

Predictive accuracy of an intraoperative aberrometry device for a new monofocal intraocular lens



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Purpose: To evaluate refractive outcomes for the Clareon monofocal intraocular lens (IOL) in terms of achieved target refraction for the ORA (ALCON) intraoperative wavefront aberrometry device and preoperative noncontact biometry.

Setting: University Eye Clinic Maastricht, Maastricht University Medical Center*, the Netherlands.

Design: Prospective observational clinical trial.

Methods: Patients with bilateral age-related cataracts undergoing phacoemulsification, either by delayed sequential surgery or on the same day, were included in the study. Exclusion criteria were an increased risk for refractive surprise or complicated surgery. Implanted IOL power was based on noncontact optical biometry data using the Barrett Universal II (BU-II) formula, optimized for the Clareon IOL. Postoperative subjective refraction was measured 4 to 6 weeks after surgery. Catquest-9SF questionnaires were completed preoperatively and 3 months after surgery.

Results: 100 eyes (51 patients) were included. The percentages of eyes within 1.0 diopters (D), 0.75 D, 0.50 D, and 0.25 D of target for ORA vs BU-II were 84% (84 eyes), 72% (72 eyes), 57% (57 eyes), and 21% (21 eyes) vs 97% (97 eyes), 88% (88 eyes), 77% (77 eyes), and 53% (53 eyes), respectively. Mean absolute prediction error was significantly higher for ORA vs preoperative biometry ($P < .001$). After global optimization, the prediction accuracy of ORA improved significantly ($P < .001$). Catquest-9SF questionnaires showed improved levels of ability at 3 months after surgery ($P < .001$).

Conclusions: This study showed lower percentages of eyes within target refraction for ORA (prior to lens constant optimization) compared with the BU-II formula when implanting the Clareon IOL. However, prediction accuracy of ORA improved significantly after global optimization. Therefore, further intraoperative measurements, postoperative measurements, and optimization are needed to improve the ORA prediction for this IOL.

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Despite many advances during the last few decades, cataract surgery is still subject to improvements. In addition, patient expectations regarding cataract surgery outcomes continue to increase.¹ One of the recurring challenges is to further improve refractive outcomes by reducing residual refractive errors after surgery. To reach this goal, modern intraocular lens (IOL) formulas have been developed, such as the Barrett Universal II (BU-II) formula, the Olsen formula, the Hill-RBF 2.0 (using artificial intelligence), and the Holladay 2 formula.^{2,3}

Besides these formulas, an intraoperative wavefront aberrometer, the ORA system (Optiwave Refractive Analysis system, Alcon Laboratories, Inc.), has been developed.⁴ This system is composed of a wavefront aberrometer, which is

attached to the surgical microscope and serves as a refractometer, and a cloud-based online database, AnalyzOR. It uses infrared superluminescent LED light for measuring sphere, cylinder, and cylinder axis. In addition, 4 LED lights provide guidance for proper alignment and focus during the measurements. The online cloud-based database is used for entering preoperative biometric data, which is needed for the intraoperative measurements, and for entering postoperative refractive outcomes. This enables the system to optimize the IOL specific constants for the ORA device (ORA System with VerifEye + 2.0 Operator's Manual Rev A).

In addition to these developments in the field of cataract surgery, a new preloaded monofocal IOL called the Clareon monofocal IOL recently became available. Potential advantages

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reported for this preloaded IOL in laboratory studies include minimal occurrence of postoperative glistenings, little axial displacement, and low levels of surface haze.⁵⁻⁷ The aim of this study was to evaluate refractive outcomes in terms of achieved target refraction and incidence of refractive surprise between the theoretical ORA device and preoperative noncontact biometry for the Clareon monofocal IOL.

METHODS

Study Design and Setting

This pilot study was designed as a prospective observational clinical trial at the University Eye Clinic Maastricht, Maastricht University Medical Center (MUMC⁺), the Netherlands. All participants were required to sign informed consent after the nature of the study had been fully explained. The study was approved by the Board of Directors of the MUMC⁺ and by the medical ethics committee azM/UM as a part of the BICAT-NL study (identifier: 172048).⁸ Furthermore, the study was performed in accordance with the tenets of the Declaration of Helsinki and Dutch legislation.

Study Population and Procedures

Patients participating in the BICAT-NL study were included if they were scheduled for bilateral cataract surgery, either for immediate sequential bilateral cataract surgery (ISBCS) or delayed sequential bilateral cataract surgery (DSBCS), from May 2019 until February 2020.⁸ When performing ISBCS, the General Principles for Excellence in ISBCS 2009 were followed.⁹ In case of DSBCS, second-eye surgery was performed 2 weeks after first-eye surgery. Patients were excluded in case of presence of risk factors for refractive surprise (eg, axial lengths <21.0 or >27.0 mm or a difference between both eyes of >1.5 mm, abnormal keratometry readings, previous refractive surgery, and myopia with posterior staphylomas), increased risk for complicated surgery (eg, previous ocular surgery, previous ocular trauma, eye/adnexal/anatomical abnormalities including pseudoexfoliation syndrome, lens luxation or iridonesis, cataract nigrans, and posterior polar cataract), or ocular comorbidities that were sight-threatening. Other exclusion criteria were age <18 years, premium IOL implantation, nonroutine cataract surgery (eg, cataract surgery combined with another ocular procedure or cataract surgery under general anesthesia), cognitive or behavioral conditions that might interfere with surgery, and an inability to comply with study procedures.

Prior to this study, the Clareon lens constant was optimized for the BU-II formula using a dataset of 90 eyes from 90 patients who had received implantation of the Clareon monofocal IOL at the University Eye Clinic Maastricht of the MUMC⁺. For the ORA device, a nonoptimized lens constant was used initially and during the study period the ORA lens constant was globally optimized (in December 2019). Preoperatively, biometric data from the IOLM700 (IOLMaster 700; Carl Zeiss Meditec AG) were entered into the AnalyzeOR cloud-based database to enable intraoperative measurements. Cataract surgery was performed by 1 of 2 surgeons (R.M.M.A.N. or N.J.C.B.). In each patient, the best of 3 ORA measurements performed during surgery was used for analysis. Implanted IOL power was based on the preoperative BU-II data. The IOL power measurements of the ORA system were recorded only for analysis of the study endpoints and were not used for adjustment of the IOL power implanted during surgery. When performing the ORA measurements, requirements for accuracy were taken into account. These requirements included checking intraocular pressure with a Barraquer tonometer prior to the ORA measurement to prevent errors in corneal curvature and axial length, the absence of disturbances in the visual axis, a correct alignment, and a well-hydrated corneal surface.^{4,10} Postoperative manifest subjective refraction was measured at 4 to 6 weeks after surgery by an optometrist. Furthermore, patients were asked to fill

in the Catquest-9SF questionnaire preoperatively and at 3 months after surgery.

Outcome Measures

The primary outcome of this study was the percentage of eyes in which the achieved spherical equivalent (SE) refraction with the Clareon monofocal IOL was within 0.5 diopters (D) of target refraction by preoperative noncontact optical biometry (using the BU-II formula on the IOLMaster 700) and by ORA-recommended IOL power selection. Secondary outcomes included the percentage of eyes in which the achieved SE refraction was within 0.25 D, 0.75 D, and 1.0 D of target and the incidence of refractive surprise (defined as an achieved refraction ≥ 1.0 D from target) for the BU-II formula vs the ORA device. In addition, patient-reported outcomes were assessed in all patients preoperatively and 3 months postoperatively using the Dutch validated version of the Catquest-SF9 questionnaire. Because the ORA Clareon lens constant was globally optimized during the study period, we also compared preoptimized results with post-optimized for the ORA device. Finally, we compared preoperative keratometric astigmatism, intraoperative astigmatism measured by ORA, and postoperative refractive astigmatism.

Statistical Analysis

Data were extracted from the AnalyzOR cloud-based database into an Excel database. Statistical analyses were performed using SPSS Statistics for Windows, (v. 23.0, IBM Corp.) and an Excel database (Office 2010, Microsoft Corp.). Baseline characteristics were reported as frequencies with percentages, as mean \pm SD, or as median and interquartile range, as appropriate. The percentages of eyes within 0.25 D, 0.50 D, 0.75 D, and 1.00 D of target refraction were presented using descriptive statistics, and the incidence of refractive surprise was analyzed using a McNemar test. Furthermore, the mean absolute prediction error for the BU-II formula vs ORA recommended power (before and after optimization) was compared using a paired-samples *t* test. The mean absolute prediction error for ORA before global optimization vs after global optimization was compared using an independent samples *t* test. Analysis on mean absolute prediction errors was performed for all eyes and for first and second eyes separately. In addition, patient-reported outcomes with the Catquest-9SF questionnaire were presented as total disability score sum and a Rasch score and analyzed using the Wilcoxon matched-pair signed-rank test. Rasch scores were obtained using a quick-access conversion table with percentile ranks for pre-, post-, and norm scores for the Dutch Catquest-9SF, as reported by Visser et al.¹¹ Finally, preoperative keratometric astigmatism, intraoperative astigmatism measured by ORA, and postoperative refractive astigmatism were presented in double-angle vector plots, using the astigmatism double-angle plot tool available on the ASCRS website.¹² Analyses to calculate vector differences (surgically induced astigmatism [SIA]) were performed using an Excel database (Office 2010). The level of statistical significance was set at 0.05 for all analyses.

RESULTS

A total of 100 eyes (51 patients) were included in the study. Forty-four patients underwent bilateral same-day surgery. In 2 patients, only 1 eye was measured using the ORA device instead of both eyes. In 1 eye of 1 ISBCS patient, the ORA device could not measure intraoperative refraction despite absence of ocular comorbidities. In 1 DSBCS patient, the second eye was not measured using ORA for logistical reasons. Mean age was 73 ± 7 years, and 41% ($n = 21$) of patients were men. Baseline characteristics are presented in [Table 1](#).

Refractive Outcomes

For the ORA system, the overall percentages of eyes with an achieved SE refraction within 1.00 D, 0.75 D, 0.50 D, and

Table 1. Baseline Characteristics.	
Age (y), mean ± SD	73 ± 7
Sex (M), n (%)	21 (41)
Patients undergoing ISBCS, n (%)	44 (86)
Biometry, mean ± SD	
Anterior chamber depth	3.14 ± 0.39
Axial length	23.83 ± 1.01
K steep	44.14 ± 1.57
K flat	43.38 ± 1.53
WTW distance	12.06 ± 0.37
Absolute cylinder	0.76 ± 0.47
Lens thickness	4.76 ± 0.38
Cataract intensity (LOCS-III), mean ± SD	
Nuclear opalescence	2.56 ± 1.12
Nuclear color	2.60 ± 1.06
Cortical	2.14 ± 0.96
Posterior capsule	1.84 ± 0.94

ISBCS = immediate sequential bilateral cataract surgery; LOCS = Lens Opacities Classification System; WTW = white-to-white

0.25 D of target were 84% (84 eyes), 72% (72 eyes), 57% (52 eyes), and 21% (21 eyes), respectively. For the preoperative biometry using the BU-II formula, the percentages of eyes within 1.0 D, 0.75 D, 0.50 D, and 0.25 D of target were 97% (97 eyes), 88% (88 eyes), 77% (77 eyes), and 53% (53 eyes), respectively (Figure 1). In addition, the incidence of a refractive surprise, defined as an achieved refraction ≥1.0 D from target, was significantly higher for ORA (16%; 16 eyes) compared with preoperative biometry (3%; 3 eyes) ($P < .001$, McNemar test). One-month results on the percentage of eyes with an achieved SE refraction within 1.00 D, 0.75 D, 0.50 D and 0.25 D of target improved for ORA after global optimization was performed, resulting in percentages within target refraction of 100% (32 eyes), 94% (30 eyes), 84% (27 eyes), and 41% (13 eyes), respectively (Figure 2).

Results on mean absolute and mean arithmetic prediction errors are reported for all eyes for ORA prior to global optimization vs BU-II and for ORA prior to optimization vs

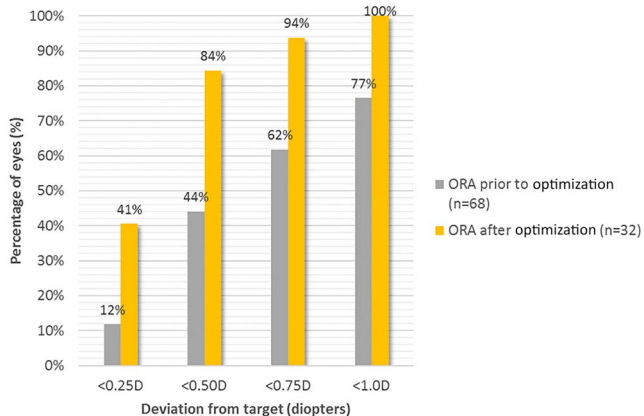


Figure 2. One-month results of the percentage of eyes with an achieved spherical equivalent refraction within 1.0 D, 0.75 D, 0.50 D, and 0.25 D of target for ORA prior to global optimization vs after global optimization.

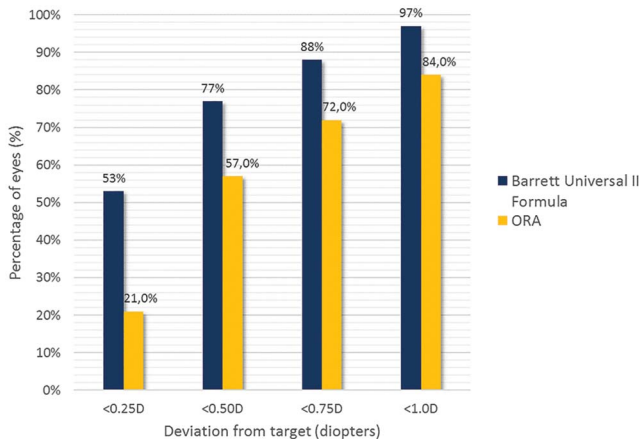


Figure 1. One-month results of the percentage of eyes with an achieved spherical equivalent refraction within 1.0 D, 0.75 D, 0.50 D, and 0.25 D of target for the Barrett Universal II formula vs ORA-recommended power (both prior and after optimization) for the Clareon monofocal IOL.

ORA after global optimization because analyses for the first and second eyes separately showed comparable results. Mean absolute prediction error (±SD) and mean arithmetic prediction error were significantly higher for ORA prior to optimization (0.67 ± 0.38 D and 0.65 ± 0.41 D, respectively) compared with preoperative biometry (0.38 ± 0.29 D and 0.29 ± 0.38 D, respectively) ($P < .001$). After global optimization of the ORA constant for the Clareon monofocal IOL, the mean absolute prediction error for ORA improved significantly (preoptimization vs postoptimization: 0.67 ± 0.38 D vs 0.33 ± 0.21 , $P < .001$). The same result was found for the mean arithmetic prediction (preoptimization vs postoptimization: 0.65 ± 0.41 D vs -0.19 ± 0.34 D; $P < .001$). Furthermore, after global optimization, a significantly higher mean absolute prediction error was found for ORA in first eyes (ORA vs BU-II: 0.33 ± 0.19 vs 0.18 ± 0.16 , $P = .001$) and in both eyes overall (ORA vs BU-II: 0.33 ± 0.21 vs 0.21 ± 0.20 , $P = .003$), but not in second eyes (ORA vs BU-II: 0.32 ± 0.23 vs 0.25 ± 0.24 , $P = .246$). When comparing the mean arithmetic prediction error after global optimization, a significantly higher prediction error was found for ORA vs BU-II in all comparisons (first eyes: -0.21 ± 0.33 vs -0.05 ± 0.24 , $P = .017$; second eyes: -0.18 ± 0.35 vs 0.04 ± 0.35 , $P < .001$; both eyes overall: -0.19 ± 0.34 vs -0.01 ± 0.28 , $P < .001$).

Astigmatism

Preoperative keratometric astigmatism measured by the IOLM700, intraoperative astigmatism measured by the ORA device, and postoperative refractive astigmatism are presented in Figure 3. Double-angle vector plots show similar astigmatism values for intraoperative ORA (centroid: 0.87 D @ 10 degrees ± 0.91 D) compared with postoperative refractive astigmatism (centroid: 0.82 D @ 9 degrees ± 1.05 D), in contrast to preoperative corneal astigmatism (centroid: 0.23 D @ 176 degrees ± 0.87 D). The vector differences (SIA) between preoperative keratometric astigmatism and postoperative manifest refraction and between ORA and postoperative

Table 2. Dutch Catquest-9SF Questionnaire Results Before and 3 Months After Surgery.

Parameter	Preop (n = 46)	3 mo post-surgery (n = 46)	P value ^a
Median total disability score sum (range)	18.0 (9.0, 34.0)	10.0 (9.0, 21.4)	<.001
Median Rasch ^b score (range)	-1.09 (-6.14, 3.61)	-4.77 (-6.14, -0.26)	<.001

^aWilcoxon matched-pair signed-rank test

^bPositive Rasch scores indicate lower levels of ability compared with the mean required level of difficulty. Negative Rasch scores indicate higher levels of ability compared with the mean required level of difficulty.³⁷

manifest refraction are presented in Figure 4. The SIA was significantly different from zero for the difference between preoperative keratometric astigmatism and postoperative manifest refraction (centroid: 0.63 @ 14 degrees ± 0.50), but not for the difference between ORA and postoperative manifest refraction (centroid: 0.06 @ 115 degrees ± 0.59).

Patient-Reported Outcomes

Table 2 shows the patients self-assessed visual function preoperatively and at 3 months after surgery measured by the validated Dutch Catquest-9SF questionnaire. Both median total disability score sum and median Rasch scores improved significantly at 3 months after surgery compared with preoperative measurements (P < .001), indicating a significant improvement of the level of ability compared with the mean required level of difficulty at 3 months after surgery.

DISCUSSION

Currently available research on intraoperative aberrometry mainly focuses on patients with cataract with a history of corneal refractive surgery, patients who receive toric IOLs,

and patients with short or long axial lengths.¹³⁻²² A recent systematic review and network analysis on IOL power calculations in eyes after myopic laser reported ORA to be one of the formulas to provide the highest proportion of eyes with a postoperative refractive error within ±0.50 and ±1.00 D.²³ Moreover, the study showed that ORA provided the lowest mean absolute error and median absolute error. However, other studies on toric and nontoric IOLs implanted in eyes with no history of corneal refractive surgery are inconclusive and show results varying from significantly better prediction accuracy for ORA to significantly better prediction accuracy for preoperative formulas.^{13,17,19} Nonetheless, also for patients with normal eyes who receive implantation of a monofocal IOL, the ORA system may have a potential benefit. For instance, there could be a benefit in case of increasing implementation of ISBCS, in which patients undergo cataract surgery on both eyes on the same day.²⁴⁻²⁷ One of the main concerns of ISBCS, besides the risk of endophthalmitis, is losing the ability to adjust IOL power for the second eye using the results of the first eye.²⁸⁻³¹ A high predictive accuracy of postoperative refraction could reduce this concern. Therefore, the question arises whether there could be a role for intraoperative aberrometry in ISBCS patients. This requires good refractive prediction accuracy for the ORA device, including relatively new monofocal IOLs such as the Clareon monofocal IOL.

Nowadays, accepted percentages of eyes within 1.00 D and within 0.50 D of preoperative calculated target SE refraction are about 90% and 70%, respectively.^{32,33} This study shows lower percentages of eyes within 1.0 D, 0.75 D, 0.50 D, and 0.25 D for ORA compared with the BU-II formula when using the Clareon monofocal IOL. For ORA, the overall percentages within 1.00 D and 0.50 D were 84% and 57%, respectively, and therefore did not fall within the currently accepted rates, in contrast to the BU-II formula (97% within 1.00 D and 77% within 0.50 D). For the BU-II formula, some

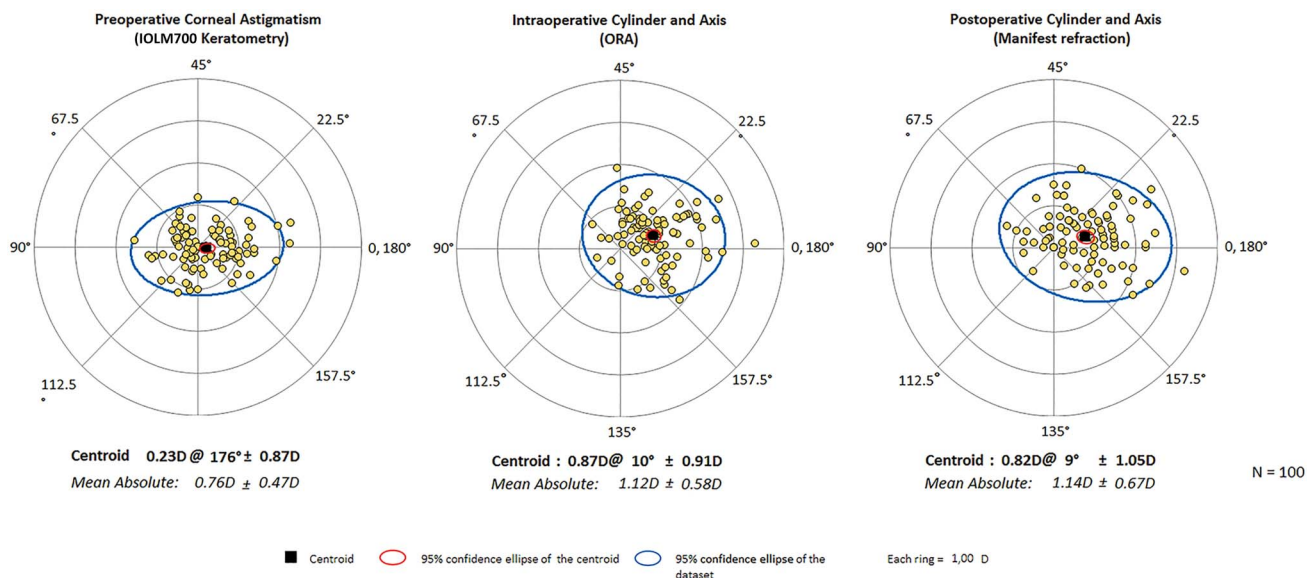


Figure 3. Double-angle vector plot of preoperative keratometric astigmatism (measured by the IOLM700), intraoperative astigmatism, and the manifest postoperative refractive astigmatism after implantation with the Clareon monofocal IOL.

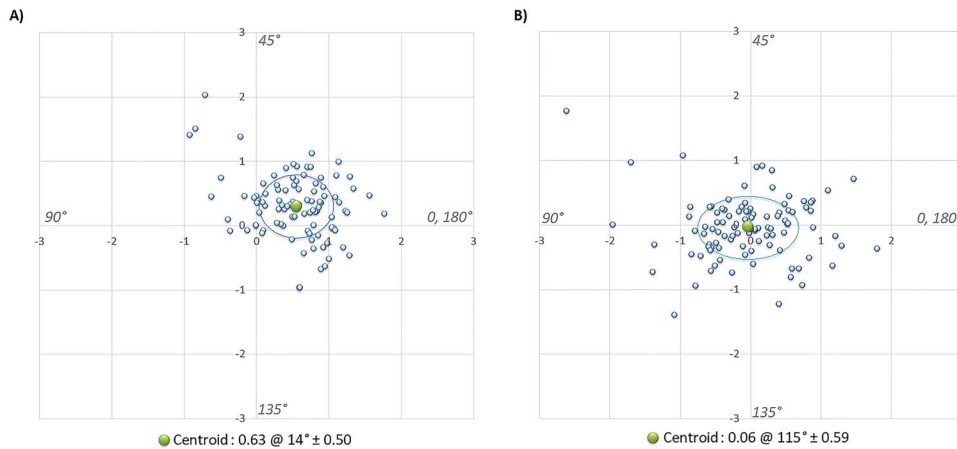


Figure 4. Double-angle vector plot of the astigmatism difference (SIA) between preoperative keratometric and postoperative manifest refraction (A) and intraoperative ORA and postoperative manifest refraction (B). SIA = surgically induced astigmatism.

studies report higher percentages within target.¹⁷ Still, our results are slightly higher than the overall accepted values reported by Lundström et al., and our findings for percentages within 0.5 D of target for the BU-II are similar to results reported in a large retrospective database by Cionni et al.^{13,32} For ORA, the nonoptimized results are lower than the generally accepted values and percentages reported by Cionni et al. and Raufi et al.^{13,17} However, these retrospective studies have a potential for selection bias and do not report on specific lens models used, although this is important when considering the constant optimization. In our study, the lens constant for the BU-II formula had been optimized prior to this study, in contrast to the non-optimized ORA constant. Especially for new IOLs, ORA-specific lens constant optimization using postoperative refractive data is required to achieve best possible outcomes. The optimization process for ORA-specific lens constants consists of 3 phases (Alcon document: Job-Aid ITCDOC-001762, v. 2.0). The first phase includes the nonoptimized phase, in which the manufacturer's recommended IOL constant is used. Thereafter, the cloud-based AnalyzOR system needs postoperative data of over 100 surgeries from at least 3 surgeons, taking into account clinical rules on visual acuity and absolute prediction error to filter reliable cases, to proceed with the global optimization phase. This global optimization phase is performed centrally so that all surgeons benefit from this process. Finally, when the ORA-specific lens constant is globally optimized, the constant can be optimized per individual surgeon (personal optimization phase) if at least 30 surgeries are performed by this surgeon for a given lens. This study showed that prediction accuracy of the ORA system improved significantly after global optimization, resulting in percentages within 1.00 D and 0.50 D of target of 100% and 84%, respectively, indicating the importance of the optimization process for the ORA device.

In addition to optimized lens constants and formulas for accurate IOL selection, accurate prediction of postoperative astigmatism is important for the quality of the refractive outcomes. However, a lack of correlation between

preoperative keratometry and postoperative refraction has been described previously and may be explained by the influence of posterior corneal astigmatism, lenticular astigmatism, and SIA.^{34,35} The ORA device allows surgeons to measure intraoperative aphakic astigmatism without the influence of lenticular astigmatism and after corneal incisions have been made. Indeed, double-angle vector plots in this study show similar astigmatism values for intraoperative ORA measurements and postoperative manifest refraction, in contrast to preoperative biometric data. This implies that adjustment of toric IOL power based on intraoperative ORA measurements could be a valuable strategy when implanting toric IOLs to decrease postoperative residual astigmatism. However, it should be noted that only anterior K values instead of True-K values are used in the current study. Therefore, the potential influence of posterior corneal astigmatism has not been taken into account in this study.

With regard to patients' self-assessed visual function, we found an improvement in Catquest-9SF Rasch scores from -1.09 preoperatively to -4.77 at 3 months after surgery. These results are slightly better than those reported in 1 smaller study on the Clareon IOL and those reported in a larger multicenter study on the validation of the Catquest-9SF questionnaire in the Netherlands.^{11,36} For the study comparing Catquest-9SF outcomes for 60 patients implanted with a Clareon IOL vs 50 patients implanted with a Tecnis ZCB00 IOL, a mean Rasch score for of -3.00 was found for the Clareon IOL at 1 month after surgery.³⁶ Furthermore, the Dutch Catquest-9SF validation, which was performed in 657 Dutch patients (IOL types not specified), reported a mean overall improvement in Rasch score from -0.56 to -3.37 and a mean improvement of 3.32 in patients who were operated on both eyes.¹¹ Still, our study was not designed to compare Catquest-9SF outcomes of the Clareon IOL with a (large) reference group, and future studies are needed to investigate this further.

Strengths of the present study include the prospective design and information on both nonoptimized and global optimized data. Furthermore, this study used a modern preoperative IOL calculation formula (the BU-II formula) for comparison with the ORA device and gives more insight

in the importance of the optimization process for the ORA constant. However, this study also has some limitations. The number of included cases is relatively low for an article on IOL power accuracy. However, the few available articles comparing ORA and preoperative formulas in normal eyes are mainly retrospective, whereas this pilot study reports on prospective data. Consequently, lower numbers of patients are included. Furthermore, most collected data on the prediction accuracy of the ORA device included non-optimized ORA constant data ($n = 68$ eyes). Globally optimized data for the ORA device were available for only 32 eyes, and no surgeon optimization (which should further improve the ORA prediction for the Clareon IOL) was performed yet. Finally, this study was performed in a single center experienced in the use of the ORA device and only included eyes without any comorbidities, which may influence the generalizability of the results.

In conclusion, this study shows lower percentages of eyes within 1.0 D, 0.75 D, 0.50 D, and 0.25 D of predicted target for the ORA device compared with the BU-II formula when implanting the new Clareon IOL. However, new IOLs require global and personal optimization to achieve best possible outcomes. The current ORA results represent data prior to these optimization phases, in contrast to the results for the optimized Barrett formula. Further evaluation of (surgeon) optimized data is needed to investigate the added value of intraoperative aberrometry for patients undergoing ISBCS.

WHAT WAS KNOWN

- Currently available research shows results varying from significantly better prediction accuracy for ORA to significantly better prediction accuracy for preoperative formulas.
- A difference between postoperative refractive astigmatism and preoperative keratometry could be explained by the influence of posterior corneal astigmatism, lenticular astigmatism, and surgically induced astigmatism.

WHAT THIS PAPER ADDS

- Double-angle vector plots showed similar astigmatism values for intraoperative ORA measurements and postoperative manifest refraction, in contrast to preoperative biometric data.
- Lower percentages of eyes within 1.0 D, 0.75 D, 0.50 D, and 0.25 D of predicted target were found for the ORA device compared with a modern preoperative IOL calculation formula in the new Clareon monofocal IOL. However, the global optimization process of the ORA lens constant significantly improved the prediction accuracy of the ORA system for this new IOL.

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