylinder. These findings suggest the importance of considering intraoperative surgical variables and of consistency of the operating environment. In that study,¹⁰ the effect of the lid speculum was evaluated by measuring the effect of a variety of speculum placements on corneal topography, not by using intraoperative aberrometry. The effects of surgically induced changes in cylinder were measured 1 hour and 1 week postoperatively using a conventional wavefront aberrometry system, manual refraction, and corneal topography. These intraoperative surgical variables were well controlled in the present study and are also given in the Ocular Response Analyzer's operator's manual.

Clinical studies have found that intraoperative aberrometry as part of an operative system is a reliable method to determine not only IOL power but also the location of the axis of astigmatism.^{11,12} A prospective cohort study¹³ analyzing the eyes of healthy patients assessed the comparability, repeatability, and interobserver variability of 3 automated keratometry (K) devices (IOLMaster, Lenstar, and SMI Reference Unit 3 [Sensomotoric Instruments GmbH]), 1 manual keratometer (Javal-Schiötz keratometer (Rodentstock GmbH), a corneal topographer (KR-1W, Topcon Corp.), and a Scheimpflug imaging device (Pentacam, Oculus Optikgeräte GmbH). Except for the Scheimpflug equivalent K, corneal astigmatism vectors were comparable for the other devices. The mean differences between the automated K, manual K, and simulated K were small (≤ 0.12 D), and within-patient standard deviations ranged from 0.05 D at 21 degrees (KR-1W) to 0.18 at 23 degrees (Lenstar). Although the repeatability of astigmatism magnitudes was acceptable, the repeatability of astigmatism meridians was only moderate.

Our study had several limitations, including the relatively short follow-up of refractive outcome stability. Although the similar results after 1 month and 6 months suggest that follow-up beyond 6 months might be unnecessary, longer term follow-up might reveal alterations in refractive outcome stability.

In conclusion, compared with the toric calculator, intraoperative aberrometry reduced postoperative astigmatism ($P = .041$) and was more likely to reduce postoperative astigmatism 0.50 D or less ($P = .006$). Moreover, the number of patients falling outside the intended astigmatic target was reduced by more than half in the intraoperative aberrometry cohort when compared with the group in which the toric calculator was used. Intraoperative

aberrometry provided more accurate toric IOL guidance (cylinder power and axis) than the preoperative toric calculator.

WHAT WAS KNOWN

- Wavefront aberrometry is widely used to improve the results of laser vision correction.
- Intraoperative aberrometry provides the surgeon with real-time power calculations during the aphakic measurement phase, cylinder power, and axis positioning for toric IOLs during the pseudophakic phase.

WHAT THIS PAPER ADDS

- Intraoperative aberrometry was more effective in achieving less than 0.50 D residual postoperative refractive astigmatism than preoperative measurement in astigmatic cataractous eyes.

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