



REPEATABILITY OF THE NEW SWEEP SOURCE OPTICAL BIOMETER IOLMASTER® 700 MEASUREMENTS

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ABSTRACT

Purpose: The Zeiss IOLMaster®700 is a new optical biometer device which measures axial length (AL), anterior chamber depth (ACD), central corneal thickness (CCT), lens thickness (LT), white-to-white (WTW), and keratometry (K) by using swept source technology. This study aims to evaluate the repeatability of measurements of intraocular distances using the Zeiss IOLMaster®700.

Design: Prospective study.

Participants: Ninety-three eyes (46 right, 47 left) of 48 healthy volunteers (26 women, 22 male; median age 35 years; age range 21–58 years) were enrolled into the study.

Main outcome measures: Five consecutive measurements of AL, ACD, CCT, LT, WTW and K were performed by one examiner using the optical biometer the Zeiss IOLMaster®700. Five repeated measurements, each with six shots, were performed in a sequence. Intraclass correlation coefficient values were calculated for agreement, and standard error of measurement and repeatability coefficients were calculated for repeatability of of measurements for each parameter.

Results: There was strong or very strong agreement between five repeated measurements for all parameters (intraclass correlation coefficient range 0.725–1.00, $p < 0.001$ for all) with minimum standard error of measurement and high repeatability coefficients.

Conclusions: The Zeiss IOLMaster®700 optical biometer device showed good agreement and repeatability in measuring AL, ACD, CCT, LT, WTW and K in healthy eyes, thus can be used in clinical practice.

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INTRODUCTION

Cataract is the most important cause of blindness in the world, especially in older age groups.¹ Improvement with intraocular lens (IOL) technology and introduction of premium IOL's (e.g., presbyopia correcting or toric IOL) along with femtosecond laser assisted cataract surgery made cataract surgery a part of refractive surgery. However, residual refractive errors after refractive IOL procedure commonly cause patient dissatisfaction particularly in younger age. Higher expectations of postoperative precise refraction and visual outcome necessitate accurate biometric measurements and IOL power calculations.²⁻⁴

Since introduction of IOLMaster (Carl Zeiss Meditec AG, Germany) to the market in 1999, optic biometers become more popular for IOL power measurements in modern cataract surgery than ultrasound biometers. The IOLMaster®500 uses partial coherence interferometry (PCI) with a 780 nm laser diode infrared light to measure axial length

(AL), corneal curvature, white-to-white (WTW) and anterior chamber depth (ACD) without assessment of cornea, crystalline lens or retinal thickness. In 2008, a new biometry device that uses optical low coherence reflectometry (OLCR), the Lenstar LS900® (Haag Streit AG)/Allegro Biograph (WaveLight AG), have been developed for measuring AL, ACD, central corneal thickness (CCT), lens thickness (LT), retinal thickness, keratometry (K), pupil size, and the WTW distance.^{5,6}

IOL measurements with both PCI and OLCR biometers can be difficult in cases of macular degeneration, tear film instability, amblyopia, glaucoma, corneal pathology, dense mature or posterior subcapsular cataract, vitreous opacities and hemorrhage, retinal detachment, head tremor, and inability to position the patient at the device (4-21% of cataract patients).⁷

The Zeiss IOLMaster®700 utilizing new swept source (SS) technology offers the advantages of measuring full-length of eye from the cornea to the retina on a longitudinal cut. The measurement range for the AL is reported to be 14-38 mm, for ACD 0.7-8.0 mm, for corneal radii 5–11 mm, for LT 1–10

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mm (phakic eye) and 0.13-2.5 mm (pseudophakic eye), for WTW 8–16 mm, and for CCT 200–1200 μm. The SS technology provides clear advantages over the PCI and OLCR systems, including the possibility of detecting unusual eye geometries, such as a tilt or decentration of the crystalline lens and extremely rapid data acquisition, and the ability to measure the AL along six different axes. Furthermore, imaging of the fovea in the macula reduces the risk of refractive surprises due to incorrect measurements caused by undetected poor fixation.^{8,9} In this study, we aimed to evaluate the repeatability of the new SS optical biometer, the Zeiss IOLMaster®700, in a clinical setup based on biometric measurements of healthy population.

METHODS

Study population

Ninety-three eyes of 48 healthy subjects with phakic eyes (26 women, 22 male; median age 35 years; age range 21–58 years) who applied to Bahcesehir University Department of Ophthalmology for regular ophthalmological assessment between October 2016 and November 2016 were prospectively studied. The patients who were unable to cooperate to biometric measurements, and whose eyes had corneal opacities or vitreoretinal pathologies, which could be interfered with readings, were excluded from study. The study was approved by the Institutional Ethics Committee of Marmara University (May/6th/2016; 09.2016.303) and conducted in accordance to with the latest version of the Declaration of Helsinki. The participants were given information on the study and signed informed consent before any study-related procedures.

Ophthalmological assessment and biometric measurements

All the patients were examined by the same ophthalmologist (OMGT). Of 93 eyes evaluated, 46 were right eyes (49.5%) and 47 left eyes (50.5%). The following parameters were measured for each eye with the optical biometer the Zeiss IOLMaster®700: AL, ACD, CCT, LT, WTW, and K. IOL measurement is provided automatically for SA60AT with SRK-2 formula.¹⁰ Five repeated measurements, each with six shots, were performed in a sequence by one examiner (OMGT) at between 9:00 and 12:00 am in one eye of each volunteer before pupillary dilatation to evaluate the repeatability of the the Zeiss IOLMaster®700. It was ensured that after each measurement the head of the volunteer was positioned on the chin rest, and the biometer was realigned.

Statistical analysis

The study data were summarized as mean±standard deviation. The box-and-whisker plots were drawn for each parameter to summarize the readings of five repeated measurements. Each measurement consisted of six shots and the mean value (MEAN) and standard deviation (SD) of the readings for these six shots were displayed automatically at the end of the measurement for all parameters. The average (meanMEAN) and standard deviation (sdMEAN) of MEANs of five repeated measurements were calculated in order to display overall description and variations of measurements. The average of SDs (meanSD) of five repeated measurements was also calculated to condense the standard deviations of all measurements. The biometric measurement plan for each eye and summary of descriptive statistics were given in Figure 1.

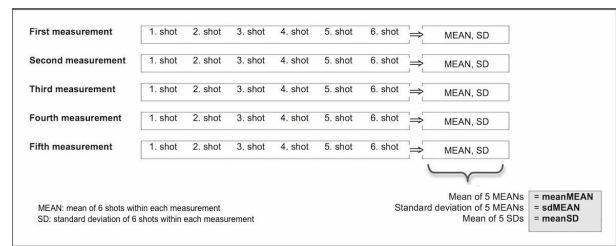


Figure 1 The biometric measurement plan for each eye with the Zeiss IOLMaster®700.

The agreement between repeated measurements with the Zeiss IOLMaster®700 device for AL, ACD, LT, CCT, K, K1, K2, WTW and SA60AT was assessed by intraclass correlation coefficient (ICC) from two-way mixed model, and presented with 95% confidence interval (CI) for each side separately because of the assumption of independence observations in ICC. The correlations between the study parameters were evaluated by Pearson correlation test or Spearman rho correlation test. Standard error of measurement (SEM) and repeatability coefficients (RC) were calculated for repeatability of AL, ACD, LT, CCT, K, K1, K2, WTW and SA60AT measurements as suggested in literature for repeatability studies. Statistical analysis was performed using IBM SPSS Statistics 21.0 commercial statistical analysis software program (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, New York, USA). The p values less than 0.05 were considered statistically significant.

RESULTS

The readings for all parameters obtained from each of five repeated measurements were summarized in Figure 2 indicating that none of the parameters show a drift from the first to last measurement. The descriptive statistics obtained from five repeated measurements overall were given in Table 1

Table 1 Descriptive statistics of the study parameters

	meanMEAN	sdMEAN	meanSD
AL (mm)	24.01±1.35	0.01±0.02	6.03±1.98
ACD (mm)	3.53±0.46	0.01±0.01	7.26±1.85
LT (mm)	3.88±0.30	0.01±0.02	12.96±6.72
CCT (μm)	525.43±36.85	2.09±1.22	3.52±0.54
K (D)	43.06±1.71	0.10±0.16	3.24±1.45
K1 (D)	42.64±1.65	0.10±0.08	5.06±2.17
K2 (D)	43.48±1.80	0.12±0.07	5.49±2.66
WTW (mm)	12.29±0.39	0.12±0.20	–
SA60AT (D)	20.01±3.96	0.11±0.13	–

MEAN and SD refer to the mean and standard deviation of six shots within each measurement, respectively. Within a sequence of five repeated measurements, meanMEAN is the average of the five MEANs, sdMEAN is the standard deviation of the five MEANs, and meanSD is the average of the five SDs. Data are presented as mean±standard deviation. AL, axial length; ACD, anterior chamber depth; CCT, central corneal thickness; LT, lens thickness; WTW, white-to-white; K, keratometry.

The meanMEAN and sdMEAN values of study parameters suggest that there was limited variability between five measurements.

Agreement and repeatability of biometric measurements

There was strong or very strong agreement between five repeated measurements for all parameters (ICC range 0.725–1.00, p<0.001 for all) with minimum SEM and high RC (Table 2). Thus, the Zeiss IOLMaster®700 measurements showed good agreement and repeatability in AL, ACD, LT, CCT, K, K1, K2, and SA60AT.

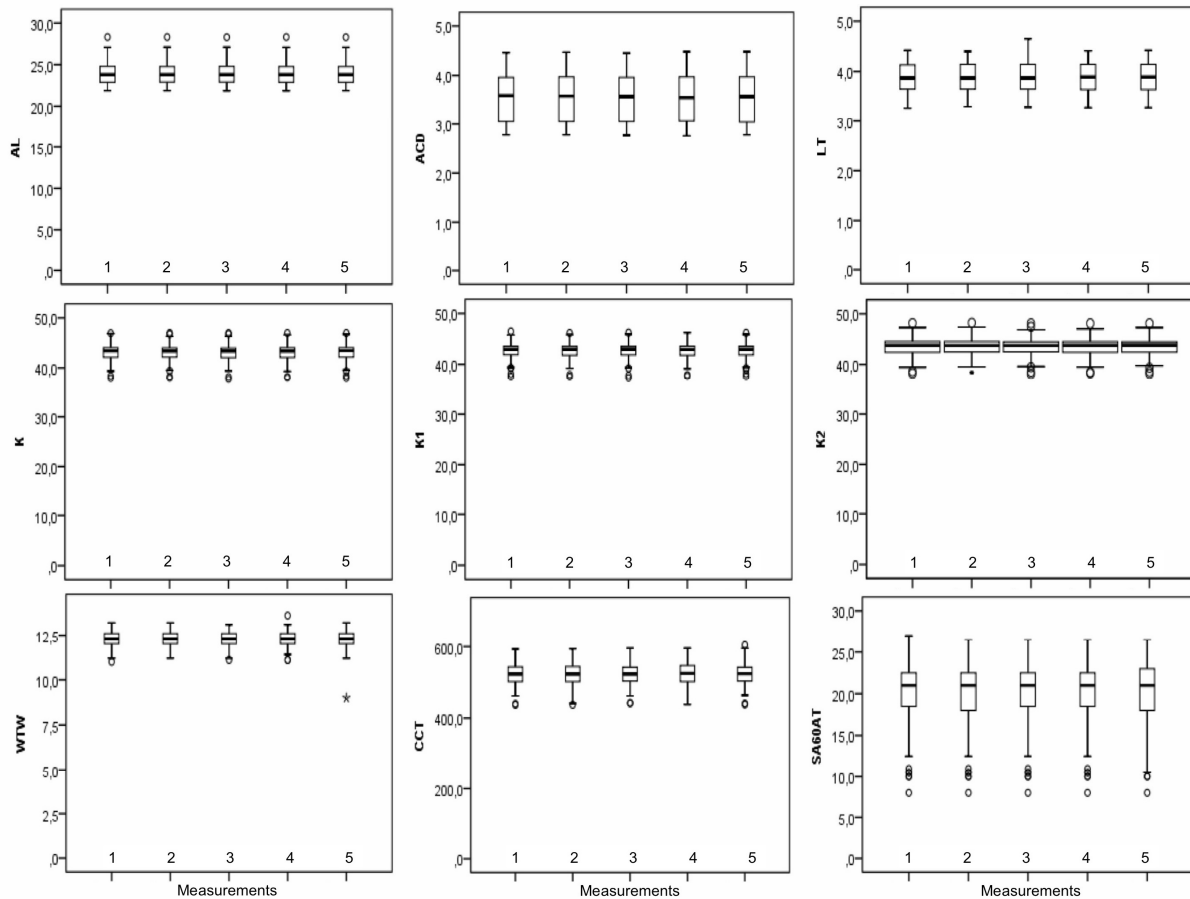


Figure 2 The box-and-whisker plots of five repeated measurements for each parameter. The horizontal line within the box indicates the median, boundaries of box indicate the 25th and 75th percentile, and the whiskers indicate the highest and lowest values of the results. The mild outliers are marked with open circles and extreme outliers with asterisks (*). AL, axial length; ACD, anterior chamber depth; CCT, central corneal thickness; LT, lens thickness; WTW, white-to-white K, keratometry.

Table 2 ICC, SEM and RCs of the parameters

Parameters	Agreement			Repeatability	
	ICC	95%CI of ICC	p	SEM	RC %95CI of RC
AL (mm)					
Right	1.000	1.000-1.000	<0.001	0.016	0.031 0.026-0.039
Left	1.000	0.999-1.000	<0.001	0.089	0.175 0.117-0.176
ACD (mm)					
Right	0.999	0.999-1.000	<0.001	0.038	0.074 0.061-0.093
Left	0.999	0.999-0.999	<0.001	0.038	0.074 0.061-0.092
LT (mm)					
Right	0.993	0.990-0.996	<0.001	0.070	0.137 0.114-0.173
Left	0.995	0.992-0.997	<0.001	0.061	0.120 0.100-0.150
CCT (µm)					
Right	0.995	0.993-0.997	<0.001	7.020	13.760 11.434-17.283
Left	0.996	0.994-0.998	<0.001	6.624	12.984 10.808-16.263
K (D)					
Right	0.978	0.966-0.986	<0.001	0.710	1.392 1.157-1.748
Left	0.998	0.996-0.998	<0.001	0.247	0.484 0.403-0.607
K1 (D)					
Right	0.993	0.990-0.996	<0.001	0.385	0.754 0.626-0.947
Left	0.995	0.992-0.997	<0.001	0.334	0.655 0.545-0.820
K2 (D)					
Right	0.994	0.991-0.996	<0.001	0.386	0.757 0.629-0.951
Left	0.995	0.992-0.997	<0.001	0.390	0.765 0.637-0.958
WTW (mm)					
Right	0.814	0.735-0.880	<0.001	0.498	0.976 0.811-1.226
Left	0.664	0.550-0.771	<0.001	0.779	1.526 1.271-1.912
SA60AT (D)					
Right	0.998	0.997-0.999	<0.001	0.457	0.895 0.744-1.125
Left	0.998	0.997-0.999	<0.001	0.492	0.965 0.804-1.209

AL, axial length; ACD, anterior chamber depth; CCT, central corneal thickness; CI, confidence interval; ICC, intraclass correlation coefficients; LT, lens thickness; RC, repeatability coefficients; SEM, standard error of measurement; WTW, white-to-white; K, keratometry.

Correlation between parameters

The meanMEAN of AL showed significant and strong correlation with the meanMEAN of ACD ($r_s=0.764$, $p<0.05$), WTW ($r_s=0.512$, $p<0.05$), and SA60AT ($r_s=-0.910$, $p<0.05$). The meanMEAN of ACD was also negatively and strongly correlated with the meanMEAN of SA60AT ($r_s=-0.844$, $p<0.05$). There was not any significant and remarkable correlation between meanMEAN and sdMEAN values of parameters except strong correlation between K, K1, and K2 parameters, which are closely related. The results of correlation analysis were given in Table 3.

DISCUSSION

Precise biometric measurement is the decisive step in order to reach target postoperative refraction in cataract surgery.¹²⁻¹⁴ In assessment of a new optic biometer, the most crucial step is the consistency of the measurement results. In the present study, we showed that biometric measurements obtained by the new SS optical biometer, the Zeiss IOLMaster[®]700, have high repeatability for AL, ACD, CCT, LT, WTW and K values in healthy subjects.

For achieving optimal postoperative results in cataract surgery, accurate AL, ACD, CCT, LT, WTW and K measurements are essential parameters for the calculation of the appropriate IOL power.¹⁵ In 1999, the first optical biometer IOLMaster (Carl Zeiss Meditec AG) was introduced into the ophthalmology.

Table 3 Spearman rho correlation coefficients between meanMEAN and sdMEAN of study parameters

		meanMEAN									sdMEAN								
		AL	ACD	LT	CCT	K	K1	K2	WTW	SA60AT	AL	ACD	LT	CCT	K	K1	K2	WTW	SA60AT
meanMEAN	AL	1.000	0.764	-0.376	-0.209	-0.317	-0.365	-0.292	0.512	-0.910	0.165	-0.063	-0.176	-0.126	-0.258	-0.195	-0.171	0.049	-0.194
	ACD	-	1.000	-0.645	0.052	-0.002	0.069	0.412	-0.290	-0.844	0.198	-0.032	-0.114	-0.150	-0.237	-0.238	-0.129	0.079	-0.050
	LT	-	-	1.000	-0.110	-0.081	-0.106	-0.097	0.126	0.431	-0.013	-0.111	-0.116	0.059	0.117	0.156	0.028	-0.135	0.001
	CCT	-	-	-	1.000	-0.084	-0.101	-0.087	-0.195	0.280	-0.041	0.042	0.012	0.047	-0.014	0.118	0.137	0.209	-0.100
	K	-	-	-	-	1.000	0.972	0.989	-0.461	-0.036	-0.051	-0.130	-0.094	0.033	0.052	0.030	0.063	0.011	0.038
	K1	-	-	-	-	-	1.000	0.942	0.501	0.023	-0.065	-0.122	-0.075	0.060	0.084	0.054	0.054	-0.027	0.054
	K2	-	-	-	-	-	-	1.000	-0.468*	-0.060	-0.047	-0.119	-0.077	0.038	0.028	0.033	0.075	0.026	0.023
	WTW	-	-	-	-	-	-	-	1.000	-0.326	-0.015	-0.052	-0.037	0.008	-0.170	-0.077	-0.069	-0.054	-0.198
	SA60AT	-	-	-	-	-	-	-	-	1.000	-0.173	0.094	0.205	0.160	0.252	0.216	0.146	-0.058	0.151
	sdMEAN	AL	-	-	-	-	-	-	-	-	1.000	0.023	-0.012	0.098	-0.046	-0.080	-0.048	0.042	0.130
ACD		-	-	-	-	-	-	-	-	-	1.000	0.685	0.384	0.162	0.077	0.154	0.043	-0.021	
LT		-	-	-	-	-	-	-	-	-	-	1.000	0.342	0.069	0.003	0.069	-0.048	-0.050	
CCT		-	-	-	-	-	-	-	-	-	-	-	1.000	0.078	0.103	0.153	-0.246	-0.026	
K		-	-	-	-	-	-	-	-	-	-	-	-	1.000	0.658	0.678	-0.250	0.307	
K1		-	-	-	-	-	-	-	-	-	-	-	-	-	1.000	0.514	-0.209	0.201	
K2		-	-	-	-	-	-	-	-	-	-	-	-	-	-	1.000	-0.213	0.120	
WTW		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1.000	-0.026	
SA60AT		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1.000	

This non-contact optical biometry has become gold standard because of higher precision, greater reproducibility and ease of use. Besides, this technology provided a reduced risk for trauma and infection, increased patient comfort, operator independency when compared with applanation ultrasound biometry. Optical biometry utilizes a laser for the signal transmission. Interference phenomenon between the reflected signal and reference signal is utilized to determine distances between interfaces. Measurements can be difficult in cases with macular degeneration, tear film instability, amblyopia, glaucoma, corneal pathology, dense mature or posterior subcapsular cataract, vitreous opacities and hemorrhage, retinal detachment, head tremor, and inability to position the patient at the device, which is seen in 4-21% of cataract patients.⁷

Optical biometers are superior to applanation ultrasound biometry in the measurement of posterior staphylomas, pseudophacic and silicone filled eyes. Optical biometers can achieve 20 µm precision as compared 100 µm with applanation ultrasound biometry in measurements of AL. IOLMaster®500 uses PCI with a 780 nm laser diode infrared light to measure AL, K, WTW, and ACD without assessment of corneal, crystalline lens or retinal thickness. ALScan® optical biometer (Nidek Co., Ltd., Aichi, Japan) also uses PCI technology with an 830 nm infrared laser diode for AL measurement.

In 2008, a new biometry device that uses OLCR, the LenstarLS900® (Haag Streit AG)/Allegro Biograph (WaveLight AG), was introduced. In addition to AL, OLCR system measures ACD, CCT, LT, and retinal thickness, K, pupil size, and WTW. Aladdin® (Topcon, Tokyo, Japan), OA-1000® (Tomey, Japan) also works according to OLCR principle and uses 820-850 nm superluminescent diode. Recently, real time imaging of entire eye in two or three dimensions with high speed and resolution come into practice of ophthalmologist with ultra-long scan depth optic coherence tomography (OCT) and SS-OCT for not to be influenced by changes due to accommodation during measurement with PCI and OLCR. Ultra-long scan depth OCT uses the light source as an 840 nm wavelength superluminescent diode with 7.7 µm resolution with drawback of shallower penetration depths because of shorter wavelength.¹⁶

In SS-OCT, the layer depth of the optical interfaces is determined by a wavelight-tunable laser source which sequentially emits various frequencies in time and a photodiode as the interference spectrum detector with the advantages of higher measuring depth (12–40 mm) with increased signal quality (<10µm) and a shorter measurement time (>100 Hz) combined with a higher signal-to-noise ratio.

Grulkowski et al.¹⁷ demonstrated that SS-OCT operates at the central wavelength of 1065 nm utilizing vertical-cavity surface emitting laser technology enables long range OCT imaging of posterior segment ocular structures and all of the parameters necessary for modern IOL power formulas. The SS-OCT promises to improve IOL power calculation and the refractive outcomes of cataract surgery even in patients with severe cataracts with volumetric full eye length biometry.^{17,18}

Recently the Zeiss IOLMaster®700 utilizing SS-OCT came into the market providing a full-length OCT image showing anatomical details on a longitudinal cut through the entire eye allowing detection of unusual eye geometries, such as a tilt or decentration of the crystalline lens. The company promises outstanding repeatability of the Zeiss IOLMaster®700 with 2000 scans per second and telecentric, and thus distance-independent, keratometry especially with restless patients.¹⁹ In our study reproducibility values of the Zeiss IOLMaster®700 for AL, ACD, CCT, LT, WTW and K measurements are excellent. In a ranking, the repeatability of AL was best (ICC=1.000), followed by ACD (ICC=0.999), SA60AT (ICC=0.998), CCT (ICC=0.996), LT, K1, K2 (ICC=0.994), K (ICC=0.988) and WTW (ICC=0.725). Reproducibility with other optical biometers leads to similar results. In a recently conducted clinical study in a sample of 32 eyes, in comparison to the Aladdin® platform and the OA-2000®, the Zeiss IOLMaster®700 revealed higher repeatability of AL, ACD, and LT measurements.²⁰

As expected, AL had positive correlation with ACD and WTW; and negative correlation with SA60AT, since as eyes get larger (myopic eyes), the ACD and cornea diameters increase and IOL diopters decrease.

The main limitation of our study was the evaluation of only healthy volunteers aged 21–58 years, which precludes us commenting on patients with cataract or elderly population. The limitation of optical biometers that need to be noted is their inability to measure AL and ACD in eyes with densely

opacified media. In the IOLMaster®500 this can be overcome by connecting it to an ultrasound probe that can provide AL measurements in those eyes with very dense corneal leukomas and/or cataracts.²¹ Additionally, other values can be entered manually. Thus, almost any type of eye can be measured with this combined technology. Moreover, with the newly available the Zeiss IOLMaster®700, featuring SS-OCT measurement, it has been shown that necessary ultrasound cases could be reduced by 92%, achieving a cataract penetration rate of 99%.²²

In conclusion, the Zeiss IOLMaster®700 optical biometer device showed good agreement and repeatability in measuring AL, ACD, CCT, LT, WTW and K in healthy eyes, thus can be used in clinical practice.

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