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Comparison of a new optical biometry with an optical low-coherence reflectometry for ocular biometry

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ABSTRACT

Objective: To evaluate the repeatability and agreement of a new partial coherence interferometry optical biometer (AL-Scan, Nidek CO, Aichi, Japan) with optical low-coherence reflectometry device (Lenstar LS 900, Haag-Streit AG, Köniz, Switzerland).
Methods: Three consecutive measurements with the 2 devices were performed by the same examiner in 65 eyes of 65 patients with cataract. Patients were divided into 2 groups: axial length (AL) between 22 and 26 mm (Group 1) and more than 26 mm (Group 2). Comparisons were performed for AL, anterior chamber depth (ACD), keratometry (K, over 2.4 mm diameter for AL-Scan and 2.3 mm diameter for Lenstar) and corneal diameter (CD). Repeatability was analyzed using the intraclass correlation coefficient (ICC) and the agreement was by the Bland-Altman method.
Results: The repeatability of both devices was high for all biometry measurements (ICC over 0.970) in Group 1 and 2. The best repeatability was achieved for AL in each group. In both groups, the differences were statistically significant for all parameters ($p < 0.05$) except for the measurement of AL and CCT ($p > 0.05$). The Bland-Altman analysis showed good agreement between devices for all measurements in both groups. The closest agreement was for the AL measurements (ranged from −0.06 to 0.08 mm in Group 1 and −0.05–0.07 mm in Group 2).
Conclusions: The new biometer provided excellent repeatability for all ocular biometry. In addition, there was good agreement between AL-Scan and Lenstar biometers for all parameters in cataractous patients with medium and long ALs.

1. Introduction

Accurate biometry is crucial in modern cataract and refractive surgery to obtain satisfactory postoperative refractive results. The biometric variables that are used for intraocular lens (IOL) calculation depend on the chosen IOL formula. Current third-generation and fourth-generation IOL power calculation formulas require the basic variables of axial length (AL), anterior chamber depth (ACD), keratometry (K), and corneal diameter (CD) values [1–3]. The IOL power calculation formulas achieve precise results in eyes with ALs between 22.0 and 25.0 mm. However, they may select IOLs with inappropriate power in eyes with long ALs which may lead postoperative hyperopia [4,5].

The ultrasound biometry has been the gold standard method for IOL power calculation before cataract surgery. In recent years, non-contact optical biometry devices have essentially replaced ultrasound biometry because of their higher precision and better refractive outcomes and reduced risk for infection [6]. However, different types of optical biometry devices may yield different IOL power results.

IOL Master (Carl Zeiss Meditec AG, Jena, Germany) was the first commercial optical biometric device using partial coherence interferometry (PCI) technology [7]. Moreover, another device (Lenstar LS 900, Haag-Streit Köniz, Switzerland) based on optical low coherence reflectometry (OLCR) with an 820 nm super-luminescent diode technology has been available for non-contact optical biometric measurements [8]. It detects anterior and posterior corneal surface and anterior crystalline lens peaks in

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the OLCR waveform to measure the central corneal thickness (CCT), ACD, AL and CD. The device also acquires K values [in the flattest meridian (KF) and in the steepest meridian (KS)] by analyzing a pattern of light-emitting diodes (LEDs). In 2012 a new biometry device, combining both optical interference and Scheimpflug principle (AL-Scan, Nidek CO, Aichi, Japan) has been introduced for performing ocular measurements. The AL is measured by the PCI technology. K values are measured by analyzing the images of two mires of spots (360°), reflected from the anterior surface of the cornea. The CCT and ACD are measured using the Scheimpflug principle, with 470 nm monochromatic light from an LED. The CD is obtained by fitting the best circle with the lowest error square to the detected edge.

It is crucial to compare the measurements of a new device (like the AL-Scan) with the measurements of a similar one which has been approved previously (like the Lenstar) to decide whether these can be used interchangeably. In clinical measurement, the repeatability of each device must be known to evaluate the interchangeability of a new measurement with a standard instrument. The current study aimed to address these arguments in cataractous eyes with medium and long ALs.

2. Materials and methods

In this prospective study we evaluated 65 eyes of 65 patients who underwent uncomplicated cataract surgery with phacoemulsification and IOL implantation. The study was conducted in accordance with the ethical standards stated in the 1964 Declaration of Helsinki. The study was approved by the Local Ethics Committee of Turgut Özal University. All patients were informed about the purpose of the study and provided their consent. We considered only consecutive adult patients who underwent uneventful phacoemulsification cataract surgery with implantation of the IOL in the capsular bag for inclusion.

Exclusion criteria for the analysis were patients with previous eye surgery including corneal refractive surgery, poor expected visual acuity after cataract surgery due to non-cataract related eye conditions such as macular degeneration, amblyopia, glaucoma, advanced corneal pathology (e.g. dystrophy, irregular astigmatism current or previous pterygium) and those with Lens Opacities Classification System III (LOCS III) [9] P-scale value greater than 3.5. Patients were divided into 2 groups: 45 patients with AL between 22 and 26 mm (Group 1) and 20 patients with AL longer than 26 mm (Group 2). Patients were excluded if there was difficulty in obtaining reliable measurements of AL, K, or ACD with each biometer and if patients were eligible for toric or multifocal IOL implantation. In group 2, patients with choroidal neovascularization and posterior staphlyoma due to high myopia were also excluded. Unreliable measurements were identified as those with motion artifact, lid abnormalities, dry eye, or lacrimal lake. Only 1 eye of each patient was randomly included in the study.

3. Measurement technique

We applied at least five minutes waiting time for two devices. Three consecutive scans were performed with each device by the same experienced examiner. All measurements were performed without pupil dilation, between 10 AM and 3 PM, in a dimly lit room, in accordance with the manufacturers' guidelines. The patients were requested to sit, place the chin on the chin rest, and lean their forehead against the headrest of the device. The patients were asked to stare into the central fixation light in front of them and were advised not to blink during the measurement. The order of the instruments for measurement was randomized. All unreliable readings (those with a signal-to-noise ratio (SNR) of less than 2.1 for each device) were ignored, and further measurements were taken as required to achieve reliable readings from each eye.

3.1. Surgery technique

Cataract surgery was performed by single experienced surgeon. A clear corneal incision 2.8 mm in width was made and phacoemulsification was performed after continuous curvilinear capsulorhexis with a diameter of 5.5 mm. Tecnis ZCB00 (AMO, USA) aspheric IOL was implanted in the capsular bag.

3.2. Measurement devices

AL-Scan (software V.1.03) is a medical device that optically measures eye components such as AL, ACD and K in 10 s. The AL of the patient's eye is measured by the optical interference principle with partial coherence superposition of light waves emitted from an 830 nm super luminescent diode. The AL-Scan measures corneal curvature radius (refractive power) and the steepest and flattest meridian directions by detecting ring image projected on the patient's cornea with a photo detector and calculating the image over areas of 2.4 mm and 3.3 mm diameter, reflected from the anterior surface of the cornea. Only the measurements of K 2.4 mm were evaluated in this study. The CCT and ACD are measured using the Scheimpflug principle, with 470 nm monochromatic light from an LED. The CD is obtained by fitting the best circle with the lowest error square to the detected edge.

The Lenstar LS 900 that utilizes optical low coherence reflectometry for measuring CCT, ACD, LT, AL and CD in 3 s. It uses an 820-nm superluminescent diode with a Gaussian-shaped spectrum to provide a high axial resolution. The device also acquires corneal radius measurements in the flat and steep meridian by analyzing a pattern of 32 LEDs, which are arranged on two rings with (diameters 1.65 mm and 2.30 mm) 16 measuring points each. The measurements of K 2.3 mm were evaluated in this study. For each measurement, the corneal curvatures are measured in two meridian ad the two readings are averaged.

3.3. Statistical analyzes

Statistical analyses were calculated using SPSS software (version 21.0, SPSS, Inc. Chicago, IL, USA). The data were normally distributed, met by the Kolmogorov–Smirnov test ($p > 0.05$). The results are presented as the mean ± standard error of the mean (SEM) followed by the standard deviation (SD). To determine the repeatability of each device, within-subject SD (Sw), within-subject coefficient of variation (CoV) and intraclass correlation coefficients (ICCs) were calculated for the three repeated measurements obtained by each of the first and second operators [10].

A paired *t*-test was used to compare the measurements between the two devices. The agreement between two devices was determined using the approach proposed by Bland and Altman. Graphs of the differences between measurements obtained by each observer against means were plotted (Bland-Altman plots). The limits of agreement (LoA) were calculated as the mean difference in measurements obtained by each observer ±1.96 SD of the differences [11]. The agreement level for the two devices or methods is decided by the amount of these limits which indicate better agreement with lower values and vice versa. The judgement regarding the limit at which it is acceptable to use the two devices interchangeably is a clinical decision [12]. Statistical significance was defined as a P value less than 0.05 (2 tailed).

Sample size calculations were performed according to the ICC results. A sample size of 26 subjects with 3 observations per subject was calculated to achieve an 81% power to detect an ICC of

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