Evaluation of corneal thickness using a Scheimpflug–Placido disk corneal analyzer and comparison with ultrasound pachymetry in eyes after laser in situ keratomileusis

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PURPOSE: To evaluate the repeatability and reproducibility of corneal thickness measurements in post-laser in situ keratomileusis (LASIK) eyes using a rotating Scheimpflug camera combined with a Placido disk corneal topographer (Sirius) and compare the results with those of ultrasound (US) pachymetry.

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

DESIGN: Comparative evaluation of a diagnostic test or technology.

METHODS: Patients were examined 3 times with the Scheimpflug–Placido topographer by 2 examiners. The central pupil corneal thickness (CT_{pupil}), apical corneal thickness (CT_{apex}), and thinnest corneal thickness ($CT_{thinnest}$) were recorded. After noncontact examinations, US pachymetry was used to obtain the central corneal thickness (CCT).

RESULTS: The Scheimpflug–Placido topographer showed high intraoperator repeatability as indicated by a test–retest repeatability of less than 8.5 μm for CT_{pupil}, CT_{apex}, and $CT_{thinnest}$. The coefficients of variation (CoV) were less than 0.7%, and the intraclass correlation coefficient was higher than 0.99. Excellent results were also obtained for interoperator reproducibility. All CoVs were less than 0.5%. The 95% limits of agreement between the Scheimpflug–Placido measurement and the US pachymetry measurements were narrow (−16.62 to 12.44 μm for CT_{pupil} versus US pachymetry CCT; −17.49 to 12.16 μm for CT_{apex} versus US pachymetry CCT; −18.59 to 10.90 μm for $CT_{thinnest}$ versus US pachymetry CCT).

CONCLUSIONS: The Scheimpflug–Placido topographer showed excellent intraoperator repeatability and interoperator reproducibility of CT_{pupil}, CT_{apex}, and $CT_{thinnest}$ measurements in post-LASIK eyes. The CCT measurements obtained using the device were in high agreement with those obtained by US pachymetry, suggesting that the 2 devices are interchangeable.

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The precision of corneal thickness measurements is a crucial part of an advanced ophthalmologic examination. Accurate measurements of central corneal thickness (CCT) allow the surgeon to safely plan corneal refractive procedures, thus reducing the risk for postoperative complications such as ectasia.[1,2] In cases in which surgery has been performed and an enhancement is required, underestimating the CCT may exclude some patients who are eligible, whereas overestimating the CCT may increase the risk for corneal ectasia.[3–6] In addition, because CCT measurements are used to correct intraocular pressure (IOP) values, inaccurate CCT measurements can affect IOP values.[7] Precise measurement of CCT is also an important step when monitoring the progression of keratoconus.[8,9]

Ultrasound (US) pachymetry is still the most commonly used method to measure CCT due to its cost-effectiveness, ease of use, and high repeatability.[10–12]

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However, US pachymetry has disadvantages, such as the need for topical anesthesia and direct contact with the cornea, which may result in a risk for corneal damage and operator dependence.[13]

Many new and sophisticated techniques have been used to overcome these limitations of US pachymetry and to provide rapid, convenient, noninvasive, and objective measurements of CCT. These techniques include optical pachymetry, scanning-slit topography, Scheimpflug imaging, and optical coherence tomography. Previous studies[14,15] have shown the safety and precision of these techniques in the measurement of CCT.

The Sirius (Costruzione Strumenti Oftalmici) is one of the most recent devices in this field. It combines a single rotating Scheimpflug camera and a Placido-disk corneal topographer. Studies[16–19] have evaluated the intraoperator repeatability of anterior segment measurements by this device. However, the interoperator reproducibility of the pachymetry measurements obtained by this instrument and their agreement with US pachymetry measurements in post-refractive surgery eyes has not yet, to our knowledge, been assessed.

The aim of the present study was to prospectively evaluate the intraoperator repeatability and interoperator reproducibility of CCT measurements obtained by the Sirius Scheimpflug–Placido topographer in eyes that had previous laser in situ keratomileusis (LASIK). The CCT measurements obtained by the Scheimpflug–Placido topographer were further compared with those derived by US pachymetry.

SUBJECTS AND METHODS

This prospective study enrolled subjects who had LASIK to correct myopia between a 3- and 6-month period before enrollment. The research protocol adhered to the tenets of the Declaration of Helsinki and was approved by the Office of Research Ethics, Wenzhou Medical College. All subjects gave informed consent after receiving a full explanation of the nature and intent of the study. Exclusion criteria consisted of age younger than 18 years; presence of ocular pathology such as keratoconus, cataract, and glaucoma; use of contact lenses; and post-LASIK complications. All measurements were performed on the undilated eye, which was selected randomly.

The precision of the rotating Scheimpflug camera and Placido-disk analyzer system was determined based on the definitions adopted by the British Standards Institution, as recommended by Bland and Altman.[20] To avoid the effects of diurnal variation on corneal thickness, patients were scanned at least 3 hours after waking up. Two experienced examiners performed all measurements as previously described.[21] The following parameters were evaluated using the Scheimpflug–Placido topographer: central pupil corneal thickness (CT_{pupil}), apical corneal thickness (CT_{apex}), and thinnest corneal thickness ($CT_{thinnest}$). Each operator obtained 3 measurements in sequence using the Scheimpflug–Placido topographer. The 3 measurements obtained by the same operator were used to estimate the intraoperator repeatability. Interoperator reproducibility was assessed by comparing the mean measurements taken by the 2 examiners.

The noncontact measurements of corneal thickness obtained by the Scheimpflug–Placido topographer were then compared with those obtained by US pachymetry. The A-scan US pachymetry (SP-3000, Tomey Corp.) was calibrated before the measurements by a single examiner. Before the measurements, the cornea was anesthetized with 1 drop of proparacaine hydrochloride 0.5% (Alcaine). The examiner then handled the probe as perpendicularly as possible to the central cornea. Five readings were obtained, with the highest and the lowest values being excluded. The mean of the remaining 3 measurements was used to calculate the CCT. All measurements were taken between 10 AM and 5 PM to minimize the diurnal effect of pachymetric measurements.[22]

Statistical Analysis

All data were analyzed using SPSS for Windows software (version 13.0, SPSS, Inc.). Results were presented as means ± standard deviations. Data distribution was checked using Kolmogorov-Smirnov tests; the results indicated that the data were normally distributed ($P > .05$). The intraoperator repeatability of the measurements was assessed by determining the within-subject standard deviation (S_w), test–retest repeatability (2.77 S_w), within-subject coefficient of variation (CoV), and intraclass correlation coefficient (ICC). The test–retest, which is calculated by multiplying the S_w value by 2.77, represents the interval within which 95% of the differences in the measurements are expected to lie.[23] The CoV is calculated as the ratio of the S_w to the overall mean and is expressed as a percentage (the lower the CoV, the higher the repeatability). The ICC represents the consistency in data measurement. Its value ranges from 0 to 1 and is commonly defined as follows: an ICC value less than 0.75 = poor agreement; from 0.75 to 0.90 = moderate agreement; more than 0.90 = high agreement. The interoperator reproducibility of measurements obtained by the 2 examiners was estimated by calculating the mean value of the measurements taken by each operator, after which the interoperator S_w, 2.77 S_w, CoV, and ICC were calculated.

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To compare the Scheimpflug–Placido topographer and US pachymetry measurements, a paired *t* test was performed using the mean CCT measurement obtained by US pachymetry and the CT_{pupil}, CT_{apex}, and $CT_{thinnest}$ values provided by the Scheimpflug–Placido topographer. Furthermore, the 95% limits of agreement (LoA) were calculated and Bland and Altman plots were generated to assess the agreement between the corneal thickness measurements provided by the 2 devices.[20]

RESULTS

The study enrolled 59 subjects (30 men, 29 women); measurements were performed in 33 right eyes and 26 left eyes. The mean age of the patients was 24.9 ± 6.0 years (range 19 to 43 years). The mean pre-LASIK manifest spherical equivalent refraction was −5.40 ±1.61 diopters (D) (range −1.375 to −8.875 D).

Repeatability of the Measurements

The CT_{pupil}, CT_{apex}, and $CT_{thinnest}$ measurements showed high intraoperator repeatability for both examiners. Table 1 shows the intraoperator repeatability of CT_{pupil}, CT_{apex}, and $CT_{thinnest}$ readings by the Scheimpflug–Placido topographer. The results of the 2 examiners were similar. The CoV values were less than 0.7%, and the respective ICC values were higher than 0.99.

Reproducibility of the Measurements

Table 2 shows the interoperator reproducibility of the measurements obtained using the Scheimpflug–Placido topographer. The difference between the CT_{pupil}, CT_{apex}, and $CT_{thinnest}$ values was small. All test–retest values were less than 6.1 μm, the CoV values were less than 0.5%, and the respective ICC values were higher than 0.99.

Agreement Between the Scheimpflug–Placido Topographer and Ultrasound Pachymetry

The mean US pachymetry CCT was 450.29 ± 30.97 μm. The mean CT_{pupil}, CT_{apex}, and $CT_{thinnest}$ readings using Scheimpflug–Placido topographer were 448.21 ± 32.26 μm, 446.46 ± 32.06 μm, and 447.63 ± 32.38 μm, respectively. The differences between the Scheimpflug–Placido topographer and US pachymetry measurements were statistically significant in all cases ($P < .05$) (Table 3). However, the slight underestimation of the mean corneal thickness by the Scheimpflug–Placido topographer (between 2 μm and 4 μm) cannot be considered clinically significant. Table 3 and Figures 1 through 3 show a relatively narrow 95% LoA and good agreement between the 2 instruments, notwithstanding the fixed bias related to the underestimation of CCT by the Scheimpflug–Placido topographer.

DISCUSSION

The present study was prospectively designed (1) to evaluate the intraoperator repeatability and interoperator reproducibility of pachymetric readings of the pupil center, corneal apex, and the thinnest corneal point in post-LASIK patients obtained using the Sirius Scheimpflug–Placido topographer and (2) to compare these values with those obtained by US pachymetry. Our results showed high intraoperator repeatability of CT_{pupil}, CT_{apex}, and $CT_{thinnest}$ measurements using the Scheimpflug–Placido topographer. A similar result was reported by Savini et al.,[24] who obtained CoV values of 0.45% and 0.46% for CT_{apex} and $CT_{thinnest}$, respectively, in post-refractive surgery eyes. The test–retest values for CT_{apex} and $CT_{thinnest}$ were 5.90 μm and 5.95 μm, respectively, and the ICC values were less than 0.99. Montalbán et al.[17] obtained similar results in normal subjects, with CoV and ICC values of 0.52% and 0.997, respectively, for both CT_{apex} and $CT_{thinnest}$. Milla et al.[18] also report a CoV value of 0.6% and an ICC value higher than 0.99 for the CCT in unoperated eyes. In the present study, we report a CoV of less than 0.7% and an ICC of higher than 0.99, which confirms the high intraoperator repeatability of CCT measurements obtained by the Sirius

Table 1. Intraoperator repeatability of CT_{pupil}, CT_{apex}, and $CT_{thinnest}$ readings by the Scheimpflug–Placido topographer.

Parameter	Mean ± SD (μm)	Sw (μm)	2.77 S_w (μm)	CoV (%)	ICC (95% CI)
1st examiner					
CT_{pupil}	448.21 ± 32.26	2.80	7.74	0.62	0.993 (0.989, 0.995)
CT_{apex}	446.46 ± 32.06	2.71	7.50	0.61	0.993 (0.989, 0.996)
$CT_{thinnest}$	447.63 ± 32.38	2.65	7.33	0.59	0.993 (0.990, 0.996)
2nd examiner					
CT_{pupil}	446.77 ± 31.97	2.85	7.88	0.64	0.991 (0.986, 0.994)
CT_{apex}	445.07 ± 31.95	3.04	8.42	0.68	0.992 (0.988, 0.995)
$CT_{thinnest}$	446.11 ± 32.07	2.89	8.01	0.65	0.991 (0.986, 0.994)

CI = confidence interval; CoV = coefficient of variation; CT_{apex} = apical corneal thickness; CT_{pupil} = central pupil corneal thickness; $CT_{thinnest}$ = thinnest corneal thickness; ICC = intraclass correlation coefficient; S_w = within-subject standard deviation

Table 2. Interoperator reproducibility of CT_{pupil}, CT_{apex}, and $CT_{thinnest}$ readings by the Scheimpflug–Placido topographer.

Parameter	S_w (μm)	2.77 S_w (μm)	CoV (%)	ICC (95% CI)
CT_{pupil}	2.20	6.09	0.49	0.995 (0.989, 0.998)
CT_{apex}	2.17	6.01	0.49	0.995 (0.988, 0.998)
$CT_{thinnest}$	2.16	5.99	0.49	0.995 (0.990, 0.998)

CI = confidence interval; CoV = coefficient of variation; CT_{apex} = apical corneal thickness; CT_{pupil} = central pupil corneal thickness; $CT_{thinnest}$ = thinnest corneal thickness; ICC = intraclass correlation coefficient; S_w = within-subject standard deviation

Table 3. Comparison of CT_{pupil}, CT_{apex}, and $CT_{thinnest}$ readings by the Scheimpflug–Placido topographer and US pachymetry.

Parameter	Mean Difference ± SD (μm)	*P* Value	95% LoA (μm)
CT_{pupil}	−2.09 ± 7.41	.034	−16.62, 12.44
CT_{apex}	−2.67 ± 7.56	.009	−17.49, 12.16
$CT_{thinnest}$	−3.84 ± 7.52	<.001	−18.59, 10.90

CT_{apex} = apical corneal thickness; CT_{pupil} = central pupil corneal thickness; $CT_{thinnest}$ = thinnest corneal thickness; LoA = limits of agreement; US = ultrasound

Scheimpflug–Placido topographer in post-LASIK patients. In addition to high intraoperator repeatability, the Scheimpflug–Placido topographer also showed a high degree of interoperator reproducibility. We believe that our study is the first to assess the interoperator reproducibility of the Scheimpflug–Placido topographer.

Previous studies report the intraoperator repeatability of corneal thickness measurements in post-LASIK eyes using other Scheimpflug or Scheimpflug–Placido systems, such as the Pentacam (Oculus Optikgeräte GmbH), Galilei (Ziemer Group), and TMS-5 (Tomey Corp.). Savini et al.[19] assessed the repeatability of the Galilei, a dual Scheimpflug analyzer combined with a Placido disk corneal topographer, in post-refractive patients. They report CoV values of 0.40% and 0.33% and test–retest values of 5.97 μm and 4.78 μm for CT_{apex} and $CT_{thinnest}$, respectively. These results were slightly better than the results we obtained using the Sirius system. Huang et al.[25] evaluated the intraoperator repeatability of CCT measurements using the Pentacam, which is a single rotating Scheimpflug camera. They obtained CoV values of 0.89%, 0.83%, and 0.74% for CT_{pupil}, CT_{apex}, and $CT_{thinnest}$, respectively. The respective ICC values were 0.984, 0.986, and 0.989, which are slightly inferior to the results that we derived with the Sirius system. Jain et al.[26] assessed the repeatability of the Pentacam system and found coefficients of repeatability of 1.0%, 0.77%, and 0.78% for CT_{pupil}, $CT_{thinnest}$, and CT_{apex}, respectively, in post-LASIK eyes. This indirect comparison shows that all the instruments based on Scheimpflug imaging have high intraoperator repeatability in post-refractive eyes and suggests that the Galilei system has the highest repeatability. This may be because the Galilei system has 2 opposite Scheimpflug cameras and the data acquired by the 2 cameras are averaged to compensate for possible misalignment in pachymetric measurements due to eye movements.[27] However, because this is an indirect comparison of Scheimpflug-based systems, we cannot make direct conclusions as to which device shows the best repeatability of CCT measurements. Therefore, a further study is needed to compare the

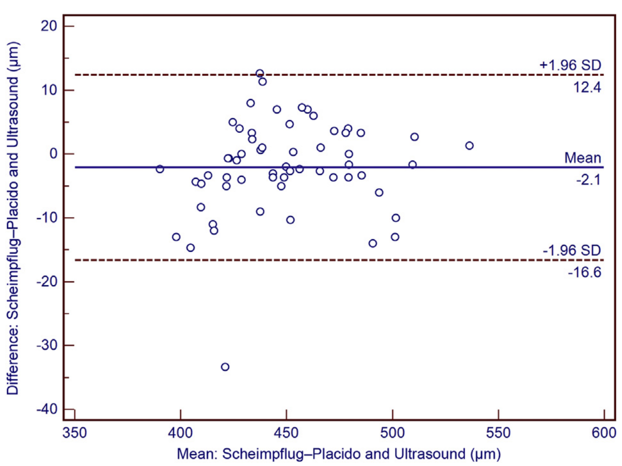

Figure 1. Bland-Altman plots comparing CT_{pupil} between the Scheimpflug–Placido topographer and the US pachymeter. The 95% LoA are shown by *dashed lines*, and the *solid line* represents the mean difference between the measurements (CT_{pupil} = central pupil corneal thickness; US = ultrasound).

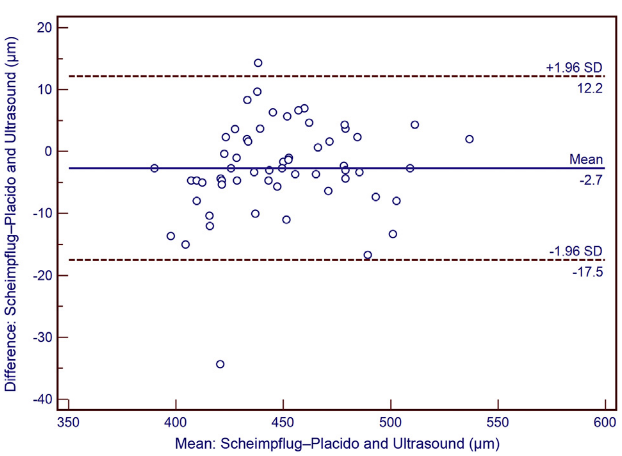

Figure 2. Bland-Altman plots comparing CT_{apex} between the Scheimpflug–Placido topographer and the US pachymeter. The 95% LoA are shown by *dashed lines*, and the *solid line* represents the mean difference between the measurements (CT_{apex} = apical corneal thickness; US = ultrasound).

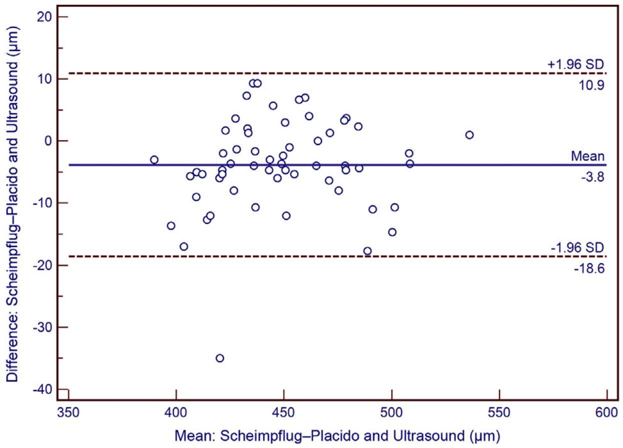

Figure 3. Bland-Altman plots comparing $CT_{thinnest}$ between the Scheimpflug–Placido topographer and the US pachymeter. The 95% LoA are shown by *dashed lines*, and the *solid line* represents the mean difference between the measurements ($CT_{thinnest}$ = thinnest corneal thickness; US = ultrasound).

3 Scheimpflug instruments under the same conditions and at the same time.

To our knowledge, this is the first study to compare CCT measurements derived from the Sirius Scheimpflug–Placido topographer and US pachymetry in post-LASIK eyes. Our results suggest that the Sirius system and US pachymetry can be used interchangeably in post-LASIK eyes, notwithstanding a small underestimation of CCT measurements (2 to 4 μm) by the Sirius system. Previous studies with other Scheimpflug cameras provide conflicting results. This is because in some cases, the mean difference in CCT measurements obtained by the optical system and US pachymetry was small; however, in other cases, the difference was considerably larger than that observed in our series. Park et al.[28] found that corneal thickness measurements obtained by the Galilei system were 13.2 μm thicker than those obtained by US pachymetry (95% LoA from −9.0 μm to 35.5 μm). Ciolino et al.[29] found that the CT_{apex} values provided by the Pentacam system were thicker by 1.4 μm than those obtained by US pachymetry and the 95% LoA ranged from −18.9 to 21.8 μm. On the contrary, Ho et al.[30] and Prospero Ponce et al.[31] found that US pachymetry CCT measurements were thicker than Pentacam measurements by mean values of 9.00 μm and 25.0 μm, which are larger than, but similar to, the measurements we obtained with the Sirius system.

Several reasons may explain the discrepancy between the CCT measurements derived from the Scheimpflug cameras and US pachymetry. First, use of topical anesthetic drops may induce corneal edema, thus increasing corneal thickness and influencing the speed of US.[10,32] Second, the posterior surface reflection point is located between Descemet membrane and the anterior chamber. The corneal thickness reading may be higher than the actual value if the posterior reflection is selected close to the anterior chamber.[33] Third, the accuracy of US pachymetry depends on the experience of the operator, who must keep the probe perpendicular to the center of the cornea. Failure to do so may lead to off-center or oblique probe positioning, ultimately yielding thicker CCT measurements. Last, LASIK may also alter the corneal refractive index and influence the results of CCT measurements obtained using various optical methods.[34]

The CCT measurements obtained by US pachymetry in post-LASIK eyes have been compared with those obtained by slit-scanning corneal topography (Orbscan and Orbscan II, Bausch & Lomb). Relevant differences have been reported, and the Orbscan and Orbscan II devices have been found to provide CCT measurements that are thinner by an amount of 30 to 60 μm compared with US pachymetry, despite the use of a different custom acoustic factor.[10,30,35,36] Given that the CCT measurements of another Scheimpflug camera (the Pentacam) have been shown to be in better agreement with those of US pachymetry than those of the Orbscan II device in post-photorefractive keratectomy (PRK) and post-LASIK eyes,[28,36,37] we can conclude that Scheimpflug imaging provides more reliable CCT measurements than slit-scanning topography. Finally, our data, along with those in previous studies evaluating the Pentacam system,[36,38] suggest better agreement between Sirius system measurements and US pachymetry measurements (95% LoA from −17.40 to 12.16 μm) than between Pentacam measurements and US pachymetry measurements (95% LoA from −25.9 to 25.5 μm).[36]

Our study has limitations that warrant further investigation. First, we did not evaluate eyes that had hyperopic LASIK; hence, our results cannot be applied to this group of eyes. Second, we did not include special cases, such as post-LASIK ectasia or post-PRK haze, which may influence the repeatability of CCT measurements by both techniques.

In conclusion, the Sirius Scheimpflug–Placido topographer showed high intraoperator repeatability and interoperator reproducibility of CT_{pupil}, CT_{apex}, and $CT_{thinnest}$ measurements in post-refractive surgery eyes. Although the corneal thickness readings obtained by the Sirius system were slightly lower, the difference cannot be considered clinically relevant. There was also excellent agreement between CCT measurements obtained by the Sirius system and US pachymetry. Thus, the Sirius system and US pachymetry can be considered interchangeable for corneal thickness measurements in most clinical settings.

WHAT WAS KNOWN

- Accurate and reliable determination of CCT is crucial for evaluating patient eligibility for corneal refractive surgery.
- Only the intraoperator repeatability pachymetry measurements with the Sirius system, based on the combination of Scheimpflug-photography and Placido-disk technology, in post-refractive surgery eyes have been reported.

WHAT THIS PAPER ADDS

- The Sirius Scheimpflug–Placido topographer provided excellent interoperator reproducibility of CT_{pupil}, CT_{apex}, and $CT_{thinnest}$ measurements in post-LASIK eyes.
- The Scheimpflug–Placido topographer corneal thickness measurement and that of US pachymetry showed high agreement. Therefore, these methods may be considered interchangeable in post-LASIK eyes for most clinical applications.

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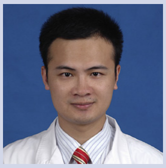

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