

Repeatability and agreement of two anterior segment OCT in myopic patients before implantable collamer lenses implantation

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Abstract

• **AIM:** To evaluate the intra-operator repeatability of time domain and swept-source Fourier domain anterior segment optical coherence tomography (AS-OCT), namely, Visante AS-OCT and Casia SS-1000 OCT, in measuring the preoperative parameters of implantable collamer lens (ICL) in myopic eyes, as well as the agreement between the two devices.

• **METHODS:** A total of 97 eyes from 49 myopes were investigated in this prospective case series study. The anterior chamber depth (ACD), angle-to-angle distance (ATA), pupil diameter (PD) and crystalline lens rise (CLR) in all subjects were measured for three times during one session by the same operator. The repeatability was evaluated using the within-subject standard deviation (Sw), repeatability limits and intraclass correlation coefficients (ICC). The agreement between the two systems was evaluated using the Bland-Altman plots and 95% limits of agreement (LoA).

• **RESULTS:** The repeatability limits of Visante AS-OCT in measuring ACD, ATA, PD and CLR were 0.099, 0.141, 0.304, and 0.079 mm, respectively. The repeatability limits of Casia SS-1000 OCT in measuring ACD, ATA, PD, and CLR were 0.105, 0.127, 0.357, and 0.082 mm, respectively. Excellent repeatability could be attained in both devices, with the ICC>0.8 for all the measured variables. The interdevice agreement was excellent ($P>0.05$) for ACD and ATA, but poor ($P<0.05$) for PD and CLR.

• **CONCLUSION:** Good repeatability can be attained by time domain and swept-source Fourier-domain OCT for all the measured variables. Moreover, interdevice agreement

analysis suggests that interchangeable measurements between two devices can be achieved for ACD and ATA, but not for PD and CLR; but the differences in measurements were not clinically significant.

• **KEYWORDS:** repeatability; agreement; Visante AS-OCT; Casia SS-1000 OCT; implantable collamer

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INTRODUCTION

It is essential to precisely measure the parameters such as anterior chamber depth (ACD) and angle-to-angle (ATA) for the preoperative evaluation of the implantable collamer lens (ICL; STAAR Surgical, Monrovia, California, USA) surgery^[1]. The accuracy of these biometric parameters is of critical importance to select the most suitable lens for every patient and to identify the risk factors of postoperative complications.

Traditionally, ultrasound biometry is the most commonly used method to obtain the biometric measurements of the anterior ocular segment; however, this technique is limited by its high variability of results, which can be ascribed to the incorrect positioning of probe and potential ocular indentation^[2]. Nowadays, the non-contact methods, such as anterior segment optical coherence tomography (AS-OCT), are more preferred over the ultrasound approaches.

Notably, the AS-OCT devices can produce high-resolution images of the anterior chamber and the iridocorneal angle^[3-4]. The OCT technology has evolved rapidly from time-domain (TD) OCT to spectral-domain (SD) and swept-source (SS) OCT over the past few years^[5]. Among them, TD-OCT devices are the first generation devices to be used in clinical and scientific imaging of the anterior segment, which have utilized the older OCT technology and are limited in the imaging speed and resolution compared with the SD-OCT devices. Thereafter, the SD-OCT devices have been extensively adopted for

visualizing the posterior segment, but some of them can also be used for the visualization of the anterior segment. However, their shorter wavelength has resulted in a shorter imaging range and incomplete visualization of the entire anterior chamber by a single scan^[6]. Recently, CASIA SS-1000 (Tomey, Nagoya, Japan) has been introduced, which is a first generation SS Fourier-domain OCT device that is characterized by its rapid imaging of the entire anterior chamber in a single section.

Currently, no gold standard device is available to verify the accuracy of AS-OCT devices as well as their image scaling algorithms^[6]. In order for the utility of such measurements to become widely accepted, the repeatability should be determined. Furthermore, it is of great importance to assess their agreement degree, so as to determine whether their results are interchangeable. Therefore, this study was carried out to address these issues by assessing the interdevice repeatability and agreement between time domain and SS Fourier-domain OCT, namely, Visante AS-OCT and Casia SS-1000 OCT.

SUBJECTS AND METHODS

Ethical Approval The study was conducted in accordance with the Declaration of Helsinki. All patients had been fully informed of the purpose and methods of the present study and provided written informed consent from themselves or their guardians. Since the study was based on ambulatory visits before previously approved ICL implantation procedures, additional Institutional Review Board/Ethics Committee Approval was not required.

SUBJECTS AND METHODS

Forty-nine consecutive patients undergoing routine preoperative examinations for ICL surgery were enrolled in this study. Both eyes of each patient were scanned. Patients that did not meet the ICL surgery indication were excluded from the study. The major contraindications for the ICL surgery are age <18y or >45y, spherical refraction error <-20.00 D, astigmatism <-5.00 D, best corrected visual acuity <20/40, ACD<2.8 mm, and endothelial cell density <2000 cell/mm². We also excluded patients with a history of certain ocular diseases (cornea or lens opacity, retinal detachment, or glaucoma), a history of ocular surgery and systemic disease. One out of the ninety-eight eyes from forty-nine patients was excluded, since its best-corrected vision acuity was as low as hand movement, which was not suitable for ICL surgery.

All eyes were examined without dilation using Visante AS-OCT (Carl Zeiss Meditec, Inc., Ireland, software version 3.0.1.8) and Casia SS-1000 OCT (Tomey, Nagoya, Japan, software version 6Q.2). Moreover, all scans were performed successively in a dim room according to the manufacturer’s instructions, and all subjects were positioned using a headrest and instructed to fixate on an internal target in the camera

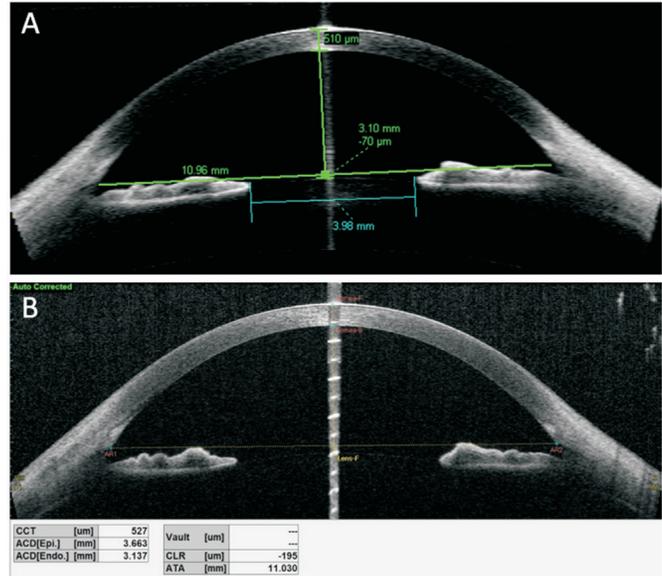


Figure 1 Biometric measurements of ACD, ATA, PD, and CLR by two AS-OCTs A: Visante AS-OCT (Carl Zeiss Meditec, Inc., Ireland); B: Casia SS-1000 OCT (Tomey, Japan).

center without blinking during the scans. Firstly, three independent scans were taken for each eye successively using Visante AS-OCT by one examiner, then the same eye was scanned three times successively using Casia SS-1000 OCT by the same examiner. Typically, Visante AS-OCT is a TD OCT, which utilizes light at the wavelength of 1310 nm, with the scanning speed of 2000 axial scans/s, as well as the axial and lateral resolution of 18 μm and 60 μm, respectively, and three enhanced anterior segment single scans were obtained for each eye. Casia SS-1000 OCT is an SS OCT, with the scanning speed of 30 000 axial scans/s, as well as the axial and lateral resolution of <10 μm and <30 μm, respectively, and three auto-3D anterior segment scans were obtained for each eye. One trained observer (Li M) masked to the identities and examination results of the subjects marked the scleral spurs and identified anterior segment structures in each image. The AS-OCT image along the horizontal (temporal-nasal) meridian was analyzed for each eye in each scan. Additionally, ACD (the distance between corneal endothelium and the anterior surface of crystalline lens), ATA distance (the distance between two scleral spurs), pupil diameter (PD, the distance between the horizontal edge of iris), and crystalline lens rise (CLR, the distance between the horizontal ATA line and the anterior surface of crystalline lens) were recorded from each scan for subsequent analysis (Figure 1).

Statistical Analysis The values of ACD (mm), ATA (mm), PD (mm) and CLR (μm) measured by the two instruments were processed and analyzed using SPSS version 20 (SPSS Inc, USA). The Kolmogorov-Smirnov test was employed to detect whether the data had conformed to normal distribution. Besides, the within-subject standard deviation (Sw) was

Table 1 Median and interquartile range for the measurements of each examined variable mean±SD (IQ range: 25 to 75)

Parameters	Visante AS-OCT	Casia SS-1000 OCT
ACD (mm)	3.210±0.249 (2.995 to 3.405)	3.216±0.261(2.985 to 3.407)
ATA (mm)	11.521±0.349 (11.265 to 11.786)	11.529±0.314 (11.282 to 11.766)
PD (mm)	4.087±0.739 (3.498 to 4.738)	4.811±0.874 (4.317 to 5.426)
CLR (μm)	-132.646±196.754 (-265.00 to -8.333)	-164.79±204.35 (-287.333 to -29.000)

IQ: Interquartile; ACD: Anterior chamber depth; ATA: Angel to angle distance; PD: Pupil diameter; CLR: Crystalline lens rise.

Table 2 Interdevice repeatability and agreement expressed through the Bland-Altman comparison analysis

Parameters	Visante AS-OCT	Casia SS-1000 OCT	95%LoA (mean difference)	P
ACD (mm)			0.121 to -0.135 (-0.006)	0.31 (t=-1.021)
Sw	0.036	0.038		
Repeatability limits	0.099	0.105		
ICC (CI)	0.980 (0.972 to 0.986)	0.946 (0.926 to 0.962)		
ATA (mm)			-0.250 to 0.232 (-0.008)	0.47 (t=-0.713)
Sw	0.051	0.046		
Repeatability limits	0.141	0.127		
ICC (CI)	0.936 (0.912 to 0.955)	0.950 (0.931 to 0.965)		
PD (mm)			-1.826792 to 0.378992 (-0.7239)	<0.001 (t=-12.671)
Sw	0.110	0.129		
Repeatability limits	0.304	0.357		
ICC (CI)	0.884 (0.837 to 0.919)	0.927 (0.899 to 0.948)		
CLR (μm)			168.323 to 104.034 (32.144)	<0.001 (t=4.557)
Sw	28.865	29.660		
Repeatability limits	79.956	82.158		
ICC (CI)	0.937 (0.913 to 0.955)	0.968 (0.956 to 0.978)		

LoA: Limits of agreement; ACD: Anterior chamber depth; Sw: Within subject standard deviation; ICC: Intraclass correlation coefficient; ATA: Angel to angle distance; PD: Pupil diameter; CLR: Crystalline lens rise.

estimated through the one-way analysis of variance and the repeatability limits ($r=\sqrt{2}\times 1.96Sw$) were calculated, so as to assess the repeatability of both instruments by three consecutive measurements^[7-8], and by calculating the intraclass correlation coefficient (ICC). Additionally, differences in parameters determined by the two instruments were compared using paired *t*-test. A *P*-value of <0.05 was considered as statistically significant. The interdevice agreement was also assessed by the Bland-Altman comparison analysis; in addition, differences between the measurements against their means were plotted and the 95% limits of agreement (LoA) were also determined (mean difference±2 standard deviations of the differences).

RESULTS

A total of ninety-seven eyes from forty-nine patients, including thirty females (61%) were examined in this study. Specifically, the mean age was 28.6±6.6y (range 18-41y), the mean spherical equivalent refractive error (SE) was -14.2±4.9 D (range 5.2-24.5 D), and the mean axial length was 28.66±2.27 mm (range 24.98-34.62 mm). Table 1 shows the medians and the

interquartile ranges for the measurements of four variables analyzed in this study. Table 2 summarizes the Sw, repeatability limits (r), ICC and inter-device agreement detected through the Bland-Altman comparison analysis. The repeatability limits of Visante AS-OCT in measuring ACD, ATA, PD and CLR were 0.099, 0.141, 0.304, and 0.079 mm, respectively, while those of Casia SS-1000 OCT in measuring ACD, ATA, PD and CLR were 0.105, 0.127, 0.357, and 0.082 mm, respectively. Apparently, both devices had excellent repeatability, with an ICC of >0.8 in all the measured variables. The calculated 95%LoA for ACD, ATA, PD, and CLR are shown in Figure 2. As could be seen, the 95%LoA values for ACD, ATA and CLR measured by the two devices were narrow, implying excellent agreement between them, even though the 95%LoA values for PD measured by the two devices were relatively wide. In addition, the calculated 95%LoA and the obtained mean differences for PD and CLR were statistically different (*P*<0.05) between Visante AS-OCT and Casia SS-1000 OCT (Table 2). Specifically, Visante AS-OCT had yielded slightly lower values of PD, but slightly higher values of CLR.

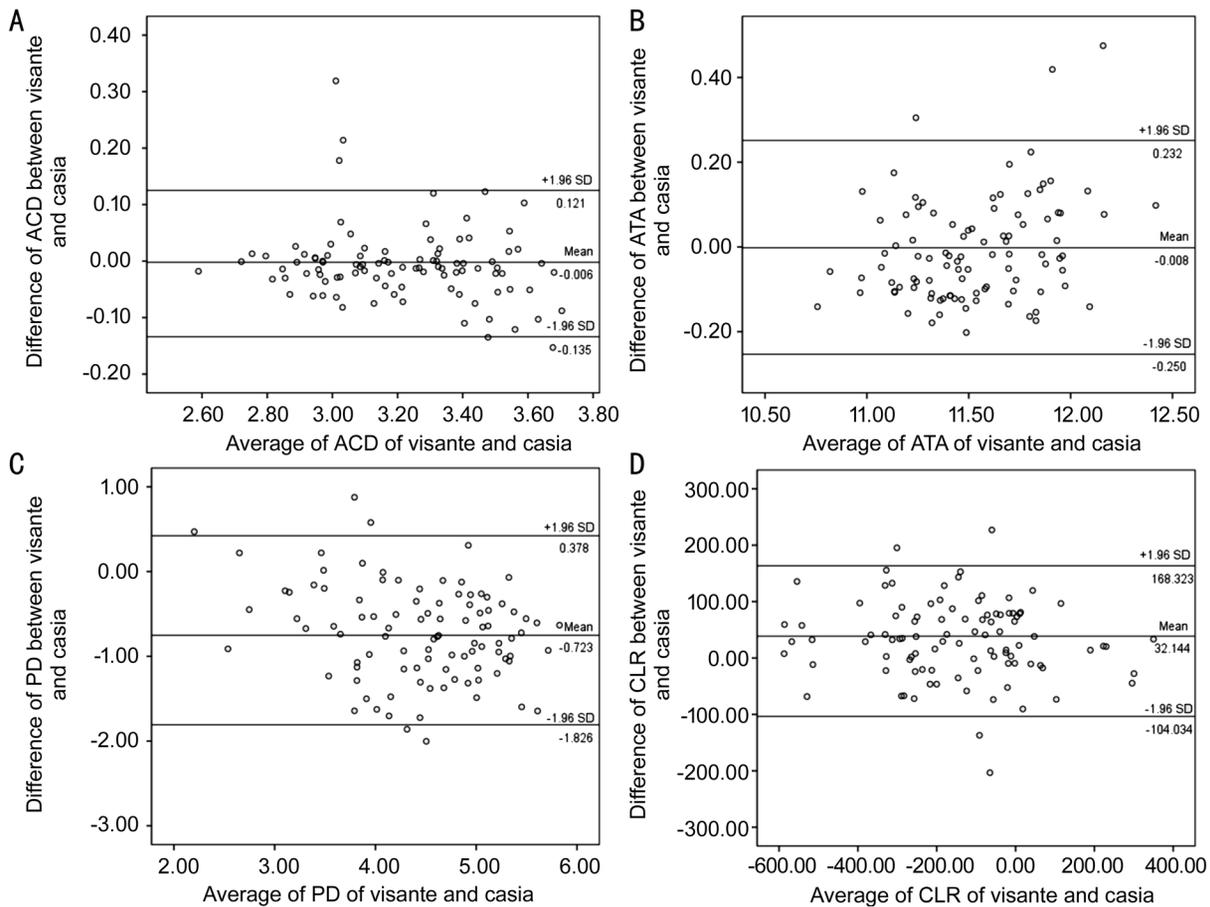


Figure 2 Bland-Altman plots shows the agreement between Visante AS-OCT and Casia SS-1000 OCT A: ACD; B: ATA; C: PD; D: CLR. The 95%LoA are represented by the solid lines.

DISCUSSION

The interdevice repeatability using Casia SS-1000 OCT, as well as the agreement between Visante AS-OCT and Casia SS-1000 OCT, has not been previously assessed for ATA, PD and CLR measurements. In this study, both Casia SS-1000 OCT and Visante AS-OCT had demonstrated excellent intradevice repeatability for all measured parameters. Besides, interdevice agreement analysis suggested that both Visante AS-OCT and Casia SS-1000 OCT could be employed interchangeably for ACD and ATA measurements, but not for PD and CLR measurements.

As could be observed from the repeatability limits obtained through measuring each parameter (Table 2), CLR and PD had shown the lowest and highest repeatability limits, respectively. Based on the above-mentioned results, the consecutive measurements of CLR and PD were expected to be within 0.079 mm and 0.304 mm from Visante AS-OCT (or 0.082 mm and 0.357 mm from Casia SS-1000 OCT), respectively, for 95% population. In the meantime, the consecutive measurements of ACD and ATA were expected to be within 0.099 mm and 0.141 mm from Visante AS-OCT (or 0.105 mm and 0.127 mm from Casia SS-1000 OCT), respectively, for 95% population. Thus, it could be concluded that both Visante

AS-OCT and Casia SS-1000 OCT could measure these ocular parameters with high repeatability.

The accurate measurement of ACD is required in ICL implantation, so as to predict the IOL position with regard to corneal endothelium, thus avoiding postoperative complications. In our study, the LoA for ACD and ATA were not statistically significant between Visante AS-OCT and Casia SS-1000 OCT, since the mean differences in ACD and ATA were <0.01 mm. Taken together, these results suggested that ACD and ATA data obtained from Visante AS-OCT and Casia SS-1000 OCT could be used interchangeably in clinical applications, such as calculation and surgery planning for ICL, as well as postoperative follow-up. However, significant differences were observed in the 95%LoA upon Bland-Altman analysis for the interdevice agreement of PD and CLR (Table 2), suggesting that these measurements obtained from the two OCT devices should not be interchanged. However, in this case, the mean differences between the measurements of PD and CLR were -0.723 and 0.032 mm, respectively, which were not clinically important even though they were statistically significant.

Neri *et al*^[9] had also assessed the measurements of ACD using Casia SS-1000 OCT, and a similar repeatability limit

of 0.035 (calculated as $1.96 \times Sw$) was obtained. Besides, previous studies using Visante AS-OCT also showed the similar repeatability limits of 0.04 and 0.07 mm for ACD measurements^[10-11]. Fukuda *et al*^[11] had also reported the repeatability limit of 0.16 for ATA measurements using Visante AS-OCT, which was comparable to that obtained in our results. However, no previous studies have reported the repeatability of ATA measurements acquired using Casia SS-1000 OCT^[12-13]. Nevertheless, no previous studies have compared the ATA measurements acquired using Visante AS-OCT with those using Casia SS-1000 OCT. In this study, the intradevice variability for ATA measurements is excellent for both devices, so the results can be interchangeable between the two devices. In the current study, PD was associated with the largest variation, which might be ascribed to the fluctuations in patient accommodation during repeated measurements. In refractive surgery, PD is an important factor in assessing postoperative glaring. The pupil size and its dynamics will be modulated by retinal illuminance, medication, accommodation, supranuclear input, emotions, attention, contextual processing, and imagery. Besides, the pupil size will also be affected by age^[14]. Some researchers have excluded the intradevice comparisons in eyes from analysis when the PD measurements have differed by >10% between the two scans, so as to minimize the effects of pupil size on the measurements^[15]. In addition, previous studies also suggest that the decrease in ACD is statistically significant during accommodation (from 0 to maximal amplitude of 9 D), so are the increase in lens thickness and slight forward movement of the lens central point. In contrast, changes in ATA measurements are not statistically significant during accommodation in healthy eyes^[9,12]. In our study, Visante AS-OCT had yielded slightly lower PD values, but slightly higher CLR values. Although the PD and CLR measurements obtained from these two OCT devices should not be used interchangeably, the differences were not clinically important. Kojima *et al*^[16] had reported that CLR was relevant to the postoperative vault (distance between the anterior lens surface and ICL). Specifically, a too-small ICL would result in a decreased distance between ICL and crystalline lens, while increasing the risk of cataract formation. In the current study, CLR was associated with the smallest variation. Although Visante AS-OCT had yielded slightly higher CLR values, the difference was not clinically important.

Compared with Visante AS-OCT, Casia SS-1000 OCT is more efficient in both the scan process and the measure process. Specifically, Visante AS-OCT has used the 1310 nm wavelength light to acquire the single cross-sectional images of the entire anterior chamber. The corneal apex reflex appears to be a vertical white line provided by the instrument along the cornea, which is required in each scan to make sure that the scan is

fully perpendicular to the corneal surface. In comparison, Tomey has employed the 1310 nm wavelength light similar to the TD-OCT devices, but is capable of acquiring 128 cross-sectional images within the span of a few seconds to create the pseudo-3D representations of the anterior chamber^[6]. In this study, the anterior segment parameter measurements from Visante AS-OCT were obtained using the built-in software and measurement tools provided by the manufacturers. Specifically, to obtain all these measurements, a horizontal line was first drawn to measure ATA, which could connect both scleral spurs. Subsequently, a perpendicular line to this ATA line was traced towards the anterior corneal surface and passed through the corneal apex. Three measurements, including CCT, ACD and CLR, could be obtained in this perpendicular line. However, the built-in CASIA image analysis process was greatly automated and time-efficient, which only required that the observer should confirm the structural segmentation and identify the scleral spurs.

The strength of our study is that it's the first study to analyze the interdevice agreement for ATA, PD and CLR using Visante AS-OCT and Casia SS-1000 OCT. With updated technology for swept-source imaging, CASIA2 is now available, which is a newer generation SS-OCT. The interdevice agreement between Visante AS-OCT and CASIA2 has been recently reported^[17]. Since Casia SS-1000 is still in clinical application, the interdevice agreement still needs to be studied. The current study had several limitations. First, one notable limitation was the use of bilateral eye data. Data from paired eyes are likely to be correlated (except in asymmetric disease) and confound correlation and regression analyses^[18]. Some authors attempt to avoid this problem by using data from only one eye while rejecting those from the fellow eye. However, paired eye data would not confound the calculations of LoA. It is appropriate to use data from both eyes in populations with asymmetric eye diseases^[7]. In this study, myopes rather than healthy individuals were recruited; as a result, it seemed to be acceptable to use data from both eyes. Second, SD-OCT was not included in our comparison. Previous research has compared the reproducibility and agreement between Tomey CASIA2 (SS-OCT) and Heidelberg Spectralis OCT2 (SD-OCT); the results suggest that the measurements for ATA, PD and CLR are consistently smaller for Tomey CASIA2 than Spectralis, and the Bland-Altman plot had demonstrated poor agreement between ATA values. According to their findings, the anterior segment measurements should not be used interchangeably between Tomey CASIA2 and Heidelberg Spectralis OCT2^[6]. Third, the reproducibility of the two devices was not evaluated in this study. Noticeably, repeatability and reproducibility are the two factors of precision. As reported in previous studies, excellent intradevice reproducibility can be obtained for

the measurements of central corneal thickness and anterior chamber angle by Casia SS-1000 OCT^[19-20], as well as for the measurements of ATA, PD and CLR by CASIA2^[6]. Besides, Visante OCT also shows excellent intradevice reproducibility of measurements for ACD and ATA^[11,21-22]. Finally, in our study, ATA instead of white-to-white (WTW, distance from limbus to limbus/corneal diameter) was used in preoperative ICL sizing. In the Visian ICL Product Information for its FDA labeling, sizing of the Visian ICL myopic lenses is determined by the horizontal WTW and the ACD measurements. However, using WTW to estimate the ICL size is reported to be associated with an error of >0.50 mm in 22% cases. On the contrary, the use of direct measurement of ATA by OCT would reduce this error to 0.02%^[23]. Moreover, the angle diameter is also believed to be more accurate in estimating sulcus diameter^[24-26].

In conclusion, both Visante AS-OCT and Casia SS-1000 OCT systems have displayed high repeatability for three consecutive measurements regarding ACD, ATA, PD and CLR. Our results suggest that the measurements of ACD and ATA parameters can be used interchangeably. Meanwhile, the results of PD and CLR cannot be used interchangeably, but the differences in measurements are not clinically important.

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