Multicenter study of optical low-coherence interferometry and partial-coherence interferometry optical biometers with patients from the United States and China

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PURPOSE: To evaluate the agreement between the measurements provided by a new optical biometer, the Aladdin, based on optical low-coherence interferometry (OLCI), and those provided by the most commonly used optical biometer (IOLMaster 500), based on partial-coherence interferometry (PCI).

SETTING: Multicenter clinical trial.

DESIGN: Prospective evaluation of diagnostic test.

METHODS: In this study, 2 samples of adult patients were enrolled, 1 in the United States and the other in China. The U.S. group included a sample of consecutive patients scheduled for cataract surgery. The China group included a sample of healthy subjects with no cataracts. In both cases, only 1 eye of each patient was analyzed. Axial length (AL), corneal power (in diopters [D]) (K), anterior chamber depth (ACD) (corneal epithelium to lens), and corneal astigmatism were measured. All values were analyzed using a paired *t* test, the Pearson product-moment correlation coefficient (*r*), and Bland–Altman plots.

RESULTS: In the U.S. and China groups, the OLCI mean AL values did not show a statistically significant difference from PCI values and showed excellent agreement and correlation. On the contrary, OLCI measured a lower mean K (−0.14 D) and a deeper ACD measurements (U.S. +0.16 mm and China +0.05 mm). These differences were statistically significant ($P < .0001$). Vector analysis did not show a statistically significant difference in astigmatism measurements.

CONCLUSIONS: Agreement between OLCI and PCI was good. However, the small but statistically significant differences in K and ACD measurements make constant optimization necessary when calculating the intraocular lens power using theoretical formulas.

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Since 1999, optical biometry has become the standard technique for axial length (AL) measurement.[1–3] The main reason for such popularity is not related to higher accuracy because its results are similar to those achieved by immersion ultrasound biometry[4] but rather a result of it being a noncontact technique, which is associated with less discomfort for the patient and less risk for corneal complications. Moreover, it is easier to perform for most surgeons and technicians. Until 2009, the IOLMaster (Carl Zeiss Meditec), based on partial-coherence interferometry (PCI), has been the only device measuring AL by the optical method. Since then, newer instruments have been introduced such as the Lenstar (Haag-Streit AG), the AL-Scan (Nidek Co. Ltd.), the Galilei G6 (Ziemer), and the Aladdin (Topcon EU,

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Visia Imaging), the latter based on optical low-coherence interferometry (OLCI).

Previous studies have shown that the Lenstar and AL-Scan provide similar measurements with respect to PCI,[5–8] although slight differences in keratometry (K), anterior chamber depth (ACD) (corneal epithelium to lens), and AL values require constant optimization for each instrument when calculating intraocular lens (IOL) power by theoretical formulas.[9–11] To date, only 1 study has investigated the biometer and did not find any statistically significant difference with respect to the IOLMaster 500 PCI biometer in mean AL, K, and ACD measurements.[12]

To validate the OLCI biometer, in this prospective study, we aimed to confirm whether the biometric measurements by PCI and OLCI have statistically significant difference in K, ACD, and AL mean values and investigate whether they provide similar astigmatism measurements. This information is mandatory before the instrument is used in clinical practice.

PATIENTS AND METHODS

Patients

This multicenter prospective observational study included 2 samples of adult patients, the former enrolled in the United States and the latter enrolled in China. The U.S. group included a sample of consecutive patients scheduled for cataract surgery between July 15, 2013, and February 15, 2014. The China group included a sample of healthy subjects with no cataracts. In both cases, only 1 eye of each patient was analyzed: in the U.S. group, the first operated eye, and in the China group, only the right eye. Using the PS program for power and sample-size calculations (version 3.0.12),[A] a sample size of 14 eyes per group was estimated to detect a difference in AL of 0.02 mm with a standard deviation of ±0.04 mm and a power of 95% at a significance level of 5%; for a power of 90%, a sample of 9 eyes was needed.

All patients provided informed consent, and the study complied with the Declaration of Helsinki. Exclusion criteria were previous corneal or intraocular surgery and history of any eye disease but cataract and mild macular degeneration.

Each eye was evaluated on the same day with the use of the OLCI unit and PCI unit. In each group, 1 unmasked examiner performed all measurements. For both instruments, the mean AL value, mean ACD value, and mean flattest and steepest K values and axis were recorded. All K values reported here are average Ks, derived from the anterior corneal curvature and using a 1.3375 keratometric index of refraction. To investigate astigmatism measurements, power vector analysis was performed so that J0 and J45 values could be obtained and compared.[13] Astigmatism was defined as with-the-rule (WTR) when the steepest axis was between 60 degrees and 120 degrees and as against-the-rule (ATR) when the axis was between 0 degrees and 30 degrees and between 150 degrees and 180 degrees; the remaining meridians were considered to be oblique.

Partial-Coherence Interferometry Measurements

The IOLMaster 500 (version 5.2) optical biometer uses PCI with a 780 mm laser diode infrared light to measure AL. The ACD is measured through a lateral slit illumination and is defined as the measurement from the corneal epithelium to the anterior lens surface. The K readings are calculated by analyzing the anterior corneal curvature at 6 reference points in a hexagonal pattern at approximately the 2.3 mm optical zone.

After ensuring the correct positioning of the subject against the chin and headrest, the PCI was focused and coarsely aligned with the participant's eye using the overview mode. The subject was directed to focus on the illuminated target. The AL measurement mode was activated, and fine alignment occurred while the subject was asked to observe the red fixation point. Five AL measurements were recorded, and any with a signal-to-noise ratio below 2.0 were repeated. With respect to K, subjects were requested to observe a yellow light and to blink to produce a continuous tear film, thus improving the reflectivity of the cornea. Six peripheral measuring points at a diameter of approximately 2.5 mm were optimally focused on the cornea as demonstrated by a green light from the PCI "traffic light system." Subsequent depression of the joystick button provided 3 consecutive K measurements, and the mean of these values was used for the IOL calculations. If any of the 6 measurement points was not correctly identified, the measurements were repeated.

Optical Low-Coherence Interferometry Measurements

The technology of the Aladdin biometer (version 1.07) is based on OLCI, with an 830 mm superluminescent diode. In addition to AL, the unit measures ACD, defined as the measurement from the corneal epithelium to the anterior lens surface. The K readings are calculated by analyzing the anterior corneal curvature at 1024 reference points orientated in circles at approximately 3.0 mm optical zones.

Subjects were carefully aligned for OLCI biometry measurements. The equipment was optimally positioned as demonstrated by a clear view of the anterior eye and the appearance of a "green eye" quality-control image, which indicated when the working distance of approximately 80 cm was achieved. The subject was asked to fixate on a

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