Precision of a new Scheimpflug and Placido-disk analyzer in measuring corneal thickness and agreement with ultrasound pachymetry

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PURPOSE: To assess the precision of corneal thickness measurements obtained by a new Scheimpflug camera combined with Placido-disk corneal topography (Sirius) and compare the measured values with those obtained by ultrasound (US) pachymetry.

SETTING: Eye Hospital of Wenzhou Medical College, Wenzhou, China.

DESIGN: Comparative evaluation of a diagnostic test or technology.

METHODS: Eyes of healthy subjects were examined with the Scheimpflug–Placido topographer. Central (CCT) and thinnest (TCT) corneal thickness were recorded after 3 consecutive measurements. For US pachymetry, only CCT was measured. Measurements were repeated within 1 week. The within-subject standard deviation (S_w), test–retest repeatability, coefficient of variation (CoV), and intraclass correlation coefficient (ICC) were calculated to evaluate intrasession repeatability and intersession reproducibility. Interdevice comparison was analyzed with paired *t* tests and Bland-Altman plots.

RESULTS: The intrasession repeatability of Scheimpflug–Placido measurements was high, with test–retest and CoV close to 9 μm and 0.6% for CCT and TCT, respectively. The intersession test–retest and CoV were close to 10 μm and 0.7%, respectively. The ICC was higher than 0.98 for repeatability and reproducibility. High agreement was found between Scheimpflug–Placido and US pachymetry measurements, with narrow 95% limits of agreement.

CONCLUSIONS: The Scheimpflug–Placido instrument showed excellent intrasession repeatability and intersession reproducibility of CCT and TCT measurements in healthy eyes. High agreement and lack of statistically significant difference suggest that the instrument's TCT and the US pachymetry–CCT measurements can be used interchangeably in subjects with normal corneal thickness.

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High accuracy and precision in corneal thickness measurements have become increasingly relevant in ophthalmic practice. Refractive surgery is routinely planned according to the preoperative measurement of corneal thickness.[1] Overestimation of central corneal thickness (CCT) may cause corneal stroma overablation and thus increase the risk for keratectasia.[2] Accurate CCT measurements can be used to correct intraocular pressure values, as measured by Goldmann applanation tonometry,[3] and are important when monitoring corneal disorders, such as keratoconus, contact lens–related complications, and dry eye.[4,5]

The most commonly used method to measure CCT is ultrasound (US) pachymetry, which is still regarded as the gold standard because of its low cost, compact design, ease of use, and high repeatability.[6,7] However, this technique has disadvantages, including the need for topical anesthesia and contact with the cornea, with a risk for epithelial abrasions and infection.[8–10] Other studies[7,11] found that the precision of US pachymetry was operator dependent and that important differences arose from using different devices. These limitations have led to new and more sophisticated techniques that provide rapid, convenient,

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noncontact, and objective measurements of the CCT. These include Scheimpflug imaging (Pentacam, Oculus Optikgeräte GmbH, and Galilei, Ziemer Group), scanning-slit topography (Orbscan, Bausch & Lomb), and optical coherence tomography. A more recent device in this field is the Sirius (Costruzione Strumenti Oftalmici), which combines a rotating Scheimpflug camera and a Placido disk. Previous studies of this instrument[12–14] focused on intrasession repeatability of anterior segment measurements and a comparison with other Scheimpflug systems. However, to our knowledge, the intersession reproducibility of pachymetry measurements obtained by this instrument has not been reported. Furthermore, no articles analyzed the agreement between this new Scheimpflug–Placido topographer and US pachymetry in measuring the corneal thickness in normal eyes.

We aimed to evaluate the intrasession repeatability and intersession reproducibility of CCT and the thinnest corneal thickness (TCT) measurements derived by the new Scheimpflug–Placido topographer and compare these measurements with those we obtained using US pachymetry.

SUBJECTS AND METHODS

This prospective study comprised healthy volunteers. The research protocol adhered to the tenets of the Declaration of Helsinki and was approved by the Office of Research Ethics, Wenzhou Medical College. Each subject gave informed consent after the nature and intent of the study had been fully explained.

Inclusion criteria were myopic sphere of −0.50 to −12.00 diopters (D) with or without astigmatism of up to −2.00 D, a spherical equivalent of no more than −12.00 D, and a spectacle-corrected logMAR distance visual acuity of at least 20/25. The exclusion criteria were age younger than 18 years, previous ocular surgery, ocular pathology (eg, keratoconus, cataract, glaucoma), fundus disease, contact lens wear, and dry eye. To avoid methodology bias, all measurements were performed in the undilated right eye of each subject.

Scheimpflug Camera–Placido Disk Topography System

The Sirius system combines a monochromatic 360-degree rotating Scheimpflug camera and a Placido disk–based corneal topographer. The scanning process acquires a series of 25 Scheimpflug images (meridians) and 1 Placido top-view image. The ring edges are detected on the Placido image so that height, slope, and curvature data are calculated using the arc-step method with conic curves. Profiles of the anterior cornea, posterior cornea, anterior lens, and iris are derived from the Scheimpflug images. Data for the anterior surface from the Placido image and Scheimpflug images are merged using a proprietary method. All other measurements of internal structures (posterior cornea, anterior lens, and iris) are derived solely from Scheimpflug data. The system can measure 35 632 points and 30 000 points for the anterior corneal surface and posterior corneal surface, respectively. A pachymetric map is then reconstructed using the data from both corneal surfaces. In this study, the CCT at the corneal apex and the TCT were recorded and analyzed.

Measurement Protocol

In the first part of the study, the precision of the rotating Scheimpflug–Placido topographer was determined based on the definitions adopted by the International Organization for Standardization[15,16] as recommended by Bland and Altman.[17] Each subject was measured by the same experienced examiner, and the first session was designed to determine intraobserver repeatability. Three valid scans were performed. After each acquisition, the device was moved backward and realigned for the next scan to eliminate interdependence of the successive measurements. The total time for acquiring all measurements did not exceed 10 minutes. Intersession reproducibility was assessed by an additional 3 scans performed by the same examiner 2 to 7 days later.

In the second part of the study, the accuracy of corneal thickness measurements by the Scheimpflug–Placido topographer and by US pachymetry was compared. In the first session, after the noncontact examination with the Scheimpflug–Placido topographer was performed, the cornea was anesthetized with proparacaine hydrochloride 0.5% (Alcaine). The A-scan US pachymeter (SP-3000, Tomey Corp.) was precalibrated for all measurements. The US velocity was set at 1640 m/s. A handheld probe was aligned as perpendicularly as possible to the central cornea. Five readings were obtained, and the highest and the lowest values were excluded. The mean of the remaining 3 readings was used and defined as US pachymetry–CCT. This value was then compared with the mean CCT and TCT values provided by the Scheimpflug–Placido topographer. All measurements were taken between 10 AM and 5 PM to minimize the effect of diurnal variation on corneal thickness.[18]

Statistical Analysis

All data were analyzed using the SPSS for Windows software (version 13.0, SPSS, Inc.). Results are presented as means ± standard deviations (SDs). The distributions of

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Table 1. Intraobserver repeatability of CCT and TCT readings by the Scheimpflug–Placido topographer.

Parameter	Mean (μm) ± SD	S_w (μm)	2.77 S_w (μm)	CoV (%)	ICC	95% CI
CCT	534.16 ± 33.93	3.27	9.06	0.64	0.991	0.985, 0.995
TCT	527.60 ± 34.28	3.23	8.96	0.61	0.991	0.985, 0.995

CCT = central corneal thickness; CI = confidence interval; CoV = coefficient of variation; ICC = intraclass correlation coefficient; Sw = within-subject standard deviation; TCT = thinnest corneal thickness

the datasets were checked for normality using Kolmogorov-Smirnov tests. The results indicated that the data were normally distributed ($P > .05$).

To determine the intrasession repeatability of each device, the within-subject SD (S_w), test–retest repeatability (test–retest, 2.77 S_w), within-subject coefficient of variation (CoV), and intraclass correlation coefficients (ICCs) were calculated for the 3 repeated measurements.[19] The test–retest was defined as 2.77 S_w, which means an interval within which 95% of the differences between measurements are expected to lie.[19] The CoV was calculated as the ratio of the S_w to the overall mean. A lower CoV is associated with higher repeatability. The ICC (range 0 to 1) determines the consistency for datasets of repeated measurements. The closer the ICC is to 1, the better the measurement consistency. To assess intersession reproducibility, the mean of the 3 readings from each session was first calculated for the Scheimpflug–Placido topographer, and then the intersession S_w, 2.77 S_w, and CoV were calculated. The intersession reproducibility of the measurement method was also evaluated by the ICC. Measurements from the 2 sessions were compared using a paired *t* test.

Comparison of the mean CCT and TCT by the Scheimpflug–Placido topographer and the US pachymetry–CCT was performed using paired *t* tests. Agreement between the 2 devices was assessed according to the method described by Bland and Altman,[17] who suggest plotting the differences between measurements (*y* axis) against their mean (*x* axis). Bland-Altman plots allow evaluation of the existence of any systematic difference between measurements (ie, fixed bias). The mean difference is the estimated bias, and the SD of the differences measures the random fluctuations around this mean. If the mean value of the difference differs significantly from 0, as determined on the basis of a 1-sample *t* test, it indicates the presence of fixed bias. The 95% limits of agreement (LoA) were defined as the means ± 1.96 SD of the differences between the 2 measurement techniques.[17]

RESULTS

The study comprised 43 healthy volunteers (27 women) with a mean age of 27.5 years ± 7.6 (SD) (range 21 to 54 years). The mean manifest spherical equivalent refraction was −4.37 ± 2.18 D (range −1.00 to −10.25 D).

Repeatability and Reproducibility of Central Corneal Thickness and Thinnest Corneal Thickness Measurements

Measurements of CCT and TCT with the Scheimpflug–Placido topographer showed high intrasession repeatability (Table 1). The intrasession test–retest and CoV were close to 9 μm and 0.6%, respectively, and the ICC was higher than 0.99.

There were no differences in the measurements between the first session and the second session. The intersession test–retest and CoV were close to 10 μm and 0.7%, respectively, and the ICC was also higher than 0.98 (Table 2).

Agreement between the Scheimpflug–Placido Topography and Ultrasound Pachymetry Measurements

The mean US pachymetry–CCT was 527.28 ± 34.77 μm. The mean CCT and TCT by the Scheimpflug–Placido topographer were 534.16 ± 33.93 μm and 527.60 ± 34.28 μm, respectively. The mean CCT by the Scheimpflug–Placido topographer was significantly higher than the mean US pachymetry–CCT (6.88 μm). There were no statistically significant differences between the latter and the Scheimpflug–Placido topographer TCT measurements (Table 3). In terms of the agreement between different devices, the CCT and TCT measurements showed narrow 95% LoA, which implied good agreement (Figures 1 and 2). A fixed bias was detected between CCT and US pachymetry–CCT, but not between TCT and US pachymetry–CCT.

Table 2. Intersession reproducibility of CCT and TCT readings by the Scheimpflug–Placido topographer.

Parameter	Mean Difference (μm) ± SD	*P* Value	S_w (μm)	2.77 S_w (μm)	CoV (%)	ICC	95% CI
CCT	−0.47 ± 5.35	.566	3.75	10.40	0.73	0.988	0.978, 0.993
TCT	0.09 ± 5.06	.905	3.53	9.79	0.67	0.989	0.980, 0.994

CCT = central corneal thickness; CI = confidence interval; CoV = coefficient of variation; ICC = intraclass correlation coefficient; Sw = within-subject standard deviation; TCT = thinnest corneal thickness

Table 3. Comparison of CCT and TCT readings by the Scheimpflug–Placido topographer and CCT by ultrasound pachymetry.

Parameter	Mean Difference (μm) ± SD	*P* Value	95% LoA (μm)
CCT	6.88 ± 6.77	.000	−6.39, 20.14
TCT	0.32 ± 6.74	.759	−12.89, 13.53

CCT = central corneal thickness; LoA = limits of agreement; TCT = thinnest corneal thickness

DISCUSSION

This study was prospectively designed to evaluate the precision of the CCT and TCT measurements by the Sirius Scheimpflug–Placido topographer and evaluate the agreement between the Scheimpflug–Placido topographer measurements and US pachymetry measurements. Our results confirm the high repeatability of the Scheimpflug–Placido topographer's measurements of the thinnest pachymetry (TCT) and apex pachymetry (CCT) in normal eyes. The ICC was close to 1, and the intrasession CoV was lower than 0.75%. Similar results have been reported.[12,14,20] Savini et al.[12] found a CoV of 0.43% and 0.48% for CCT and TCT, respectively, in healthy unoperated eyes; test–retest was 6.59 μm for CCT and 7.37 μm for TCT. According to Milla et al.,[14] the CoV and test–retest of the CCT were 0.6% μm and 8.6 μm, respectively. Montalbán et al.[20] report a CoV of 0.52% for both CCT and TCT and ICC values close to 1. Chen et al.[21] found that the test–retest of the Sirius device was 9.18 μm. Therefore, our study confirms the results in previous studies of the intrasession repeatability of Sirius measurements. Furthermore, we found that the pachymetric measurements of the Scheimpflug–Placido topographer had a high degree of intersession reproducibility.

Several authors have assessed the repeatability of CCT measurements with other Scheimpflug cameras. Savini et al.[22] report that the repeatability of the measurements by the Galilei, which combines a dual Scheimpflug camera and a Placido disk corneal topographer, was higher; the test–retest of CCT and TCT was 5.97 μm and 4.78 μm, respectively, while the CoV was 0.40% and 0.33%, respectively. An even lower CoV (0.25%) for CCT was reported by Wang et al.[23] for the Galilei. Nam et al.[24] found that the Pentacam system, which is based on a single Scheimpflug camera, provided comparable measurements and reported a test–retest and CoV of CCT of 10.0 μm and 0.67%, respectively. The results of the Pentacam measurements reported by Chen et al.[25] were in agreement with ours. A recent study by Guilbert et al.[26] showed that the repeatability of TMS-5 (Tomey Corp.), which combines a single Scheimpflug camera and a Placido disk corneal topographer, was excellent (ICC 0.953), but slightly lower than our results. These indirect comparisons suggest that the reliability of CCT measurement by the 4 Scheimpflug systems is excellent and that the Galilei may provide the best repeatability. However, a future prospective study comparing these Scheimpflug systems using the same method and under the same research conditions is required to assess which instrument provides the highest repeatability for corneal thickness measurements.

To our knowledge, this is the first study comparing the Sirius Scheimpflug–Placido topographer and US pachymetry. The mean CCT by the

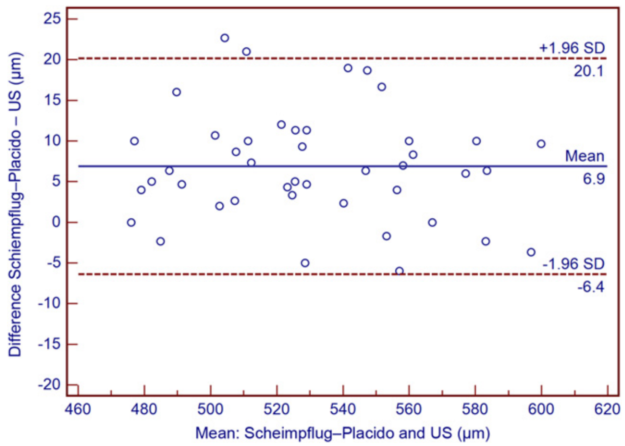

Figure 1. Bland-Altman plot shows 95% LoA between CCT by the Scheimpflug–Placido topographer and CCT by US pachymetry. The mean difference is represented by the solid line and the 95% LoA by the dotted lines (US = ultrasound).

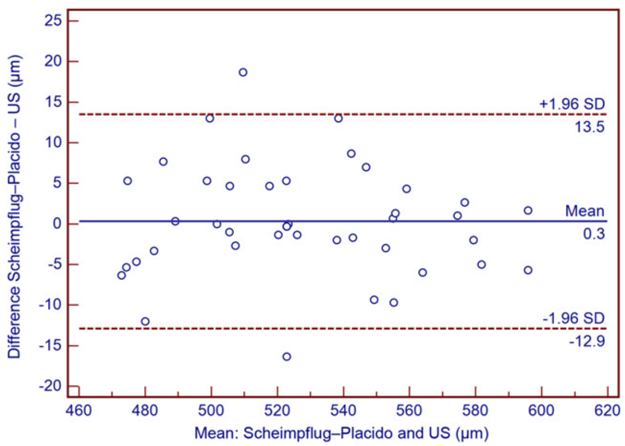

Figure 2. Bland-Altman plot shows 95% LoA between mean TCT by the Scheimpflug–Placido topographer and CCT by ultrasound pachymetry. The mean difference is represented by the solid line and the 95% LoA by the dotted lines (US = ultrasound).

Scheimpflug–Placido topographer overestimated the mean US pachymetry–CCT by an average of 6.88 μm. On the contrary, no statistically significant difference in TCT was found between the Scheimpflug–Placido topographer and the US pachymetry–CCT. These differences are clinically insignificant and are consistent with those in previous studies that compared other Scheimpflug cameras with US pachymetry in normal healthy corneas. Uçakhan et al.,[27] Chen et al.,[25] and Al-Mezaine et al.[28] found Pentacam CCT measurement to be thicker than US pachymetry by 2.7 μm, 5.7 μm, and 8.2 μm, respectively. Jahadi Hosseini et al.[29] compared the CCT measurements obtained with the Galilei system and US pachymetry in 47 healthy corneas and found that the CCT measurements obtained with the Galilei system were thicker (mean 560.57 ± 29.10 μm) than those with US pachymetry (mean 548.61 ± 29.92 μm). In a recent study, Karimian et al.[30] also reported that Galilei CCT measurements were higher than US pachymetry measurements by a nearly fixed amount of 10 μm.

Several reasons may explain the discrepancy between Sirius and US pachymetric values. First, the Sirius system uses the corneal vertex as the reference center, whereas US pachymetry is centered on the pupil. Second, the US pachymetry probe may displace the tear film and compress the epithelium, leading to lower measured values.[31,32] Third, the accuracy of US pachymetry depends on the experience of the operator, who must keep the probe perpendicular to the center of the corneal surface. This condition may not always be achieved. Finally, the exact location of the posterior corneal reflection of US is unknown because it ranges from Descemet membrane to the anterior chamber: If the posterior reflection is selected anterior to the endothelium, the measurements may be lower than the actual thickness.[27]

Agreement between the Sirius system and US pachymetry–CCT was good for CCT and TCT, as shown by the 95% LoA (from −6.39 to 20.14 μm and from −12.89 to 13.53 μm for CCT and TCT, respectively). The differences were small and comparable to those in previous studies of the 95% LoA between the Galilei system and US pachymetry (from −11.03 to 34.94 μm), the Pentacam system and US pachymetry (from −13.4 to 24.0 μm), the TMS-5 system and US pachymetry (from −35.4 to 8.4 μm), and the Orbscan II system and US pachymetry (−12.6 to 28.0 μm).[25,26,29] Interestingly, these values were close to the reported diurnal CCT fluctuation (±18 μm) measured with a rotating Scheimpflug camera.[33]

This study has limitations that warrant further investigation. Only 1 US pachymetry device was evaluated, and our results may not be valid when considering other US pachymetry models. It is not possible to apply our findings to other conditions, such as keratoconus and post-refractive surgery eyes; any degree of corneal opacity could induce mistakes in the precision of an optical pachymeter, which is the subject of an ongoing study.

In conclusion, the Sirius Scheimpflug–Placido topographer showed excellent intrasession repeatability and intersession reproducibility of CCT and TCT measurements in healthy eyes and good agreement with US pachymetry. The Sirius CCT and US pachymetry–CCT measurements can be considered clinically interchangeable in eyes with normal corneal thickness.

WHAT WAS KNOWN

- The Sirius is a relatively new rotating Scheimpflug camera combined with a Placido-disk corneal topographer that provides highly repeatable measurements of central and thinnest corneal thickness.

WHAT THIS PAPER ADDS

- The Sirius provided high intersession reproducibility of central and thinnest corneal thickness measurements.
- Thinnest corneal thickness measurements by the Sirius showed a high level of agreement with those obtained by US pachymetry, and these values may be considered clinically interchangeable.

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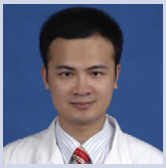

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