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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 diopters (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. 8794 [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.

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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 diopters (D) or less,[6] whereas in another study, the proportion was 68%.[A] 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

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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.[2,3] 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.[4,8,9,B] 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 that 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 previously had refractive surgery were excluded. Eyes that had preexisting ocular disease that might interfere with the IA device measurement or refractive outcome (eg, keratoconus, severe dry eye, corneal transplant, etc.) were excluded.