A large retrospective database analysis comparing outcomes of intraoperative aberrometry with conventional preoperative planning

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Purpose: To evaluate differences between the absolute prediction error using an intraoperative aberrometry (IA) device for intraocular lens (IOL) power determination versus the error that would have resulted if the surgeon’s preoperative plan had been followed.

Setting: Multiple centers in the United States.

Design: Retrospective analysis of data collected using an IA device.

Methods: The database information was limited according to predetermined inclusion/exclusion criteria. Primary endpoints included the difference between mean and median absolute prediction error with IA use versus preoperative calculation, and the percentage of cases were compared when the prediction error was 0.5 dipters (D) or less.

Results: A total of 32,189 eyes were analyzed. The IA mean absolute prediction error was lower than the preoperative calculation, 0.30 D ± 0.26 (SD) versus 0.36 ± 0.32 D (P < .0001). The aberrometry absolute median prediction error was lower than the preoperative calculation, 0.24 D versus 0.29 D (P < .0001). There was a significantly greater percentage of eyes with an aberrometry absolute prediction error of 0.5 D or less than eyes with a preoperative absolute prediction error of 0.5 D or less (26,357 [81.9%] of 32,189 vs. 24,437 [75.9%] of 32,189, P < .0001). In addition, in those cases in which power of the IOL implanted was different than the preoperatively planned IOL power, significantly more eyes had an aberrometry absolute prediction error of 0.5 D or less (10,385 [81.3%] of 12,779 vs. 8,794 [68.8%] of 12,779, P < .0001).

Conclusions: In a database of more than 30,000 eyes, calculations incorporating IA outperformed preoperative calculations. The difference was more pronounced in those cases in which the preoperatively planned IOL power was different than the power of the IOL implanted.

J Cataract Refract Surg 2018; 44:1230–1235 © 2018 ASCRS and ESCRs

More than 11 million eyes each year undergo intraocular lens (IOL) implantation worldwide, and most patients regain functional postoperative vision. In addition, recent trends in cataract surgery show decreasing visual acuity thresholds for surgery, decreasing surgical complication rates, and better visual outcomes.1 The success and safety of this procedure are attributable to continuous advances in surgical technique and measurement methods.

Despite those advances, prediction error, or more specifically, achieving the predicted postoperative spherical equivalent (SE), remains a major concern in cataract surgery.2–5 Published studies have shown variability in toric IOL refractive outcomes between surgeons using the same surgical devices and IOLs. One study showed that only 53.3% of eyes resulted in residual refractive cylinder of 0.50 dipters (D) or less,6 whereas in another study, the proportion was 68%.7 In a large study that included more than 17,000 procedures, emmetropia (SE −0.5 to +0.5 D and <1.0 D astigmatism) was reached in only 55% of cases.7 Factors that prevented achieving emmetropia included remaining corneal astigmatism and biometry...

Submitted: September 13, 2017 | Final revision submitted: June 7, 2018 | Accepted: July 4, 2018
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Financial support for this article was provided by Alcon, Inc., Fort Worth, Texas, USA. The sponsor or funding organization participated in the design of the study, conducting the study, data collection, data management, data analysis, interpretation of the data, preparation, and review or approval of the manuscript.
Medical writing assistance was provided by Kathryn Clausen Fogarty, PhD and Jennie G. Jacobson, PhD of Fishawack Communications Ltd., funded by Alcon Laboratories, Inc.
Presented at the annual meeting of the American Society of Cataract and Refractive Surgery, Los Angeles, California, USA, May 2017.
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Published by Elsevier Inc.
0886-3350/$ - see frontmatter
https://doi.org/10.1016/j.jcrs.2018.07.016
prediction errors in ametropic eyes. In the same study, the mean absolute biometry prediction error was 0.402 D ± 0.338 (SD) in all eyes; however, astigmatic eyes and eyes planned for myopia or hyperopia had higher biometry prediction errors.

To achieve the desired refractive outcome, several factors are involved, including the lens constant, that is the A-constant, the surgeon factor, or anterior chamber depth in the IOL power calculation, which can improve the refractive outcome.2-4 Lens constant optimization should be considered for improving refractive outcomes. In addition, at the time of surgery, the surgeon could treat significant refractive cylinder using advanced technology toric IOLs or arcuate incisions. Planning for these options should include surgically induced astigmatism into the calculation process as well as accounting for cyclorotation using digital or manual marking. Errors in estimation of corneal power can cause IOL calculation errors in eyes with normal corneas. Even greater difficulties in measuring corneal power are encountered in eyes with diseased, scarred, or postsurgical corneas. Problematic issues include quantifying anterior corneal power and measuring posterior corneal power and astigmatism.5

New corneal imaging technology and IOL calculation formulas have improved outcomes and hold great promise for ongoing progress.4,6,9,10 Intraoperative aberrometry (IA) addresses many of the issues involved in IOL power calculations by measuring the refractive state of the eye during surgery, after the crystalline lens has been removed. In addition, it provides real-time IOL spherical and cylinder power calculation information during the aphakic measurement phase, as well as axis positioning for toric IOLs during the pseudophakic phase.10,11 The intraoperative aberrometer measures the total refractive astigmatism in the eye in the aphakic phase, which is particularly important in patients whose anterior corneas have been reshaped by keratorefractive procedures.12,13

The Optiwave Refractive Analysis IA device with wavefront analyzers (ORA System, with Verifeye and Verifeye+, all Alcon Surgical, Inc.) represent the third- and fourth-generation versions of the IA systems developed by WaveTec Vision, which provides these aforementioned measurements. The system’s database (Analyzor) stores patients’ preoperative, intraoperative, and postoperative data, allowing the database to be retrospectively studied for the purpose of improving the science of refractive cataract surgery and outcomes. It is a secure web-based data system that stores patient data in an encrypted, U.S. Health Insurance Portability and Accountability Act–compliant format. The system can only be accessed by authorized individuals who have been given a set of unique login credentials. The system’s database also connects to the surgical cart in the operating room to download and upload data relevant to each surgical case.

The purpose of the current study was to retrospectively test for differences between the absolute prediction error using an IA device (aberrometry prediction error) and the surgeon’s formula-estimated absolute preoperative prediction error (preoperative prediction error).

PATIENTS AND METHODS
This was a retrospective analysis of data obtained from patients who had cataract extraction by phacoemulsification in at least one eye with the use of the IA device. An Institutional Review Board/Independent Ethics Committee (IRB/IEC) Waiver of Informed Consent was obtained before the first database transfer, and data were collected only from sites for which the waiver was granted. All sites were in the United States. With the exception of obtaining informed consent, this clinical trial was conducted in accordance with the principles of the Declaration of Helsinki, and in compliance with Good Clinical Practice, the U.S. Food and Drug Administration 21 Code of Federal Regulations 812, whichever affords greater protection to patients, and all other applicable regulations.

Retrospective Analysis Overview
This is a retrospective analysis of data from more than 30,000 eyes in the IA device database. The data in the database were validated to ensure accuracy of data entered in real time. Key validations relevant to the analyses presented here were applied as follows: (1) required fields were specified to prevent missing data, (2) accuracy of the date was ensured by preventing the user from specifying that the postoperative examination date was older than surgery completion date, and (3) the steep keratometry (K) value had to be greater than the flat K value.

The entire database was limited according to predetermined inclusion/exclusion criteria (see below). In addition, the dataset was further limited to eyes with IOLs manufactured by Alcon Laboratories, Inc. to potentially limit any variations attributable to lens design, material, or performance across manufacturers. The eyes meeting the criteria were anonymized, and the data were transferred to Alcon for biostatistics analyses. The analyses were performed in two stages: the first stage was exploratory, to generate the hypotheses, and the second stage was confirmatory, to test the hypotheses. The first stage was performed using a 10% of the sample chosen randomly; the remaining 90% of the sample was used for the second stage.

The preoperative plan, including the IOL model and the IOL calculator used to determine the IOL model, is independent of the IA system’s database. Information about the preoperative plan is stored in the system’s database; however, it is not used in the IA system’s IOL power formula. The prediction error resulting from the preoperative calculation was determined by the standard formula that the surgeon used to calculate the IOL power based on the preoperative data.

Inclusion/Exclusion Criteria
Only eyes from patients covered by a waiver of consent that had been issued by an IRB/IEC were included. In addition, only patients who had cataract extraction by phacoemulsification in at least one eye with the use of the IA system with the wavefront analyzer and wavefront analyzer +, with preoperative, intraoperative, and postoperative data in the database (at least 10 days of follow-up and from surgeons with at least 30 IA cases), and implanted with IOL models for which refined regression coefficients and personalized surgeon factors had been assigned were included. Data collected using premarket versions of the system’s database software, and from centers with fewer than 30 patients for analysis, were excluded. Eyes that had previous history of ocular disease that might interfere with the IA device measurement or refractive outcome (eg, keratoconus, severe dry eye, corneal transplant, etc.) were excluded.
Primary Outcome Measures

The primary outcome measures were as follows: (1) to compare the difference between the mean and median absolute IA prediction error for the IOL implanted (IA prediction error; the absolute IA prediction for the IOL implanted was the difference between the manifest refraction spherical equivalent [MRSE] predicted intraoperatively for the IOL implanted and the MRSE achieved with the IOL implanted) and the mean and median preoperative formula–estimated absolute preoperative prediction error (preoperative prediction error; the preoperative formula estimated absolute preoperative prediction was the difference between the MRSE predicted by the IOL formula used for the preoperatively planned IOL and the MRSE that would have been achieved if the preoperatively planned IOL had been implanted) for all cases; (2) to compare the difference between the mean and median IA prediction error, and the mean and median preoperative prediction error in those cases in which the power of the IOL implanted was different from the power of the IOL planned preoperatively; (3) to compare the percentage of cases where the IA prediction error was 0.5 D or less with the percentage of cases in which the preoperative prediction error was 0.5 D or less for all cases; and (4) to compare the percentage of cases in which the IA prediction error was 0.5 D or less with the percentage of cases in which the preoperative prediction error was 0.5 D or less in those cases where the power of the IOL implanted was different from the power of the IOL planned preoperatively. This last measure was selected to determine how the initial preoperative IOL power calculations and the IA power calculations differ in their predicted refractive outcome.

Exploratory and Subgroup Analyses

The exploratory analyses of the study included the percentage of cases in which the IOL power recommended by IA was different than the preoperatively planned IOL power and the surgeon implanted the IOL power recommended by IA, the surgeon implanted the preoperatively planned IOL power, or the surgeon implanted neither the preoperatively planned IOL power nor the IOL power recommended by IA system (in these situations, the surgeon implanted an IOL power between the preoperative IOL power and the IA IOL power). Exploratory analyses also included the percentage of cases in which the power of the IA recommended IOL and the power of the preoperatively planned IOL were the same and the surgeon implanted the IOL power recommended by IA, the surgeon implanted the preoperatively planned IOL power and the surgeon implanted the IOL power recommended by the preoperative plan. Neither the IOL power recommended by IA nor the preoperatively planned IOL power were used in 4199 (13.0%) of the 32 189 cases. For example, if the preoperative plan called for a 20.5 D IOL and the IA recommendation was 22.0 D, the final implant might have been 21.0 D.

Mean Absolute Intraoperative Aberrometry Prediction Error Versus the Mean Absolute Preoperative Calculation Prediction Error

Table 3 shows the differences between the mean absolute IA prediction errors and the mean absolute preoperative calculation prediction errors for all eyes, stratified by IOL type. The mean preoperative calculation prediction error was statistically significantly greater than the IA prediction error ($P < .0001$). Similar differences were seen when results were stratified by IOL type.

Median Absolute Intraoperative Aberrometry Prediction Error Versus the Median Absolute Preoperative Calculation Prediction Error

Table 4 shows the IA median prediction error and the preoperative calculation median prediction error, and similar differences were seen when the results were stratified by IOL type.

Comparison of the Percentage of Cases with Absolute Prediction Error of 0.5 D or Less

Figure 1 shows the comparison of the percentage of cases in which the absolute IA prediction error was 0.5 D or less versus the percentage of cases in which the absolute preoperative calculation prediction error was 0.5 D or less. There was a significantly greater percentage of eyes with an absolute IA prediction error of 0.5 D or less than eyes with an absolute preoperative calculation prediction error 0.5 D or less ($P < .0001$). Similar differences were seen when results were stratified by IOL type.

Figure 2 shows cases in which the IA power of the IOL implanted did not agree with the preoperative calculations,
the difference in the proportion of eyes with absolute IA prediction error of 0.5 D or less and the proportion of eyes with an absolute preoperative calculation prediction error of 0.5 D or less was even greater ($P < .0001$).

**DISCUSSION**

Refractive outcomes after cataract surgery play a central role in shaping patient satisfaction.14,15 Newer IOL power formulas are improving our ability to reach the spherical refractive target. However, despite the use of newer IOL calculation formulas, many patients are still left with unwanted refractive error. The objective of this study was to evaluate the differences between the IA prediction error and the surgeon’s preoperative prediction error.

In this study, there were no restrictions on AL or IOL power. Extreme ALs would not need to be excluded because the global regression coefficient is optimized, in part, on AL groupings that are based on AL ranges, starting from extremely short to extremely long ALs. For the hydrophobic acrylic IOLs investigated in this study (Acrysof, Alcon Laboratories, Inc.), there are 20 AL groupings. These hydrophobic acrylic IOLs were chosen because they comprised a vast majority of the IOL models in the database.

Intraoperative aberrometry provided a result within ±0.5 D of the predicted postoperative SE 81.9% of the time, whereas the preoperative calculations provided a result within ±0.5 D of the predicted postoperative SE 75.9% of the time, a difference of 6.0%. The refractive error threshold that moves a patient to request an enhancement depends on many factors that are challenging to measure such as each patient’s expectations and each patient’s specific visual requirements. However, it is generally accepted in the ophthalmologic community that SE less than 0.5 D is within target and anything outside of that range is more likely to result in a disappointing outcome for the patient and the possible need for an enhancement. These results indicate that 6 more eyes out of every 100 eyes could have been within target if IA had been used, thereby decreasing the risk for requiring an enhancement. There was no apparent variation in differences between the preoperative calculation and IA predictions observed by IOL type.

In those cases where the power of the IOL implanted was different from the preoperative planned IOL power, the difference in the percentage of cases that fell below the 0.5 D or less error between the IA system prediction, and the preoperative prediction was even more pronounced (81.3% vs. 68.8% within ±0.5 D of target). These results indicate that in those cases where the surgeon deviates from the preoperatively planned IOL power based on the IA predictions,
as many as 125 out of every 1000 eyes might avoid the need for enhancement because of the use of IA.

Although previous studies on the use of IA in IOL surgery are limited, and those studies include a small number of eyes, results are promising: Hatch et al.1 reported on 64 eyes and showed that patients undergoing cataract extraction with toric IOL placement aided by IA were 2.4 times more likely to have less than 0.50 D of residual refractive astigmatism compared with standard methods.16 In a second study of 245 eyes that had previous keratorefractive surgery for the treatment of myopia, results showed that use of IA resulted in a significantly lower mean absolute prediction error than the other methods studied, with 67% of eyes within ±0.50 D of the predicted outcome.12

A major factor that limits the willingness of surgeons to offer refractive cataract surgery to their patients is the concern of missing the refractive target. Many surgeons have limited experience with refractive enhancements or access to an excimer laser. Based on the results found in this analysis, in a practice where 100 refractive cataract surgeries are performed each month, 6 fewer patients might, on average, require enhancement each month based on spherical power error alone. Other studies have shown an even greater benefit when considering toric IOL implantation.13 The enhanced ability IA provides to achieve the refractive target with the primary surgery prevents patients from having to undergo an additional surgery and provides confidence in the surgeon that an additional surgery will not be necessary to achieve the desired result.

One limitation of the current study is that the preoperative formulas used were not standardized (surgeons used whatever preoperatively formula they preferred). However, this study’s database provides a very large source of real-world data from a wide variety of surgical centers and surgeons, which allows in-depth comparison between preoperative and IA calculations in a real-world setting. In addition, the authors understand that certain factors, such as surgeon experience with IA and the variability of office refractions, are difficult to measure, and can add to the variability of the results. Efforts were made to exclude the most inexperienced IA surgeons by excluding surgeons with fewer than 30 cases in the database. However, this study did not allow for tighter control of office refractions. Still, the results reported herein represent real-world outcomes and thus have real-world value. Another limitation of this study is that it has been reported that certain ophthalmic viscosurgical devices, if used inconsistently, can affect IA outcomes and prediction error.17 Specific media used to pressurize the anterior chamber were not identified as a parameter in the evaluation.

Accurate biometric analysis, use of advanced IOL power calculation formulas, and careful IOL selection, combined with modern techniques for cataract surgery, help surgeons move toward the goal of transforming cataract surgery into a refractive procedure with outcomes resulting in minimal refractive error. However, despite significant advances, residual refractive error still occurs after cataract surgery. Identifying factors that minimize those errors is an important goal. The addition of IA to the surgical procedure might be a way to improve refractive outcomes in cataract surgery.

In a database of more than 30 000 eyes, IA calculations outperformed preoperative calculations. In those cases where the IA altered the surgeon’s decision regarding which IOL power to implant, the difference between the proportions of cases with 0.5 D or less error (IA vs. preoperative) was even more pronounced.

WHAT WAS KNOWN
- Continuous advances in surgical technique, biometry, and preoperative calculation and planning have led to continued success and improved outcomes with the IOL implantation procedure after cataract removal. Despite those advances, prediction error remains a major concern in cataract surgery. Intraoperative aberrometry has been shown to improve astigmatic outcomes in toric IOL cases, and it has been demonstrated that IA can improve SE outcomes in post-myopic laser in situ keratomileusis patients.

WHAT THIS PAPER ADDS
- In a large database of real-world cases, IA calculations outperformed preoperative calculations, improving SE outcomes in eyes having no previous corneal refractive surgery.
REFERENCES


OTHER CITED MATERIALS

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Disclosures: Dr. Cionni is a consultant to Alcon Laboratories, Inc. Dr. Dimalanta, Dr. Breen, and Dr. Hamilton are employees of Alcon Laboratories, Inc.

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