Repeatability and Reproducibility of a New Partial Coherence Interferometer; AL-Scan Optic Biometer

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Abstract

The purpose of this study was to evaluate the intra-observer repeatability and inter-observer reproducibility of the ocular parameter measurements in cataract eyes using the new partial coherence interferometer, AL-Scan. Eighty-six eyes with cataracts were included in this prospective study. Axial length, average keratometry, anterior chamber depth, central corneal thickness, white-to-white distance and intraocular lens power calculation with the SRK-T formula were determined by two observers. The measurements were repeated by the same observers using the same AL-Scan unit on the same eye approximately 2 weeks later, just before surgery. Inter-observer reproducibility was excellent, with very high interclass correlation coefficients (>0.984) for all measured parameters. Standard deviations (Sw) and coefficients of variation (CV) of the repeated measurements were low, which demonstrated high intra-observer repeatability, except for the central corneal thickness and white-to-white distance measurements (Sw≤0.224 ∞CV≤ 1.072). The precision of the measurements obtained by the AL-Scan biometer is highly reliable and observer-independent.

Keywords: Partial coherence interferometer, cataract, biometry, AL-Scan

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Introduction

Cataract surgery is now considered a form of refractive surgery that leads to increased patient expectations of modern surgical techniques. Accurate measurment of the ocular dimensions that are used for calculating intraocular lens (IOL) power, including axial length (AL), anterior chamber depth (ACD), and corneal power, are crucial for satisfactory postoperative results [1,2]. The most common method used for optic biometry is ultrasound A scan. A study by Olsen reported that 54% of the error in predicted refraction was attributed to AL errors, 8% to corneal power errors, and 38% to errors in the estimation of the postoperative ACD [3]. Optical biometry with partial coherence interferometry was introduced in 1999 (IOL Master optical biometer; Carl Zeiss Meditec, Germany) and has become so popular that it has replaced ultrasonography as the gold standard, due to its non-contact nature (avoiding corneal abrasion and contamination) and highly accurate, repeatable measurement of AL [4-6].

The AL-Scan (Nidek Gamagori, Japan) is a new optical biometer that performs six different types of measurements in 10 seconds: AL, corneal curvature radius, ACD, central corneal thickness (CCT), white-to-white distance (WTW), and pupil diameter. The biometer uses an 830 nm superluminescent diode laser for AL measurement with the partial coherence laser interferometry system. The AL-Scan has a measurement range of 14-40 mm for AL measurement and incorporates three-dimensional auto-tracking and auto-shot features to simplify use. The Scheimpflug principle is used to measure ACD and CCT. Corneal power is determined with a double mire ring keratometer which evaluates 360 points oriented in 2 circles of 2.4 mm and 3.3 mm. Measurements obtained from the 2.4 mm circle is used in the calculation of intraocular lens power.

When using a new measurement technique in the clinic, the repeatability and reproducibility of the device must be determined. Repeatability is defined as the intra-observer variability and reproducibility is defined as the inter-observer variability [7]. The purpose of this study was to evaluate the repeatability and reproducibility of the AL-Scan in cataract eyes.

Material and Method

This prospective study analyzed the measurements of 86 eyes of 65 patients with cataracts in the Department of Ophthalmology, Dumlupinar University School of Medicine. The purpose of the study was explained and informed consent was received from all subjects. The study was approved by the local ethics committee and conformed to the tenets of the Declaration of Helsinki. Exclusion criteria included: eyes with any anterior and/or posterior segment pathology, advanced corneal pathology, macular degeneration, glaucoma, posterior subcapsular score greater than 3.5 based on the Lens Opacities Classification System III, or advanced cataracts [8]. Patients were also excluded if there was difficulty in obtaining reliable measurements.

The parameters analyzed were AL, CCT, average keratometry (Kavg), ACD, WTW and IOL calculation with SRK-T formula. Measurements were obtained initially through an undilated pupil by two experienced technicians during the first visit and then repeated by the same technicians using the same AL-Scan unit on the same eye approximately 2 weeks later, just before surgery. Patients withdrew their head from the device between measurements. The technicians had no access to the first set of measurements when performing the second set. The average of the two technicians' measurements was used for inter-observer statistical comparison.

Statistical analyses were performed using SPSS software version 16.0 (SPSS Inc., Chicago Illinois, USA). Intra-observer repeatability was evaluated using standard deviation (Sw) and coefficient of variation (CV). Inter-observer reproducibility was assessed by the method of Bland-Altman, who suggest plotting the differences between the measurements against their means, with a mean difference ± 1.96 standard deviation. Intra-observer measurements were compared using a paired t test, and a P value less than 0.05 was considered statistically significant. Inter-observer reproducibility was calculated with interclass correlation coefficients (ICC) [9].

Results

This study included 65 patients (38 male and 27 female), with a mean age of 61.7 ± 10.08 years (range: 35-83 years), who were listed for cataract surgery. In total, there were 86 eyes with cataracts.

The mean AL, Kavg, ACD, IOL, CCT, and WW measurements of the first observer (first vs second visit) were 23.32±0.74 vs 23.33±0.74 (p=0.505), 44.18±1.68 vs 44.17±1.66 (p=0.750), 3.15±0.37 vs 3.17±0.36 (p=0.221), 20.92±1.9 vs 20.91±1.9 (p=0.637), 537.7±32.2 vs 534.5±32.3 (p=0.024), and 11.61±0.3 vs 11.54±0.3 (p=0.568), respectively.

The mean AL, Kavg, ACD, IOL, CCT, WW measurements of the second observer (first vs second visit) were 23.33±0.74 vs 23.33±0.74 (p=0.823), 44.15±1.65 vs 44.15±1.61 (p=0.311), 3.16±0.35 vs 3.16±0.36 (p=0.084), 20.91±1.9 vs 20.95±1.9 (p=0.306), 534.0±33.0 vs 534.8±33.0 (p=0.364), and 11.69±0.3 vs 11.67±0.3 (p=0.466), respectively (Table 1). The differences in the intra-observer measurements were not statistically significant except for the CCT measurement of the first observer. The Sw and CV of repeated measurements were low, which shows good intra-observer repeatability, except for the CCT and WW measurements (Sw≤0.224, ∞CV≤1.072).

The ICC of all measurements obtained by the observers was higher than 0.984, which shows excellent inter-observer reproducibility (Table 2). The Bland-Altman plot shows excellent agreement (Figures 1-3).

Table 1. Summary of intraobserver measurements

	Measurement 1			Measurement 2			
	Mean(±SD)	**Min**	**Max**	**Mean(±SD)**	**Min**	**Max**	**P value**
Observer 1							
AL(mm)	23.32±0.74	21.69	24.76	23.33±0.74	21.67	24.76	0.505
Kavg(D)	44.18±1.68	40.96	47.40	44.17±1.66	40.96	47.4	0.750
ACD(mm)	3.15±0.37	2.44	4.74	3.17±0.36	2.45	4.40	0.221
IOL(SRK T)	20.92±1.9	16.5	26.5	20.91±1.9	16.0	26.50	0.637
CCT(µm)	537.7±32.2	481	595	534.5±32.3	483	596	0.024
WW(mm)	11.61±0.3	10.9	12.3	11.54±0.3	10.9	12.4	0.568
Observer 2							
AL(mm)	23.33±0.74	21.69	24.75	23.33±0.74	21.68	24.75	0.823
Kavg(D	44.15±1.65	40.96	47.33	44.15±1.61	40.96	47.30	0.311
ACD(mm)	3.16±0.35	2.45	4.73	3.16±0.36	2.45	4.74	0.084
IOL(SRK T)	20.91±1.9	16.5	26.5	20.95±1.9	16.5	26.50	0.306
CCT(µm)	534.0±33.0	484	598	534.8±33.0	476	599	0.364
WW(mm)	11.69±0.3	10.9	12.3	11.67±0.3	10.9	12.3	0.466

AL= axial length, Kavg= average keratometry ACD= anterior chamber depth , IOL=intraocular calculation with SRK-T formula CCT= central corneal thickness, WW= white to white distance

Table 2. Summary of interobserver measurements

	Observer 1			Observer 2			
	Mean	**Sw**	**CV**	**Mean**	**Sw**	**CV**	**ICC**
AL(mm)	23.328	0.024	0.107	23.335	0.030	0.130	1.000
Kavg(D)	44.178	0.104	0.236	44.154	0.123	0.279	0.999
ACD(mm)	3.168	0.099	0.133	3.165	0.014	0.446	0.988
IOL(SRK T)	20.92	0.224	1.072	20.93	0.222	1.061	0.997
CCT(µm)	536.1	9.491	1.770	534.4	5.837	1.092	0.984
WW	11.58	0.782	6.753	11.68	0.139	1.196	1.000

AL= axial length, Kavg= average keratometry ACD= anterior chamber depth , IOL=intraocular calculation with SRK-T formula CCT= central corneal thickness, WW= white to white distance
Sw =Standard deviation of repeated measurements CV= coefficient of variation of repeated measurements, ICC= interclass correlation coefficients

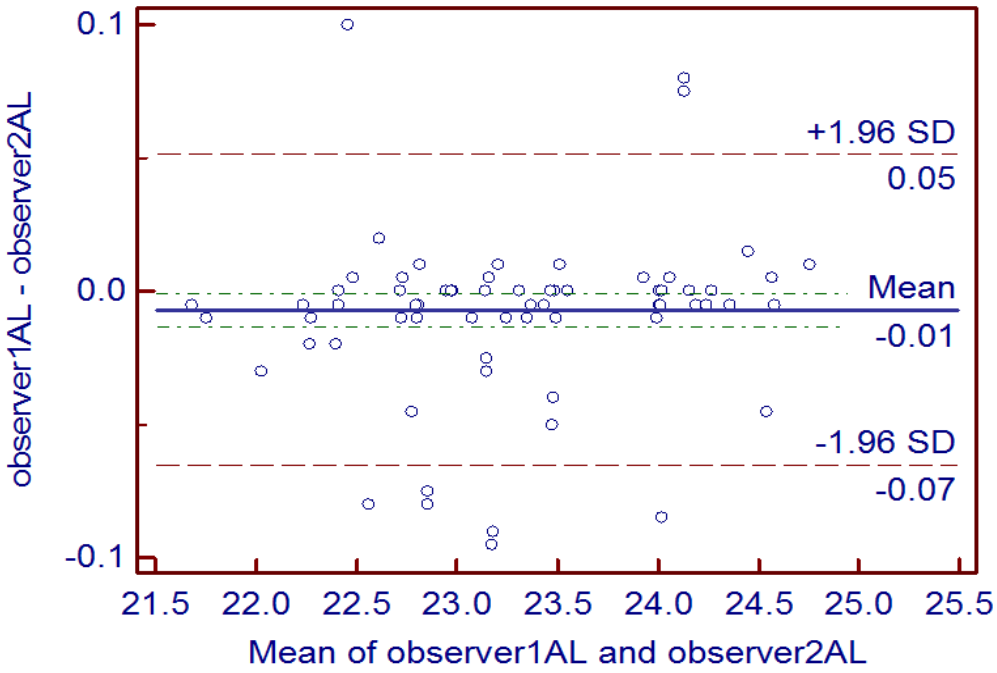

Figure 1. Bland-Altman plot showin difference in AL between the observer 1 and the observer 2 plotted against the mean value for both calculated as mean ±1.96SD (N=86 eyes)

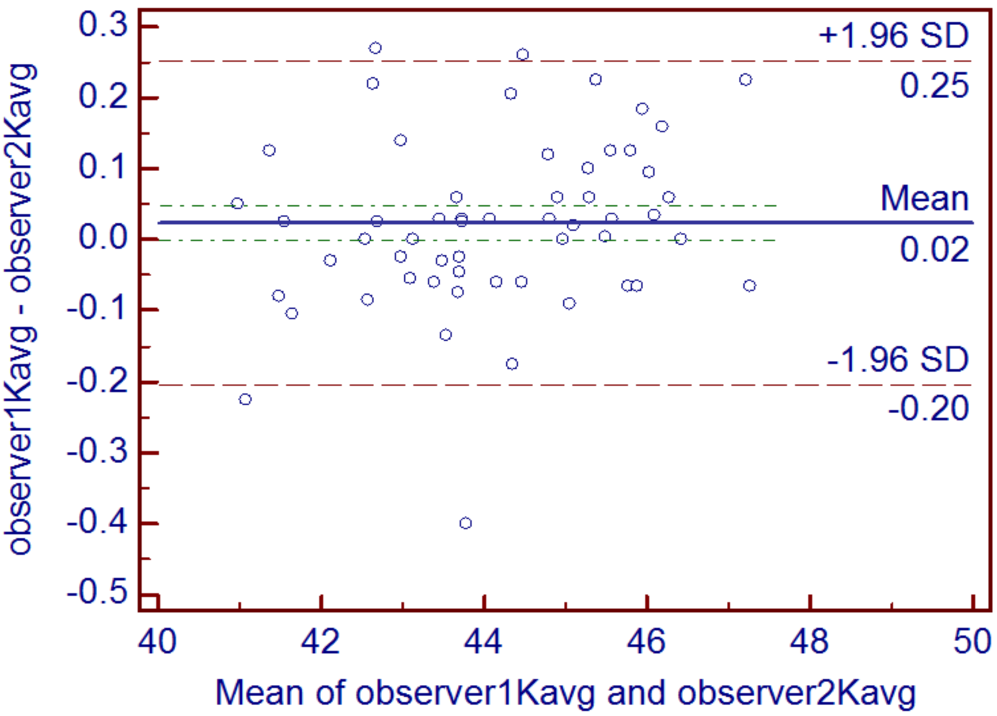

Figure 2. Bland-Altman plot showin difference in Kavg between the observer 1 and the observer 2 plotted against the mean value for both calculated as mean ±1.96SD (N=86 eyes)

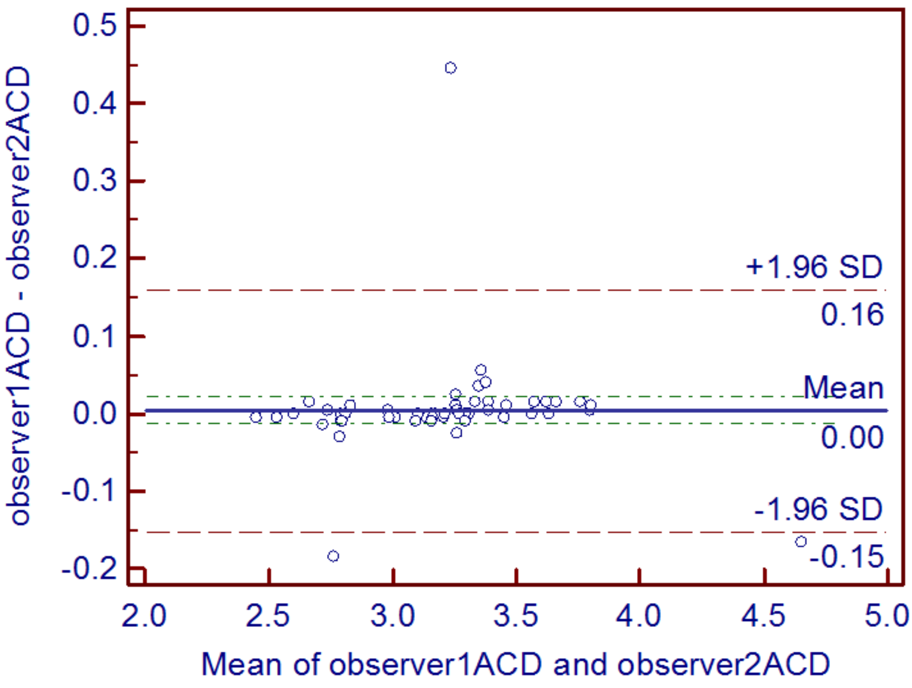

Figure 3. Bland-Altman plot showin difference in ACD between the observer 1 and the observer 2 plotted against the mean value for both calculated as mean ±1.96SD (N=86 eyes).

Discussion

Accurate measurement of ocular biometry is critical to achieving optimal refractive outcome in patients undergoing cataract surgery [10,11]. Optical biometry is a rapid, easy to use and non-contact method to assess the eye's biometry and calculate the IOL power, so the method is preferred by many ophthalmologists [12-14]. Recently, the AL-Scan optical biometer has been introduced into clinical practice, and has shown good agreement with the common optical biometer, IOL Master [15,16].

Repeated measurements of different parameters are often used in clinical research. When two observers measure the same parameter with the same device at different times and find similar results, the device is shown to work independently of the observer and closer to the real value of the measured parameter [17] We aimed to evaluate the intra-observer repeatability and inter-observer reproducibility of the AL-Scan, which has been tested in limited studies in the literature.

The most common cause of errors in IOL power calculations are incorrect AL measurements. A 0.1 mm error in AL measurement is equivalent to an refractive error of about 0.27 D, so AL measurement is the most crucial step in the IOL power calculation. Another important step in the IOL power calculation is the K reading; a 1 D error in the K measurement results in a 1 D refractive error [18]. The IOL Master is currently considered the gold standard biometer for AL measurements, showing good repeatability and accuracy [19]. Huang et al. [15] demonstrated that the AL measurements of the AL-Scan and IOL Master were very close to each other, with 95% of the readings within -0.12 to 0.1 mm. The authors also found the K value comparable between the two devices. Kaswin et al. [16] showed excellent correlations in AL measurements and K readings between the AL-Scan and IOL Master in cataractous eyes. In our study, intra-observer and inter-observer differences in AL values were 0.002 and 0.007 mm, respectively, which affects the final refraction by 0.005 D and 0.018 D. The intra-observer and inter-observer differences in Kavg values were 0.005 D and 0.024 D, respectively, which affects the final refraction by 0.005 D and 0.024 D. Intra-observer and inter-observer precision of the AL and K measurements with the AL-Scan optic biometer was very high, with ICCs of 1.000 and 0.999, respectively. We found excellent repeatability and reproducibility of the AL and K measurements by the AL-Scan. The three-dimensional auto-tracking and auto-shot system of AL-Scan made considerable contributions and granted the examiner the most ease, comfort, and accuracy on all measurements, regardless of the experience of the examiner.

The Scheimpflug principle is used by the AL-Scan to measure ACD and CCT. Measurements of CCT and ACD with an instrument (EAS-1000 Nidek CO, Pentacam; Oculus) that uses this technique showed high repeatability and reproducibility [20,21]. Huang et al. [15] found that there was a good agreement between the AL-Scan and IOL Master for measurements of ACD. The preoperative ACD does not affect the IOL power calculation when using the SRK/T, Holladay1, or Hoffer Q formulas, but in order to increase the accuracy of the IOL power calculation, the ACD is used in some IOL power calculation formulas, like Haigis. According to the Haigis formula, a 0.06 mm difference in the ACD affects the final refraction by only 0.05 D [22-25]. In our study, intra-observer and inter-observer differences in ACD were 0.002 and 0.003, respectively, which affects final refraction by 0.001 D and 0.002 D. These differences are clinically insignificant in patients who have cataract surgery. Intra-observer and inter-observer differences in mean CCT were 3.2 µm and 1.7 µm. The precision of the ACD and CCT measurements was high, with ICCs of 0.988 and 0.984, respectively.

Baumeister et al. [26] compared two manual methods (a Holladay-Godwin gauge and a measuring caliper) and two automated devices (the IOL Master and the Orbscan II) in measuring the horizontal corneal diameter, and found that automated measurement of the WTW distance ensures more exact results than manual measurement of the WTW distance. The IOL Master had the highest reliability in measuring corneal diameter. Huang et al. [15] found a wider WTW distance using the AL-Scan than the IOL Master. In our study, intra-observer and inter-observer differences in WTW measurements were 0.06 mm and 0.1 mm, respectively, with an ICC of 1.00. The precision of the WTW measurements was high. Precise measurement of WTW is important in the IOL power calculation when third-generation formulas are used for determining IOL power and when the selection of angle supported and posterior chamber phakic IOL depend on calculations using the WTW [11,16].

Kaswin et al. [16] reported that in 94% of cases, the mean IOL power difference between the AL-Scan and IOL Master was equal to or less than 0.5 D and the SRK/T formula provided very similar results between devices. This result showed that the AL-Scan can be used interchangeably with the IOL Master. We found the intra-observer and inter-observer differences in the IOL power, using the SRK/T formula, to be 0.03 D and 0.01 D, respectively. The ICC value (0.977) reflected an excellent repeatability and reproducibility in the AL-Scan's IOL power calculation using the SRK/T formula.

The main limitations of our study include a lack of cataract typing and lack of highly myopic and hyperopic patients. In addition, we did not compare the AL-Scan with other optic biometers.

The AL-Scan biometer is easy to use. Its main disadvantage is an inability to measure AL in dense subcapsular and posterior polar cataracts, like other partial coherence interferometers. However, the AL-Scan has an optional built-in ultrasound biometer, which can overcome this limitation. Our findings demonstrated excellent intra-observer repeatability and inter-observer reproducibility in measuring AL, Kavg, ACD, CCT, IOL power, and WTW with the AL-Scan optic biometer.

Decleration of interest

The autors report no conflict of interest. The autors alone are responsible for content writing of the article.

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