

Biometry and intraocular lens power calculation results with a new optical biometry device: Comparison with the gold standard

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PURPOSE: To evaluate the agreement in axial length (AL), keratometry (K), anterior chamber depth (ACD) measurements; intraocular lens (IOL) power calculations; and predictability using a new partial coherence interferometry (PCI) optical biometer (AL-Scan) and a reference (gold standard) PCI optical biometer (IOLMaster 500).

SETTING: Service d'Ophtalmologie, Hopital Bicêtre, APHP Université, Paris, France.

DESIGN: Evaluation of a diagnostic device.

METHODS: One eye of consecutive patients scheduled for cataract surgery was measured. Biometry was performed with the new biometer and the reference biometer. Comparisons were performed for AL, average K at 2.4 mm, ACD, IOL power calculations with the Haigis and SRK/T formulas, and postoperative predictability of the devices. A *P* value less than 0.05 was statistically significant.

RESULTS: The study enrolled 50 patients (mean age 72.6 years \pm 4.2 SEM). There was a good correlation between biometers for AL, K, and ACD measurements ($r = 0.999$, $r = 0.933$, and $r = 0.701$, respectively) and between IOL power calculation with the Haigis formula ($r = 0.972$) and the SRK/T formula ($r = 0.981$). The mean absolute error (MAE) in IOL power prediction was 0.42 ± 0.08 diopter (D) with the new biometer and 0.44 ± 0.08 D with the reference biometer. The MAE was 0.20 D with the Haigis formula and 0.19 with the SRK/T formula ($P = .36$).

CONCLUSION: The new PCI biometer provided valid measurements compared with the current gold standard, indicating that the new device can be used for IOL power calculations for routine cataract surgery.

Financial Disclosure: No author has a financial or proprietary interest in any material or method mentioned.

J Cataract Refract Surg 2014; 40:593–600 © 2014 ASCRS and ESCRS

With the improvement in surgical techniques, cataract surgery not only focuses on visual rehabilitation but is now considered a form of refractive surgery.¹ Final refractive outcomes and patient satisfaction are essential for determining the success of cataract surgery. Thus, accurate preoperative intraocular lens (IOL) power calculations are fundamental to achieving the desired refractive outcomes.² To determine IOL power, biometry data are necessary; these include axial length (AL), keratometry (K) values, and anterior chamber depth (ACD) (corneal epithelium to lens). To achieve optimum outcomes, precise preoperative measurements are necessary and an accurate IOL

power formula must be used. A previous study of ultrasound (US) biometry³ reported that 54% of the errors in predicted refraction after IOL implantation can be attributed to errors in AL measurements, 8% to keratometric error, and 38% to incorrect estimation of the postoperative effective lens position (ELP).

Historically, the AL was measured with A-scan US using an applanation or immersion technique. With the introduction in 1999 of the first optical biometer (IOLMaster, Carl Zeiss Meditec AG), the optical method for AL assessment has shown higher precision and greater reproducibility than US biometry.^{4,5} The current IOLMaster model, the IOLMaster 500, uses

partial coherence interferometry (PCI) with a 780 nm laser diode infrared light to measure AL. Optical biometry is a fast, easy-to-use technique. The advantages of optical biometry over applanation US include the reduced risk for trauma and infection, increased patient comfort, and improved accuracy and repeatability of measurements.⁶ At present, optical biometry with the IOLMaster 500 is considered the gold standard for AL measurement.⁷⁻⁹

In 2012, the AL-Scan optical biometer (Nidek Co., Ltd.) was introduced for clinical practice in Europe. This optical biometer uses an 830 nm infrared laser diode for AL measurement with PCI. Most of the technical features of the IOLMaster and AL-Scan are comparable, including AL measurement with PCI, K readings at a 2.4 mm diameter, and ACD measurement.

The IOLMaster device uses dual-beam PCI to measure the reflection of the infrared laser from internal tissue interfaces; that is, the optical path length from the anterior surface of the cornea to the retinal pigment epithelium.¹⁰ The K readings are calculated by analyzing the anterior corneal curvature at 6 reference points in a 2.4 mm diameter optical zone. Measurement of ACD is performed through a lateral slit illumination.¹¹ The AL-Scan also uses the principle of PCI to measure AL. The K readings are measured with a double-ring keratometer, akin to a corneal topographer. The K readings are measured at 2 diameters; that is, 2.4 mm (the same as the IOLMaster) and 3.3 mm, which corresponds to the diameter used in keratometers manufactured by Nidek. The ACD is calculated from a rotating Scheimpflug camera. All parameters are measured in a single step with a single alignment, allowing rapid examination. The simplified handling procedure and the mostly automated measurement mode are designed to decrease measurement time. The AL-Scan biometer operates in a fully automated mode that acquires all biometric parameters without realignment.

Submitted: November 28, 2012.

Final revision submitted: August 27, 2013.

Accepted: September 4, 2013.

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Regardless of the technology used for AL measurement, the choice of IOL is also based on the use of accurate IOL power calculation formulas. Accurate formulas are essential for predicting postoperative refractive outcomes.²

The first-generation formulas were introduced by Fyodorov, Gernet, and von der Heide and were dependent on a constant for ACD. A second-generation formula, introduced by Hoffer in 1983, was the first to vary the ACD using the AL ($ELP = 2.93 \times AL - 2.92$). A third-generation formula was originally introduced by Holladay and others, such as the Hoffer Q and SRK/T, were introduced later.¹²⁻¹⁶ These formulas use the AL and K values to predict the ELP.¹²⁻¹⁶ Alternatively, the Haigis formula uses preoperative ACD measurements in addition to AL values but does require K readings.¹¹ The third-generation formulas are almost universally accepted.^{17,18}

As with any new device introduced into clinical practice, studies that compare it with the most common clinically accepted device are warranted. The purpose of this prospective study was to compare the measurements of the AL-Scan biometer and the IOLMaster 500 biometer. In this paper, the AL-Scan is referred to as the new biometer and the IOLMaster 500 as the reference biometer. In addition, we assessed the accuracy of IOL power calculations using the Haigis and SRK/T formulas and predictability using the SRK/T formula with the new device.

PATIENTS AND METHODS

All patients referred to Bicêtre Hospital, Department of Ophthalmology, University Paris-Sud, France, for cataract surgery between January and March 2012 were considered for inclusion in this prospective study. The study adhered to the Declaration of Helsinki. The local ethics committee approved the study design and protocol. All patients were informed about the purpose of the study and provided their consent.

Only consecutive adult patients who required cataract surgery with no history of corneal refractive surgery were considered for inclusion. To restrict the comparison to eyes highly suitable for the Haigis and SRK/T formulas, only patients with ALs between 22.0 mm and 27.0 mm were selected. Patients were excluded if there was difficulty in obtaining reliable measurements of AL, keratometry, or ACD with either biometer and if patients were eligible for toric or multifocal IOL implantation. Unreliable measurements were identified as those with motion artifact, lid abnormalities, dry eye, or lacrimal lake. In case of bilateral cataract, only 1 eye of each patient was included in the study.

The order of the instruments for measurement was randomized (reference biometer or vice versa). According to the manufacturer's recommendations, 5 AL and ACD measurements and 3 keratometry measurements were performed with the reference biometer. Six AL and 3 keratometry and ACD measurements were performed with the new biometer based on the manufacturer's recommendations.

Five surgeons performed surgery using a similar small-incision (2.2 mm) technique with implantation of the IOL in the bag. Two types of hydrophobic 1-piece monofocal aspheric IOLs were implanted: the Acrysof SN60WF (Alcon Laboratories, Inc.) and the Tecnis ZCB00 (Abbott Medical Optics, Inc.). The A-constants used for the IOL power calculations were 118.7 and 119, respectively, based on manufacturer recommendations. Because the reference biometer was considered the current gold standard at the time of the study, the final choice of IOL power was based on measurements of the reference biometer combined with the SRK/T formula, with the appropriate A-constant. The expected refractive result was emmetropia or as close to emmetropia as possible based on increments of IOL power.

The postoperative final objective refraction was performed with the Tonoref 2 autorefractor/tonometer (Nidek Co. Ltd.) 4 to 6 weeks after cataract surgery. Subjective refraction was performed by the surgeon at the same visit.

The biometry measurements (AL, K, and ACD) and IOL power calculations were compared between groups.

To compare the predictability between the biometers, the expected refractive results were compared with the obtained refractive error (objective and subjective). The comparison used the mean absolute error (MAE), defined as the average absolute value of the numeric error (ie, the final objective and subjective postoperative spherical equivalent [SE] minus the predicted postoperative SE). The predictive accuracy was analyzed by comparing the MAEs between devices. The results are presented as the mean \pm standard error of the mean (SEM) followed by the standard deviation (SD). The Wilcoxon signed-rank test was used to test the difference between instruments for the Haigis and SRK/T formulas. Bland-Altman plots were used to determine the agreement between devices for the Haigis and SRK/T formulas. Continuous variables were analyzed using the Student *t* test or the coefficient of correlation (*r*) for linear regression analysis. Statistical significance was defined as a *P* value less than 0.05 (2 tailed).

RESULTS

Fifty eyes of 50 patients (29 women) were included in this study. The mean age of the patients was 72.6 years \pm 4.2 (SD) (range 41 years to 89 years).

The new biometer and the reference biometer provided comparable mean AL measurements (*P* = .70), and the correlation between the results was almost perfect (*r* = 0.999). The keratometry measurements were similar (*P* = .59, *r* = 0.701) (Table 1 and Figure 1). The mean difference between keratometry measurements at 2.4 mm and 3.3 mm for the new biometer was 0.031 ± 0.022 D; 0.139 D (95% confidence interval [CI], 0.077 to -0.015 D). This difference was not statistically significant (*P* = .176).

The new biometer and the reference biometer provided comparable mean IOL power calculation using the Haigis formula and the SRK/T formula (Table 2). The correlations between the 2 devices for IOL power using the Haigis formula or SRK/T formula were very high (*r* = 0.972 and *r* = 0.981, respectively) (Figure 2).

Figure 3 shows the distribution of the differences in IOL power calculation between the 2 biometers. The reference power was chosen as the one that targeted a final refractive error as close to plano (perfect emmetropia) as possible. With the Haigis formula, there was no difference in 24 eyes (48%), the difference was ± 0.50 D in 23 eyes (46%), and the difference was ± 1.00 D in 3 eyes (6%). With the SRK/T formula, there was no IOL power difference between the calculations with the 2 biometers in 29 eyes (58%) and the difference was ± 0.50 D in 21 eyes (42%). With the reference biometer, the mean spherical equivalent error (MSE) in IOL power prediction was 0.02 D \pm 0.52 (SD), and 29 eyes (58%) were within ± 0.50 D, 48 eyes (96%) were within ± 1.00 D, and all eyes were within ± 1.50 D. With the new biometer, the MSE in IOL power prediction was 0.03 D \pm 0.51 (SD) and 32 eyes (64%) were within ± 0.50 D, 48 eyes (96%) were within ± 1.00 D, and all eyes were within ± 1.50 D (Figure 4).

The predictability of the IOL power calculation with the reference biometer, and by extrapolation with the

Table 1. Comparison of parameter measurements between the 2 biometers (50 patients).

Parameter	Reference Biometer	New Biometer	Difference Between Biometers (Absolute Value)
Axial length (mm)			
Mean \pm SEM (SD)	23.71 \pm 0.25 (0.88)	23.71 \pm 0.25 (0.88)	0.01 \pm 0.004
Range	22.10, 27.06	22.09, 26.99	0.00, 0.07
Keratometry (D)			
Mean \pm SEM (SD)	43.91 \pm 0.45 (1.59)	43.93 \pm 0.46 (1.61)	0.17 \pm 0.03
Range	41.06, 47.92	40.77, 47.95	0.00, 0.45
ACD (mm)			
Mean \pm SEM (SD)	3.12 \pm 0.11 (0.38)	3.17 \pm 0.12 (0.41)	0.13 \pm 0.04
Range	2.23, 3.85	1.95, 3.95	0.00, 1.08

ACD = anterior chamber depth; SEM = standard error of the mean

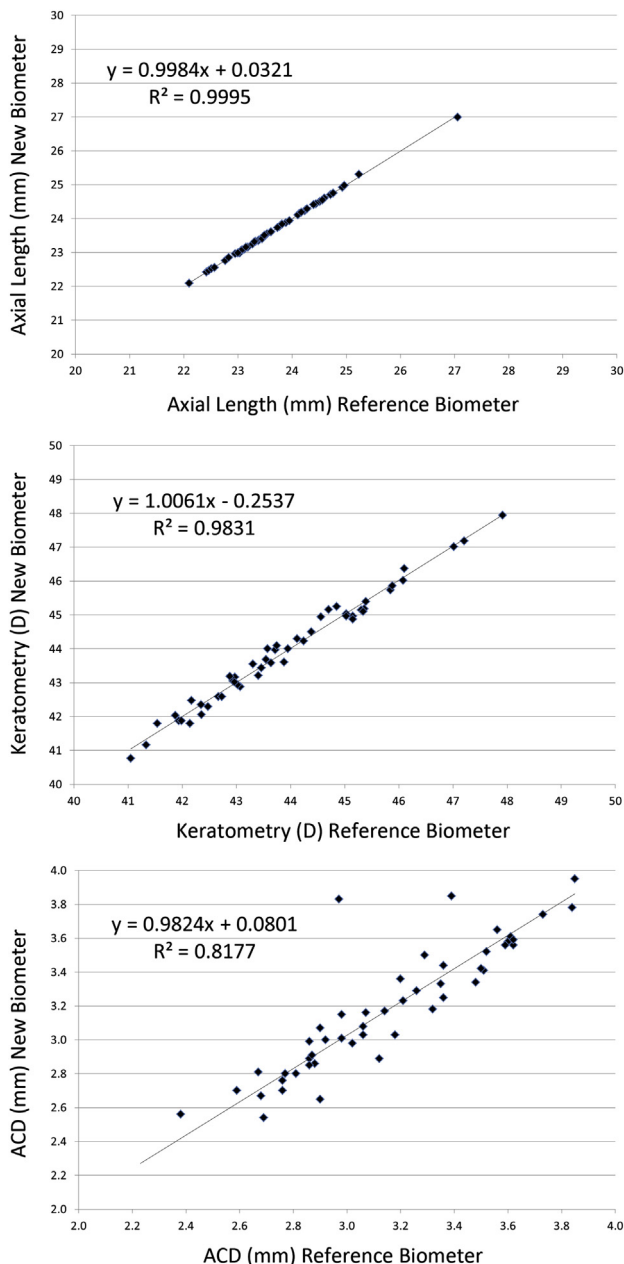


Figure 1. Correlation between AL, K, and ACD measurements with the reference biometer and the new biometer.

new biometer, was very similar (using the SRK/T formula and the A-constant recommended by the manufacturers for the reference biometer). With the reference biometer, the objective MAE in IOL power prediction was 0.44 ± 0.08 D (0.28 D); 29 eyes (58%) were 0.50 D or less, 19 eyes (38%) were between 0.50 D and 1.00 D, and 2 eyes (4%) were between 1.00 D and 1.50 D. Based on the new biometer measurements, the same IOL would have given an MAE of 0.42 ± 0.08 D (0.29 D); the MAE would have been

less than 0.50 D in 32 eyes (64%), between 0.50 D and 1.00 D in 16 eyes (32%), and between 1.00 D and 1.50 D in 2 eyes (4%). The MAE was 0.20 D (range 0.00 to 0.82 D) with the Haigis formula and 0.19 D (range 0.00 to 0.55 D) with the SRK/T formula ($P = .36$).

With the IOLMaster 500, 34 (68%) of the subjective MAEs were less than 0.50 D, 12 (24%) were between 0.50 D and 1.00 D, and 4 (8%) were between 1.00 D and 1.50 D. Based on the AL-Scan measurements, the same IOL would have given an MAE less than 0.50 D in 34 eyes (68%), between 0.50 D and 1.00 D in 14 eyes (28%), and more than 1.00 D in 2 eyes (4%).

The mean difference between devices for the Haigis formula was -0.021 ± 0.048 D (0.334 D) (95% CI, 0.076 to -0.118 D). This difference was not statistically significant ($P > .05$). The mean difference between devices for the SRK/T formula was -0.029 ± 0.037 D (0.253 D) (95% CI, 0.045 to -0.102 D). This difference was not statistically significant ($P > .05$). Figure 5 shows the Bland-Altman plots. There were no statistically significant differences for the IOL formulas between devices (all $P > .05$) (Figure 5).

DISCUSSION

Accurate and predictable IOL power calculations are essential for achieving the intended outcomes and patient satisfaction after cataract surgery.^{19–21}

The AL measurement of the IOLMaster biometer is considered the current gold standard and is comparable to other biometry devices in routine use. This biometer sequentially measures the AL, K, and ACD in a fully automated mode without realignment. The rapid automated measurements allow greater patient comfort, especially in the geriatric patients who have coexisting conditions (eg, arthritis). The repeatability of optical biometry is reported to be good.²² At present, optical biometry is considered the gold standard for AL measurement in normal eyes,²³ but not in uncooperative patients, in eyes with dense cataract, or in cases of fixation instability (macular degeneration).^{24–26}

Several studies have compared the Lenstar (Haag-Streit AG), a recently released noncontact imaging instrument using optical low-coherence reflectometry (OLCR), with the IOLMaster 500 PCI optical biometer. For example, Holzer et al.²⁷ report high correlations for AL and keratometry measurements ($r = 0.9957$ and $r = 0.9859$, respectively) but moderate correlation for ACD ($r = 0.4456$). Rohrer et al.²⁸ found high correlations for AL ($r = 0.999$), ACD ($r = 0.875$), and for corneal radius and the axis of the flattest radius (flattest radius, $r = 0.927$; steep radius, $r = 0.929$; axis of the flattest radius, $r = 0.938$). Hoffer et al.¹¹ report a good correlation between AL, ACD, and K

Table 2. Comparison of IOL power with the SRK/T and Haigis formulas between the 2 biometers (50 patients).

Formula	IOL Power (D)		
	Reference Biometer	New Biometer	Difference Between Biometers (Absolute Value)
SRK/T			
Mean \pm SEM (SD)	20.44 \pm 0.67 (2.37)	20.45 \pm 0.67 (2.35)	0.21 \pm 0.04
Range	13.50, 24.00	14.00, 23.50	0.00, 0.50
Haigis			
Mean \pm SEM (SD)	20.46 \pm 0.72 (2.52)	20.43 \pm 0.71 (2.49)	0.29 \pm 0.05
Range	14.50, 24.50	15.00, 24.00	0.00, 1.00

IOL = intraocular lens; SEM = standard error of the mean

measurements in 50 eyes with cataract ($r = 0.9995$, $r = 0.8211$, and $r = 0.9959$, respectively). The MAE in IOL power prediction was 0.455 ± 0.32 D with the OLCR unit and 0.461 ± 0.31 D with the PCI unit ($P > .1$).¹¹

The AL-Scan optical biometer, based on technology that is similar to that of the IOLMaster, was recently introduced. We compared its performance with the established gold standard, the IOLMaster 500 (reference

biometer), with the aim of evaluating the AL-Scan (new biometer) for routine cataract surgery.

In this study, there was excellent correlation in AL measurements ($r = 0.999$) and K readings ($r = 0.983$) between the reference biometer and the new biometer in cataractous eyes. There was no statistical or clinical difference between measurements at 2.4 mm and 3.3 mm with the new biometer. There

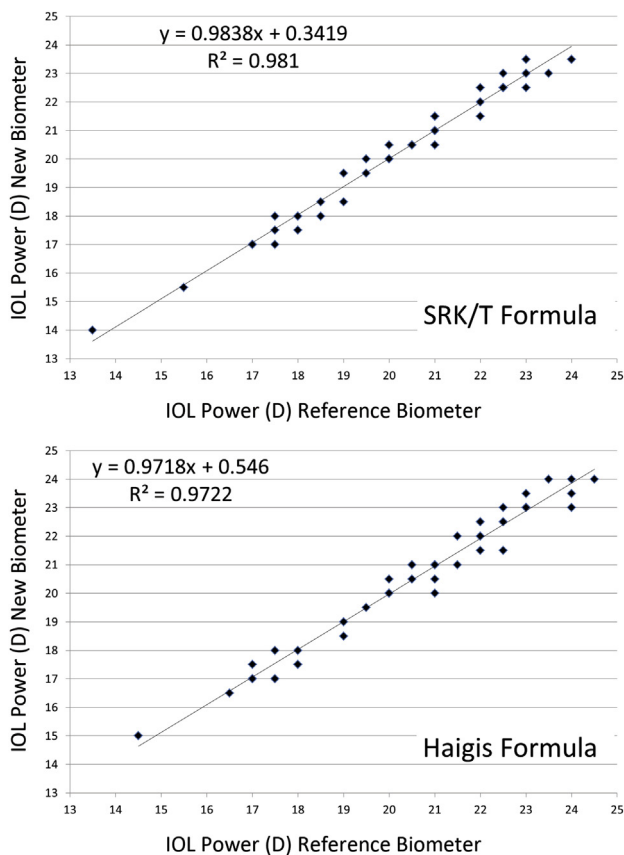


Figure 2. Correlation between measurements for IOL power calculation with the Haigis and SRK/T formulas with the reference biometer and the new biometer (IOL = intraocular lens).

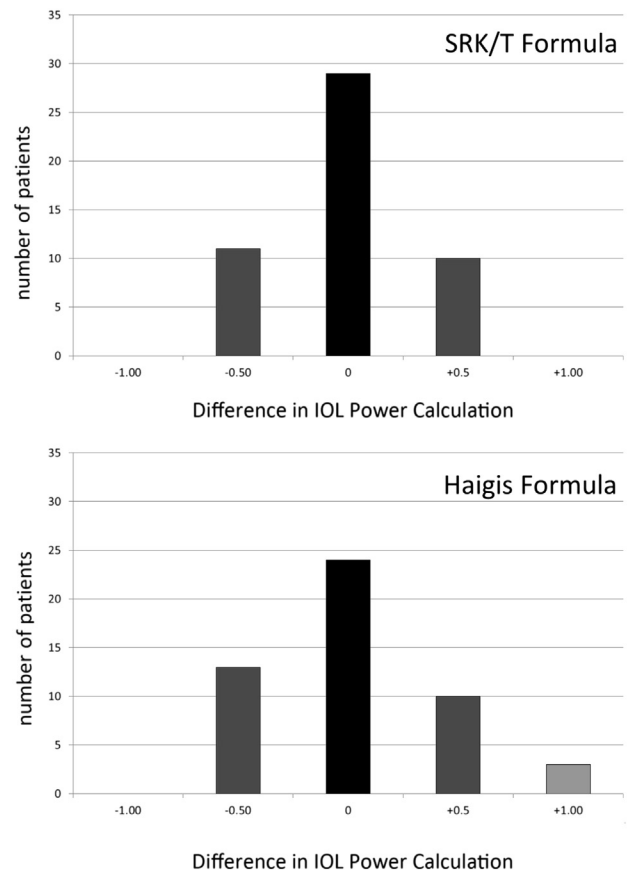


Figure 3. Distribution of IOL power differences: reference biometer – new biometer (IOL = intraocular lens).

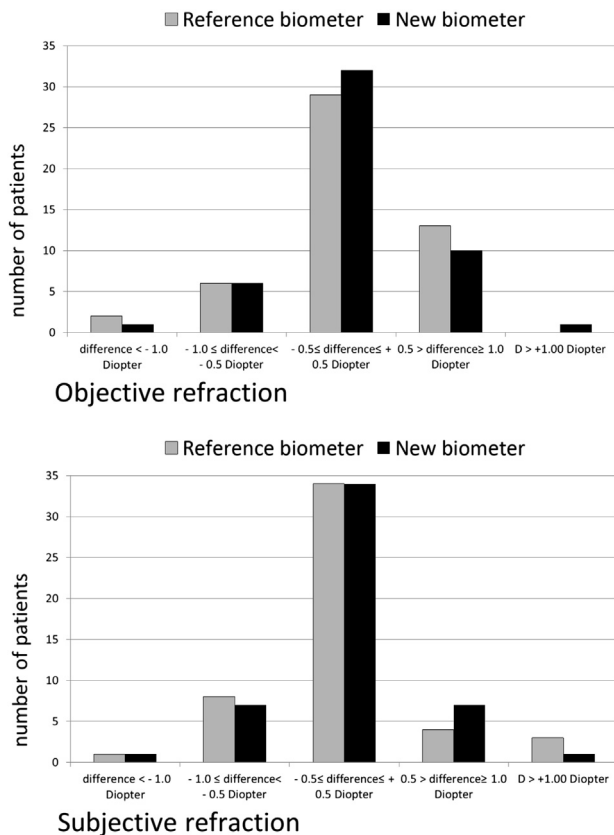


Figure 4. Predictability of objective and subjective refraction of the 2 devices.

was also good agreement in ACD measurements between devices ($r = 0.701$), although the agreement was lower than that in AL and K readings. The variability in ACD measurements might play a significant role in formulas that require input of this parameter (ie, Haigis).

The IOL power calculations were also highly comparable between devices. The third-generation SRK/T formula, which bases its calculations on AL and K measurements, provided very similar results between devices ($r = 0.981$). There was no positive or negative trend with either device, indicating that neither the reference biometer nor the new biometer tends to overestimate or underestimate measurements in relation to the other device. In all cases, the mean IOL power difference between devices was equal to or less than 0.5 D. With the Haigis formula, which integrates the ACD for IOL power calculations, the correlation was also very high ($r = 0.972$) and the difference between IOL calculations was well balanced. In 94% of cases, the mean IOL power difference between the 2 devices was 0.50 D or less. These outcomes indicate that the differences are clinically negligible for most patients having cataract surgery. Hence, initial IOL calculations with the new PCI optical biometer can be accurately performed using the same constants as the reference biometer before A-constant personalization. There was no statistical or clinical difference for the Haigis or SRK/T formula between devices (all $P > .05$).

The MAE (\pm SEM) in the 50 eyes that had surgery was slightly (but not statistically) lower with the new biometer measurements than with the reference biometer measurements (0.42 ± 0.08 D versus 0.44 ± 0.08 D) ($P = .65$). This outcome indicates the new biometer is at least equivalent to the reference biometer for IOL power calculations in cataract surgery patients. However, this conclusion only applies to eyes with an AL from 22.0 mm to 27.0 mm because we did not include eyes with an AL outside this range. This range of AL represents the majority of eyes that have cataract surgery. Comparison with the previous literature is not possible because we believe

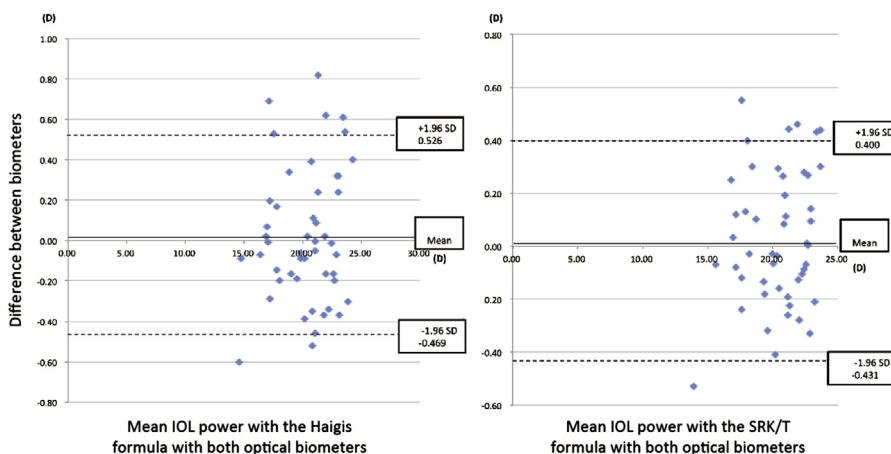


Figure 5. Bland-Altman plots of IOL power calculation with data from the reference biometer and new biometer (IOL = intraocular lens).

that this study is the first in the peer-reviewed literature to compare the IOLMaster 500 biometer and the AL-Scan biometer.

There are drawbacks to the current study. A larger sample could increase the power of the study. However, considering the results in our study for the refractive errors obtained with the IOL power designed for emmetropia using the IOLMaster or the AL-Scan device, we can assume that showing a significant difference between the 2 biometers would need a study with a very large sample, which was beyond the scope of the present study. Of note, theoretically targeting emmetropia for the IOL power calculations based on IOLMaster data, we observed a mean refractive error of 0.44 ± 0.08 D (0.28 D). When this was extrapolated targeting emmetropia with the AL-Scan device, the mean refractive error was 0.42 ± 0.08 D (0.29 D). On the basis of these outcomes, the predicted size of the study for achieving a statistical difference (with a power of 80% and a 2-tailed α at 0.05) would require 6378 patients. Such a sample size is much larger than the majority of studies that validate new devices and materials in cataract surgery. We included only 1 eye for each patient to ensure that all observations were independent, as required for most comparative analyses. The majority of patients agreed to participate in the study; however, some were unwilling to have measurements with a new instrument. However, it is unlikely that the patients who refused to participate (<5% of all patients) would have changed the final results. Measurement with both instruments was an inclusion criterion; thus, we did not record the number of eyes that could not be measured with the AL-Scan biometer. Our experience is that this rate seems to be equivalent between devices. Last, data from short eyes and long eyes and reproducibility are required for future studies.

In conclusion, the AL-Scan optical biometer provided precise biometry data and IOL power calculations in cataract patients within an average range of ALs. The measurements were comparable to those obtained with the IOLMaster 500 device, which is considered the current gold standard. In addition, the 2 biometers have several similar features, including rapid automated measurements and the use of PCI. The differences between instruments had no clinical impact, and the predictability of the AL-Scan was also comparable using the SRK/T formula and the A-constant recommended for the IOLMaster 500 device. These results suggest that the AL-Scan biometer can be used for routine clinical practice to acquire accurate biometry measurements for IOL power calculation.

WHAT WAS KNOWN

- In cataractous eyes, preoperative optical biometry has become the de facto standard for data during IOL calculations. As newer optical aberrometers are introduced, they must be evaluated in relation to the current unit in clinical use.

WHAT THIS PAPER ADDS

- Data in eyes with ALs ranging from 22 to 27 mm from the AL-Scan biometer were the same as with the IOLMaster 500 biometer.
- The newly introduced AL-Scan biometer provided accurate IOL calculations in eyes with normal AL having IOL implantation.

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