Intraoperative Refractive Biometry for Predicting Intraocular Lens Power Calculation after Prior Myopic Refractive Surgery

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Purpose: To evaluate a new method of intraoperative refractive biometry (IRB) for intraocular lens (IOL) power calculation in eyes undergoing cataract surgery after prior myopic LASIK or photorefractive keratectomy.

Design: Retrospective consecutive cases series.

Participants: We included 215 patients undergoing cataract surgery with a history of myopic LASIK or photorefractive keratectomy.

Methods: Patients underwent IRB for IOL power estimation. The Optiwave Refractive Analysis (ORA) System wavefront aberrometer was used to obtain aphakic refractive measurements intraoperatively and then calculate the IOL power with a modified vergence formula obtained before refractive surgery. Comparative effectiveness analysis was done for IRB predictive accuracy of IOL power determination against 3 conventional clinical practice methods: surgeon best preoperative choice (determined by the surgeon using all available clinical data), the Haigis L, and the Shammas IOL formulas.

Main Outcome Measures: Median absolute error of prediction and percentage of eyes within ±0.50 diopters (D) and ±1.00 D of refractive prediction error.

Results: In 246 eyes (215 first eyes and 31 second eyes) IRB using ORA achieved the greatest predictive accuracy (P < 0.0001), with a median absolute error of 0.35 D and mean absolute error of 0.42 D. Sixty-seven percent of eyes were within ±0.5 D and 94% were within ±1.0 D of the IRB’s predicted outcome. This was significantly more accurate than the other preoperative methods: Median absolute error was 0.6, 0.53, and 0.51 D for surgeon best choice, Haigis L method, and Shammas method, respectively.

Conclusions: The IOL power estimation in challenging eyes with prior LASIK/photorefractive keratectomy was most accurately predicted by IRB/ORA.

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a methodology first proposed and reported in 2005 by Ian-chulev et al,20 whereby intraoperative refractive biometry (IRB) is performed after crystalline lens extraction to determine the aphakic spherical equivalent, which is subsequently used to derive the emmetropic IOL power. Intraoperative aphakic refractive biometry is used to minimize or eliminate dependence on preoperative anatomic measurements such as K or AL.

The objectives of the study were to validate the Optiwave Refractive Analysis (ORA) System WaveTec Vision, Inc (Aliso Viejo, CA) intraoperative wavefront aberrometer and to compare it with conventional preoperative methods: Surgeon best choice, and the Haigis L and Shammas formulas sourced from the American Society of Cataract and Refractive Surgery online calculator.

Methods

The study involved 66 investigators who were trained users of the ORA System intraoperative aberrometer for IOL calculation. The study protocol was exempted from review by an independent review board in accordance with US Code of Federal Regulations 45 CFR 46.101(b). Patients who met the criteria of operable cataract in the setting of prior myopic LASIK or photorefractive keratectomy and absence of significant ocular comorbidities were queried from the ORA surgical outcomes database, which contains a registered log of all ORA case data and postoperative refractive outcomes where intraoperative biometry was used. Patients or eyes were not eligible if any of the following exclusion criteria were met: history of ocular trauma, presence of significant ocular comorbidities, best-corrected visual acuity postoperatively of >20/40, a diagnosis of corneal ectasia or keratoconus, or anticipated poor visual potential that would compromise the accuracy of a postoperative refraction. Eyes with unreliable preoperative biometric measurements also were excluded. Patients who met the enrollment criteria were included in the analysis regardless of the IOL type that was selected. No patients were excluded based on preoperative values for biometric parameters (AL, K, or anterior chamber depth) that were at the extreme end of the normative distribution.

In addition to the ORA System intraoperative aberrometer, all patients underwent preoperative biometry. Preoperatively, the AL was obtained by partial coherence optical biometry using either the IOL Master (Carl Zeiss Meditec, Jena, Germany) or the Lenstar 900 (Haag Streit, Köniz, Switzerland). Keratometry values were obtained with the same instrument used for AL measurement. For each study eye, the surgeon entered preoperative biometry data into the American Society of Cataract and Refractive Surgery online calculator and calculated the IOL power using their preferred IOL formula. Historical data were used when available. From the varying results obtained through different calculation methodologies, surgeons used their personal judgment to select the actual IOL power to be implanted.

All IOLs were implanted in the capsular bag after phacoemulsification through a sutureless, temporal, clear corneal incisions and a capsulorrhexis. There were no significant intraoperative complications reported, including capsulorrhexis tear.

In all cases, intraoperative wavefront refractive biometry was obtained using the ORA System (WaveTec Vision, Inc, Aliso Viejo, CA) after cataract extraction and before IOL implantation. The WaveTec aberrometer attaches to the operative microscope so that it can be used during surgery. It provides on-demand evaluation of sphere, cylinder, and axis. Conventional wavefront technologies such as Shack–Hartmann are capable of measuring refractive power in a limited dynamic range, typically from −15 to +7 or +8 D. Although this range is sufficient for refractive applications such as LASIK, it is not adequate for aphakic eyes during cataract surgery. The WaveTec aberrometry system has a large dynamic range, which allows for accurate measurement of aphakic eyes intraoperatively to enable application in the refractive intraoperative setting. The WaveTec applied predictive formula is then used to derive the emmetropic IOL power.

Aphakic aberrometry measurements were obtained after the anterior chamber was inflated to a normotensive level (verified between 15 and 21 mmHg) with balanced salt solution, and were then used to immediately calculate the aphakic spherical equivalent.

The ORA System has the integrated capability to calculate the IOL power based on the aphakic spherical equivalent and the patient’s preoperatively measured AL and K in an algorithm to estimate the ELP. For the specific IOL type to be implanted in the patient, the IOL power for the target postoperative refraction was immediately calculated intraoperatively after the aberrometry measurements were obtained. Where there was a difference, the surgeon was allowed to use either the new ORA calculated IOL power or their IOL power selected preoperatively based on the formula they preferred for that given eye.

Postoperatively, best-corrected visual acuity and the spherical equivalent were calculated using a single refraction performed between 30 and 90 days after cataract surgery, with an average of 39 days for the entire cohort. The IOL power prediction error for the implanted IOL power was calculated as the difference between the originally targeted refraction and the postoperative outcome. The same was done for the ORA predicted IOL power and the Haigis L and Shammas methods. Mean and median absolute errors were derived for all refractive outcomes across all four methods. For median absolute error, the 95% confidence interval for each method was calculated and a binomial proportion method (SAS proc freq; SAS, Inc, Chicago, IL) was used to perform 2-sided tests of the null hypothesis that there was no difference between each comparator method and the ORA method. For mean absolute error, repeated-measures analysis of variance was used to compare ORA with the other 3 methods. Study eye was the unit of analysis and the method was repeated for each eye. For the percentage of eyes achieving an absolute error within 0.5, 0.75, and 1.00 D, general estimating equations were used, modeling the relationship to the endpoint with a logistic link function.

Results

A total of 246 consecutive eyes from 215 patients were included in the series. Thirty-one eyes were fellow follow-on eye surgeries. All had undergone myopic LASIK or photorefractive keratectomy surgery before their cataract surgery. The baseline ocular characteristics of the study cohort are summarized in Table 1. The study population had a broad representative range of anatomic variability, with AL ranging from 21.50 to 30.23 mm and
average K from 34.13 to 46.95 D. Also, the power of the implanted IOLs ranged from 13.0 to 28.5 D. The eyes were obviously on the myopic side. Table 1 summarizes baseline characteristics of study eyes.

The ORA was a significant factor in the cataract surgeons’ IOL selection and decision making. Of the total 246 eyes, in 68% of the time, ORA either influenced (38%) or was chosen (30%) over the preoperative IOL power calculation. In the additional 13% of cases, ORA confirmed the preoperative IOL power calculation.

Refractive outcomes are summarized in Table 2. Figure 1 compares the IOL predictive outcomes obtained with ORA versus conventional preoperative methodologies, namely, surgeon best choice, Haigis L, and Shammas formulas. Because 12.5% of all cases were second eye surgeries, refractive outcomes were additionally analyzed without the second eye cases but there was no appreciable change in aggregate results (Table 2).

For the main outcome of median absolute error, IRB using ORA achieved the lowest error of 0.35 D (95% confidence interval, 0.35–0.43 D; \( P < 0.0001 \) for IRB vs each other method). All other methods demonstrated at least a 45% higher error than IRB, which in the case of surgeon best choice was 70% higher at 0.60 D (95% confidence interval, 0.58–0.73 D; Table 3; Fig 2). Additionally, 67% of eyes were within 0.5 D of target with the IRB method—almost 45% more than the surgeon best choice (46%) and 34% more than the Shammas method, which came in second at 50% within 0.5 D. These outcomes were consistent across all endpoints for 0.75- and 1.0-D postoperative refractive thresholds.

**Discussion**

Our study reports the largest series of outcomes using IRB for IOL power calculation based on the ORA System intraoperative wavefront aberrometer. It is also among the largest outcome studies of IOL power prediction after prior keratorefractive surgery. The results from 246 consecutive eyes demonstrate improved predictive accuracy of IOL power estimation using the Talbot-Moiré IRB compared with conventional preoperative methodologies. These favorable composite results were obtained with a large number of surgeons and a wide variance in ocular ALs. In this series, IRB performed substantially better than each of the surgeon-selected conventional methodologies for postrefractive IOL power calculation.

The accuracy of the intraoperative aphakic biometric method is greater than that previously reported based on conventional preoperative IOL calculation methodologies after prior keratorefractive surgery for myopia. In a recent comparative analysis of >25 different preoperative methods of IOL calculation for 173 postmyopic LASIK eyes, the 5 most accurate methods achieved only 70% to 85% of eyes within 1.0 D of the targeted refractive error. The Masket method would have resulted in only 55% to 58% of eyes coming within ±0.50 D of their target refraction. This is in line with the results from the current series in which only 46% of eyes were within 0.5 D of the target using investigator-selected conventional IOL calculation methodologies (including Masket). In contrast with most conventional methodologies, the IRB method, which achieved closer to 70% of eyes within 0.5 D of target refraction, requires neither historical clinical refractive data nor any adjustments to biometric measurements.

These results of IRB-predicted IOL power in postmyopic LASIK/photorefractive keratectomy cases are comparable with those seen with conventional methods in eyes without prior keratorefractive surgery. The ability to improve refractive predictability without historical data in
this challenging population is particularly important, considering that the number of such patients requiring cataract surgery will steadily rise in the future.

Our results also show that using automated intraoperative wavefront aberrometry to obtain the aphakic refraction is a significant improvement over the first IRB efforts with handheld autoretinoscopy, which was used by Ianchulev et al.20 Wong et al21 showed that this latter method was reliable in eyes without prior refractive surgery, but 25% to 30% of cases had IOL power prediction errors of at least ±1.00 D error. The ORA System used for this study employs Talbot-Moiré wavefront aberrometry, which is specifically designed and calibrated for a wide range of intraoperative conditions, including aphakia. In addition, further refinements of the aphakic formula used to predict the IOL power have greatly improved the predictive accuracy of this methodology.

There are a number of limitations to this study. The preoperative IOL calculation methodology was not standardized, and the various investigators used different preoperative methods and formulas. Historical refractive data were not always available, and the surgeon was allowed to determine which method, or combination of methods, was used to select the IOL power preoperatively for any given eye. As a result, IRB was not compared with any clinical history preoperative methodologies, but only with Haigis L and Shammas formulas. The study population included 62 bilateral eyes from 31 patients. Because the refractive result of the first eye may have influenced the IOL power selection for the second eye, including both eyes in the study may have introduced estimation bias toward greater accuracy of the preoperative methodology. Finally, different types of IOLs were used in the study population, which introduced additional variables that could have affected prediction accuracy of either the preoperative or intraoperative methodologies.

This study demonstrated a number of potential advantages of this new intraoperative methodology for IOL power calculation. The aphakic refraction is an optical measurement obtained directly from the infrared laser reflection off the retina. Instead of relying on the estimated corneal power, it therefore automatically accounts for the refractive state of the entire optical media, including the aqueous and vitreous. Second, the IOL power calculation relies more on refractive optical biometry and much less on the corneal power as extrapolated from K. Surgically induced corneal changes, including astigmatic keratotomy, might also render the latter preoperative estimation less accurate. Although this study compared IRB with preoperative IOL calculation methodologies in a specific higher risk population, pre- and intraoperative methodologies are not mutually exclusive. We believe that IRB can provide benefits as an adjunct to traditional preoperative biometry in all eyes undergoing cataract surgery.

It is important to acknowledge that some unpredictability of IOL calculations using IRB with intraoperative wavefront aberrometry remains. Indeed, 6% of eyes in this study had

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Table 3. Refractive Outcomes in First Study Eye Only (n = 215) Using Intraoperative Refractive Biometry (IRB), Conventional Preoperative Intraocular Lens Calculation Methodology, Haigis L, and Shammas No Clinical History Method

<table>
<thead>
<tr>
<th>Refractive Outcomes</th>
<th>IRB Using ORA</th>
<th>Conventional Preoperative Methodology (Surgeon Best Choice)</th>
<th>Haigis L Method</th>
<th>Shammas Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>MedAE, D (95% CI)</td>
<td>0.35* (0.35—0.45)</td>
<td>0.60 (0.59—0.75)</td>
<td>0.52 (0.52—0.66)</td>
<td>0.50 (0.49—0.60)</td>
</tr>
<tr>
<td>MAE ± SD (D)</td>
<td>0.44±0.40</td>
<td>0.70±0.53</td>
<td>0.66±0.60</td>
<td>0.60±0.54</td>
</tr>
<tr>
<td>% within ±0.50 D</td>
<td>67%</td>
<td>46</td>
<td>47</td>
<td>49</td>
</tr>
<tr>
<td>% within ±0.75 D</td>
<td>85%</td>
<td>63</td>
<td>65</td>
<td>72</td>
</tr>
<tr>
<td>% within ±1.00 D</td>
<td>95%</td>
<td>75</td>
<td>80</td>
<td>87</td>
</tr>
</tbody>
</table>

CI = confidence interval; D = diopeters; MAE = mean absolute error; MedAE = median absolute error; ORA = Optiwave Refractive Analysis; SD = standard deviation.

*P < 0.0001 for IRB versus Surgeon Best Choice, IRB versus Haigis L, and IRB versus Shammas (2-sided binomial proportion test).

1P < 0.001 for IRB versus Surgeon Best Choice, IRB versus Haigis L, and IRB versus Shammas (repeated measures analysis of variance).
an IOL power prediction error of >1.0 D. The most important variable that cannot be measured intraoperatively is the final ELP of the IOL. The ELP would be expected to vary according to preexisting anatomic variables, as well as surgical variables such as capsulorhexis diameter and overlap. In addition, a number of other factors might affect the accuracy of intraoperative biometry. These include patient fixation, the intraocular pressure, increased corneal thickness, and external pressure from the lid speculum. Further studies and optimization of predictive modeling should be pursued to increase the accuracy of intraoperative aphakic biometry.

References


Footnotes and Financial Disclosures

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