

Accuracy of Intraoperative Aberrometry-Based Prediction of Postoperative Refraction and Astigmatism After Novel Toric Intraocular Lens Implantation

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Purpose: This study prospectively assessed the refractive and astigmatism prediction accuracy of intraoperative aberrometry, Optiwave Refractive Analysis (ORA), in eyes implanted with Clareon toric intraocular lenses (IOLs).

Patients and Methods: Patients with age-related cataracts who underwent phacemulsification and toric IOL implantation using ORA were prospectively included in this single-center study. The absolute refractive prediction error (RPE) and rate of RPE for ORA, Sanders–Retzlaff–Kraft/Theoretical (SRK/T), and Barrett Universal II were evaluated 3 months after surgery. Uncorrected visual acuity (UCVA), residual astigmatism, refractive astigmatism prediction error, and the difference between the preoperatively planned axis and actual inserted axis recommended by ORA were assessed.

Results: Eighty eyes (80 patients, mean age: 75.0 ± 8.8 years) were included in this study. Mean $\pm$ standard deviation (SD) of preoperative corneal astigmatism was 1.91 ± 1.03 D. The median absolute RPE values for ORA, SRK/T, and Barrett Universal II were 0.17, 0.14, and 0.14 D, respectively. At the 3-month follow-up after surgery, the mean $\pm$ SD of UCVA and residual astigmatism were 0.06 ± 0.16 logarithm of the minimum angle of resolution and 0.43 ± 0.48 D, respectively. The refractive astigmatism prediction errors were 0.11 D in the centroid for both ORA and the Barrett toric formula, at 67° and 63° , respectively. The mean absolute values were 0.38 D for ORA and 0.41 D for the Barrett toric formula. The median absolute value of the axis difference between the planned and actual inserted axes based on ORA was 4.00° .

Conclusion: The accuracy of ORA in the prediction of spherical refraction and astigmatism was comparable to that of the preoperative IOL calculation formula in eyes with Clareon toric IOLs. ORA is a useful tool for determining IOL power and improving preoperative corneal astigmatism.

Keywords: astigmatism, intraoperative aberrometry, refractive prediction error, toric intraocular lenses

Introduction

Cataract surgery is one of the most common surgeries performed worldwide. Preoperative accurate refractive prediction is important for ensuring postoperative patient satisfaction. Furthermore, reducing residual astigmatism is important for patient satisfaction and visual outcomes after cataract surgery.¹ The persistence of low-level residual astigmatism, such as 0.5–0.75 D after cataract surgery affects visual performance.¹

Toric intraocular lenses (IOLs) reduce residual astigmatism after cataract surgery. The correction of astigmatism with toric IOLs provides better outcomes than that with other procedures, such as the corneal relaxing incision method,² and, therefore, toric IOL constitutes the most popular solution for the correction of preoperative corneal astigmatism. However, the effect of astigmatism correction with a toric IOL is diminished by toric misalignment from the target axis or rotation following toric IOL implantation. Every degree of misalignment from the target axis reduces the effect of astigmatism correction by approximately 3.3%.^{3–6} Furthermore, toric IOL-based correction of astigmatism is influenced

by preoperative corneal measurements of both the anterior and posterior surfaces. If only the measurements from the anterior surface of the cornea are used for cylindrical power calculations, the predicted residual astigmatism will be overestimated and underestimated in patients having with-the-rule and against-the-rule astigmatism, respectively.^{7,8} Therefore, it is preferable to use an IOL calculation formula that incorporates details of posterior corneal astigmatism in the preoperative IOL calculation formula.

The Optiwave Refractive Analysis (ORA) system (Alcon Vision LLC, Fort Worth, TX, USA) is an intraoperative wavefront-aberration analyzer system that enables surgeons to measure the whole-eye refraction, including the anterior and posterior cornea, and determine cylindrical and spherical IOL powers in the aphakic eye.^{9,10} In addition, ORA can indicate an axis position for the toric IOL that maintains residual astigmatism within 0.5 D in the pseudophakic eye. Although some studies have reported that ORA conferred better refractive and astigmatism outcomes compared with those predicted using preoperative IOL power calculation formulas, other studies have reported that ORA is equal to or inferior to the preoperative IOL power calculation formulas in terms of refractive outcomes.^{9–11} Sometimes, the IOL power and toric axis recommended by ORA differ from the preoperatively planned IOL power and toric axis. This creates uncertainty or doubt in the IOL power determination and access by the surgeon.

To date, only limited data are available regarding the evaluation of refractive and astigmatism outcomes for ORA in eyes implanted with Clareon material toric IOLs.¹² Therefore, this study evaluated the refractive prediction and refractive astigmatism prediction errors for ORA and compared them with those derived from the preoperative IOL calculation formulas in eyes implanted with Clareon toric IOLs.

Material and Methods

Study Design

This was a prospective observational single-site study and included patients who underwent cataract surgery and toric IOL implantation. The study protocol was reviewed and approved by the MINS institutional review board of an independent and nonprofit organization in Tokyo, Japan (approval number: 220220) and performed in accordance with the Ethical Guidelines for Medical and Biological Research Involving Human Subjects in Japan and the tenets of the Declaration of Helsinki. Written informed consent was obtained from all patients involved in this study. The included patients aged ≥ 50 years with cataract for whom cataract surgery with implantation of Clareon toric IOL (model: CNW0Tx, Alcon Vision LLC) or Clareon PanOptix toric IOL (model: CNWTTx, Alcon Vision LLC) was planned, and intraoperative aberrometry with ORA was conducted. The exclusion criteria were having undergone additional surgery between cataract surgery and 3 months postoperatively, a history of corneal transplantation and corneal refractive surgery, presence of corneal disease that affected or prevented accurate ORA measurements, presence of any ocular pathology, use of medications that affected visual acuity, or ciliary zonule. One eye from each patient was included in this study. In the case of patients who with both eyes eligible for inclusion, the first operated eye was selected for analysis to minimize selection bias and ensure consistency.

Surgery

Swept Source OCT biometer ARGOS[®] (ARGOS, Alcon Vision LLC) was used for preoperative ocular measurement and IOL power calculations with Sanders–Retzlaff–Kraft/Theoretical (SRK/T) and Barrett Universal II formulas. The cylindrical power was calculated using Barrett toric formula with the measurement values by the ARGOS and the surgically induced astigmatism (SIA) of 0.4 D. In this study, we used an arched knife, which is a slit knife with a curved blade creating a 2.9 mm arc-shaped incision (Mani, Inc. Tochigi, Japan). When converted to a standard incision size, this corresponds approximately to a 2.7-mm horizontal width. The incision was made along the steep meridian on the anterior surface of the cornea. The SIA value was selected based on our clinical experience optimized with the arched knife. The Barrett toric formula can account for posterior corneal curvature, either by incorporating predicted values or by using actual measurements obtained from devices such as the Pentacam. In our study, we used the Barrett toric formula with predicted posterior corneal astigmatism values. Cataract surgery with phacoemulsification and IOL implantation were performed by only one experienced surgeon (A.O). After removing the crystalline lens with the phacoemulsification

using the Centurion[®] Vision System (Alcon Vision LLC), intraoperative wavefront measurements were performed using the ORA system. CNW0T or CNWTT0 toric IOLs were implanted into the capsule bag and the axis of the toric IOL was aligned according to the recommendations of ORA. Spherical power calculated using the Barrett Universal II formula and cylindrical power calculated using the Barrett toric formula, both based on measurements from the ARGOS biometer, were used as a reference preoperatively. However, in all cases, the final decision regarding both spherical and cylindrical IOL power was made based on recommendations provided by the ORA system, with the goal of targeting emmetropia or slight myopia.

Endpoints and Postoperative Examination

The primary endpoint of this study was the absolute refractive error (RPE). Additional endpoints were rate of eyes with an absolute RPE ≤ 0.25 , ≤ 0.50 , ≤ 0.75 , ≤ 1.0 D, monocular best corrected visual acuity (BCVA), monocular uncorrected visual acuity (UCVA), residual astigmatism, refractive astigmatism prediction error, axis difference between preoperative planning axis and actual inserted axis based on ORA recommendation, and toric IOL rotation after the surgery was completed.

The RPE was defined as the difference between the predicted spherical equivalent (SE) and the actual subjective SE at 3 months after surgery. Visual acuity and subjective refraction were examined at a distance of 5 m. Monocular BCVA, monocular UCVA, and subjective refraction were evaluated at 1 week and 3 months postoperatively.

Statistical Analysis

Statistical analysis was conducted with JMP[®] Pro 18 software (SAS Inc, Cary, NC, USA). The sample size for the mean absolute RPE with a confidence level of 95% and confidence width of 0.10 D was 68 eyes, when the standard deviation (SD) of the RPE was 0.41 D.¹³ Considering a dropout rate of 20%, the final sample size was estimated as 82 eyes.

Data on patient demographics, visual acuity, refraction, and RPE for ORA, SRK/T, and Barrett Universal II formulas were summarized using the descriptive statistics of the mean, SD, and median. The mean RPE was adjusted to zero for ORA and each IOL calculation formula to eliminate systematic errors from the chosen IOL constant based on reported method.¹⁴ The rate of eyes with absolute RPE (≤ 0.25 , ≤ 0.50 , ≤ 0.75 , and ≤ 1.0 D) was described as percentages. The Friedman test was used for comparison of absolute RPE in the group. Monocular BCVA and UCVA were converted into logarithm of the minimum angle of resolution (logMAR) visual acuity. Cumulative histogram of the preoperative corneal and postoperative refractive subjective (residual) astigmatism was described with astigmatism ≤ 0.25 , ≤ 0.5 , ≤ 0.75 , ≤ 1.0 , ≤ 1.5 , and ≤ 2.0 D. Vectors of the preoperative corneal astigmatism measured by the ARGOS and residual astigmatism were plotted on double-angle plots. The vector of the refractive astigmatism prediction error for the Barrett toric formula and ORA was plotted on double angle plots. Wilcoxon signed-rank test was used for comparison of the refractive astigmatism prediction error between the Barrett toric formula and ORA.

Results

Patient Demographics

Table 1 shows the patient demographics. In total, 80 eyes of 80 participants who completed the 3-month postoperative follow-up were included from among 86 patients who were initially enrolled in this study. Overall, 6 patients were excluded because they lacked data for the 3-month follow-up visit. Of the 80 eyes, 9 had mild glaucoma and 1 an epiretinal membrane. No intra-or postoperative complications were observed. In total, 36 right eyes and 44 left eyes were selected for analysis. Among the 80 eyes included in the study, 62 received CNW0Tx and 18 received CNWTTx. A subgroup analysis showed no significant differences in any of the evaluated endpoints between the two groups. ($p > 0.05$ for all comparisons) ORA led to changes in the final IOL selection compared with the recommendation by preoperative Barrett formula. Specifically, the spherical power was modified in 54 eyes (68%) and the cylindrical power was adjusted in 59 eyes (74%) based on intraoperative ORA measurements.

Table 1 Demographic Data of the Study Participants

Parameter	Value
Age, years (mean $\pm$ SD)	75.01 $\pm$ 8.84
Sex, male/female, (N)	44/36
Right eyes/ left eyes, (N)	36/44
Averaged keratometry, D (mean $\pm$ SD)	44.47 $\pm$ 1.59
Keratometric astigmatism, D (mean $\pm$ SD)	1.91 $\pm$ 1.03
Axial length, mm (mean $\pm$ SD))	23.97 $\pm$ 2.03
Anterior chamber depth, mm (mean $\pm$ SD)	3.16 $\pm$ 0.39
Preoperative BCVA, logMAR (mean $\pm$ SD)	0.26 $\pm$ 0.30
Preoperative UCVA, logMAR (mean $\pm$ SD)	0.69 $\pm$ 0.40
Preoperative IOP, mmHg (mean $\pm$ SD)	16.43 $\pm$ 3.14
IOL type (number of eyes)	
Model: CNW0Tx	62
Model: CNWTTx	18

Abbreviations: BCVA, best-corrected visual acuity; IOL, intraocular lens; IOP, intraocular pressure; logMAR, logarithm of the minimum angle of resolution; SD, standard deviation; UCVA, uncorrected visual acuity.

Refractive Prediction Error

The mean absolute RPE for ORA was 0.25 D (SD: 0.28, 95% confidence interval [CI]: 0.19–0.31). The median absolute RPE for ORA, SRK/T, and Barrett Universal II was 0.17, 0.14, and 0.14 D, respectively ($p=0.8682$, Friedman test) (Table 2). The rates of the absolute RPE within 0.25 D for ORA, SRK/T, and Barrett Universal II were 68.6%, 70.0%, and 68.4%, and those within 0.5 D were 83.8%, 90.0%, and 83.5%, respectively (Table 2).

Visual Acuities

Table 3 summarizes the postoperative visual acuity and refractive outcomes 1 week and 3 months postoperatively. The monocular UCVA at 1 week after surgery was 0.09 ± 0.18 logMAR (median: 0.05 [−0.18–0.70]) and that at 3 months after surgery was 0.06 ± 0.16 logMAR (median: 0.02 [−0.18–0.82]). The monocular BCVA at 3 months was -0.03 ± 0.12 logMAR (median: −0.08 [−0.18–0.30]).

Table 2 Refractive Outcomes in All Eyes

	Mean RPE $\pm$ SD (D)	Med Absolute RPE (D)	Percentage of Absolute RPE Within (%)			
			0.25 D	0.50 D	0.75 D	1.00 D
ORA	0.00 $\pm$ 0.38	0.17	68.6	83.8	93.8	98.8
SRK/T	0.00 $\pm$ 0.38	0.14	70.0	90.0	93.8	98.8
BUII	0.00 $\pm$ 0.40	0.14	68.4	83.5	93.7	97.5

Abbreviations: BUII, Barrett Universal II; D, diopters; Med absolute RPE, median absolute refractive prediction error; RPE, refractive prediction error; SD, standard deviation.

Table 3 Postoperative Visual and Refractive Outcomes

Parameter	1 Week	3 Months
Postoperative BCVA, logMAR (mean $\pm$ SD)	-0.02 ± 0.12 Median: -0.08 [$-0.18-0.30$]	-0.03 ± 0.12 Median: -0.08 [$-0.18-0.30$]
Postoperative UCVA, logMAR (mean $\pm$ SD)	0.09 ± 0.18 Median: 0.05 [$-0.18-0.70$]	0.06 ± 0.16 Median: 0.02 [$-0.18-0.82$]
Subjective refraction, D (mean $\pm$ SD)	0.17 ± 0.34	0.19 ± 0.43
Residual subjective astigmatism, D (mean $\pm$ SD)	-0.44 ± 0.50	-0.43 ± 0.48
Spherical equivalent, D (mean $\pm$ SD)	-0.05 ± 0.35	-0.03 ± 0.38
Objective refraction, D (mean $\pm$ SD)	0.47 ± 0.47	0.47 ± 0.45
Residual objective astigmatism, D (mean $\pm$ SD)	-0.67 ± 0.41	-0.66 ± 0.37
Postoperative IOP, mmHg (mean $\pm$ SD)	14.43 ± 3.22	14.39 ± 3.09

Abbreviations: BCVA, best corrected visual acuity; D, diopters; IOP, intraocular pressure; logMAR, logarithm of the minimum angle of resolution; SD, standard deviation; UCVA, uncorrected visual acuity.

Astigmatism

Figure 1A shows a cumulative histogram of the magnitude of preoperative corneal and postoperative residual astigmatism. The preoperative corneal astigmatism and residual astigmatism at 3 months were 1.91 ± 1.03 and 0.43 ± 0.48 D, respectively. The centroid of preoperative corneal astigmatism was 1.04 D at 183° and that of residual astigmatism was 0.04 D at 83° (Figure 1B and C, respectively). Double-angle vector plots for preoperative corneal and residual astigmatism are shown in Figure 1B and C, respectively. The postoperative refractive astigmatism prediction error for the Barrett toric formula was 0.11 D at 63° in centroid and 0.41 D in mean absolute value, whereas the postoperative refractive astigmatism prediction error for ORA was 0.11 D at 67° in centroid and 0.38 D in mean absolute value (x axis; $p=0.8685$, y axis; $p=0.9357$, paired t test) (Figure 2A and B, respectively).

Axis Difference

The difference between the preoperatively planned axis using the Barrett toric formula and the actual inserted axis based on ORA recommendation was calculated for 76 eyes, as shown in Figure 3A. The difference was $0.09 \pm 7.79^\circ$, and the median absolute value of the difference was 4.00° . The maximum difference was observed at 21° ; approximately 63.2% of the eyes were within 5.0° and 80.3% were within 10.0° . The toric IOL rotation from the end of the surgery was assessed in 53 eyes (Figure 3B). The median absolute value of rotation was 2.00° .

Discussion

To achieve high postoperative patient satisfaction, it is important to meet the targeted refraction and reduce residual astigmatism by accurately measuring ocular components and predicting postoperative refraction and astigmatism. In the current study, the refractive and astigmatism accuracies of ORA predictions in eyes with Clareon toric IOLs were compared with those of preoperative IOL calculation formulas. The results showed that ORA provided accurate refractive and astigmatism predictions in eyes with Clareon toric IOLs.

In this study, the rate of the eyes with absolute RPE ≤ 0.5 D at 3 months after surgery was 83.8% for ORA, consistent with the 84% rate for ORA after the optimization in eyes implanted with Clareon monofocal IOL- reported by Spekrijse et al.¹⁵ In addition, Melendez et al reported that the rate of the eyes with absolute RPE ≤ 0.5 D for ORA when using ARGOS and femtosecond laser was 75% in eyes with Clareon PanOptix toric IOL.¹² The refractive prediction for preoperative IOL calculation formulas using ARGOS in eyes with Clareon IOLs was accurate and the rates of the eyes

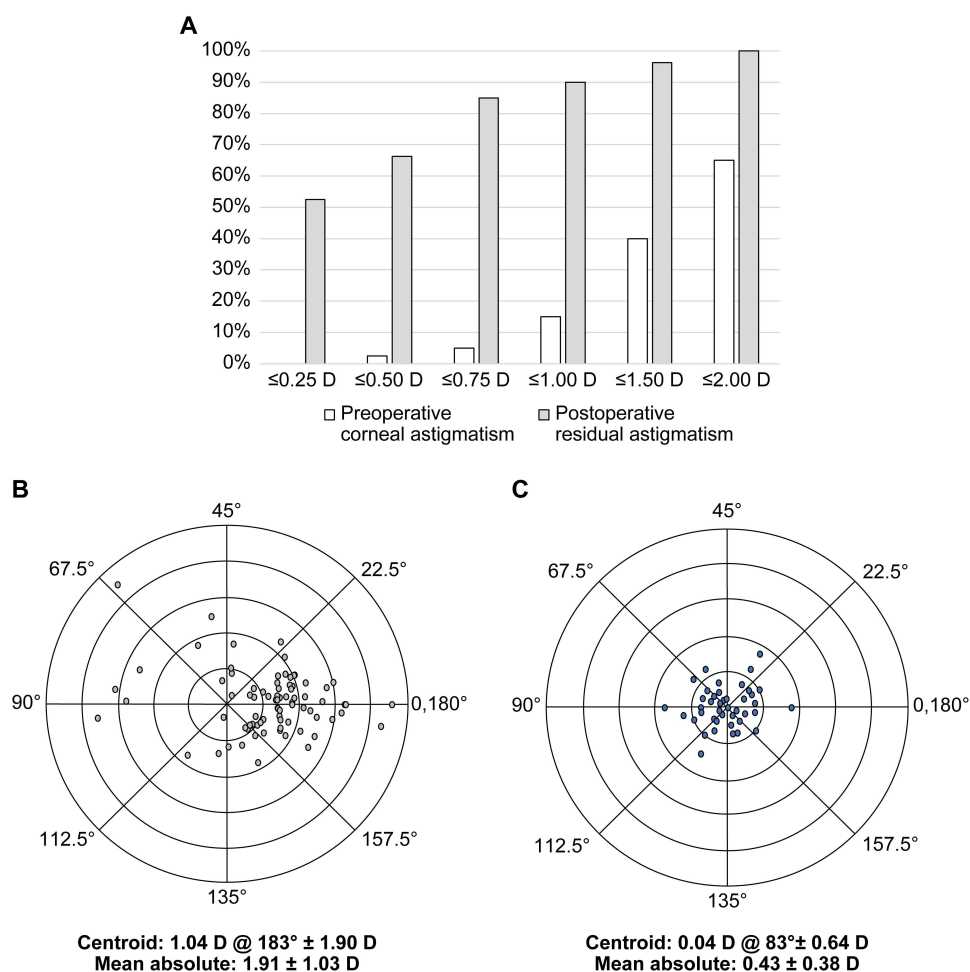


Figure 1 (A) Cumulative histogram of the magnitude of preoperative corneal and postoperative residual astigmatism; (B) double-angle plots of preoperative corneal astigmatism; and (C) double-angle plots of postoperative residual astigmatism.

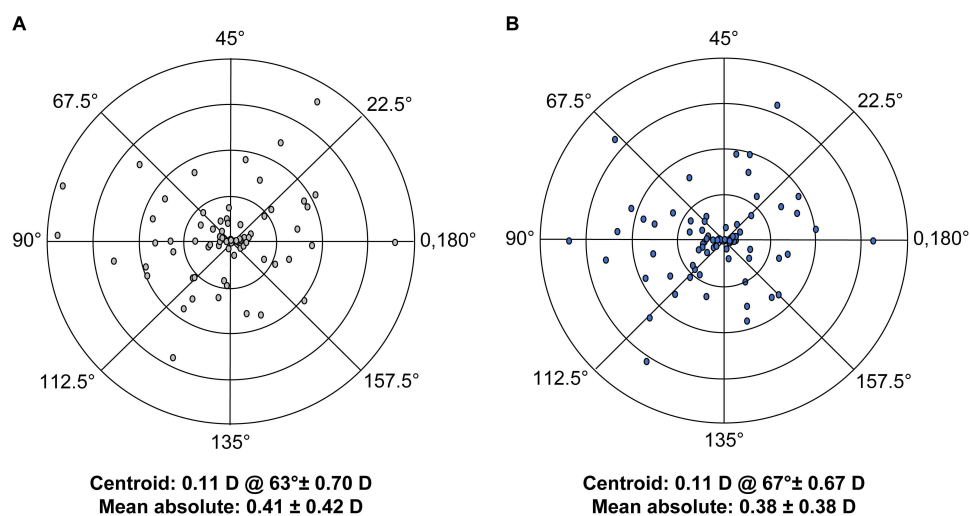


Figure 2 Double-angle plots of prediction errors regarding postoperative refractive astigmatism. (A) Barrett toric formula; and (B) Optiwave Refractive Analysis.

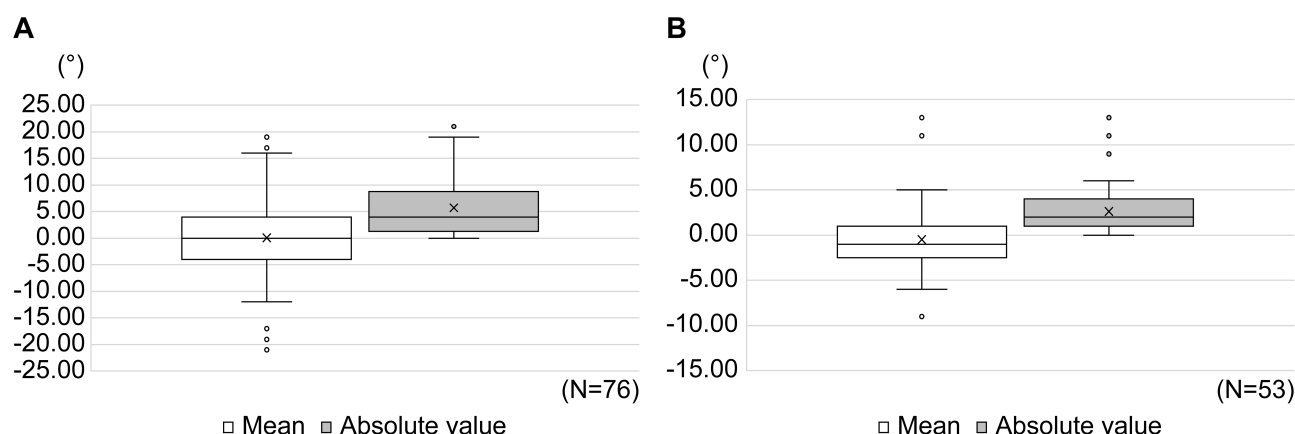


Figure 3 Distributions of mean (left) and absolute value (right). **(A)** The difference between the preoperative planning axis ascertained by the Barrett toric formula and the actual inserted axis based on the Optiwave Refractive Analysis recommendation; and **(B)** the toric IOL rotation from the end of surgery.

with absolute RPE ≤ 0.5 D ranged from 69.7% to 86.3%.^{13,16} The results of refractive prediction for the SRK/T and Barrett Universal II formulas using the ARGOS were accurate, with 83.5% and 90.0% rates, respectively, for the eyes in the present study.

Several studies have used ORA to evaluate residual astigmatism after cataract surgery with toric IOL implantation. The rate of eyes with residual astigmatism ≤ 0.5 D in eyes implanted with AcrySof IQ toric IOL using ORA were 75.4%–89.4%.^{17–26} Furthermore, the rate of eyes with residual astigmatism ≤ 0.5 D in eyes implanted with Clareon PanOptix toric IOL using ORA, digital image tracking, and femtosecond laser was 80%.¹⁴ In the present study, the rate was 63%, which was lower than that reported in the previous study.¹⁴ Although most previous studies used a femtosecond laser for cataract surgery and only one type of toric IOL, in the current study, we did not use a femtosecond laser, we included two types of Clareon toric IOLs, and we used a specific arched knife to create a corneal incision at the steep median. All these factors could have led to the differences between the results of the previous studies and that of the present study.

ORA can measure whole-eye refraction and astigmatism, including posterior corneal astigmatism in aphakic eyes, and intraoperatively recommends the axis and cylindrical power for toric IOL implantation. In contrast, the Barrett toric formula can estimate posterior corneal astigmatism with an as yet unpublished algorithm and preoperatively recommends the axis and cylindrical power for toric IOL implantation. The results of the present study showed that both ORA and the Barrett toric formula accurately predicted astigmatism. In addition, the distribution of the double-angle vector plot of ORA in the refractive astigmatism prediction error is very similar to that of the Barrett toric formula. Despite the slight difference between the planning axis using the Barrett toric formula and the actual ORA-recommended inserted axis in this study, the difference in the axis did not affect the refractive astigmatism prediction error. Felipe et al reported that toric IOL rotation $<10^\circ$ changed the eye's refraction by <0.5 D.⁶ The rate of the eyes with $<10.0^\circ$ axis difference was 80.3% in this study, which resulted in no effect on the refractive astigmatism prediction error.

In some cases, ORA had better prediction accuracy, whereas, in other cases, preoperative calculation formulas demonstrated better prediction accuracy.^{17,20} For instance, although ORA showed no clear advantage in eyes with post-radial keratotomies or short axial lengths, it was particularly effective in eyes with axial myopia, especially in reducing hyperopic surprises, compared with Barrett Universal II formulas.^{21–23} Furthermore, some reports indicated similar or slightly higher astigmatism prediction accuracy using predicted posterior corneal astigmatism than using the actual measured posterior corneal astigmatism.^{24–26} For the reasons stated above and the results from the current study, it may be better for determining IOL power to consider comprehensive calculated results including the modern preoperative IOL power calculation formula, such as the Barrett formula, as well as ORA, rather than making all decisions based on ORA. Future studies with larger sample size and predefined subgroup analyses are warranted to better guide the effective use of ORA in IOL power selection.

This study has some limitations. The number of included patients was relatively small for evaluating refractive accuracy. However, although most of the previous studies that evaluated refractive accuracy had a retrospective design, this study had a prospective design, and only one of the eyes from each patient was used for evaluation. These differences constitute the strengths of this study. Two types of Clareon IOLs were used in the study, which may increase the variation in the results. Future studies with only one type of IOL should be considered to confirm the refractive accuracy of ORA. Finally, we acknowledge that future studies may consider performing astigmatism analysis using objective refraction data as well, to provide a more comprehensive understanding of astigmatism prediction accuracy.

Conclusion

ORA can effectively predict visual and refractive outcomes in eyes with Clareon toric IOL implantation. The accuracy of ORA in the prediction of the postoperative refractive index and astigmatism was equivalent to that of the ARGOS-based preoperative IOL calculation formula. ORA is a useful tool for determining IOL power and improving preoperative corneal astigmatism.

Abbreviations

ORA, Optiwave Refractive Analysis; IOL, intraocular lens; RPE, refractive prediction error; SRK/T, Sanders–Retzlaff–Kraft/Theoretical; UCVA, uncorrected visual acuity; SD, standard deviation; BCVA, best corrected visual acuity; SE, spherical equivalent; logMAR, logarithm of the minimum angle of resolution.

Data Sharing Statement

Data that support the findings of this study are available from the corresponding author upon request.

Ethics Approval and Informed Consent

The study protocol was approved by the MINS institutional review board of an independent and nonprofit organization (Tokyo, Japan, Approval number: 220220), and was performed in accordance with the tenets of the Declaration of Helsinki and the Ethical Guidelines for Medical and Biological Research Involving Human Subjects in Japan. Written informed consent for study participation was obtained from all participants.

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Disclosure

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