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Refractive Results Using a New Optical Biometry Device

Comparison With Ultrasound Biometry Data

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Abstract: The aim of the study was to compare the measurements of optical (AL-Scan; Nidek Co., Ltd.) and ultrasonic (Echo Scan US-800; Nidek Co., Ltd.) biometry devices and to assess refractive results after cataract surgery.

Eighty-one cataractous eyes of 81 patients were included in this study. Biometry was performed using the AL-Scan and an ultrasonic biometer (USB). Axial length (AL), keratometry (K) data, and intraocular lens (IOL) power calculations using the SRK/T formula were compared. Bland–Altman analysis was used to assess the extent of agreement between AL-Scan and USB data in terms of AL measurement and IOL power calculation. The K measurements of the AL-Scan were compared to autorefractor data (Canon Autorefractor RK-F1).

The AL-Scan assessed the AL as longer (average difference 0.06 ± 0.18 mm; ICC = 0.987; $P < 0.001$) and the IOL power as greater (average difference 0.19 ± 0.66 D; ICC = 0.964; $P < 0.001$) than the USB. The AL-Scan also measured average K values (average difference 0.25 ± 0.25 D; ICC = 0.985; $P < 0.001$) greater than those given by the autorefractor. The postoperative mean absolute error was $+0.30 \pm 0.04$ D (minimum: -0.51 D, maximum $+1.04$ D). The postoperative mean K value change was 0.36 ± 0.29 D ($P < 0.05$).

The differences between measurements afforded by the AL-Scan and USB may be clinically acceptable. Keratometric changes that develop after cataract operations compromise the attainment of good refractive outcomes.

(*Medicine* 94(48):e2169)

Abbreviations: ACD = anterior chamber depth, AL = axial length, AR = autorefractor, BCVA = best-corrected visual acuity, CCT = central corneal thickness, IOL = intraocular lens, IOP = intraocular pressure, K = keratometry, MAE = mean absolute error, USB = ultrasound biometry, WTW = white-to-white distance.

Editor: Patrick Wall.

Received: September 6, 2015; revised: October 29, 2015; accepted: November 4, 2015.

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The authors have no conflicts of interest to disclose.

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ISSN: 0025-7974

DOI: 10.1097/MD.0000000000002169

INTRODUCTION

Accurate preoperative intraocular lens (IOL) power calculation is critical to ensure satisfactory refractive outcomes after cataract surgery.¹ Third-generation formulae, such as the Hoffer Q and SRK/T, use the axial length (AL) and keratometry (K) values to predict IOL power.^{2,3} For this reason, precise measurements of keratometric data and AL is very important. To this end, ultrasound biometry (USB) and optical biometric devices are widely used in practice. The optical biometric method employs partial coherence interferometry and affords higher precision and greater reproducibility than USB.^{4,6} The advantages of optical biometry compared with USB include reduced risks of trauma and infection, and increased patient comfort.⁷ However, optical biometry cannot be used in eyes with dense cataracts and certain macular diseases.^{5,8}

To the best of our knowledge, no comparison has been made between a new optical biometry (AL-Scan; Nidek Co., Ltd.) and USB (Echo Scan US-800; Nidek Co., Ltd.). We conducted the present study to evaluate the refractive results and accuracies achieved using the AL-Scan compared with USB, which remains commonly used.

METHODS

This study was prospective, case-controlled, and comparative. All of the patients gave written informed consent prior to enrollment. All of the procedures conformed to the tenets of the Declaration of Helsinki. The study was approved by the Ethics Committee of the Diskapi Yildirim Beyazit Training and Research Hospital.

In total, 81 cataractous eyes of 81 adult patients who required cataract surgery, with no history of corneal refractive surgery, were enrolled. Detailed ophthalmological examinations were performed in the following order: measurement of refractive error and K using an autorefractor (Canon Autorefractor RK-F1; Canon, Tokyo, Japan); assessment of best-corrected visual acuity (BCVA) using a Snellen scale; slit lamp biomicroscopy; biometric measurements using optical (AL-Scan) and ultrasonic devices (Echo Scan US 800); retinoscopy; intraocular pressure (IOP) measurement via Goldmann applanation tonometry; and indirect ophthalmoscopy. Optic biometry was performed prior to USB, because the optical device was noncontact in nature, and we sought to avoid errors induced by corneal compression during USB. According to the manufacturer's recommendations, 6 AL and 3 K measurements were performed using the AL-Scan. Five AL and 3 K measurements were performed with the USB and AR instruments. In instances of bilateral cataracts, we included only 1 eye for each patient to ensure that all of the observations were independent. Patients with any history of previous ocular surgery, a pterygium, corneal scarring, pre-existing astigmatism >3.0 diopters (D), ALs <22.0 mm or >27.0 mm, previous contact lens use (within 4 wk), severe dry eye, inflammatory disease of the eye, and/or systemic connective tissue disease were excluded.

TABLE 1. Comparisons of Parameters Measured by the 2 Devices (70 Patients)

Parameters	AL-Scan	USB/AR	Difference Between Devices	P value*
Axial length (mm)				
Mean \pm SD	23.29 \pm 0.79	23.23 \pm 0.81	0.06 \pm 0.18	0.662
Range	21.63/25.03	21.66/25.62		
Keratometry (D)				
Mean \pm SD	44.34 \pm 1.45	44.09 \pm 1.42	0.25 \pm 0.25	0.254
Range	41.56/47.60	41.25/47.50		

AR = autorefractor, SD = standard deviation, USB = ultrasonic biometer.

*The Mann–Whitney *U* test was used to explore the significances of differences between measurements.

TABLE 2. Pairwise Comparison of AL and K Measurements Using AL-Scan, USB, and AR

Pairwise Comparison (n = 70)	MD \pm (SD)	ICC	95% LOA	P value
AL: ALS-USB (mm)	0.06 \pm 0.18	0.987	0.40 to -0.29	<0.001
K: ALS-AR (D)	0.25 \pm 0.25	0.985	0.74 to -0.25	<0.001
IOL power: ALS-USB (D)	0.19 \pm 0.67	0.964	1.49 to -1.11	<0.001

AL = axial length, ALS = AL-Scan, AR = autorefractor, K = keratometry, USB = ultrasonic biometer.

One surgeon performed all of the cataract surgeries using a small incision (2.4 mm) technique with implantation of the IOL in a bag. Phacoemulsification of the clear corneal incision was performed on the steep corneal axis, because surgically induced astigmatism was to be minimized. Only 1 type of hydrophobic, single-piece monofocal IOL (AcrySof SA60AT, Alcon Laboratories, Inc) was implanted. The A-constants used for IOL power calculations with AL-Scan and USB were 118.8 and 118.4, respectively. Because optic biometry is currently considered to be the gold standard, the final choice of IOL power was based on measurements from the AL-Scan. To restrict the comparison of eyes, IOL power calculations were performed only using the SRK/T formula, which is universally accepted and suitable for ALs between 22.0 and 27.0 mm.

The postoperative final objective refraction was measured using an autorefractor (Canon RK-F1) 4 weeks after cataract surgery. Subjective refraction was evaluated at the same visit. Comparisons were performed in terms of AL, K, and IOL power calculations derived using the SRK/T formula. K measurements of the AL-Scan were compared to AR data.

Statistical analyses were performed using the Statistical Package for Social Sciences (version 20.0, SPSS Inc., Chicago, IL). As data distributions were not normal, nonparametric tests were used in analyses. The Mann–Whitney *U* test was applied to explore the significances of differences between the measurements yielded by the 2 devices. Bland–Altman analysis was used to assess correlations and the extents of agreement between AL-Scan and USB data on AL measurements and IOL powers. *P* values less than 0.05 were considered statistically significant.

RESULTS

In total, 81 eyes of 81 patients (39 females) were enrolled in the study. In 11 patients (13.6%), the AL-Scan could not measure AL because dense cataracts were present. In addition, 3 of these 11 patients had posterior subcapsular cataracts and 8 dense nuclear cataracts. These patients were excluded; thus,

70 patients (35 females) completed the study. The mean age of all of the patients was 66.87 ± 9.11 (SD) years (range 39 years to 86 y). The preoperative mean BCVA (Snellen) was 0.32 ± 0.21 (range 0.03–0.5). Table 1 compares AL and K data of all patients. The mean ALs measured via AL-Scan and USB were 23.29 ± 0.79 mm (range 21.63–25.03 mm) and 23.23 ± 0.81 mm (range 21.66–25.62 mm), respectively. The mean difference between the 2 devices was 0.06 ± 0.18 mm, and was not statistically significant ($P = 0.662$). The average K readings were also similar ($P = 0.254$) (Tables 1 and 2). The correlations between the devices in terms of AL and K measurements were very high (ICC = 0.978 and 0.985, respectively) (Table 2, Figs. 1 and 2).

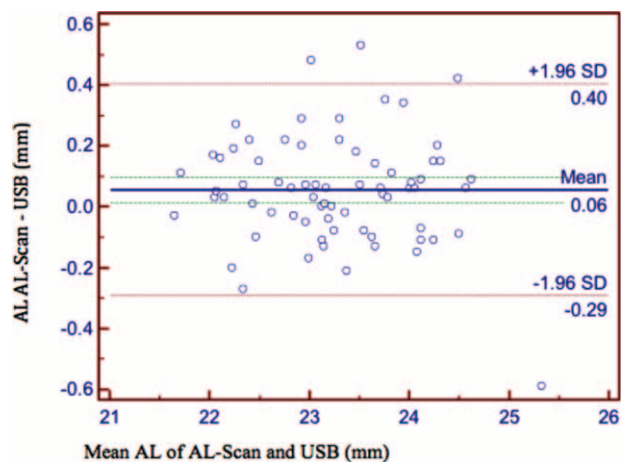


FIGURE 1. A Bland–Altman plot showing differences in axial length (AL) measurements between the AL-Scan and USB. The bold horizontal line shows the mean differences between devices. The dotted lines above and below that line represent the 95% limits of agreement. USB = ultrasonic biometer.

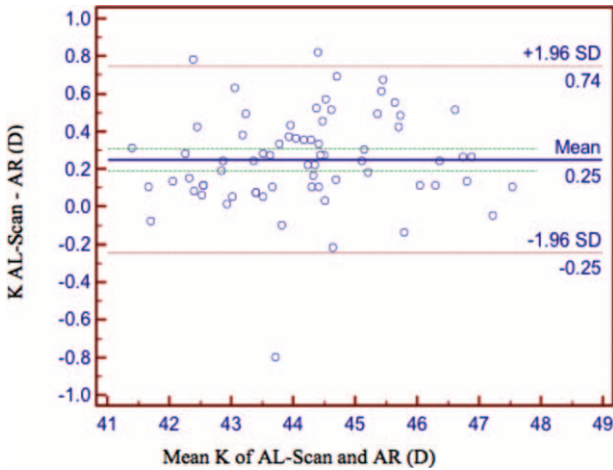


FIGURE 2. A Bland–Altman plot showing differences in average keratometry (K) readings between the AL-Scan and USB. The bold horizontal line shows the mean differences between devices. The dotted lines above and below that line represent the 95% limits of agreement. USB = ultrasonic biometer.

Figure 3 shows the Bland–Altman plot demonstrating differences in average IOL power measurements between the devices. The correlations between the 2 devices in terms of IOL power calculated using the SRK/T formula were very high ($ICC = 0.964$; $P < 0.001$). Four weeks after cataract surgery, the mean spheric value was 0.15 ± 0.29 (SD) D (range 0.50–1.00 D). The AR data revealed a 0.36 ± 0.29 D change in the mean K value ($P < 0.05$). The distributions of postoperative spherical and other refractive values are shown in Figures 4–7. Table 3 lists the postoperative refractive features of all patients.

DISCUSSION

Accurate IOL power calculation is very important for attainment of patient satisfaction after cataract surgery.^{9–11} A less-than-satisfactory refractive outcome is a major cause of

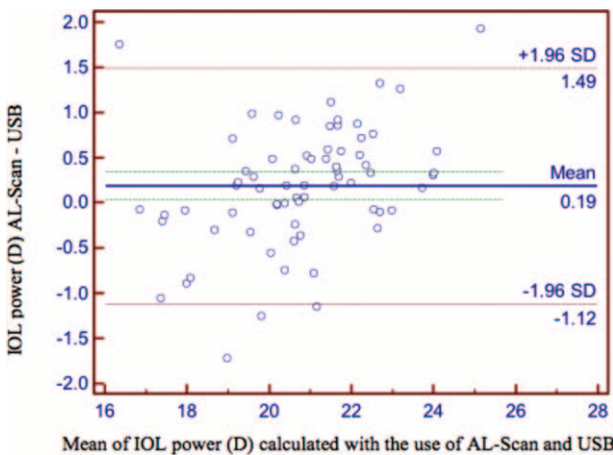


FIGURE 3. A Bland–Altman plot showing differences in IOL power calculation using the SRK/T formula between the AL-Scan and USB. The bold horizontal line shows the mean differences between devices. The dotted lines above and below that line represent the 95% limits of agreement. IOL = intraocular lens, USB = ultrasonic biometer.

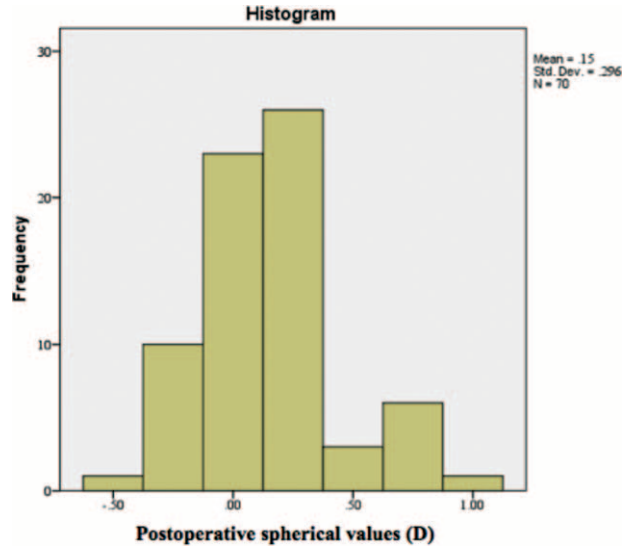


FIGURE 4. The distribution of postoperative spherical values.

IOL explantation.¹² The most common causes thereof are K errors and incorrect AL determination.¹³

Currently, AL measurement via optical biometry is considered to be the gold standard.¹⁴ However, in cases with dense cataracts, USB is more successful.¹⁵ The AL-Scan is a new noncontact optical reflectometer/keratometer using an 830 nm superluminescent diode as a light source. The device is very fast, performing 6 different types of measurements in 10 seconds: AL, corneal curvature radius, anterior chamber depth (ACD), central corneal thickness (CCT), pupil size, and white-to-white distance (WTW). The device employs the partial coherence laser interferometry principle to measure AL within the range 14 to 40 mm. The system incorporates 3-dimensional autotracking and autoshot features to simplify device use in practice. The Scheimpflug principle is used to measure both ACD and CCT. Corneal power is determined via double mire ring keratometry, which evaluates 360 points oriented on 2 circles 2.4 and 3.3 mm in diameter. The 2.4-mm circle data are

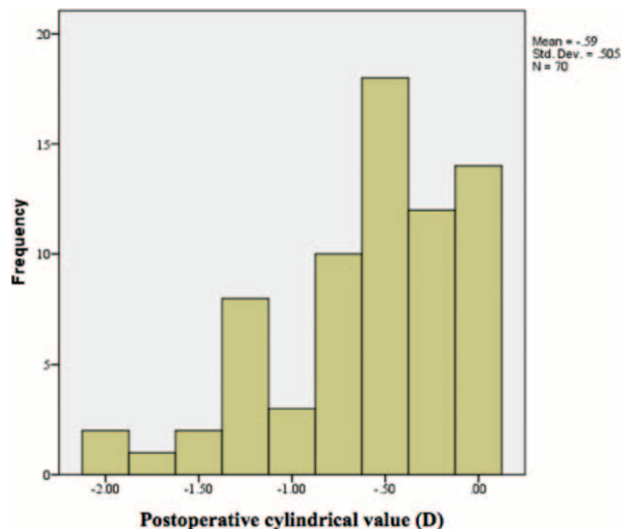


FIGURE 5. The distribution of postoperative cylindrical values.

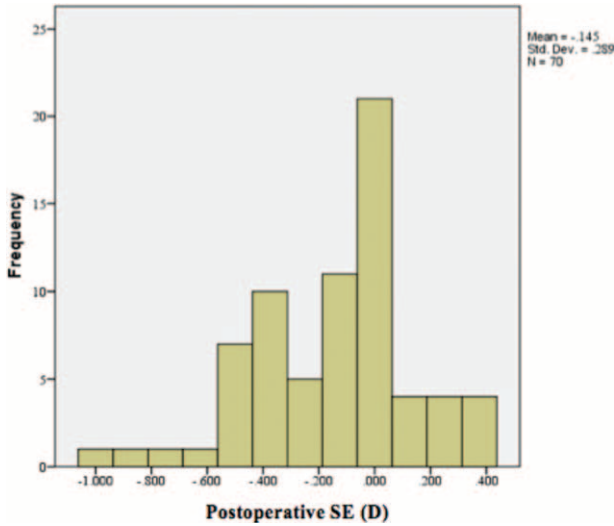


FIGURE 6. The distribution of postoperative spherical equivalent (SE) values.

used to calculate IOL power. In USB, power is calculated by measuring the time delay of the sound wave echo received from the surface of the cornea and the internal limiting membrane. In contrast, laser light is reflected from the retinal pigment epithelium.¹⁶ USB measurements are performed along the optical axis. USB requires eye contact, and the quality of data is operator-dependent.¹⁷

Several studies have compared the refractive outcomes yielded by optical devices with those afforded by USB, mainly in the context of IOL calculations.^{5,6,18–20} These studies found that optical devices afforded more successful results than USB. Németh et al⁵ reported a very high correlation between the AL measurements by IOL Master and USB in normal eyes ($r = 0.985$; $P = 0.001$). They reported that the AL measurements of IOL Master were 0.39 ± 0.36 mm longer than USB. Goel et al⁶ found that the AL measurements by Lenstar give more reliable results than those of USB. According to Bjeloš

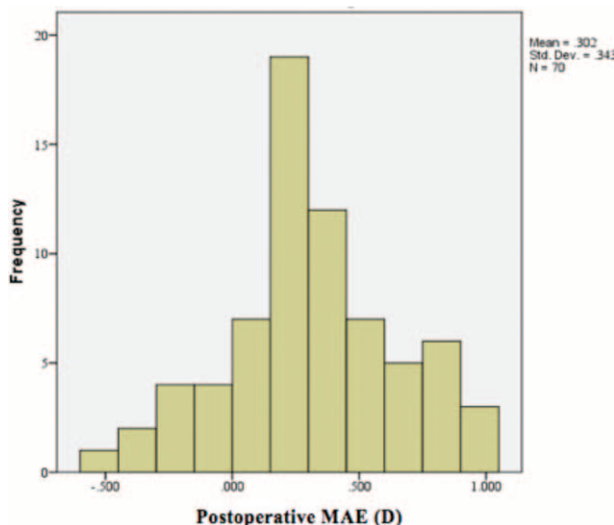


FIGURE 7. The distribution of postoperative mean absolute error (MAE) values.

TABLE 3. Postoperative Refractive Features of the Patients

Refractive Feature	Mean \pm SD	Minimum	Maximum
Sphere (D)	0.15 ± 0.29	-0.50	1.00
Cylinder (D)	-0.59 ± 0.50	-2.00	0.00
SE (D)	-0.14 ± 0.29	-1.00	0.37
MAE (D)	0.30 ± 0.34	-0.51	1.04

MAE = mean absolute error, SE = spherical equivalent.

Rončević et al,¹⁹ AL measurements by USB were 0.248 ± 0.266 mm shorter than those of Lenstar, within the 95% limits of agreement. To the best of our knowledge, the current literature lacks any comparison between the AL-Scan and the USB. In our current study, similar to the results mentioned above, AL-Scan measured AL as 0.06 ± 0.18 mm longer ($P = 0.662$) than USB within the 95% limits of agreement ($ICC = 0.987$; $P < 0.001$). In contrast, Buckhurst et al¹⁸ and Çınar et al²¹ reported that USB measured ALs either 0.14 ± 0.15 mm or 0.10 ± 0.76 mm longer than the Lenstar, within the 95% limits of agreement ($r = 0.99$, $P < 0.001$; and $ICC = 0.75$; $P < 0.001$, respectively). We suggest that such differences may be associated with patient compliance, indentation of the cornea during USB, the use of different measuring points, and the resolutions of the 2 methods.

The literature contains reports comparing the measurements of the AL-Scan and IOL Master.^{22,24} These studies found very high correlations between the AL measurements of these systems in normal eyes. Huang et al²² reported that the repeatability and reproducibility of AL-Scan was excellent in terms of all parameters, except the WTW and PD. Excluding WTW, good agreement was found between the AL-Scan and IOL-Master. Srivannaboon et al²³ also found that the repeatability and reproducibility of both devices were high for all ocular biometry measurements tested ($ICC = 0.87–1.00$). Except for the WTW and corneal diameter ($ICC = 0.44$), the extent of agreement between the 2 instruments was high ($ICC = 0.98–0.99$). Kaswin et al²⁴ found that the mean absolute error (MAE) in terms of IOL power prediction was 0.42 ± 0.08 D with the AL-Scan. In our current study, the MAE was 0.30 ± 0.34 D (range -0.50 D to 1.04 D). This difference may be associated with errors in AL and K measurements. It is well known that K values are essential for IOL power calculations. In our current study, IOL power calculations were performed using the SRK/T formula, which employs AL and K values to predict the power. Previous studies reported that K values changed after cataract surgery and variation in the locations of incisions created different levels of astigmatism.^{25–27} We suggest that surgically induced astigmatism may cause MAE errors. In previous studies of the AL-Scan, the locations of corneal incisions were not reported. In our current study, a clear corneal incision was created on the steep corneal axis, because surgically induced astigmatism was to be minimized. We found a 0.36 ± 0.29 change in mean K values ($P < 0.05$). In our present study, the K readings of the AL-Scan and the AR were in excellent correlation ($ICC = 0.985$; $P < 0.001$).

There are some limitations to this study. Optical and USB measurements were performed by the same examiner. Knowing the results of optical biometry might add bias in USB measurements. Using optimized surgeon specific A-constant increases the success of the refractive outcome. The lack of it in the current study is another limitation.

In conclusion, the AL-Scan, USB, and AR exhibited very strong ICCs and interdevice agreement. Keratometric changes developing after cataract operations constitute an obstacle to achievement of good refractive outcomes.

ACKNOWLEDGMENTS

The authors have no financial or proprietary interest in any material or method mentioned.

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