

Refractive Prediction Accuracy Using Intraoperative Aberrometry versus Barrett True-K Formula Following Corneal Refractive Surgery

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Purpose: To compare the refractive prediction accuracy of the Optiwave Refractive Analysis (ORA) SYSTEM with the Barrett True-K (BTK) formula in calculating intraocular lens (IOL) power in eyes that underwent cataract surgery after previous myopic photorefractive keratectomy (PRK) or laser-assisted in situ keratomileusis (LASIK).

Methods: This retrospective study evaluated patients aged ≥ 22 years with prior myopic PRK or LASIK who underwent unilateral or bilateral cataract removal and monofocal IOL implantation using the ORA SYSTEM at 177 sites in the United States. Two datasets were analyzed: All Eyes (ie, all eligible eyes) and First Surgery Eyes (ie, each patient's first implanted eye). All Eyes were subgrouped by axial length (AL) and further analyzed. The main outcomes included paired differences in absolute prediction errors (APEs) between the ORA SYSTEM and BTK and differences in the proportion of eyes with APEs of ≤ 0.25 diopter (D) and ≤ 0.50 D.

Results: 1067 eyes were analyzed, including 897 First Surgery Eyes. Significantly higher proportions of All Eyes had APEs of ≤ 0.25 D ($P = 0.0128$) and ≤ 0.50 D ($P < 0.0001$) using the ORA SYSTEM than the BTK formula. Similarly, significantly higher proportions of First Surgery Eyes had APEs of ≤ 0.25 D ($P = 0.0037$) and ≤ 0.50 D ($P = 0.0004$) using the ORA SYSTEM than the BTK formula. In both datasets, mean ($P < 0.0001$) and median ($P \leq 0.0005$) APEs were significantly lower with the ORA SYSTEM than with the BTK formula. AL did not affect the differences in prediction accuracy between these IOL power calculations.

Conclusion: In post-myopic PRK or LASIK eyes undergoing cataract surgery, the ORA SYSTEM provided significantly more accurate refractive predictability than the BTK formula, as determined by mean and median APE.

Keywords: absolute prediction error, intraoperative aberrometry, Barrett True-K formula, post-myopic corneal refractive surgery

Introduction

An increasing number of patients develop age-related cataracts and present for cataract surgery after having undergone keratorefractive surgery.^{1,2} These patients generally seek to achieve some level of spectacle independence and tend to have heightened expectations of excellent uncorrected vision.¹ However, accurate intraocular lens (IOL) power calculation remains challenging in patients with prior keratorefractive surgery. Laser vision correction alters the curvature of the cornea in the area of the ablation zone, as well as the anterior/posterior curvature ratio, making conventional lens power calculations less accurate.² Current methods that have been proposed to improve the accuracy of IOL power calculation in post-refractive eyes include no clinical history post-laser refractive surgery formulas, such as the Haigis-L,³ Masket,⁴ Shammas,⁵ and Barrett True-K (BTK)⁶⁻⁸ formulas, and combinations of conventional formulas, such as the traditional Haigis⁹ and Emmetropia Verifying Optical (EVO)¹⁰ formulas, with total keratometry results obtained with the optical biometer IOLMaster 700 (Carl Zeiss Meditec).

In 2013 the Optiwave Refractive Analysis SYSTEM with VeriEye (ORA SYSTEM; Alcon, Inc., Fort Worth, TX), which integrates a Talbot-Moiré aberrometer, was launched.¹¹ The ORA SYSTEM is capable of measuring the refractive power of aphakic and pseudophakic eyes during cataract surgery, allowing for intraoperative IOL power calculation through a proprietary process that accounts for the contribution of the anterior and posterior corneal curvatures/powers to the overall refractive power of the eye.^{11,12} Aphakic measurements are designed to refine/confirm the IOL power (ie, sphere and total astigmatism), whereas pseudophakic readings help to adjust the orientation of an IOL in the case of a toric implantation.¹³ Furthermore, by including postoperative refractive data, the ORA SYSTEM can optimize IOL specific lens constants and regression coefficients used in IOL power calculations, which enable improved refractive outcomes.¹⁴

Although most studies of post-refractive eyes have reported that the ORA SYSTEM provides equal or better refractive outcomes compared with other IOL power calculation formulas, those studies included small patient populations.^{1,15–18} The purpose of this study was to retrospectively compare the refractive prediction accuracy of the ORA SYSTEM with the BTK formula in a large cohort of patients who underwent cataract surgery with the ORA SYSTEM after myopic photorefractive keratectomy (PRK) or laser-assisted in situ keratomileusis (LASIK). Real-world data from multiple sites in the United States were extracted from the ORA SYSTEM AnalyzOR database, and a secondary sensitivity analysis using the first surgery eye set was performed to control for bias that might have occurred when selecting the IOL power of the second eye knowing the outcome of the first eye. The effects of axial length (AL) on post-refractive outcomes were also evaluated.

Methods

Study Design

This retrospective study utilized data entered into the ORA SYSTEM AnalyzOR database from multiple sites in the United States (N = 177 sites and N = 267 surgeons) between October 2016 and February 2021. The study was conducted in accordance with the principles of the Declaration of Helsinki and in compliance with Good Clinical Practice, the US Food and Drug Administration 21 Code of Federal Regulations 812, as well as laws and regulations of foreign countries, whichever afforded greater protection to patients, and all other applicable regulations. The study protocol was approved by the Institutional Review Board of Salus, which waived the requirement for informed consent, with data collected only from sites specified in the waiver. The defined dataset was anonymized according to US HIPAA §164.514(a)-(b) privacy laws and guidelines for deidentification of personal information prior to analysis.¹⁹

Eligibility Criteria

At the time of data extraction, the ORA SYSTEM AnalyzOR database included a total of 2,096,029 eyes. The data set was limited by the specific inclusion/exclusion criterion in the planned analysis. Eligible patients in the database had to be aged ≥ 22 years, had to have a history of undergoing myopic PRK or LASIK, and had to have been implanted with AcrySof monofocal IOLs (models SN60WF, SA60WF, SN60AT, or SA60AT; Alcon, Inc., Fort Worth, TX) at the time of cataract surgery. Refined ORA regression coefficients and global or personalized surgeon factors had been assigned to all IOLs. All included patients had undergone cataract extraction by phacoemulsification in at least one eye, with the ORA SYSTEM providing assistance with IOL power selection. Eyes with a history of ocular disease, an absolute prediction error (APE) of ≥ 2.75 diopters (D), a history of radial keratotomies, or unavailable preoperative, intraoperative, and/or postoperative data (with at least 10 days follow-up) were excluded from the study.

Data Collection

The ORA AnalyzOR database includes data recorded by surgeons regarding the IOL power calculation formula used during pre-operative planning and the IOL power suggested by the formula. During the study period between October 2016 and February 2021, the database did not record the BTK version used or lens constant information.

Clinical data recorded included preoperative keratometry, AL, and white-to-white measurement. Preoperative data also included the IOL power calculated using the preoperative measurements and the BTK formula, as well as the

predicted postoperative spherical equivalent as determined by the calculation of preoperative IOL power. The primary endpoints for comparison were the differences in the percentages of eyes in which the APEs for the IOLs implanted were ≤ 0.50 D and ≤ 0.25 D, as determined by the ORA SYSTEM and the BTK formula, and the differences in means and medians of the APEs obtained with the ORA SYSTEM and the BTK formula. The absolute ORA SYSTEM prediction error for the IOL implanted was defined as the absolute value of the difference between the manifest refraction spherical equivalent (MRSE) predicted intraoperatively by the ORA SYSTEM for the IOL implanted and the actual MRSE achieved by the IOL implanted. The APE for the IOL power calculated preoperatively using the BTK was back calculated by taking the difference between the MRSE predicted by the formula and the MRSE that would have been achieved if the preoperatively planned IOL had been implanted, taking into account the difference between the power of the IOL implanted and the power of the IOL calculated preoperatively at the spectacle plane. Postoperative MRSE was included in the analysis if it was determined ≥ 10 days after surgery.

The primary end points were assessed using two analysis sets: All Eyes and First Surgery Eyes. The All Eyes set contained all eligible eyes and was also used for subgroup analyses by AL (< 26 mm vs ≥ 26 mm). The First Surgery Eyes set contained each eligible patient's first implanted eye according to the earliest surgery date in the case of bilateral implantation and was considered secondary as a supportive sensitivity analysis. No safety or follow-up data were included, as the data collection was retrospective in nature and based on real-world data entered into the ORA SYSTEM AnalyzOR database.

Statistical Analysis

Statistical analysis was performed using SAS software (SAS Institute Inc., Cary, NC). No sample size calculation was conducted for this analysis. Differences between the refractive outcomes of the ORA SYSTEM and BTK formula were tested with paired Chi-squared tests (for proportions), paired t-tests (for means), and Wilcoxon signed-rank tests (for medians). The superiority of the ORA SYSTEM over the BTK formula in the All Eyes and First Eye sets and in subgroups stratified by AL was tested by applying one-sided tests, with statistical significance defined as a *P* value of < 0.025 .

Results

The All Eyes set consisted of 1067 eyes, with refractive results collected an average 44.9 days postoperatively (Table 1). All patients had a history of myopic PRK or LASIK and had undergone unilateral or bilateral IOL implantation. The First Surgery Eyes set consisted of 897 (84.1%) of the 1067 eyes. The most commonly implanted IOL model was SN60WF (79.1%; 844/1067), followed by SA60WF (18.2%; 194/1067), SA60AT (1.8%; 19/1067), and SN60AT (0.9%; 10/1067).

Table 1 Ocular Baseline Characteristics in the All Eyes Set (N = 1067)

Variable (Unit)	All Eyes (N = 1067)
Preoperative keratometry (D)	
Mean (SD)	41.189 (2.197)
Median (min, max)	41.28 (34.96, 48.10)
AL (mm)	
Mean (SD)	25.408 (1.355)
Median (min, max)	25.32 (22.12, 30.26)
AL < 26 mm, n (%)	737 (69.1)
AL ≥ 26 mm, n (%)	330 (30.9)
White-to-white distance (mm)	
Mean (SD)	12.165 (0.411)
Median (min, max)	12.16 (10.57, 13.50)

Abbreviations: AL, axial length; D, diopter; SD, standard deviation.

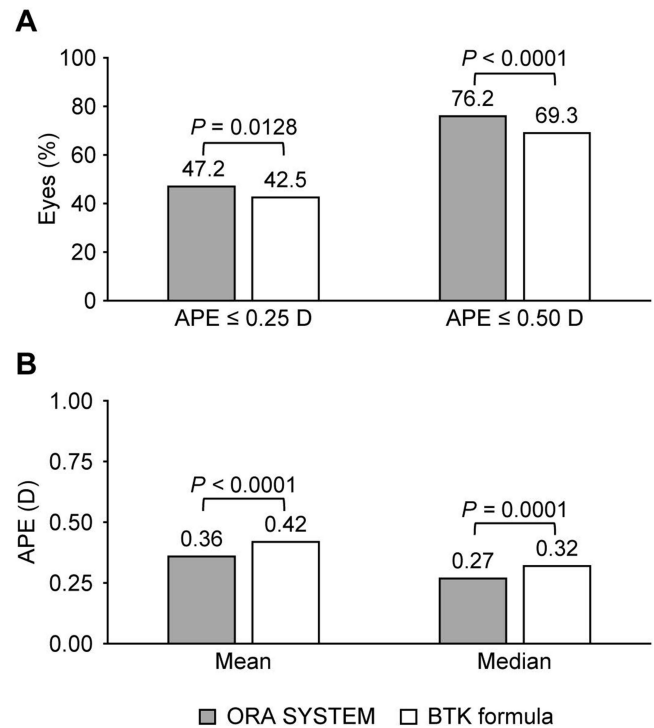


Figure 1 Proportion of eyes with postoperative APE ≤ 0.25 D or ≤ 0.50 D (**A**) and mean and median (**B**) APEs in the All Eyes set (N = 1067) with the BTK formula and the ORA SYSTEM.

Abbreviations: APE, absolute prediction error; BTK, Barrett True-K; D, diopter; ORA, Optiwave Refractive Analysis.

Analyses of the All Eyes set showed that, compared with the BTK formula, use of the ORA SYSTEM resulted in significantly higher proportions of eyes with APEs of ≤0.25 D (47.2% vs 42.5%, $P = 0.0128$) and ≤0.50 D (76.2% vs 69.3%, $P < 0.0001$), resulting in differences of 4.7% and 6.9%, respectively (Figure 1A). In addition, significantly lower mean and median APEs were achieved with the ORA SYSTEM than the BTK formula, with paired differences of −0.060 D (0.36 D vs 0.42 D, $P < 0.0001$) and −0.020 D (0.27 D vs 0.32 D, $P = 0.0001$), respectively (Figure 1B). The mean arithmetic prediction errors determined by the ORA SYSTEM and the BTK formula for All Eyes did not differ significantly (Table 2).

Similarly, analyses of the First Surgery Eyes set showed that, compared with the BTK formula, use of the ORA SYSTEM resulted in significantly higher proportions of eyes with APEs of ≤0.25 D (46.8% vs 40.9%, $P = 0.0037$) and ≤0.50 D (75.5% vs 69.1%, $P = 0.0004$) using the ORA SYSTEM than the BTK formula, resulting in differences of 5.9% and 6.4%, respectively (Figure 2A). In addition, mean and median APEs were significantly lower when using the ORA

Table 2 Mean Arithmetic Prediction Errors Determined by the ORA SYSTEM and the BTK Formula for All Eyes and for First Surgery Eyes

	ORA System	BTK Formula	Paired Difference	p-value*
All Eyes (N = 1067)				
Mean ± SD	0.00 ± 0.49	−0.02 ± 0.57	Mean 0.014; 95% CI −0.015, 0.043	0.3495
Min, Max	−1.78, 2.34	−3.14, 3.01		
First Surgery Eyes (n = 897)				
Mean ± SD	0.00 ± 0.49	−0.02 ± 0.58	Mean 0.013; 95% CI −0.018, 0.045	0.4100
Min, Max	−1.78, 2.34	−3.14, 3.01		

Note: *by paired difference t-test.

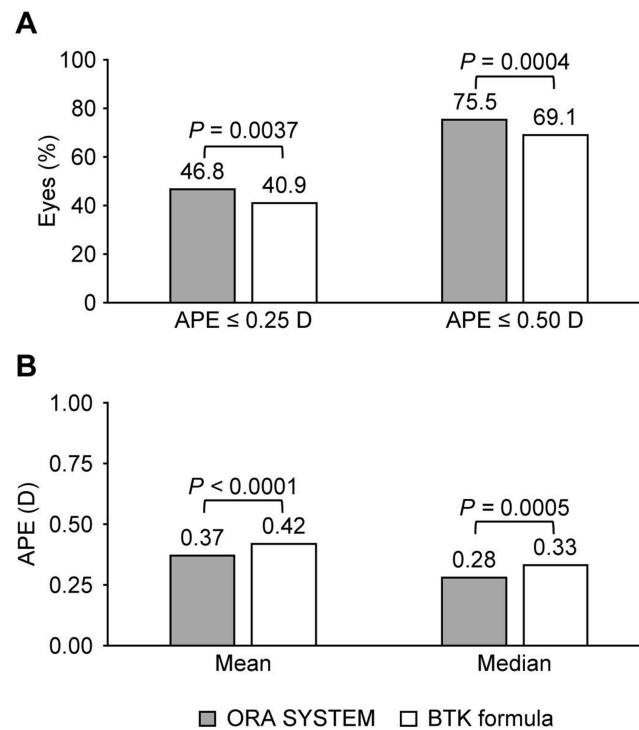


Figure 2 Proportion of eyes with postoperative APE ≤ 0.25 D or ≤ 0.50 D (**A**) and mean and median APEs (**B**) in the First Surgery Eyes set ($n = 897$) with the BTK formula and the ORA SYSTEM.

Abbreviations: APE, absolute prediction error; BTK, Barrett True-K; D, diopter; ORA, Optiwave Refractive Analysis.

SYSTEM than the BTK formula, with paired differences of -0.058 D (0.37 D vs 0.42 D, $P < 0.0001$) and -0.025 D (0.28 D vs 0.33 D $P = 0.0005$), respectively (Figure 2B). Similar to results observed for All Eyes, the mean arithmetic prediction errors determined by the ORA SYSTEM and the BTK formula for First Surgery Eyes did not differ significantly (Table 2).

Statistically significant differences between the ORA SYSTEM and the BTK formula were also observed when eyes from the All Eyes dataset were subgrouped by AL (Figure 3). The proportion of eyes with an AL of < 26 mm and APE of ≤ 0.50 D was significantly higher using the ORA SYSTEM than the BTK formula (78.2% vs 71.2% , $P = 0.0002$; Figure 3A). Compared with the BTK formula, the ORA SYSTEM resulted in significantly lower mean (0.34 D vs 0.39 D, paired difference of -0.049 D, $P = 0.0002$) and median (0.26 D vs 0.30 D, paired difference of -0.025 D, $P = 0.0005$) APEs (Figure 3B). Similarly, the proportion of eyes with an AL of ≥ 26 mm and APE of ≤ 0.50 D was significantly higher using the ORA SYSTEM than the BTK formula (71.8% vs 64.8% , $P = 0.0279$; Figure 3C). Compared with the BTK formula, the ORA SYSTEM resulted in significantly lower mean (0.40 D vs 0.49 D, paired difference of -0.091 D, $P = 0.0006$) and marginally lower median (0.31 D vs 0.37 D, paired difference of -0.010 D, $P = 0.0817$) APEs (Figure 3D).

Discussion

Patients who have undergone successful keratorefractive surgery, resulting in excellent uncorrected vision and spectacle independence, also have high expectations for a similarly successful cataract surgery.¹ Nevertheless, calculating the optimal IOL power is challenging in post-refractive eyes.² After corneal tissue ablation via keratorefractive surgery, conventional keratometry methods assuming a fixed ratio of anterior to posterior corneal curvature to extrapolate corneal power are subject to inaccuracy. A hyperopic refractive result after myopic LASIK is primarily due to an overestimation of the corneal power, whereas a myopic refractive result after hyperopic LASIK is primarily due to underestimation of corneal power.²

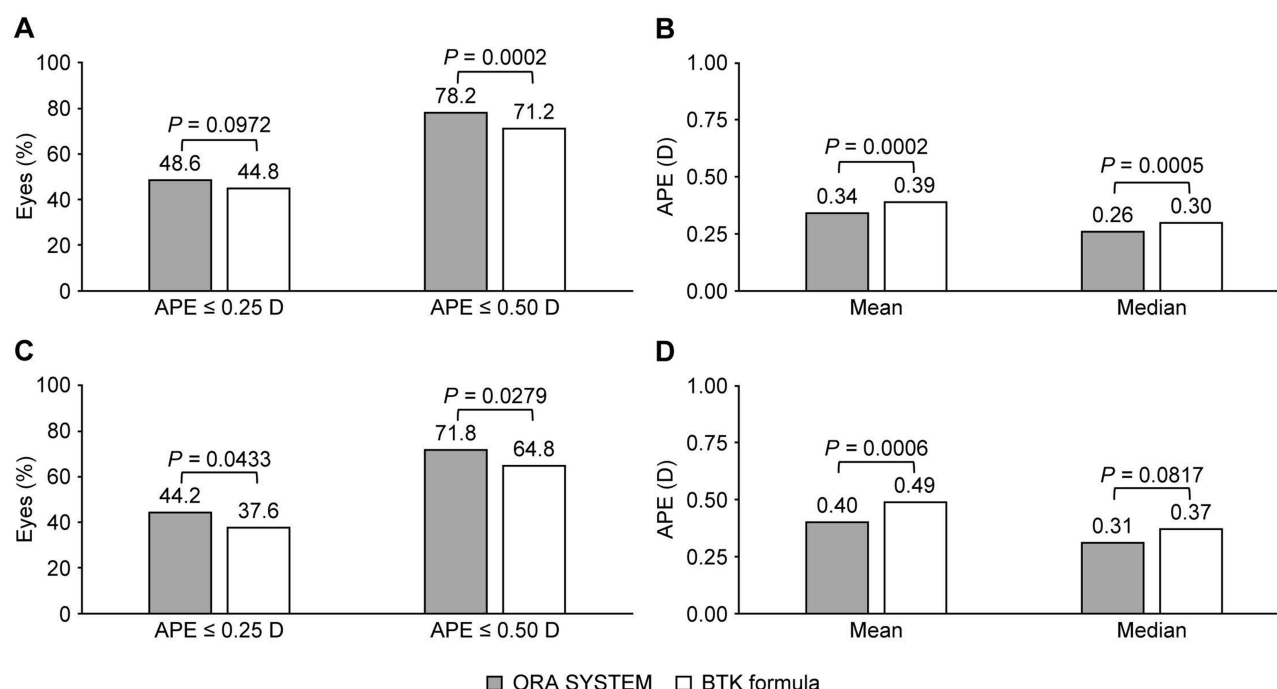


Figure 3 Proportion of eyes with postoperative APE ≤ 0.25 D or ≤ 0.50 D (**A** and **C**) and mean and median APEs (**B** and **D**) of All Eyes for AL < 26 mm (**A** and **B**) or AL ≥ 26 mm (**C** and **D**). P values of < 0.025 demonstrated statistical significance in favor of the ORA SYSTEM being superior to the BTK formula.

Abbreviations: AL, axial length; APE, absolute prediction error; BTK, Barrett True-K; D, diopter; ORA, Optiwave Refractive Analysis.

The errors inherent in conventional keratometry methods in post-refractive eyes have led to the development of advanced IOL power calculation formulas, such as the Haigis-L,³ Masket,⁴ Shammas,⁵ and BTK^{6–8} formulas, and the introduction of intraoperative aberrometry during cataract surgery.^{9–11} In post-refractive eyes, the Haigis-L, Masket, Shammas, and BTK formulas have been shown to achieve an APE ≤ 0.50 D in 45.5% to 93.3% of eyes.^{3,4,16,20} The BTK formula incorporates a modified double-K method with separate algorithms for previous hyperopic and myopic procedures. Not only can this formula incorporate measurements of keratometry and refraction before and after laser correction,^{3,4,20} but also calculate the required power of the IOL in the absence of pre-refractive surgery measurements (no-history formula).⁶ BTK has been shown to achieve equal or better refractive predictability than other formulas including the Shammas and Haigis-L formulas.⁶ The ORA SYSTEM was found to provide refractive outcomes in post-refractive eyes that were equal to or better than outcomes obtained with the Haigis-L, Shammas, and Masket formulas.^{1,16} For example, a study of 116 eyes from 79 patients reported that a higher proportion of post-myopic eyes achieved refractive outcomes with an APE ≤ 0.50 D following keratorefractive surgery using the ORA SYSTEM (73%) than using the BTK formula (69%), although the difference was not statistically significant.¹⁶

To our knowledge, the present study is the largest investigation to date to retrospectively compare the refractive prediction accuracy of the ORA SYSTEM with the BTK formula to determine IOL power in post-myopic PRK and LASIK eyes. The primary outcome measures were the proportion of eyes with APEs of ≤ 0.25 and ≤ 0.50 D and the mean and median APEs. Similar to a previous study,¹⁶ reasonably accurate refractive outcomes were observed using the BTK formula and ORA SYSTEM. Additionally, significantly higher proportions of eyes had APEs ≤ 0.25 D and ≤ 0.50 D with the ORA SYSTEM than with the BTK formula, with the ORA SYSTEM resulting in lower mean and median APEs.

This study also evaluated the mean arithmetic prediction errors in both groups. Not surprisingly, the between-group differences in these errors were not statistically significant. Using the mean arithmetic prediction errors (signed values) usually results in means that are very close to 0.00 because both hyperopic and myopic errors are included. Inasmuch as the numbers and magnitudes of minus errors are usually similar to the numbers and magnitudes of plus errors, the means are generally very close to 0.00. Thus, the absolute values of the prediction errors are usually used when measuring and comparing prediction errors, as these absolute values are more accurate than arithmetic values in representing the

magnitude of the error. Interestingly, the range of errors reported in the present study were smaller for ORA than for the BTK formula.

The improved refractive predictive accuracy of the ORA SYSTEM may be due to its ability to measure the refractive error of the aphakic eye intraoperatively, thus improving the IOL power calculation by incorporating the aphakic spherical equivalent.^{11,12,21} With ORA, the aphakic spherical equivalent is calculated using the aphakic sphere and the total refractive astigmatism of the eye, taking into account the total corneal power. Adapting total keratometry (TK) measurements has shown benefits within the existing framework of post-refractive IOL power calculation methods. For example, calculation of IOL power in post-myopic LASIK or PRK eyes using a combination of the Haigis formula and TK measurement resulted in a greater proportion of eyes having an APE ≤ 0.50 D compared with calculations using the Haigis formula alone (N = 53; 58.5% vs 35.8%, respectively).⁹ The Barrett True-K formula was recently updated (BTK-TK) to incorporate measurements of posterior corneal astigmatism (PCA). A recent study of 40 eyes showed that a statistically significantly higher percentage of eyes that had undergone post-myopic keratorefractive surgery had APEs ≤ 0.50 D with the BTK TK formula than the BTK formula (75% vs 62.5%).⁷ Similarly, another study reported that the BTK TK formula, when compared with the BTK formula, increased the proportion of eyes with APEs ≤ 0.50 D in patients who had previously undergone myopic keratorefractive surgery (N = 116 eyes; 72% vs 69%, respectively).¹⁶ Similar proportions of eyes using ORA (73%) were reported to have APE ≤ 0.50 D, although the difference in mean APE was not statistically significant when determined by either BTK or BTK-TK.¹⁶

According to the manufacturer, the ORA SYSTEM AnalyzOR database allows for optimization of the lens constants and lens-specific regression coefficients used in the SYSTEM's proprietary IOL power formula, with postoperative data input into the database. The present study included data of patients implanted with four IOL models from the same platform, for which refined regression coefficients and global or personalized lens constants were utilized. This feature may have also contributed to the improved refractive outcomes observed with the ORA SYSTEM calculations and resulted in statistically significant differences in mean APE as well as the distributions of APEs, when compared with the BTK formula.

Despite advances in IOL power calculation methods, residual refractive errors still occur following cataract surgery due to difficulties in predicting effective lens position and ocular surface considerations. Confounding factors, such as unstable tear film during preoperative biometry measurements, can also alter the accuracy of IOL calculations.^{22,23} An APE ≤ 0.50 D is generally regarded as being on target, whereas an APE > 0.50 D has been associated with a refractive miss and an undesired patient outcome, possibly needing further refractive enhancements.²⁴

A retrospective analysis of 32,189 eyes found that the mean ($0.30 \text{ D} \pm 0.26$ vs $0.36 \pm 0.32 \text{ D}$, $P < 0.0001$) and median (0.24 D vs 0.29 D , $P < 0.0001$) APEs were significantly lower, and that the percentage of eyes with APEs ≤ 0.50 D was significantly higher (81.9% vs 75.9%, $P < 0.0001$), using intraoperative aberrometry than conventional preoperative planning.²⁴ In addition, evaluation of the 12,779 eyes in which the power of the preoperative planned and actually implanted IOLs showed that the percentage with APEs ≤ 0.50 D was significantly higher using intraoperative aberrometry than conventional preoperative planning alone (81.3% vs 68.8%, $P < 0.0001$). These findings suggested that the introduction of intraoperative aberrometry to the surgical cataract procedure may be beneficial, not only to surgeons concerned about missing the refractive target, but also to patients seeking emmetropia following myopic keratorefractive surgery. No formula, however, including that of the ORA System, can currently achieve 100% accuracy in calculating optimal IOL following myopic keratorefractive surgery.

Errors in preoperative estimation of effective lens position, postoperative manifest refraction, and inaccurate preoperative AL measurements have been reported to be the largest contributors to errors in IOL power calculations (35%, 27%, and 17%, respectively).²⁵ In the present study, AL did not affect the difference in refractive accuracy observed between the two IOL power calculation approaches, with the ORA SYSTEM having statistically significantly better results in all study end points in eyes with an AL of < 26 mm (except in a proportion of eyes with APEs ≤ 0.25 D), and in mean APE in eyes with an AL of ≥ 26 mm. These findings suggest that intraoperative aberrometry may enhance the accuracy of IOL power calculations in post-myopic keratorefractive eyes, especially those with an AL < 26 mm. However, care should be taken when extrapolating these results to real-world practice, as subgroup analysis by AL was not weighted.

The main limitation of this study was its retrospective design, which did not allow for full monitoring of data captured in the database, as would a prospective study. The numbers of eyes that underwent PRK and LASIK could not be determined in the database extraction, and access to patients' raw clinical data was not possible. Furthermore, the AnalyzOR Database used in this study currently cannot distinguish between with-History and No-History methods or between with and without PCA measurements for the BTK formula.

Conclusion

This large retrospective analysis of post-myopic PRK or LASIK eyes implanted with AcrySof monofocal IOLs at multiple centers showed that the ORA SYSTEM produces refractive outcomes with significantly greater accuracy than the BTK formula alone, as demonstrated by the achievement of lower APEs. However, prospective studies are needed to more thoroughly evaluate the refractive predictability of IOL power calculation compared with multiple formulae, including the BTK-TK, EVO, and emerging AI formulae, in post-myopic keratorefractive surgery patients. The use of large database analyses and optimization and future artificial intelligence-based formulae may offer significant advances and promise to improve IOL calculations in patients who have undergone myopic keratorefractive surgery.

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Disclosure

Nicole R. Fram and John Davidson are ophthalmological surgeons who contributed to the data cited in this study, as well as being consultants and speakers for Alcon; Xiaolin Gu and Raiju J Babu are employees of Alcon, and Michael Breen was an employee of Alcon at the time of this study.

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