Repeatability and agreement in optical biometry of a new swept-source optical coherence tomography–based biometer versus partial coherence interferometry and optical low-coherence reflectometry

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PURPOSE: To estimate the repeatability of biometric parameters obtained with a new swept-source biometer and to compare the agreement with that of partial coherence interferometry (PCI) and optical low-coherence reflectometry (OLCR).

SETTING: Department of Ophthalmology, Helios Hospital Erfurt, Erfurt, Julius-Maximilians University, Würzburg, and Philipps University, Marburg, Germany.

DESIGN: Prospective comparative multicenter clinical study.

METHODS: Biometry was taken with the use of 3 different biometers: the IOLMaster 700 swept-source biometer, the PCI-based IOLMaster 500, and the OCLR-based Lenstar LS 900. Axial length (AL), anterior chamber depth (ACD), and spherical equivalent (SE) were compared between swept-source and PCI biometry and central corneal thickness (CCT) and lens thickness (LT) between swept-source and OLCR biometry. The repeatability of swept-source biometry was evaluated on the basis of 3 measurements captured for each patient.

RESULTS: One hundred twenty cataract eyes were included in the study. The mean difference between swept-source and PCI biometry for AL, ACD, and SE measurements was 4 μm $\pm$ 25 (SD), 17 $\pm$ 122 μm, and -0.001 $\pm$ 0.19 diopter (D), respectively. The mean difference between swept-source and OLCR biometry for LT and CCT measurements was 21 $\pm$ 122 μm and 0.15 $\pm$ 4.51 μm, respectively. Differences between swept-source biometry and the other devices distributed around zero without statistical significance. The standard deviation of repeatability for AL, ACD, LT, CCT, and SE was 8.8 μm, 9.8 μm, 2.3 μm, 19.5 μm, and 0.1 D, respectively.

CONCLUSIONS: Swept-source biometry showed high repeatability performance for all biometric parameters. The agreement of AL, ACD, and SE between swept-source and PCI biometry as well as that of LT and CCT between swept-source and OLCR biometry was excellent. It remains to be validated whether high repeatability shown by swept-source biometry will result in better postoperative refractive outcomes.

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The IOLMaster 700 (Carl Zeiss Meditec AG) is a new optical biometry instrument. It measures the axial length (AL), anterior chamber depth (ACD), lens thickness (LT), and central corneal thickness (CCT) as well as the corneal radii and white-to-white distance required for the calculation of the intraocular lens (IOL) refractive power.

Optical biometry based on A-scan technology was launched commercially for the first time in 1999 by Carl Zeiss with the introduction of the IOLMaster.[1] In the meantime, devices of various manufacturers applying this technology were developed. The Lenstar LS 900 (Haag-Streit), Aladdin (Topcon), OA-2000 (Tomey), AL-Scan (Nidek), and Galilei G6 (Ziemer) are in use worldwide.[2–5]

The biometric longitudinal measurement technique of most devices available on the market today is based on time-domain interferometry (A-scans).[6] Additional technologies used by devices are slitlamp or Scheimpflug imaging for anterior chamber measurement[7] as well as keratometry or Placido-based topography for corneal curvature measurement. The IOLMaster 700 uses swept-source optical coherence tomography (SS-OCT) technology[8] (laser with variable wavelength) to generate optical B-scans (optical cross-sections) to determine the biometric data of the eye. Cross-sectional visualization of the eye (in vivo imaging) and measurement of corneal and LT were added to the existing measurements of the IOLMaster 500 partial-coherence interferometry (PCI)-based biometer (Carl Zeiss Meditec AG).

The present study was performed in eyes with cataract to compare and estimate the (1) agreement of the parameters' AL, ACD, and keratometry-based spherical equivalent (SE) between SS-OCT biometry and PCI biometry, (2) agreement of the parameters LT and CCT between SS-OCT biometry and low-coherence reflectometry (OLCR) biometry, and (3) repeatability of AL, ACD, LT, CCT, and SE of the SS-OCT biometer.

MATERIALS AND METHODS

Study Design

Eyes intended for cataract surgery were included in the study. The study was performed in accordance with the European Guidelines for Good Clinical Practice and the Declaration of Helsinki of 1975 (6th revision, 2008). The study protocol was approved by the institutional review boards of the participating eye hospitals (Helios Hospital, Erfurt, Julius-Maximilians University, Würzburg, and Philipps-University, Marburg, Germany). In a prospective multicenter nonblinded approach, patients were included in this series after written consent was obtained; this followed an explicit explanation of the purpose and potential adverse side effects of the procedure. Ocular history and examination were conducted on consenting patients to determine further eligibility in the study.

Patients qualified to continue had biometric measurements with the study device (IOLMaster 700) and the comparative devices (IOLMaster 500 and Lenstar LS 900). Each study site had 1 unit of SS-OCT biometry, 1 unit of PCI biometry, and 1 unit of OLCR biometry. Only 1 eye of each patient was designated as the study eye. For patients with both eyes qualifying for inclusion, the clinical investigator decided which eye was designated as the study eye. This decision was based on the recommendation of the referring physician on which eye needed surgery first.

Data Collection

Patient examination with the 3 study devices took place in 1 session. Operators attempted to take 5 SS-OCT biometry measurements and 1 each with the PCI biometry and the OLCR biometry in the study eye. The time elapsed between measurement devices included a short break for the patient to relax vision for tear film recovery, and to avoid fatigue.

No other examinations or measurements of the eye involving contact, such as applanation tonometry or ultrasonic measurements, were conducted on the same day prior to the start of measurements with the study device and the comparison devices. No eye received medication that could influence the biometric values; for example, topical anesthesia or tear fluid substitute. No restrictions existed with regard to other medications.

The SS-OCT biometer was used to generate optical B-scan images with the following biometric parameter values: AL (mm), ACD (mm), LT (mm), and CCT (μm).

The PCI biometer was used to generate optical A-scans and slitlamp images with the following biometric parameter values: AL and ACD.

The SS-OCT and PCI biometers were used for keratometry to calculate SE.

The OLCR biometer was used to generate optical A-scans with the following biometric parameters: LT and CCT.

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Study Devices

Swept-Source Optical Coherence Tomography Biometer
The IOLMaster 700 is a computerized biometry device for measuring all distances in the human eye along the visual axis (ie, CCT, ACD, LT, and AL). The device acquires multiple measurements for each of the various eye parameters in 1 measurement-capture process and presents an average value per triggered measurement.

The length measurement is based on swept-source frequency-domain OCT enabling a 44 mm scan depth with 22 μm resolution in tissue. The speed of the length measurement system allows acquisition of full-eye length tomograms at 2000 A-scans/s. In contrast to the PCI biometry and all other optical biometry devices from various manufacturers using optical A-scans, swept-source biometry applies optical B-scan technology to determine the biometric data. The optical B-scan technology allows cross-sectional visualization of structures along the visual axis. Thus, the examiner can check whether ocular interfaces are detected correctly by the algorithm (Figure 1).

Additionally, the keratometry mode was used for calculation of the SE by projection of reflected light spots on the surface of the cornea.

Partial Coherence Interferometry Biometer
The IOLMaster 500 is the current benchmark of PCI-based biometry to measure the AL of the eye. It also detects ACD using slitlamp illumination. Generally speaking, optical A-scans are obtained along the visual axis.[A]

Optical Low-Coherence Reflectometry Biometer
The Lenstar LS 900 also acquires optical A-scans of the eye. Optical low coherence reflectometry is used to measure the biometric parameters CCT, ACD, LT, and AL along the visual axis.[B]

Statistical Analysis

The measurement results were evaluated using SPSS software (version 20, IBM). Baseline demographic observations were summarized by descriptive statistics.

Device Comparison/Agreement
For comparison/agreement, only the first of 5 SS-OCT biometry measurements was taken to analyze the difference between SS-OCT biometry and the comparison devices because this best mimics a clinical setting, in which usually only 1 scan of each type is acquired. For the parameters AL, ACD, and SE, the difference in measurements between SS-OCT biometry and PCI biometry was calculated for each eye by subtracting the value of PCI biometry from the value of SS-OCT biometry. The same was done for the parameters LT and CCT comparing SS-OCT biometry and OLCR biometry. Because of the sample size for AL and ACD and for LT and CCT, by the central limit theorem, the sample means of the differences for each of the parameters is nearly normal; therefore a t test for paired samples was performed for comparison. A P value less than 0.05

indicated a statistically significant difference between the SS-OCT biometry and PCI and OLCR biometry. The Lin concordance correlation coefficient was calculated. The 95% limits of agreement (LoA) was provided along with Bland-Altman plots.

Repeatability
To minimize dropout rates caused by missing data points, the first 3 valid of 5 measurements of the SS-OCT biometer were taken for calculation. This ensured a suitable number of measurements available for analysis.

The repeatability standard deviation (SD) was estimated by the square root of the estimated variance due to measurement error, based on the random-effect analysis of variance model. The coefficient of variability (CoV) was calculated by the quotient of the SD from repeatability and the mean of all used measurements.

RESULTS

The study comprised 120 eyes. Demographic data of the study population are summarized in Table 1.

For agreement comparison, the AL and ACD in 9 eyes and the LT and CCT in 11 eyes had to be excluded because of missing data points. Repeatability analysis was performed for 111 eyes for biometry and 107 eyes for keratometry. Nine eyes for biometry and 4 eyes for keratometry had to be excluded because of missing data or data that did not meet quality criteria (ie, biometry: retinal pathology detected on B-scan, dense vitreous floaters, insufficient opening of the lid aperture; keratometry: missing corneal spots, tear-film problems, eyelid closure).

Mean values and ranges (minimum and maximum) for all parameters are summarized in Table 2.

Agreement: Comparison of the Devices

Overall, the difference between SS-OCT biometry and the comparison devices was distributed around zero without an apparent trend (Table 3).

Figure 1. Correct detection of the ocular interfaces (cornea, lens, and retina) in a SS-OCT biometry optical B-scan.

Table 1. Demographics of the entire study population.				
Parameter	All Eyes (N = 120)	Erfurt (n = 49)	Marburg (n = 41)	Würzburg (n = 30)
Age (y)				
Mean	68.2	71.4	66.2	65.6
SD	9.89	8.7	10.8	9.2
Min	37	49	37	44
Max	89	84	89	84
Sex, n (%)				
Male	54 (45.00)	23 (46.94)	15 (36.59)	16 (53.33)
Female	66 (55.00)	26 (53.06)	26 (63.41)	14 (46.67)
Eye, n (%)				
OD	55 (45.83)	24 (48.98)	19 (46.34)	12 (40.00)
OS	65 (54.17)	25 (51.02)	22 (53.66)	18 (60.00)

Table 2. Mean values and ranges of SS-OCT biometer and comparison devices.

Device/Parameter	n	Mean ± SD	Range
SS-OCT vs PCI			
SS-OCT biometry			
AL (mm)	111	23.655 ± 1.831	20.49, 34.56
ACD (mm)	111	3.061 ± 0.418	2.03, 4.12
PCI biometry			
AL (mm)	111	23.651 ± 1.822	20.53, 34.54
ACD (mm)	111	3.044 ± 0.405	2,09, 4.08
SS-OCT vs OLCR			
SS-OCT biometry			
LT (mm)	109	4.646 ± 0.410	3.70, 5.60
CCT (μm)	109	550.20 ± 36.22	430, 655
OLCR biometry			
LT (mm)	109	4.626 ± 0.416	3.70, 5.62
CCT (μm)	109	550.20 ± 36.22	430, 655
SS-OCT vs PCI			
SS-OCT keratometry			
SE (D)	113	43.175 ± 1.326	39.36, 47.13
PCI keratometry			
SE (D)	113	43.176 ± 1.329	39.32, 47.06

ACD = anterior chamber depth; AL = axial length; CCT = central corneal thickness; LT = lens thickness; OLCR = optical low-coherence reflectometry; PCI = partial coherence interferometry; SE = spherical equivalent; SS-OCT = swept-source optical coherence tomography

The difference for each patient between the 2 devices (SS-OCT biometer and comparison devices) was tested with the *t* test for paired samples.

The *t* test showed no significant difference in any parameters; that is, AL, ACD, and SE for comparison between SS-OCT and PCI biometry and LT and CCT for SS-OCT and OLCR biometry (Table 4).

Table 4 also lists the Lin concordance correlation coefficients of the biometric parameters for the SS-OCT biometer and comparison devices. It was 1.00 for the AL and 0.96 for the ACD. Consequently,

the coefficient of determination (R^2) was high for all biometric parameters (Table 4).

Figure 2 provides the Bland-Altman plots for all parameters between SS-OCT biometry and the 2 comparison devices. The graphs show the similarity in measurements between these devices.

Repeatability

Table 5 summarizes the repeatability SD, the limits of the measurements, and the CoV for cataract eyes taken with the SS-OCT biometry. The CoV for repeatability was 0.037%. The SDs and limits of repeatability are small and acceptable for all biometric parameters.

DISCUSSION

Differences in measurements of the devices and their relevance for IOL calculation are discussed on the basis of a study by Norrby[9] of error sources in optical IOL calculation.

Axial length obtained with the new device that uses SS-OCT biometry showed a high correlation with PCI biometry AL (Lin concordance correlation). Indeed, all study eyes had a correlation of 100%. Consequently, the coefficient of determination (R^2) was very high.

The mean difference of 0.004 mm between the 2 IOLMaster devices was small. On the basis of optical calculations, a difference in AL of 0.030 mm would result in a refraction error of approximately 0.1 diopter (D) in eyes with average AL and corneal curvature. Minimum detectable changes in refraction are 0.25 D.[9] This would correspond with an AL of 0.075 mm. The 95% confidence interval (CI) is smaller than the clinically relevant value. The maximum magnitudes of lower and upper CI do not include this limit. Therefore, the difference between the 2 devices is negligible. The mean difference in AL between

Table 3. Differences in parameters between devices and LoAs.

Comparison/Parameter	n	Difference		Limits of Agreement	
		Mean ± SD	95% CI	Lower	Upper
SS-OCT vs PCI biometry					
AL (mm)	111	0.004 ± 0.025	−0.001, 0.009	−0.045	0.053
ACD (mm)	111	0.017 ± 0.122	−0.006, 0.040	−0.222	−0.222
SS-OCT vs OLCR biometry					
LT (mm)	109	0.021 ± 0.122	−0.003, 0.044	−0.219	0.260
CCT (μm)	109	0.15 ± 4.51	−0.71, 1.00	−8.69	8.99
SS-OCT vs PCI keratometry					
SE (D)	113	−0.001 ± 0.190	−0.037, 0.034	−0.374	0.371

ACD = anterior chamber depth; AL = axial length; CCT = central corneal thickness; CI = confidence interval; LT = lens thickness; OLCR = optical low-coherence reflectometry; PCI = partial coherence interferometry; SE = spherical equivalent; SS-OCT = swept-source optical coherence tomography

Table 4. Paired samples (*t* test), coefficient of determination, and Lin concordance correlation coefficient for SS-OCT biometry versus comparison devices (PCI biometry and OLCR biometry).

Parameter	*P* Value *t* Test for Paired Samples	Coefficient of Determination (R^2)	Lin Concordance Correlation
SS-OCT vs PCI			
AL (mm)	.093	1.000	1.000
ACD (mm)	.151	0.915	0.956
SS-OCT vs OLCR			
LT (mm)	.083	0.915	0.955
CCT (μm)	.735	0.985	0.922
SE (D)	.937	0.980	0.990

ACD = anterior chamber depth; AL = axial length; CCT = central corneal thickness; LT = lens thickness; OLCR = optical low-coherence reflectometry; PCI = partial coherence interferometry; SE = spherical equivalent; SS-OCT = swept-source optical coherence tomography

SS-OCT biometry and PCI biometry was smaller than the clinically relevant difference.

With the use of a *t* test for paired samples, we also compared SS-OCT biometry and PCI biometry data. The *t* test showed no significant difference in the study eyes (*P* = .093). Therefore, the difference in AL between the 2 devices is neither clinically nor statistically significant.

Lin correlation for ACD was high. All eyes had a correlation greater than 95%. Consequently, the coefficient of determination was high. This result leads to the conclusion that the devices have a good correlation between each other.

The *t* test for paired samples showed no significant difference (*P* = .151). The mean difference (0.017 mm) is clinically not relevant. The CI was compared with a clinically relevant difference. On the basis of optical calculations, a difference of ACD of 0.100 mm would lead to a change in refraction of approximately 0.15 D in eyes with an average AL and corneal curvature.[9]

As mentioned above, the smallest detectable difference in subjective refraction was 0.25 D, which corresponds to a difference of 0.167 mm in ACD. With maximum magnitudes of lower and upper CIs on the order of −0.22 mm to 0.25 mm, the differences approached clinical relevance.[9] Taking into account high repeatability shown by the SS-OCT biometer for ACD measurements, the LoA probably are due to the lower repeatability performance of the PCI biometer. The 95% CI of the present data correlates very well with published data by Shammas and Chan[10] (95% CI, −0.086 to +0.024 mm).

Lens thickness is a parameter that was implemented in an IOLMaster device for the first time. Therefore, the

LT of the SS-OCT biometer biometry was compared with the LT of the OLCR biometer.

The coefficient of determination was high. Both devices had a very good correlation. The mean difference of 0.021 mm between the LT measured by the 2 devices is small. This value is far below clinical relevance. On the basis of common IOL calculation formulas, even changes in LT of up to 50 μm would not lead to a different result in IOL power. Furthermore, the *t* test for comparison showed no statistical significance (*P* = .083). However, maximum magnitudes of lower and upper CIs were on the order of −0.22 mm to 0.26 mm. It is more likely that the relatively high limits were due to the predicate device, the OLCR biometer (see repeatability data). The new SS-OCT biometer performed with very high repeatability, which is likely to have a beneficial effect on IOL power calculation for formulas that depend on LT.

Central corneal thickness is the second parameter that could be measured with the SS-OCT biometry device for the first time. The measurement of CCT was compared between that biometer and the OLCR biometer.

The Lin concordance correlation was greater than 92%. The 2 devices showed a very good correlation. The *t* test for paired samples did not reveal any statistical significance (*P* = .735). The mean differences between the CCT measurements of both devices were very small (0.15 μm).

Central corneal thickness has little influence on IOL power. However, there are several clinical implications, depending on accurate measurements of CCT.

Central corneal thickness values are important for correct measurement of intraocular pressure (IOP) in glaucoma patients. Kohlhaas et al.[11] confirm that the difference between measured and real IOP was significantly dependent on CCT (*P* < .001). The association between IOP readings and CCT states an approximately 1 mm Hg correction for every 25 μm deviation from a CCT of 550 μm. Normally hydrated, thicker corneas lead to higher readings and thinner corneas to lower readings. Kohlhaas et al.[11] state a value of ±1.5 mm Hg as clinically relevant, which complies with a CCT value of approximately ±37.5 μm. Furthermore, each 40 μm decrease in CCT is associated with a relative risk of 1.71 for the development of primary open-angle glaucoma.[12]

Central corneal thickness measurement is critical in preoperative assessment for keratorefractive surgery. It is important when considering patient eligibility for corneal refractive surgery to avoid postoperative complications such as ectasia. A preoperative CCT thinner than 500 μm is a relative contraindication to microkeratome laser in situ keratomileusis.[12]
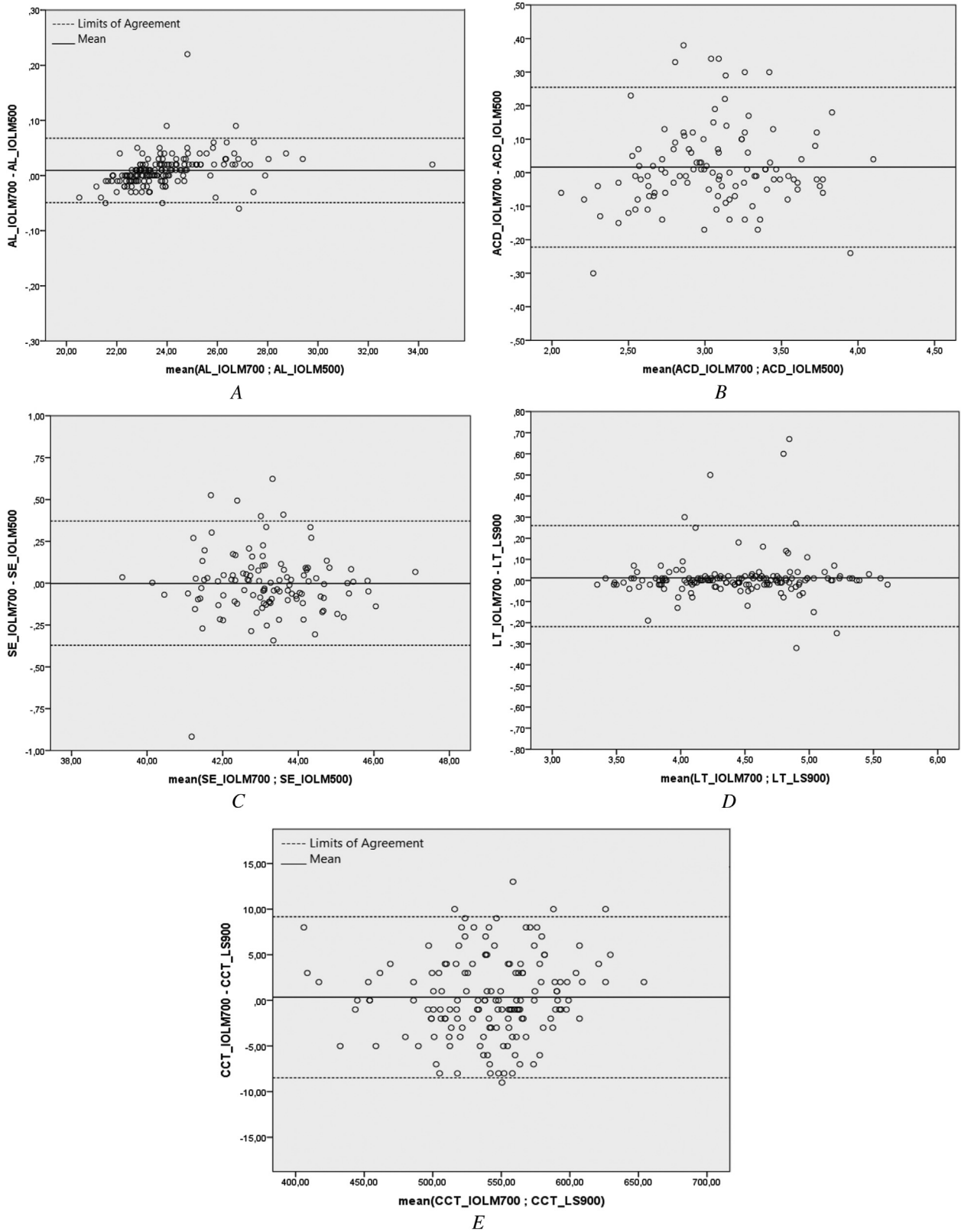
Figure 2. Bland-Altman plots of the difference in AL (mm) (*A*), ACD (mm) (*B*), and SE (D) (*C*) between SS-OCT biometry and PCI biometry and of the difference for LT in (mm) (*D*) and CCT (μm) (*E*) between SS-OCT biometry and OLCR biometry (ACD = anterior chamber depth; AL = axial length; CCT = central corneal thickness; LT = lens thickness; OLCR = optical low-coherence reflectometry; PCI = partial coherence interferometry; SE = spherical equivalent; SS-OCT = swept-source optical coherence tomography).

Table 5. Repeatability of SS-OCT biometry.

Parameter	n	Mean*	Repeatability		
			SD	Limit	CoV (%)
AL (mm)	111	23.656	0.0088	0.0247	0.03
ACD (mm)	111	3.061	0.0098	0.0274	0.320
CCT (μm)	111	550.16	2.2621	6.3339	0.411
LT (mm)	111	4.653	0.0195	0.0547	0.420
SE (D)	107	43.134	0.1005	0.2814	0.233

ACD = anterior chamber depth; AL = axial length; CCT = central corneal thickness; LT = lens thickness; Repeatability CoV = Coefficient of Variation = Repeatability SD ÷ Mean (× 100); Repeatability Limit = 2.8 × Repeatability SD; Repeatability SD = standard deviation under repeatability; SE = spherical equivalent
*Estimated general mean in the random analysis of variance model for the repeatability and reproducibility calculation

Natural fluctuations in the CCT at different times of the day should also be considered. Corneal thickness varies about a few microns over a day, in single cases up to 20 μm.

In our dataset, the maximum magnitudes of the lower and upper CI as well as the mean differences between the devices are far below the limits mentioned above.

The calculation of *P* values by means of the *t* test revealed no statistically relevant difference in SE between the 2 measuring devices ($P = .937$). The mean difference was −0.001 D, which is far below the smallest by the subjective refraction detectable value of 0.25 D and therefore is not clinically relevant.[13]

The coefficient of determination was high (99.0%). The LoA were −0.374 D to 0.371 D (width 0.745 D). These values are comparable with another study conducted by Mehravaran et al.,[14] who performed keratometry measurements with 5 different devices in 42 healthy eyes. The mean K value (calculation equivalent to SE) showed the smallest LoA for the difference of the devices: Topcon 8800 (Topcon) and IOLMaster 500 with 0.32 D to 0.26 D (width 0.58 D). Both devices showed a difference similar to that in the present study (−0.03 D) and a high correlation (0.994). By taking into consideration that Mehavaran et al. examined young and healthy eyes exclusively (mean age 31.74 ± 6.82 years), the present data from cataract eyes show very good results and even the LoAs are clinically acceptable LoA. Browne and Osher[15] confirm these findings with a range of LoA of ±0.327 D measured in 87 eyes planned for toric IOL implantation.

Axial length shows a very good SD of repeatability of 0.0088 mm for cataract eyes (n = 111), the main

target group of measurements with an optical biometry device. This value lies below the published repeatability value of the PCI biometer, with an SD of ± 0.025 mm[1,A] and the SD of the comparison OLCR device, with ±0.037 mm (as stated in the current manufacturer's brochure).[B] The CoV was 0.037% for repeatability. This is below the CoV of the AL-Scan biometry device, published by Huang et al.[16] of 0.08%.

The SD of repeatability for the parameter CCT was also very small, with a value of 0.0023 mm and a CoV of 0.411%. This value is comparable with the Lenstar in vivo repeatability of 0.002 mm.[B] The CoV is almost equivalent to the 0.37% reported by Huang et al.[16] for the AL-Scan.

The current analysis shows a very good SD of repeatability for the ACD. With a value of 0.0098 mm for all 111 cataract eyes, the SS-OCT biometry is far below the published values for the PCI biometer (±0.033 mm)[5] and the OLCR biometer (±0.040 mm).[A] The CoV of 0.320% is far below the published CoV for the AL-Scan (0.48% and 0.64%).[16]

Lens thickness resulted in very good repeatability SDs of 0.0197 mm. In contrast to these values, OLCR biometry had an in vivo repeatability of 0.080 mm.

It remains to be validated whether the high repeatability shown by the SS-OCT biometer will result in better postoperative outcomes. However, image-based acquisition to visually verify the correct measured structures probably will result in fewer refractive surprises, especially in challenging cases.

The SE was repeatable, with SDs of repeatability of 0.10 D for all 107 cataract eyes. The limit of repeatability is 0.1 D. A spherical value of 0.25 D is the smallest detectable value by subjective measurement. Therefore, these values are clinically acceptable and not relevant. The CoV of 0.21% is comparable to findings of Huang et al.,[16] who found a CoV of 0.26%.

In conclusion, in general, the results of SS-OCT biometry yielded very good comparability to the comparison devices that use PCI biometry and OLCR biometry, although there was slight variation in individual parameters.

Because there was no statistically significant difference in the SE measured with the IOLMaster 700 and IOLMaster 500, the keratometry of both devices is equivalent and ULIB (User Group for Laser Interference Biometry) compatibility is given.

In summary, the new SS-OCT biometer consistently delivered results with the same degree of accuracy as established biometry devices. In contrast to the PCI biometry and the OLCR biometry devices, the SS-OCT biometer had higher repeatability performance for all parameters.

WHAT WAS KNOWN

- Optical biometry has become the method of choice for the selection of an appropriate IOL after cataract extraction.

- Current optical biometry is based on optical A-scans.

- This technique offers accurate and reproducible measurements for cataract biometry assessments.
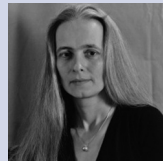
WHAT THIS PAPER ADDS

- The SS-OCT biometer showed high repeatability for all biometric parameters.

- Agreement between the SS-OCT biometer and the comparison devices (optical A-scan biometers) was excellent for the evaluated biometric measurements.

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