Agreement on Keratometry Readings and Computed IOL Power using Haigis and SRK/T formulas between Ray Tracing (iTrace®) and Partial Coherence Interferometry (IOLMaster®) among Patients in an Outpatient Surgical Center

Thonnie Rose O. See, MD, Richard L. Nepomuceno, MD

DOH Eye Center
East Avenue Medical Center
East Avenue, Diliman, Quezon City, Philippines

Correspondence: Thonnie Rose O. See, MD
DOH Eye Center
East Avenue Medical Center
East Avenue, Diliman, Quezon City, Philippines
Email: seethonnieroseo@yahoo.com

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ABSTRACT

Objective: To determine if there is an agreement between keratometry readings and intraocular lens (IOL) power calculation using Haigis and Sanders, Retzlaff and Kraff theoretical (SRK/T) formulas obtained by iTrace® and IOLMaster®.

Methods: A retrospective chart review of patients who underwent preoperative biometry using both IOLMaster® and iTrace® from January 2015 to July 2015 and satisfied the inclusion/exclusion criteria were included in the study. The average keratometry, cylinder power and predicted IOL power were computed accordingly. Agreement between devices was analyzed using Bland Altman.

Results: A total of 70 eyes from 35 study participants were included in the analysis. The means of average keratometry values obtained from IOLMaster® and iTrace® were 43.9 ± 1.3 D and 43.6 ± 1.3 D respectively. The paired mean differences in the average keratometry and cylinder power between instruments were -0.3 ± 0.3 and 0.1 ± 0.4 respectively. There was a statistically significant difference in the proportion between the number of times there will be a need to change IOL power and the number of times IOL power will remain the same using the Haigis formula with a p value of <0.0005.

Conclusion: Average keratometry values, cylinder power and IOL calculation using the Haigis formula obtained by the two devices tested did not show agreement. There is agreement using the SRK/T formula.

Keywords: ray tracing, partial coherence interferometry, keratometry, IOL power, SRK/T, Haigis
Phacoemulsification is one of the most successful and commonly performed cataract surgeries worldwide. With the advent of toric intraocular lenses (IOLs) IOLs and refractive surgical techniques, patients now demand for independence from spectacles after cataract surgery. Despite the introduction of optical biometers, residual spherocylindrical refractive error after surgery is not uncommon.

In calculating an accurate IOL power, biometry data – which include axial length (AL), keratometry (K) values and anterior chamber depth (ACD) – are necessary. With improvements in measuring axial length, keratometry is the next important source of potential biometry error. Keratometry involves determination of the curvature of the anterior corneal surface, expressed in diopters (D) or in mm of radius of curvature. The automated keratometer (IOLMaster®), currently the gold standard for biometry, measures anterior curvature using six points of light arranged in a hexagonal pattern within a 2.3 to 2.5 mm diameter ring compared to ray tracing (iTrace®) which measures the anterior curvature within the zone of 3 mm. Because the IOLMaster® measures only six points on a 2.5 mm ring and does not use Snell law, it overestimates the power within the zone below 4.5 mm and then underestimates the zonal power above 4.5 mm. In order to minimize measurement errors and improve patient satisfaction, it was hypothesized that iTrace®, which obtains zonal average keratometry values, will then give a different representation of the central refractive power of the cornea. In this study, we compared the keratometry values of iTrace® (Tracey Technologies, Texas, 1999) and IOLMaster® (Carl Zeiss Meditec, Germany, 1999), using the latter as the gold standard. As with any new device introduced into clinical practice, studies that compare it with the most common clinically accepted device are warranted. This study determines if there is a significant difference between the keratometry values and computed IOL power calculation between the two machines through a retrospective chart review of patients who had undergone keratometry measurements using both IOLMaster® and iTrace® in an outpatient surgicenter.

**METHODOLOGY**

**Study Operational Definitions:**

**A. Partial Coherence Interferometer – (IOLMaster®)**

IOLMaster® uses a partial coherence interferometer to determine the anterior corneal curvature by projecting six lights in a hexagonal array onto 2.3 to 2.5 mm diameter from the corneal apex. This reflection is then analyzed to determine the keratometry reading (Figure 1).12

![Figure 1. IOLMaster® printout](image)

**B. Ray tracing Placido format – (iTrace®)**

iTrace® uses ray tracing Placido format that covers the central cornea at around 0.6 mm to up to 10 mm in the normal peripheral cornea (Figure 2). A bundle of rays parallel to the instrument axis and passing within the entrance pupil of the eye was traced through the anterior and posterior corneal surfaces using the Snell law. For each incoming ray, its intersection with the anterior corneal surface and its angle of incidence relative to the anterior surface normal were calculated. The ray refracted by the anterior surface was obtained using the Snell law, with \( n_\text{air} = 1.0 \) and \( n_\text{stroma} = 1.376 \). This ray was considered as the incoming ray for the posterior corneal surface and the same procedure as above will be applied to calculate the ray refracted by this surface using the Snell law, with \( n_\text{stroma} = 1.376 \) and \( n_\text{aqueous} = 1.336 \).2

![Figure 2. iTrace® printout](image)
The study was done in an outpatient surgical center. Patients undergoing either cataract surgery or refractive surgery routinely had their preoperative keratometry readings using both IOLMaster® and iTrace®, therefore, a formal ethics committee approval was not required for the study. A minimum of 39 patients were needed based on 95% reliability, 80% power and mean difference of 0.09 ± 0.14. A retrospective chart review of all patients who underwent preoperative biometry using both IOLMaster® and iTrace® from January 2015 to July 2015 satisfying the inclusion/exclusion criteria were included in the study. Inclusion criteria was all patients who had undergone biometry using both machines. Patients with ocular trauma, corneal pathologies, previous eye surgeries, pediatric patients and patients who could not fixate were excluded from the study (Figure 3).

In this study, keratometry values from each machine were obtained in diopters. Averaged keratometry readings of the two machines were used for the analysis. The following measurements were retrieved from the chart of each patient: \( K_1 \), \( K_2 \) and average \( K \) (Ave \( K \)) for the iTrace®; and \( K_1 \), \( K_2 \), axial length and Ave \( K \) for the IOLMaster®. Cylinder power and predicted IOL power calculation usingSanders, Retzlaff and Kraff theoretical (SRK/T) and Haigis formulas for both machines using their respective keratometry values were computed using the IOLMaster®’s calculator. Data was then tabulated. Paired t-test was used to compare between the following: Ave \( K \) (IOLMaster®) vs Ave \( K \) (iTrace®) and cylinder power (IOLMaster®) vs cylinder power (iTrace®). The difference between the computed IOL power using two different formulas, SRK/T and Haigis, was determined. Using IOLMaster® as the gold standard, the difference in the proportions between the number of times there will be a need to change IOL power and the number of times IOL power will remain the same was compared using Chi-square of two proportions. Two-tailed confidence intervals were estimated and conclusions were based on a 95% level of confidence interval. Agreement between the devices was then tested using Bland Altman analysis. SPSS v21 was used in data processing and analysis.

RESULTS

Seventy eyes of 35 patients were included in this study (Table 1). The mean age of the patients was 54 years ± 12 with a range of 28 to 91 years old. The average keratometry readings of the iTrace® and IOLMaster® were 43.6 ± 1.3 and 43.9 ± 1.3 respectively, with a paired mean difference of -0.3 ± 0.3 (p=0.000). The average cylinder powers of iTrace® and IOLMaster® were -0.2 ± 0.9 and -0.3 ± 1.0 respectively, with a paired mean difference of 0.1 ± 0.4 (p=0.006) (Table 2). The new biometer and the reference biometer provided comparable mean IOL power calculation using the SRK/T formula (p=0.317). There was a

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<th>Table 1. Demographic characteristics</th>
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<td>Age in years</td>
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<td>Male</td>
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<td>Female</td>
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<tr>
<th>Table 2. Keratometry and calculated cylinder power of IOLMaster® and iTrace®</th>
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<td>iTrace®</td>
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<td>Average</td>
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<td>Cylinder</td>
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* Highly significant at 95% Confidence Interval.
DISCUSSION

IOLMaster® has become established as the gold standard for biometry and IOL power measurement for the past 10 years. In 2010, a survey done by the American Society of Cataract and Refractive Surgery (ASCRS) showed that 71% of surgeons use the IOLMaster® as the preferred method of keratometry. A meta-analysis by Bullimore et al of 28 published clinical papers showed that the mean reported reduction in astigmatism postoperatively using IOLMaster® was 74% without considering misalignment. This tells us that there is still 26% of residual astigmatism postoperatively even with the use of IOLMaster®. The study concluded that IOLMaster® is at least as good as those using manual or automated keratometry.

iTrace® is a relatively new machine. It is manufactured by Tracey™ Technologies which was founded in 1999 at Houston, Texas. iTrace® is a combined Placido corneal topographer with ray tracing aberrometer. In a poster by Chung et al at the ASCRS in 2009, they compared six different keratometers using the manual keratometer as the standard and concluded that iTrace® approximated the standard the most with a Pearson Correlation coefficient of 0.947 compared with IOLMaster® that only had 0.857. A literature search shows that so far there is no study comparing keratometry values of iTrace® directly with the currently used gold standard, IOLMaster®.

Most studies comparing multiple keratometry measurement modalities have reported close concordance. Keratometry readings should therefore not vary by more than 0.50 D and 10 degrees between instruments. This is important because a toric IOL can lose 30% of its astigmatic effect if it is misaligned, and a misalignment of ≥10 degrees is generally regarded as an indication for surgical repositioning.

In this study, we determined that the new ray tracing Placido based keratometer (iTrace®) produces statistically significant different keratometry values, computed cylinder power and IOL power using the Haigis formula compared with IOLMaster®. It was noted in this study that IOLMaster® gives steeper keratometry values than iTrace® which was consistent with the findings of several other studies comparing IOLMaster® with other devices. Though from this study, the chances of changing IOL power when computed with SRK/T was not statistically significant, it

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<th>With change of IOL power</th>
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<tr>
<td>SRK/T, n (%)</td>
<td>38 (54%)</td>
<td>32 (46%)</td>
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<td>Haigis, n (%)</td>
<td>51 (72%)</td>
<td>19 (28%)</td>
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* Highly significant at 95% Confidence Interval.
is worth mentioning that more than half of the eyes tested would need a different IOL power which may deem clinically significant.

CONCLUSION

Average keratometry values, cylinder power and IOL calculation using the Haigis formula obtained by the two devices tested did not show agreement. There is an agreement using the SRK/T formula.

REFERENCES