

Agreement between a Spectral-Domain Ocular Coherence Tomography Biometer with a Swept-Source Ocular Coherence Tomography Biometer and an Optical Low-Coherence Reflectometry Biometer in Eyes with Cataract

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Abstract

Purpose: To assess the agreement between biometric parameters measured by a spectral-domain optical coherence tomography optical biometer device (Optopol Revo NX) with a validated swept-source biometer (IOLMaster 700) and a validated optical low-coherence reflectometry biometer (Lenstar LS 900), in cataract surgery candidates.

Methods: In this prospective comparative study, 100 patients (100 eyes) who were eligible for cataract surgery were involved. Bland–Altman plots were used to assess agreement between devices for biometric parameters including axial length (AL), anterior chamber depth (ACD), lens thickness (LT), and central corneal thickness (CCT).

Results: AL measurements were successful in 82 eyes (82.0%) with Revo NX, in 91 eyes (91.0%) with Lenstar LS 900, and in 97 eyes (97.0%) with IOLMaster 700. When Revo NX was compared to IOL Master 700 and Lenstar LS 900, the mean differences were as follows: -0.02 ± 0.02 mm and -0.02 ± 0.03 mm ($P = 0.313$, $P = 0.525$) for AL, 0.01 ± 0.03 mm and 0.10 ± 0.03 mm ($P = 0.691$, $P = 0.002$) for ACD, -0.15 ± 0.03 mm and 0.001 ± 0.04 mm ($P < 0.001$, $P = 0.95$) for LT, and -2.29 ± 0.92 μ m, and 0.73 ± 1.43 μ m ($P = 0.015$, $P = 0.612$) for CCT. Three devices were highly correlated for AL, ACD, LT, and CCT (interclass correlation coefficient > 0.75). Bland–Altman plots showed a narrower 95% limit of agreement (-0.35 to 0.31) between Revo NX and IOLMaster 700 in measuring AL.

Conclusions: Despite the higher measurement failure rate in eyes with cataract, the Revo NX showed very good agreement with the IOLMaster 700 and Lenstar LS 900 optical biometers in measuring AL, ACD, LT, and CCT. However, ACD and LT measurements cannot be considered interchangeable between these devices.

Keywords: Cataract, IOLMaster 700, Lenstar LS 900, Optical biometry, Revo NX

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INTRODUCTION

In an era of modern cataract surgery, accurate biometric measurements of the eye are instrumental for the accurate

determination of intraocular lens (IOL) power and optimized refractive outcomes.¹ Axial length (AL) and anterior chamber

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depth (ACD) can be measured with ultrasound, partial coherence interferometry, optical low-coherence reflectometry (OLCR), and recently optical coherence tomography (OCT) devices.²

Since the introduction of the IOLMaster (Carl Zeiss Meditec AG, Germany) in 1999, optical biometry has been a gold standard in ocular biometry measurements for a long period of time.³ IOLMaster 700 was the first swept-source OCT (SS-OCT)-based biometry device, which acquired OCT images across the entire length of the eye.⁴ Although the IOLMaster 700 provides excellent anterior segment OCT images, it cannot offer high-quality scans of the retina and optic nerve, simultaneously.

Lenstar LS 900 (HAAG-STREIT AG, Switzerland) works based on the OLCR technology. It combines optical biometry with automated keratometry.⁵ The agreement, validity, and interchangeability of IOLMaster 700 and Lenstar LS 900 have been reported in previous studies.^{4,6-8}

The recently introduced Revo NX device (OPTOPOL Technology Sp, Poland) is a combination of anterior and posterior segment spectral-domain OCT (SD-OCT) with optical biometry.⁵ The Revo NX is the first anterior/posterior OCT system that enables simultaneous measurement of AL, ACD, lens thickness (LT), and central corneal thickness (CCT).⁹ The biometric measurement provided by the previous version (software version 8.0.3) of Revo NX biometer was found not to be in agreement with Lenstar LS 900.⁵ After improving its calibration by the manufacturer, the upgraded version (9.5.0) claims to be able to compete with other devices, and a recent study, comparing the upgraded version of Revo NX optical biometer with the two other validated optical biometers (e.g. IOLMaster 700 and Lenstar LS 900) found a good agreement between devices in healthy individuals.³ This study sought to assess the acquisition success rate and agreement of biometry measurements obtained by Revo NX biometer (software version 9.7.0) with IOLMaster 700 and Lenstar LS 900 in cataract surgery candidates.

METHODS

This prospective study was performed on patients presenting for cataract surgery between November 2019 and September 2020 at Noorafarin tertiary eye clinic. The study was approved by the Ethics Committee of Mashhad University of Medical Sciences. Cataract types and grading were recorded according to Lens Opacities Classification III scoring system (LOCS III-Grade 2–4).¹⁰ Patients were invited to participate in the study after an explanation of the study and its purpose. All participants gave informed consent to participate in research and the research followed the tenets of the Declaration of Helsinki. For all patients, a full medical and ocular history was taken. All patients underwent a full anterior and posterior segment slit-lamp examination as well as macula and optic disc OCT scans.

One hundred patients with cataract over the age of 50 years were included. Eyes were excluded if ocular comorbidities

were expected to alter biometry measurements. Eyes with the following pathologies were excluded: pterygium, corneal transplantation, corneal dystrophy, keratoconus, and corneal scarring. Patients were also excluded if they were unable to fixate on the fixation target.

All biometry examinations were performed in a random order, by one experienced operator between 4 and 8 pm. All participants underwent biometry with each three devices. During the procedure, patients were asked to steadily fixate to the fixation light and blink to provide a continuous tear layer. All examinations were repeated three times and the results were averaged. Focused and high-quality images were included and the results were averaged for the statistical analysis. AL, ACD, LT, and CCT parameters were extracted for the agreement analysis.

The Revo NX SD-OCT device has an axial resolution of 5 mm, a transverse resolution of 12 mm, and a scanning depth of 2.4 mm. It can produce 110,000 scans per second. The optical biometry program within the device measures the AL, ACD, LT, and CCT. It performs 10 B-scans for each measurement to calculate a precise mean value.⁹

Lenstar LS 900 OLCR biometer uses a super luminescent diode with 820 nm wavelength to measure the AL, LT, CCT, and ACD and also provides keratometry values and pupil size.¹¹ IOLMaster 700 measures AL and ACD along with CCT and LT using an adjustable 1050 nm laser infrared light and multi-point keratometer, acquiring over 2000 scans per second.⁹

Statistical analysis

Statistical analysis was performed using the SPSS 23 software (SPSS Institute, Inc., Chicago, IL, USA), and MedCalc software (Version 20; MedCalc Inc., Ostend, Belgium). Kolmogorov–Smirnov test was used to assess the parametric distribution of the data. Repeated measures analysis of variance and Bonferroni posttest were used to assess the difference between devices. The measured data of each device were plotted by Bland–Altman diagram to investigate the qualitative distribution and compare the compatibility or dispersion of data provided by Revo NX compared to IOLMaster 700 and Lenstar LS 900. The mean \pm 1.96 standard deviation of the difference between the two measurement techniques defined the 95% limits of agreement. The mountain plots were used to show the measurement differences between devices. The interclass correlation coefficient (ICC) was defined as the ratio of the variance between subjects to the sum of the pooled intra- and inter-participant variance. ICC more than 0.9 is defined as a high agreement, between 0.7 and 0.9 considered a good agreement, and an ICC $<$ 0.7 considered a poor agreement between measurement techniques.¹² $P <$ 0.05 was considered statistically significant.

Based on the previous studies,⁴ the sample size calculation performed to detect a mean difference of 0.01 mm of AL with a standard deviation of 0.02 mm, with a power of 80% and significance level of 0.05 using the Bland-Altman method,

revealed a minimum sample size of 83 is needed for each group within a paired analysis.

RESULTS

One hundred patients (100 eyes) including 55 women (55.0%) and 45 men (45.0%) with a mean age of 61.85 ± 7.90 years (range, 50–82 years) were included. AL was successfully measured in 82% of the patients using Revo NX biometer, 91.0% of patients using Lenstar LS 900, and 97.0% of all patients using IOLMaster 700. Table 1 shows the baseline characteristics of ocular biometric parameters measured using the three devices. The mean of LT and ACD was significantly different between the three devices ($P < 0.001$ and $P = 0.005$, respectively). Table 2 shows paired difference and agreement between parameters measured with the three devices. Bonferroni test showed a significant difference between IOLMaster and Revo NX in LT and CCT measurements ($P < 0.001$, and $P = 0.015$). Furthermore, ACD measured using Revo NX was significantly higher than Lenstar ($P = 0.007$).

All parameters measured with Revo NX biometer were in high agreement with Lenstar and IOLMaster [Table 2]. A high degree of agreement was found between Revo NX and the other 2 biometers in AL and CCT measurements ($ICC > 0.90$). This agreement was lower but good for LT and ACD measurements ($ICC: 0.75–0.81$).

The agreement of parameters between Optopol OCT, Lenstar, and IOLMaster was assessed and represented using the Bland-Altman plots [Figure 1]. A narrower 95% limit of agreement (-0.35 to 0.31) was found between Revo NX and

IOLMaster 700 in measuring AL. Furthermore, mountain plots showed high agreement between Revo NX and the two other devices for the measured biometric parameters [Figure 2].

DISCUSSION

In this study, the biometric parameters measured by Revo NX biometer, Lenstar LS 900, and IOLMaster 700 were compared in candidates presenting for cataract surgery. A good to a high agreement was found between devices, especially in the measurement of AL and CCT. The agreement of the IOLMaster 700 and Lenstar LS 900 devices has also been previously investigated, and a high agreement between devices and no clinically relevant differences were found.^{7,8}

In the present study, the failure rate of IOL Master 700, Lenstar LS 900, and Revo NX OCT in measuring AL was 3%, 9%, and 18%, respectively. This is in keeping with previous studies showing that SS-OCT-based biometers demonstrate greater penetration of the cataractous lens.¹³ Sikorski and Suchon also reported a higher failure rate of the SD-OCT Revo NX in measuring AL compared to the SS-OCT IOLMaster 700 and proposed this to be due to the difference in OCT technology used by the Revo NX.¹²

In the present study, AL measurements obtained by IOLMaster 700 were marginally higher than the other devices, but the differences were not clinically and statistically significant. This is similar to the results reported by Kanclerz *et al.*, comparing the same devices in healthy eyes.³ The authors found a high level of agreement ($r > 0.95$) between Revo NX and IOLMaster 700, and Lenstar LS 900 when measuring AL. A mean

Table 1: Demographic characteristics of ocular biometric parameters measured using three devices

	AL (mm)		LT (mm)		ACD (mm)		CCT (μ m)	
	Mean \pm SD	Range	Mean \pm SD	Range	Mean \pm SD	Range	Mean \pm SD	Range
Revo NX	23.46 \pm 0.18	21.21–32.67	4.15 \pm 0.04	3.34–5.15	3.25 \pm 0.05	2.15–4.78	520.02 \pm 3.37	438–595
Lenstar LS 900	23.48 \pm 0.18	21.27–32.50	4.15 \pm 0.05	3.27–5.27	3.15 \pm 0.05	2.04–4.76	519.29 \pm 3.37	438–601
IOLMaster 700	23.48 \pm 0.17	21.22–32.48	4.30 \pm 0.04	3.29–5.40	3.24 \pm 0.05	1.89–4.68	522.31 \pm 3.32	441–603
<i>P</i> *	0.625		<0.001		0.005		0.06	

*Repeated measures analysis of variance. SD: Standard deviation, AL: Axial length, LT: Lens thickness, ACD: Anterior chamber depth, CCT: Central corneal thickness, IOL: Intraocular lens

Table 2: Mean \pm standard deviation, paired differences, and 95% limits of agreement between axial length, lens thickness, anterior chamber depth, and central corneal thickness parameters measured by Lenstar LS 900, IOLMaster 700, and Revo NX biometer

	Paired difference* with Revo NX, mean \pm SD (<i>P</i>)		Agreement with Revo NX			
	Lenstar LS 900	IOLmaster 700	Lenstar LS 900		IOLMaster 700	
			95% LoA	ICC	95% LoA	ICC
AL (mm)	-0.02 \pm 0.03 (0.525)	-0.02 \pm 0.02 (0.313)	-0.46 to 0.43	0.989	-0.35 to 0.31	0.994
LT (mm)	0.001 \pm 0.04 (0.95)	-0.15 \pm 0.03 (<0.001)	-0.55 to 0.53	0.750	-0.69 to 0.39	0.770
ACD (mm)	0.10 \pm 0.03 (0.007)	0.01 \pm 0.03 (0.691)	-0.59 to 0.62	0.810	-0.47 to 0.67	0.80
CCT (μ m)	0.73 \pm 1.43 (0.612)	-2.29 \pm 0.92 (0.015)	-26.20 to 27.70	0.910	-19.70 to 15.10	0.960

*Bonferroni multiple comparisons. ICC: Interclass correlation coefficient, SD: Standard deviation, AL: Axial length, LT: Lens thickness, ACD: Anterior chamber depth, CCT: Central corneal thickness, IOL: Intraocular lens, LoA: Limits of agreement

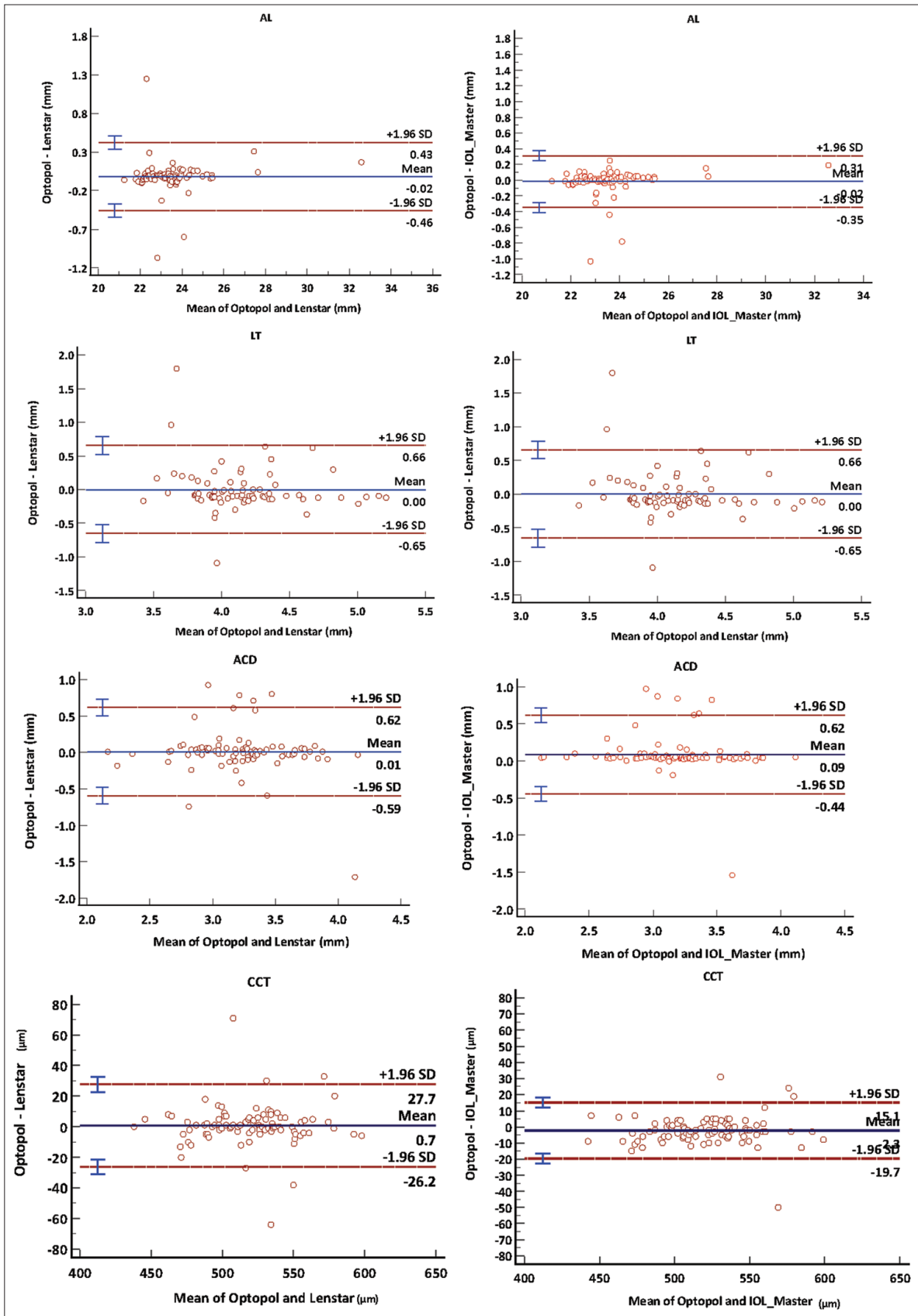


Figure 1: Bland-Altman plots demonstrate the agreement between Lenstar LS 900 and IOLMaster 700 with Revo NX biometer in measuring axial length, lens thickness, anterior chamber depth, central corneal thickness. IOL: Intraocular lens, SD: Standard deviation, ACD: Anterior chamber depth, CCT: Central corneal thickness, LT: Lens thickness, AL: Axial length

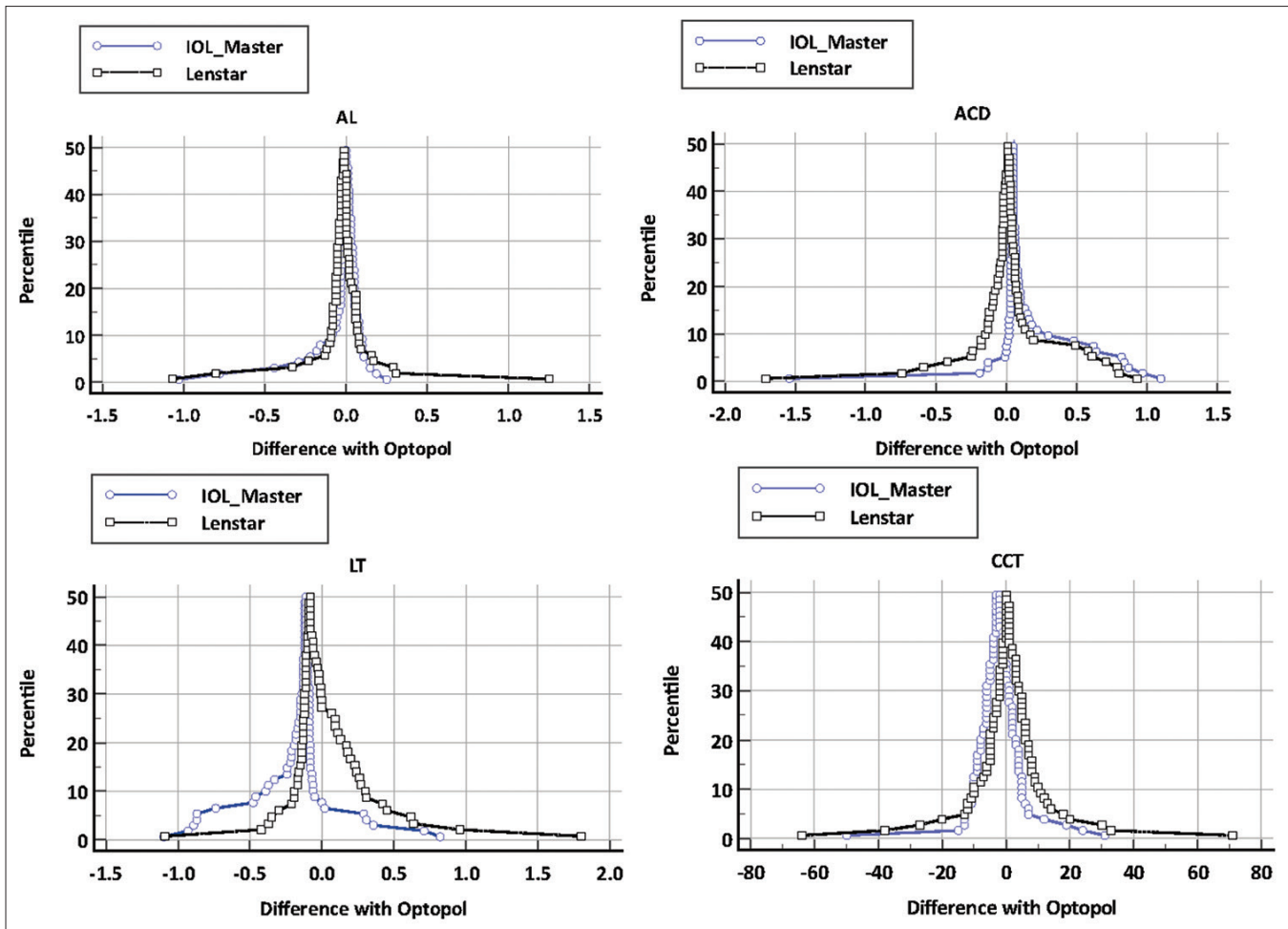


Figure 2: Mountain plots demonstrate the distribution differences between Revo NX and IOLMaster 700 and Lenstar LS 900 measurements. IOL: Intraocular lens, LT: Lens thickness, CCT: Central corneal thickness, ACD: Anterior chamber depth, AL: Axial length

difference of -0.001 mm to 0.01 mm for AL measurement has been reported between Revo NX and IOLMaster 700.^{3,12} In our study, the mean paired difference between AL measured by Revo NX and IOLMaster 700 was -0.02 mm. Moreover, mean difference of -0.02 mm was also found between Revo NX and Lenstar LS 900 which is similar to the results of the study by Kanclerz *et al.*,^{3,5} who found a mean difference of -0.002 to 0.11 mm when measuring AL in healthy eyes using Revo NX and Lenstar LS 900. Previous investigators have proposed a difference of 0.1 mm to be acceptable between AL measurements (almost equivalent to an error of about 0.27 D in IOL power).¹⁴

In terms of CCT, a mean difference between Revo NX and IOLMaster 700 of -2.29 μm ($P < 0.05$) was found. This is similar to previous studies reporting a mean difference between the two devices of -0.80 to -4.40 μm .^{3,12} The mean difference between Revo NX and Lenstar LS 900 was 0.73 μm which is consistent with other studies reporting a mean difference of between -0.83 and 3.80 μm .^{3,5} Although differences in CCT measurements between these devices are not clinically significant, more difference in the measured CCT using Revo

NX and IOLMaster 700 has been justified with the several-fold smaller pixel size in Revo NX.¹² The Optopol OCT Revo NX offers a resolution of 5 micrometers, which is more than four times better than the IOLMaster 700 and enables it to define the boundaries of the layers of eye tissue more accurately.¹² Due to these capabilities, more accurate measurements can be made in the eyes with structural abnormalities or pathology. In this respect, the Revo NX surpasses the IOLMaster 700 in measuring AL in irregularly structured eyes.¹² More studies on the limitations and benefits of this device in comparison with other biometry systems are needed in patients with different cataract types and severities.

With respect to ACD, the mean difference of ACD measured with Revo NX and IOLMaster 700 was 0.01 mm and 0.10 mm as measured by the Revo NX and Lenstar LS 900. Other studies have reported a mean difference between 0.003 and 0.005 mm between Revo NX and IOLMaster 700, and 0.01 and 0.05 mm between Revo NX and Lenstar LS 900.^{3,5,12} Depending on AL of the eye, a 0.25 mm error in ACD measurement results in a difference in IOL power between 0.50 and 1.0 D.¹⁵ Based on these findings, the differences in

CCT measurements between the above platforms are likely clinically insignificant.

The mean difference of LT between Revo NX and IOLMaster 700 was -0.15 mm ($P < 0.05$), which is significantly more than previous reports (0.001 – 0.002 mm).^{3,5,12} The mean difference of LT measured with Revo NX and Lenstar LS 900 was 0.001 mm, and significantly less than similar studies which report a mean difference of between 0.008 and 0.03 .^{3,5,12} The differences between our results and previous studies are likely related to the fact that our study was performed on a cataractous group of patients. Dense lens and poor fixation may contribute to the ACD and LT measurement differences found in this study compared to previous studies. However, in the clinical practice, in IOL calculation formula which use LT parameter, a difference of 0.20 mm may change the IOL power by 0.20 diopter.¹⁵ Based on these findings, statistically significant differences between Revo NX and IOLMaster 700 may not be considered clinically significant.

Previous studies showed that Revo NX SD-OCT offers high repeatability and reproducibility in measuring ACD and LT in healthy eyes.⁵ It has been also reported to have a very strong correlation with the Lenstar LS 900 biometric measurements. However, AL and ACD measured with these devices were not considered interchangeable.⁵ Similarly, we found a statistically and clinically significant difference between ACD measured with Revo NX and Lenstar LS 900 (0.10 mm), but the AL measurement was in a very good agreement. A newer version of Revo NX OCT was used in this study and there was a very good correlation between this device and IOLMaster 700 in all measured biometric parameters (according to ICC). Furthermore, narrower limit of agreement was found between parameters measured using Revo NX and IOLMaster 700 compared to the Revo NX and Lenstar LS 900.

Strengths of the study include its prospective nature, the large number of eyes included, and the inclusion of only one eye per patient. However, our study had number of limitations including lack of a healthy control group. Different grades of cataract may lead to different levels of agreement between devices. Studies on the effect of cataract grade on the agreements will be worthwhile. Although our participants were aged 50–82 years, a residual accommodation may lead to a change in the LT and consequently a change in ACD and should be controlled.

In conclusion, in the eyes with cataract, despite the higher measurement failure rate, the Revo NX biometer showed very good agreement with the IOLMaster 700 and Lenstar LS 900 validated optical biometers in measuring AL, ACD,

LT, and CCT. However, ACD and LT measurements cannot be considered interchangeable between these devices.

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Conflicts of interest

There are no conflicts of interest.

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