

# Evaluation and comparison of a novel Scheimpflug-based optical biometer with standard partial coherence interferometry for biometry and intraocular lens power calculation

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**Abstract.** In the present study, the axial length (AL), corneal curvature, anterior chamber depth (ACD) and white-to-white (WTW) distance were assessed using the Pentacam AXL (Oculus Optikgeraete GmbH), a novel Scheimpflug-based optical biometer with standard partial coherence interferometry (PCI). The Pentacam AXL and PCI biometer (IOLMaster 500; Carl Zeiss AG) were compared in terms of their intraocular lens (IOL) power calculations. The medical records of patients (eyes, n=190) who underwent cataract surgery were retrospectively reviewed. Biometry measurements involved the eyes of patients with cataract and were performed by the same examiner with the Pentacam AXL biometer and the IOLMaster 500 device. Following determination of the AL, mean keratometry (Km), ACD and WTW distance, the IOL power calculation was compared between the two devices using the Sanders, Retzlaff and Kraff theoretical (SRK/T) and Haigis formulas. The AL, Km and WTW values for the Pentacam AXL group were significantly lower compared with those of the IOLMaster 500 group. The difference was  $-0.02\pm 0.04$  mm,  $-0.20\pm 0.28$  D and  $-0.10\pm 0.20$  mm, respectively ( $P<0.001$ ). The ACD for the Pentacam AXL group was higher compared with that of the IOLMaster 500 group with a difference of  $0.02\pm 0.13$  mm ( $P=0.13$ ). The IOL power calculated using the SRK/T and

Haigis formulas exhibited significant differences between the two devices ( $t=11.48$  and  $10.97$ , respectively;  $P<0.001$ ). In conclusion, the AL, ACD, WTW measurement and IOL power indicated optimal agreement and strong correlations between the two devices. However, constant optimization may be necessary for the novel biometer Pentacam AXL.

## Introduction

The advancement of modern technology has enabled the improvement in the quality of vision in numerous patients. In certain cases, cataract surgery, which is a form of refractive surgery, has also been performed. Patients have higher expectations for accurate refractive outcomes and consequently, biometry measurement and intraocular lens (IOL) power calculations have become increasingly important in ophthalmic practice (1). Multiple methods of measuring biometry data have been used to calculate the IOL power required for implantation. Ultrasound biometry, including indirect infiltration and direct contact measurement, has been widely used for several decades (2). The IOLMaster (Carl Zeiss AG) is the first optical biometry device based on partial coherence interferometry (PCI), which was introduced for the first time in 1999. It has the advantages of being a noncontact technique and objectively determining biometry measurements without the risk of infection and indentation. Therefore, it is considered the gold standard for biometry measurement and IOL power calculations (3).

The Pentacam AXL is a novel device for biometry that has the advantages of the Pentacam HR (both from OCULUS Optikgeraete GmbH). In addition, it contains a Scheimpflug-based anterior segment topographer and may be used to perform PCI-based axial length (AL) measurements (4). The device measures a range of biometry data, including anterior and posterior corneal curvature, topography, pachymetry, corneal and pupillary diameter, anterior chamber depth (ACD), lens density and AL. It also provides formulas for the calculation of the IOL power. The major difference between the Pentacam AXL and the IOL Master is that the anterior segment parameters measured by the Pentacam AXL are based on a Scheimpflug image (5).

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*Abbreviations:* AL, axial length; ACD, anterior chamber depth; WTW, white-to-white; Km, keratometry; IOL, intraocular lens; PCI, partial coherence interferometry; LED, light-emitting diode; LoA, limits of agreement

*Key words:* corneal curvature, anterior chamber depth, keratometry, IOLMaster, IOLMaster 500

Due to this difference, it is essential to evaluate the accuracy of the data generated by this novel biometry device before it becomes widely available for preoperative cataract examination. Thus, the purpose of the present study was to evaluate the AL, mean keratometry (Km), ACD and white-to-white (WTW) measurements of the Pentacam AXL biometer. In this investigation, the Pentacam AXL was considered the novel biometer and the IOLMaster 500 was the reference biometer. Furthermore, the accuracy of IOL power calculations was assessed using the Sanders, Retzlaff and Kraff theoretical (SRK/T) and Haigis formulas.

## Subjects and methods

**Subjects.** The present prospective study was performed at the Department of Ophthalmology of Beijing Tongren Hospital, Capital Medical University (Beijing, China). A total of 190 patients scheduled for cataract surgery between October 2018 and February 2019 were included in the present study. The study was performed in accordance with the guidelines of the Declaration of Helsinki and was approved by the ethics committee of Beijing Tongren Hospital, Capital Medical University (Beijing, China; approval no. TRECKY2018-049). Each patient was informed of the procedures involved and provided the relevant written informed consent.

The following inclusion criteria were used: i) Patients who underwent cataract surgery; ii) patients with good fixation; and iii) inclusion of one eye in the case of bilateral cataracts. The following exclusion criteria were used: i) Patients with any ocular diseases other than cataracts (corneal disease, glaucoma and vitreous or retinal disease); ii) patients with severe ocular trauma and a history of any type of ocular surgeries that may affect outcomes; iii) patients with unobtainable ocular biometric values due to severe posterior capsular opacity; and iv) patients with unreliable data, such as a signal-to-noise ratio <2.0 for either device. Following screening of the patients according to the aforementioned exclusion criteria, data from 190 eyes (91 right and 99 left) of 190 patients (87 males, 103 females) were extracted. The mean age of the patients was  $64.44 \pm 11.03$  years (range, 35–88 years). Preoperatively, all patients underwent routine ophthalmological examinations, including the determination of visual acuity and intraocular pressure, as well as anterior slit-lamp biomicroscopy and ocular ultrasonography for the observation of the posterior segment.

**Biometers and measurements.** The IOLMaster 500 is based on PCI and has been regarded as the standard optical biometer (3). The biometer was used to measure the AL by a PCI method, which involved a multimode laser and detection at 780 nm. Keratometry was performed by projecting six green spots onto the central 2.3-mm length of the cornea. The ACD was measured using lateral slit illumination. The WTW was measured using a light-emitting diode (LED) light source according to the configuration of the iris (6).

The Pentacam AXL combines an optical biometer and a Scheimpflug-based anterior segment topographer. The device uses a high-resolution rotating Scheimpflug camera and blue LED with a wavelength of 475 nm to illuminate the cornea, which enables the capture of 138,000 data points in <2 sec (7).

It offers a three-dimensional model of the anterior segment, including the corneal curvature of the anterior and posterior corneal surfaces, elevation maps and pachymetry maps. The keratometry readings used for routine IOL power calculations were from a 15-degree ring centered at the apex of the cornea. Similar to a standard IOLMaster 500, this setting provides an AL measurement based on PCI.

The same examiner (ZW) performed the biometry measurements in all patients using standardized conditions (7). The patient was instructed to look at the fixation light in the device while the measurements were performed. The patients were allowed to blink during each capture. All processes were completed within 15 min. Pentacam AXL scans were included that fulfilled the quality specification 'OK' for analysis.

The parameters AL, Km, ACD and WTW were recorded. Corneal curvature data were converted to corneal power using a standard refractive index of 1.3375. For both devices, ACD was defined as the distance from the corneal epithelium to the anterior lens capsule on the optical axis. Subsequently, the IOL power was calculated using the SRK/T and Haigis formulas on the devices' software. The Acrys of SN60WF IOL (Alcon) was used as the model IOL. The SRK/T A constant was estimated to 119.0, whereas the Haigis constants had the following values:  $a_0 = -0.769$ ,  $a_1 = 0.234$  and  $a_2 = 0.217$ . These parameters were optimized from the User Group for Laser Interference Biometry (ULIB) (8).

**Statistical analysis.** Statistical analysis was performed using SPSS version 22.0 (IBM Corp.) and MedCalc (version 16.2; MedCalc Software, Ltd.). Values are expressed as the mean  $\pm$  SD. The normality of the distribution of data was evaluated using the Kolmogorov-Smirnov test. The paired t-test was used to compare the mean values of the parameters obtained using the two biometers. Bland-Altman analysis was used to assess the agreement between the two devices by plotting the differences between measured and average values. The 95% limits of agreement (LoA) were also calculated using the mean difference of  $\pm 1.96$  SD. The Pearson correlation coefficient  $r$  was calculated to evaluate the correlations among all optical parameters and an  $r$  of  $>0.6$  was considered to indicate a high correlation. A scattergram was drawn to perform a linear regression analysis.  $P < 0.05$  was considered to indicate a statistically significant difference.

## Results

**Biometry data.** Table I indicates the range of the biometric parameters and the IOL power calculations to reach emmetropia as measured with the Pentacam AXL and the IOLMaster 500. The AL, Km and WTW values measured using the Pentacam AXL were significantly lower compared with those determined with the IOLMaster 500. The corresponding differences were  $-0.02 \pm 0.04$  mm,  $-0.20 \pm 0.28$  D and  $-0.10 \pm 0.20$  mm, respectively. All of the aforementioned differences were significant ( $t = -7.55$ ,  $-10.02$  and  $-6.79$ , respectively;  $P < 0.001$ ; Table II). Although the ACD in the Pentacam AXL group was higher compared with that in the IOLMaster 500 group, the differences noted ( $0.02 \pm 0.13$  mm) were not significant ( $t = 1.51$ ,  $P = 0.13$ ; Table II).

Table I. Parameters of AL, Km, ACD, WTW distance and IOL power obtained with the Pentacam AXL and IOLMaster 500.

Parameter	Pentacam AXL		IOLMaster 500	
	Mean $\pm$ SD	Total range	Mean $\pm$ SD	Range
AL (mm)	23.51 $\pm$ 1.18	20.62, 27.31	23.53 $\pm$ 1.18	20.61, 27.29
Km (D)	43.98 $\pm$ 1.60	40.30, 49.00	44.18 $\pm$ 1.61	40.51, 48.46
ACD (mm)	3.09 $\pm$ 0.41	1.73, 4.04	3.07 $\pm$ 0.40	2.02, 3.98
WTW (mm)	11.35 $\pm$ 0.41	10.10, 12.50	11.44 $\pm$ 0.40	10.34, 12.61
IOL power (D)				
SRK-T	20.80 $\pm$ 3.24	10.31, 29.10	20.52 $\pm$ 3.23	10.02, 28.22
Haigis	20.81 $\pm$ 3.25	10.52, 28.59	20.47 $\pm$ 3.24	10.21, 27.59

AL, axial length; ACD, anterior chamber depth; WTW, white-to-white; Km, keratometry; IOL, intraocular lens; SRK/T, Sanders, Retzlaff and Kraff theoretical; SD, standard deviation.

Table II. Mean and SD of the difference between the two biometers, P-value from paired t-test, 95% LoA and correlation coefficient r of the parameters.

Parameter	Mean $\pm$ SD	t value	P-value	95% LoA		Correlation coefficient r
				Lower	Upper	
AL (mm)	-0.02 $\pm$ 0.04	-7.55	<0.01	-0.11	0.06	0.99
Km (D)	-0.20 $\pm$ 0.28	-10.02	<0.01	-0.74	0.33	0.98
ACD (mm)	0.02 $\pm$ 0.13	1.51	0.13	-0.25	0.28	0.95
WTW distance (mm)	-0.10 $\pm$ 0.20	-6.79	<0.01	-0.49	0.30	0.88
IOL power (D)						
SRK-T	0.28 $\pm$ 0.32	11.48	<0.01	-0.34	0.90	0.99
Haigis	0.34 $\pm$ 0.40	10.97	<0.01	-0.44	1.12	0.99

AL, axial length; ACD, anterior chamber depth; WTW, white-to-white; Km, keratometry; IOL, intraocular lens; SD, standard deviation; SRK/T, Sanders, Retzlaff and Kraff theoretical; LoA, limits of agreement.

**Association analysis.** Bland-Altman analysis was used to evaluate the association between the results obtained with the two devices. Table II indicates the differences in the parameters estimated (mean  $\pm$  SD), the results of the paired t-test, the 95% LoA and the correlation coefficients between the measurements performed by the two devices. The 95% LoA range was -0.11 to 0.06 mm for the AL, -0.74 to 0.33 mm for the Km, -0.25 to 0.28 mm for the ACD and -0.49 to 0.39 mm for the WTW distance. The Bland-Altman plots are provided in Fig. 1. The data indicated that all parameters measured using the Pentacam AXL and IOLMaster 500 were in good agreement.

**Correlation analysis.** The highest correlation coefficient was noted for the AL parameter ( $r=0.99$ ), whereas the WTW exhibited the lowest correlation between the two biometers ( $r=0.88$ ). All differences were significant ( $P<0.001$ ). The scattergrams and linear regression equations are presented in Fig. 2. It was indicated that there was a significant correlation between the two biometers.

**IOL power calculation.** Significant differences were noted between the two devices regarding the IOL powers to calculate emmetropia (SRK/T and Haigis formulas;  $t=11.48, 10.97$ , respectively;  $P<0.01$ ). The IOL power calculated for the Pentacam AXL was higher than that of the IOLMaster 500 and the difference determined was  $0.28\pm0.32$  and  $0.34\pm0.40$  D, respectively. Bland-Altman analysis indicated that the 95% LoA range was -0.34 to 0.90 D for SRK/T and -0.44 to 1.12 D for Haigis (Table II; Fig. 1). The linear correlation between the IOL powers obtained by the two devices is presented in Fig. 2 ( $r=0.99$ ;  $P<0.001$ ).

## Discussion

Modern cataract surgery is not only used for visual rehabilitation but has also become a form of refractive surgery. Several factors affect visual results following cataract surgery. The most important criteria are accurate ocular biometry measurements and precise IOL power calculations (1). Several biometric instruments in current

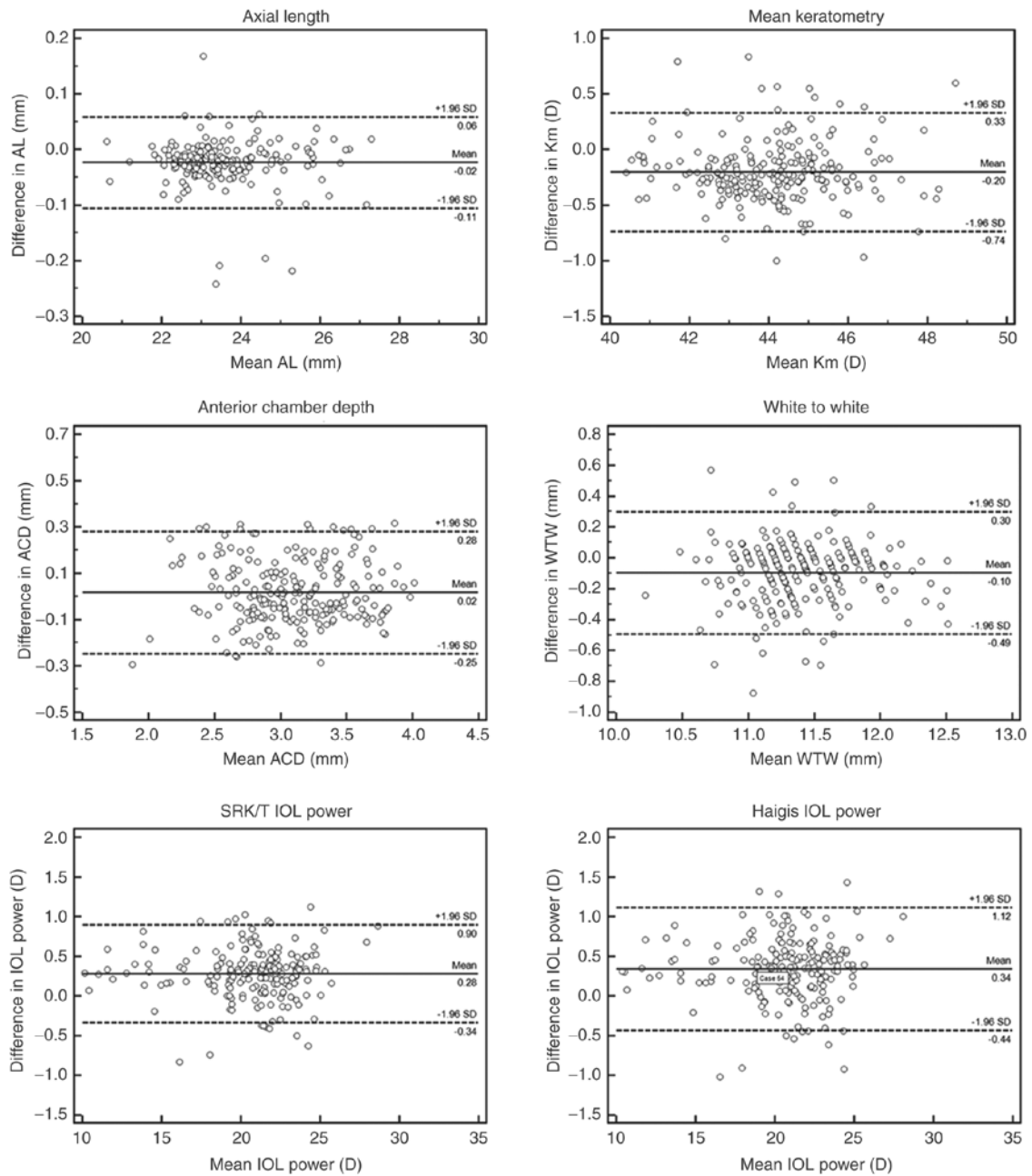


Figure 1. Bland-Altman plots indicating agreement in the parameters AL, Km, ACD, WTW distance and IOL power as calculated with the SRK/T and Haigis formulas between the Pentacam AXL and IOLMaster 500. The mean difference is represented by the solid line and the 95% LoA is represented by the dotted lines. AL, axial length; Km, mean keratometry; ACD, anterior chamber depth; WTW, white-to-white; IOL, intraocular lens; LoA, limits of agreement; SD, standard deviation; SRK/T, Sanders, Retzlaff and Kraff theoretical.

use are based on different technologies, such as PCI, optical low-coherence reflectometry (9) and swept-source optical coherence tomography (10). The IOLMaster 500, which is the most widely used device and has been proven to be accurate and repeatable, is based on PCI. This device has served as a benchmark for biometry in various studies (11).

The Pentacam AXL is a novel optical biometer. It combines Scheimpflug imaging for anterior segment tomography with the PCI method for AL measurement. Although AL measurement is based on the same system as that of the IOLMaster 500, anterior segment parameter measurements using the Pentacam AXL are considerably different. Therefore, the efficacy of the novel device to provide reliable measurements and its ability

to be used interchangeably must be assessed. The novel device was reported to exhibit optimal repeatability in an earlier study (5). In the present study, the major biometric parameters determined with the two different instruments, Pentacam AXL and IOLMaster, were compared, including AL, Km, ACD, WTW distance and the IOL power, the latter of which was calculated using the SRK/T and Haigis formulas.

The novel Scheimpflug device provided slightly lower AL values than the standard PCI device and the average difference was -0.02 mm. A similar difference was noted in a previous study, which indicated that the mean difference between the two biometers for AL was -0.026 mm (12). In the present study, the difference was small but significant. The different

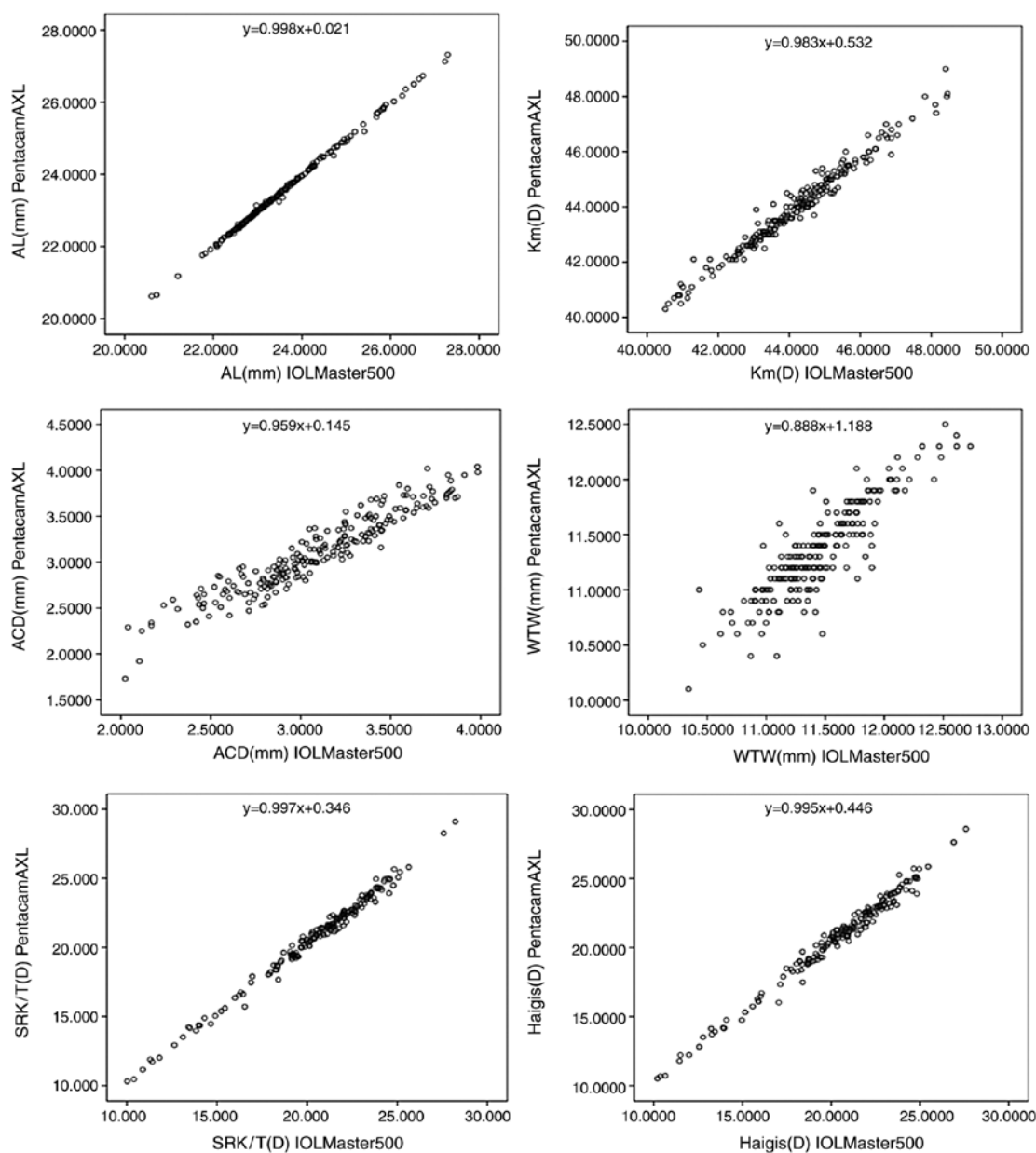


Figure 2. Scattergram of AL, Km, ACD, WTW distance and IOL power as calculated with the SRK/T and Haigis formula compared between the Pentacam AXL and IOLMaster 500. SRK/T, Sanders, Retzlaff and Kraff theoretical; AL, axial length; Km, mean keratometry; ACD, anterior chamber depth; WTW, white-to-white; IOL, intraocular lens.

internal calibrations between the two devices may have led to this result. Furthermore, the correlation in AL between the two devices was high ( $r=0.99$ ). The Bland-Altman plots indicated optimal agreement with 95% LoA from  $-0.11$  to  $0.06$  mm for AL. A 1-mm difference in the AL value of a normal eye may result in a  $\sim 2.7$  D difference in the IOL power calculation with the SRK-T formula (13). The aforementioned 95% LoA would result in a difference ( $-0.30$  to  $0.16$  D) that is not clinically relevant.

One major limitation of optical biometry is the failure to measure the AL for dense or posterior subcapsular cataracts (14). The light may penetrate the refractive interstitium, which is limited to a specific opacity. In a previous study, the failure rate was estimated to be 35-38% with an IOLMaster (15). In the present study, the parameter AL was measured using the same PCI technology. However, the failure rate was signifi-

cantly higher for the novel Scheimpflug biometry than that noted for the standard PCI device. This may be attributed to the composite software in the IOLMaster that was used as an attempt to improve the failure rate (16). Accordingly, subsequent versions of the Scheimpflug device may require further improvement and upgrades.

In the present study, the novel Scheimpflug biometer measured significantly lower Km values than those determined with the standard PCI biometer. The mean difference was estimated at  $-0.20$  D, with a 95% LoA of  $-0.74$  and  $0.33$  D. The wide LoA indicated that the Km determined with the Scheimpflug and the PCI device may not be used interchangeably. This may be attributed to the different methods used by each device to measure the corneal curvature (17). A Scheimpflug device measures K values by analyzing 25,000 true elevation data-points for the cornea. The simulated K values used for the IOL

power calculation were derived from a 15-degree ring centered on the corneal apex. By contrast, the standard PCI biometer used a distance-independent telocentric keratometry system that projected six green spots onto the cornea within a 2.3-mm radius.

In clinical practice, certain differences between K values are equalized by adjusting an appropriate IOL formula constant (18). Özyol and Özyol (19) suggested that a Km difference  $>0.14$  D between two devices requires a different optimization constant for IOL power calculation compared with those provided by ULIB. Therefore, constant optimization may be necessary for the novel Scheimpflug biometer to minimize the differences noted from the standard PCI biometer device (20). From the formula for IOL power calculation, it may be observed that there is no linear correlation between AL, Km, ACD, WTW distance and IOL power. Therefore, the effects of parameter changes on different patients are different. For instance, if the eye axis changes by 1 mm, the change of the IOL power is greater for patients with a short axis than for those with a long axis. Therefore, there is no clear and unified definition of a reasonable LoA in the clinic. Thus, this part does not appear in the methods but only in the discussion section.

The present results indicated that the difference in the ACD measured by the two devices was not significant. The ACD parameter obtained using the Pentacam AXL was slightly higher than that measured with the IOLMaster 500. The mean difference was 0.02 mm and the 95% LoA range was estimated as  $-0.25$  to 0.28 mm. As previously reported, the preoperative ACD change of 0.2 mm caused a difference of  $\sim 0.1$  D in IOL power (21) and the aforementioned difference was too small to represent a significant change. Furthermore, the correlation with ACD indicated no clinically relevant deviation between the two devices. The novel biometer measured ACD from Scheimpflug data, while the standard PCI biometer used lateral slit-imaging technology. The three-dimensional display of the anterior segment that is independent of the subject's fixation angle in the Scheimpflug images may provide a more precise ACD measurement (22).

An exact WTW distance measurement is important for the implantation of a phakic IOL, sulcus IOL and anterior chamber IOL (23). The appropriate IOL size may be selected based on the WTW distance to avoid vaulting-associated complications, such as pupillary block glaucoma, endothelial damage, chronic inflammation and cataract formation (24). Furthermore, the WTW distance is one of the major constants used to evaluate an effective lens position in the Holladay 2 formula (25). Both devices measure the horizontal corneal diameter using iris recognition technology. In addition, arcus senilis in older patients is a major factor affecting the identification of the corneal edge (26). In the present study, WTW measurements exhibited a small yet significant difference and the correlation of the WTW distance measured by the two biometers was the lowest among the parameters measured ( $r=0.88$ ). However, the difference was not sufficient to be clinically relevant.

Another major concern regarding a novel optical biometer is whether it is reliable to use the IOL constants provided by the ULIB website directly (27). Validation of the IOL constants derived from the ULIB website (8) is required for the novel Scheimpflug device. The present study indicated a strong positive correlation between the mean IOL power provided by

both devices with an Acrys of SN60WF IOL using the SRK/T and Haigis formulas. Although the mean difference in the IOL power was not clinically significant (0.28 D for SRK/T, 0.34 D for Haigis), the range determined for the 95% LoA (1.24 D for SRK/T, 1.56 D for Haigis) was wide. In addition, the difference exceeded 1 D for two eyes as determined by the SRK/T formula and for 12 eyes as determined by the Haigis formula. Therefore, the difference in calculating the IOL power between the two devices may be significantly different for specific patients and constant optimization may be required for the IOL power calculation with the novel Scheimpflug biometer.

The Pentacam anterior segment analysis system is more widely used with the increasing requirement of functional IOLs and the emergence of new ray-tracing formulas. It provides various ocular parameters. In cases of corneal astigmatism or irregularities, the Pentacam system provides more information on the corneal topography that is useful in the assessment of individual IOLs or calculations required for toric or aspheric IOLs (28). Furthermore, the Pentacam system is able to measure the posterior corneal curvature and axis. Zheng *et al* (29) reported that neglecting posterior corneal astigmatism yielded significant estimation errors for total corneal astigmatism in certain patients with cataracts. Furthermore, Pentacam is the first biometric instrument that may be used for ray-tracing Olsen formulas (30).

One drawback of the present study was that the data used were only from the eyes of patients with cataracts. The validity of the measurements of both devices in patients with other ocular diseases should be explored in further studies. In addition, in the present study, the differences and consistency between the two biometry instruments in the measurement of ocular parameters prior to cataract surgery and the calculation of the IOL power were compared, and in a future study, the actual postoperative outcomes will be assessed.

In conclusion, in the present study, a Scheimpflug biometer (Pentacam AXL) and a PCI biometer (IOLMaster 500) were evaluated and compared in terms of their biometry measurements and IOL power calculations. The results indicated optimal agreement and strong correlations between the two devices. However, the wide range of differences for the keratometry measurements and IOL power calculations suggested that constant optimization may be necessary for the novel biometer.

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### Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

## Authors' contributions

ZW and WY confirmed the authenticity of the raw data. ZW designed the current study, searched the literature, acquired and analyzed the data, and wrote the manuscript. WY conceived and designed the current study, defined intellectual content, and wrote and edited the manuscript. DL, WC, QZ, YL, RC, LS and JX performed the experiments. All authors read and approved the final manuscript.

## Ethics approval and consent to participate

The study was conducted in accordance with the tenets of the Declaration of Helsinki and approved by the Ethics Committee of the Beijing Tongren Hospital, Capital Medical University (Beijing, China; approval no. TRECKY2018-049). Each patient was informed about the purpose of this study and provided written informed consent.

## Patient consent for publication

Not applicable.

## Competing interests

The authors declare that they have no competing interests.

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