STUDY ON PRECISION OF A NEW SCHEIMPFLEG AND PLACIDO-DISK ANALYZER IN MEASURING CORNEAL THICKNESS AND AGREEMENT WITH ULTRA SOUND PACHYMETRY AS A PRE-OPERATIVE MEASURE

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ABSTRACT

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 Pachymetry (Nidek Model Up-1000).

SETTING
Private Practice Setup.

DESIGN
Comparative evaluation of a Diagnostic technology

METHODS
At this centre, healthy subjects who came for laser vision correction were examined pre-operatively with the Scheimpflug Placido Topographer. Central (CCT) and thinnest (TCT) corneal thickness were recorded after three consecutive measurements. For US Pachymetry, only CCT measured. Central (CCT) and TCT were measurements with Scheimpflug and placido-disk analyser were repeated, after ten minutes in the same session.

The within subject Standard Deviation(SW) test-retest repeatability, coefficient of variation and intra class correlation coefficient (ICC) were calculated to evaluate within session repeatability and inter device comparison is analyzed with Paired T-test and Bland-Altman plots.

RESULTS
The within session repeatability of Scheimpflug measurements are high with test-retest and CoV close to 2.61 μm and 0.21 %, for CCT and TCT. The ICC is higher than 0.998 for repeatability. High agreement was found between Scheimpflug placid and US Pachymetry measurements with a narrow 95% Limits of agreement.

CONCLUSION
The Scheimpflug placid instrument showed excellent within session repeatability of CCT and TCT pre-operatively in healthy eyes and lack of statistically significant difference with US Pachymetry CCT measurements.

The CCT measurements obtained by Sirius system can be used inter-changeably in subjects with normal thickness and cases can be taken safely for refractive laser surgery.

KEYWORDS
CCT, TCT, ICC.


INTRODUCTION
High accuracy and precision is required in corneal thickness measurements in refractive laser procedures. Laser refractive procedures are planned according to the pre-operative measurements of the corneal thickness.[1]

Errors like over estimation of central corneal thickness (CCT) may result in excess stromal ablation and results in increased risk of keratectasia.[2]

CCT measurements are helpful in monitoring intraocular pressure values measured by Goldmann Applanation Tonometry,[3] and are important when monitoring corneal disorders such as keratoconus, contact lens related complications post-surgical cases and dry eyes.[4,5]

Ultrasound Pachymetry (US) is the most commonly used method to measure CCT, which is still regarded as the gold standard because of its low-cost compact design, easy to use option and high repeatability.[6,7] It has certain disadvantages like need for topical anaesthesia and contact with the cornea with a risk of epithelial aberrations and infections.[8-10]

Few studies,[7-11] are found that the precision of the US Pachymetry is operator dependent and important differences arose from using different devices. The newer sophisticated devices provide more rapid and convenient non-contact objective measurements of the CCT.
Newer generation devices include Scheimpflug imaging (Pentacam, Oculus Optikgerate, GMBH and Galilei, Zeimer Group, scanning slit topography (ORB SCAN, Bausch and Lomb) and optical coherence tomography.

The more recent device in this area is the Sirius (COSTRUZIONE STRUMENTI OPTALMICI) which combines a rotating Scheimpflug camera and a placido disk topographer.

Earlier studies of this instrument highlighted on within session repeatability of anterior segment measurements and comparison with other Scheimpflug systems.

To our knowledge within session (Intra session), inter session reproducibility and comparison between Sirius system and US Pachymetry (US Pachymeter SP-3000 Tomey Corp) are reported.

But the present study focused on agreement between this new (Sirius) SCHEIMPFLUG Placido Disk Topography and US Pachymeter Nidek Ultrasonic Pachymeter model UP-1000m which has been in use for the past 6 years, proved to be safe in our previous experience in measuring the corneal thickness for pre-operative cases and this model is very popular.

To our knowledge no study focused on agreement between Sirius system and Nidek ultrasound Pachymetry. We aim to analyse the within session repeatability of CCT and TCT measurements obtained by the Sirius system and compare these Measurements with those obtained by using US Pachymeter (NIKED Model UP-1000) in pre-operative cases.

SUBJECTS AND METHODS

This prospective study comprised of pre-op cases came for laser vision correction. The study protocol adhered to the tenets of declaration of Helsinki. Each subject gave informed consent and was explained clearly about the investigations before surgery.

The inclusion criterion are Refractive errors ranging between 0.50D sph to 13.00 D sph with/without astigmatism up to 3.00 D cyl.

The exclusion criterion are patients younger than 18 years and unstable refractive error 6 months earlier previous ocular surgery, keratoconus, glaucoma, Cataract, posterior segment pathologies and dry eyes.

Scheimpflug camera placid disk topography system (SIRIUS)

The Sirius Scheimpflug system combines monochromatic 360 degree rotating camera and a placido-disk corneal topographer. In this system, scanning process acquires series of 25 images (Meridians) and one placido top view image.

Ring edges are detected on the placido image so that height, slope and curvature details are calculated using the Arc-step method with conic curves. All the profiles of the Anterior CORNEA AND Posterior cornea, anterior lens and Iris are derived from the Scheimpflug images.

Data for the anterior surface from the placido disk image and Scheimpflug imaged are merged using proprietary method.

Other measurements like internal structures (Posterior cornea, anterior lens and Iris) are derived entirely from Scheimpflug data.

This system can measure 35,632 points and 30,000 points for the anterior corneal surface and posterior surface respectively. The Pachymetric map is then reconstructed using the data from both the corneal surfaces. The present study analyzed the central corneal thickness (CCT) AT THE Apex of the cornea and the thinnest corneal thickness (TCT) were recorded, analyzed and compared with the CCTs of the US Pachymetry (NIDEK-UP 1000).

MEASUREMENT PROTOCOL

The Precision of the Sirius topography is determined based on the definition adopted by the international organization for the standardization. As recommended by BLAND and ALTMAN each patient is examined by the experienced optometrist under the supervision of the presenting author. The session is designed to determine intra-observer repeatability. First Time 3 valid scans performed and average values are taken, after that the device is moved backward and realigned. After a gap of 10 minutes, the patient is examined again for acquisition of the data by the same examiner.

After the non-contact examination with the Scheimpflug –placido topographer is performed; the cornea is anaesthetized with pro-paracaine hydrochloride 0.5% (Algaine). The US Pachymeter (NIKED Ultrasonic Pachymeter Model UP-1000) is pre-calibrated for all measurements. The US velocity is set to 1640m/s. A hand held probe is aligned as perpendicularly as possible to the Apex of the cornea. The mean of the three readings is used and defined as US Pachymetry central corneal thickness (CCT). This CCT value is compared with the mean CCT and TCT values provided by the Scheimpflug Placido disk topography.

All the measurements are taken between 11.00 AM to 1.00 PM to minimize the effect of Diurnal Variation on corneal thickness.

STATISTICAL ANALYSIS

All the data is analysed using Microsoft Excel, "R" and Minitab statistical software.

Results are presented as Mean ± Standard Deviation (SD’S). The distribution of the data sets is checked for normality using KOLMOGOROV–SMIRNOV Tests. The results indicated that data are normally distributed (P-value >.05). To determine the within session repeatability of the device, the within-subject SD(SW) test-retest repeatability (TEST-RETEST, 2.77 Sw) within subject co-efficient of variation (CoV) and intra class correlation co-efficient (ICCs) are calculated for the repeated measurements.

The test-retest is defined as 2.77 Sw, which means an interval within which 95% of the differences are expected to lie.

The CoV is calculated as the ratio of the SW to the overall mean. The 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 is the measurement consistency.
Comparison of the mean CCT and TCT by the Sirius system and the US Pachymeter CCT was performed using paired T-tests. Agreement between the two devices is assessed according to the method described by BLAND-ALTMAN. [17] Who suggested the plotting the differences between the measurements (Y-axis) against their mean (X-axis).

BLAND-ALTMAN plots facilitates evaluations of the existence of any systematic differences between measurements (i.e. 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 indicated 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]

<table>
<thead>
<tr>
<th>Parameters</th>
<th>MEAN DIFFERENCE µm ± SD</th>
<th>P Value</th>
<th>95% LoA µm</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCT</td>
<td>518.62 ± 32.36</td>
<td>0.00</td>
<td>3.90, 8.99</td>
</tr>
<tr>
<td>TCT</td>
<td>515.81 ± 32.60</td>
<td>0.00</td>
<td>6.69, 11.82</td>
</tr>
</tbody>
</table>

Table 2: Comparison of CCT AND TCT readings by Scheimpflug-Placido Topographer and Ultra Sound Pachymetry
DISCUSSIONS

This study is prospectively designed to evaluate the precision and accuracy of the CCT and TCT measurements in Pre-op cases by the Sirius system and evaluate the agreement between the US Pachymetry and Sirius System.

Our study confirms the high repeatability of the Scheimpflug systems’ thinnest corneal thickness (TCT) and Apex Pachymetry (CCT) in pre-op cases. The ICC is close to 0.998 and within session CoV is lower than 0.21%. 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 un operated 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.

Montalban et al.\[20\] reported CoV of 0.52% for both CCT and TCT and ICC values close to 1.

Chen et al.\[21\] reported the test-retest of the Sirius device was 9.18 µm.

Our study confirms the results in previous studies of the within session repeatability of Sirius measurements.

Many Authors have assessed the repeatability of CCT measurements with other Scheimpflug Cameras.

Savini et al.\[22\] reported the repeatability of the measurements, by the Galleili, which combines a dual Scheimpflug Camera and Placido Topographer were high. The test-retest of CCT and TCT Was 5.97 µm and 4.78 µm respectively, while CoV is 0.40% and 0.33% respectively.

Even Lower CoV (0.25%) for CCT was reported by Wang et al.\[23\] for the Galleili.

Nam et al.\[24\] found Pentacam system, which is based on a single Scheimpflug camera, reported a test-retest and CoV of CCT of 10 µm and 0.67 % respectively.

The reports of the Chen et al.\[25\] are in agreement with Jinhai Huang et al Studies.\[34\]

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 studies by Jinhai Huang et al.

Jinhai Huang et al.\[34\] conducted a comparative study between New Sirius Scheimpflug system and US Pachymetry (SP-3000, Tomey Corp). Sirius System over estimated the Mean US Pachymetry CCT by an average of 6.88 µm.

Contrary to this, no statistically significant difference in TCT is found between the Sirius system and US Pachymetry CCT. But in our study both CCT and TCT of the Sirius system are lower by an average of 10 µm for TCT and 7 µm for CCT.

Ulakhan et al.\[27\] Chen et al.\[25\] and A Mezaine et al\[28\] found Pentacam measurement to be thicker than US Pachymetry by 2.7 µm, 5.7 µm and 8.2 µm respectively.

Jahadai Hosseini et al.\[29\] measured CCT with Gallilei system and US Pachymetry and found that the CCT measurement obtained by the Gallilei system were thicker. Recent study by Karimian et al.\[30\] also reported higher values for CCT with Gallilei, by 10 µm fixed amount than US Pachymetry.

There are several reasons to explain the discrepancy between the Scheimpflug’s and US Pachymetry values. The Scheimpflug system uses the corneal vertex as the reference centre, where as Ultra sound Pachymetry is centred on the Pupil.

US Pachymetry Probe, may displace the tear film and compress the epithelium leading to lower measured values.\[31,32\]

The accuracy of US Pachymetry depends on the experience of the operator, who must keep the probe perpendicular to the centre of the corneal surface. This may not be achieved every time. The exact location of the posterior...
corneal reflection of Ultra Sound is unknown, because it ranges from Descemet’s membrane to the Anterior chamber. If the posterior reflection is from Descemet’s Membrane, the measured values may be lower than the actual thickness [27].

The agreement between this Sirius system and US Pachymetry CCT is good for CCT AND TCT as shown by the 95% LoA from 3.90 µm to 8.99µm and from 6.69 µm to 11.82 µm CCT and TCT respectively.

The Differences are small and comparable to those in previous studies of the 95% LoA between different systems and US Pachymetry measurements, [25,26,29]

There are reports of Diurnal CCT fluctuations (±18µm) in measurements, with a rotating Scheimpflug Camera. [33]

The study by Jinhai Huang et al. [34] shown agreement between Sirius system and US Pachymetry-CCT was good for CCT and TCT as shown by 95% LoA (From-6.39 µm to 20.14 µm and from-12.89µm to 13.5 µm for CCT and TCT respectively, in that order).

The present study shows Agreement between Sirius system and US pachymetry CCT is good for CCT and TCT. This study is done using a different Ultra Sonic Pachymeter, NIDEK’S MODEL UP-1000.

In the earlier study, Jinhai Huang. [34] has used US Pachymeter (SP-3000 TOMEY Corp).

This study is conducted in south Indian City using Ultra Sonic Pachymeter for comparison, which was in use for more than six years, reliable, proved to be safe and accurate according to the Authors’ experience. The present study comparing the Sirius system and US Pachymeter slightly differs from the other studies.

In our study the CCT and TCT obtained by Sirius system are consistently lower than the CCT of the Nidek ultrasound pachymeter. The reasons could be because of the examiners inaccuracy in applying the probe on to the centre of the cornea in obtaining CCT of the ultrasound pachymeter. The other reason could be the ultrasound waves may be reflecting from the anterior chamber in this particular ultrasound pachymeter (Ultrasound UP model 1000). The other reason could be a Sirius system may be underestimating the values. However, there is good agreement between the two devices.

In conclusion, the Sirius Scheimpflug Placido Topographer, has shown excellent intra session (Within session) repeatability of CCT and TCT in Pre-op eyes and good agreement with US Pachymeter.

The US Pachymeter CCT and Sirius CCT measurements can be considered clinically interchangeable and Sirius System is proved to be safe, accurate and precise.

REFERENCES


