Agreement and reliability in measuring central corneal thickness with a rotating Scheimpflug–Placido system and ultrasound pachymetry

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A R T I C L E   I N F O

A B S T R A C T

Purpose: We compare the agreement and the reliability in measuring central corneal thickness (CCT) using two different technologies.

Method: The right eyes of 35 healthy individuals who had a negative history of ophthalmic disease, or ocular surgery were examined. The CCT was determined sequentially with a rotating Scheimpflug camera (Sirius; CSO), and an ultrasound pachymeter (P-1; Takagi). For statistical analysis, we used the methods suggested by Bland and Altman.

Results: The mean values of CCT obtained from Sirius, and ultrasound were $537 \pm 28\ \mu$m, and $550 \pm 35\ \mu$m, respectively. There was a high correlation between Sirius and ultrasound ($r = 0.92$; $p < 0.001$), but the difference between the two measurements was statistically significant ($t = -5.7$; $p < 0.00001$). The precision of Sirius and ultrasound were 9.4 and 15.9 μm; repeatability 13.3 and 22.4 μm, and coefficient of variation 0.9% and 1.5%, respectively. The intraclass correlation coefficient was 0.97 for Sirius and 0.95 for ultrasound.

Conclusions: The average difference between corneal thickness measured with Sirius and ultrasound pachymetry was small but clinically significant. This means that the two instruments cannot be used interchangeably. Sirius showed precision and repeatability almost twice as much as ultrasound pachymetry. Confidence interval of 13.3 μm for Sirius can show variations in corneal thickness with an uncertainty value lower than 2.5% in 95% of cases. The simplicity of use, the possibility to obtain pachymetric maps, and less invasiveness make this instrument potentially useful in contact lens practice.

1. Introduction

Corneal thickness measurement is clinically important for several reasons: it allows the evaluation of physiological and pathological variations of the cornea structure [1,2]; it is important to evaluate suitable patients for refractive surgery [3,4]; preoperative pachymetry is mandatory before cross-linking treatment of progressive keratoconus [5]; and knowledge of an individual's central corneal thickness (CCT) provides valuable information about their glaucoma risk [6,7]. Furthermore, as contact lens wear could affect corneal thickness, corneal pachymetry is an important factor in contact lens (CL) practice [8–11].

Ultrasound pachymetry (USP) is currently considered the gold standard method to assess corneal thickness. It is widely used for its good repeatability, low cost, portability and relative ease of use [12–15]. However, USP shows some limits as the difficulties in centration and alignment that can rise variability of measurement. Moreover the USP procedure has some aspects of invasiveness: a need for topical anaesthesia, possible risk of epithelial lesions or transmission of infection, and discomfort for the patients [16].

Nowadays, less invasive new technologies, that provide more figures, have been developed in order to obtain pachymetric maps of the whole cornea. These include slit scanning corneal topography (SSCT), optical coherence tomography (OCT), and Scheimpflug camera systems (SCS). A recent device in this field is the Sirius (CSO, Florence, Italy), which combines a rotating Scheimpflug camera and a Placido disk.

We compare the reliability and the agreement in measuring central corneal thickness (CCT) using this new Scheimpflug–Placido topographer and USP.

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2. Methods

2.1. Subjects

Thirty-five (25 females, 10 males) volunteers were selected among students of the Optics and Optometry Degree Course of Roma TRE University (Rome). The subject's average age was 25.9 ± 6.7 years (min 20 max 44). Each subject was examined before the experiment with slit lamp. Subjects with corneal pathology and corneal opacities were excluded. Contact lens wearers were enrolled only if they had taken their lenses out 12 h before the experiment. All subjects had been informed about the experiment in detail and they signed the consent document in compliance with the Declaration of Helsinki before the experiment.

2.2. Instruments

2.2.1. Scheimpflug camera system

Sirius acquiring system (CSO, Florence, Italy) is made up of one Placid disc and one Scheimpflug rotating camera (led light $\lambda = 475$ nm) located in the peripheral zone of Placid disc. The scanning process acquires a series of 25 anterior segment tomographic Scheimpflug images and one Placido videokeratoscopic image. The Scheimpflug camera rotating $180°$ acquires sequentially 25 radial section images of the anterior segment. Checking the acquired images, it is possible to discover some artefacts (e.g. eyelid covering of corneal surface) and the instrument software allows the manual editing of both tomographic and videokeratoscopic images in order to improve acquisition quality. Finally the software provides Scheimpflug and videokeratoscopic image quality indices: the higher the image quality the more precise is the measurement because all the acquired points of cornea are elaborated. Sirius provides anterior and posterior corneal surface topographic maps as well as pachymetric and anterior chamber depth maps. In the pachymetric map some points of clinical interest are available: thinnest point, thickness at pupil centre, thickness at geometric centre point, thickness at corneal apex. In this study, the CCT at the pupil centre was recorded and analyzed.

2.2.2. Ultrasound pachymeter

The USP uses sound waves reflection to obtain corneal thickness measure. It is able to read the delay of sound wave reflection on posterior corneal surface with respect to the anterior surface and then convert it in corneal thickness measurement through inverse velocity formula. The USP for many years has been the most widely used device to measure corneal thickness both for clinical and research aims. In this study, USP was measured using the handheld ultrasound pachymeter P-1 (Takagi Seiko Co., Ltd., Nagano, Japan) with a measurement range between 150 and 1200 μm. Frequency is set up at 20 MHz. The instrument used an ultrasound velocity (acoustic index) of 1640 m/s and was calibrated by the manufacturer.

2.3. Procedure

This was a cross-over, longitudinal with repeated measurements and non-randomized experimental study. All measurements were taken between 9 AM and 2 PM to minimize diurnal change of corneal thickness. The first measurement was always effectuated with Sirius. The reason for this choice is that Sirius is not as invasive as USP (it requires topical anaesthesia and corneal touch). The same investigator took all clinical measures with Sirius. Note that the investigator (an optometry student involved in his thesis) was not experienced in using this instrument; he began to use it only few months before the experiment.

Three consecutive measures were taken with Sirius. During measurement the subject was asked to position his head on the chin rest and to gaze into the light in the centre of Placid Disc without moving his/her eyes. After each acquisition, the subject was asked to pull back from the chin rest and to blink without squinting. In order to minimize examiner errors, after three measurements with Sirius the image quality was evaluated. According to the instrument quality indices, measurements not sufficiently good were eliminated, with a minimum of three valid measurements.

After the Sirius measures, a second investigator, expert in the use of this kind of instrument, that was not aware of the previous results with Sirius, performed the USP procedure. He did not read and wrote down the measures given by the instrument; another investigator did this task. Each subject received one drop of oxybuprocaine (0.4% Novesin, Novartis Farma SpA, Varese) in the right eye. After a few minutes five consecutive measures with ultrasound pachymeter were taken but only the last four of them were considered for analysis. The first measurement was performed only to make the patient confident with the procedure.

The subject, sitting on chair, was asked to fixate on an optotype chart on a distant wall (6 m). Then, as best as could be judged manually, the probe was aligned centrally and perpendicularly to the cornea at the pupil centre.

2.4. Statistical analysis

Statistical analysis was performed using Microsoft Excel (Microsoft Corporation, Redmond, Washington, USA) and SPSS (SPSS Inc., Chigago, IL). The Kolmogorov–Smirnov test was used to evaluate the normality of distribution of the pachymetric datasets. The results indicated that the data were normally distributed ($p > 0.9$), so, parametric statistics were justified.

Person correlation coefficient (r) evaluated relation between Sirius and USP measures. Then it was evaluated between measures regression. Through Student's t-test it verified the hypothesis that measure averages with two instruments were significantly different. Finally Bland–Altman plot was used to assess the difference in the measurement between the two instruments as function of the mean thickness value obtained with the two instruments [17–19].

Repeatability was evaluated through coefficient of precision (CP) and coefficient of repeatability (CR). CP was calculated as $1.96 \times s_w$, where s_w was within-subjects standard deviation for repeated measures. Instrumental measure error ranges between two standard deviation with a 95% probability. On the contrary CR was calculated as $1.96 \times \sqrt{(2s_w^2)}$, that is the value under which it would be the difference between two measurements in the 95% of probability [20,21]. S_w is the square root of s_w^2 (mean square error). S_w^2 was calculated by ANOVA (one-way analysis of variance) [20,21]. ANOVA is valid only if the standard deviation of each subject measure does not depend on measure size. This could be verified by plotting standard deviation on measure size and calculating Kendall's τ [20].

Measure error was also calculated as coefficient of variation (CV) and interclass coefficient (ICC). CV is the standard deviation (s_w) in ratio to the mean of measurements and it is expressed as a percentage [21]. ICC is evaluated as the homogeneity between the repeated measurements in ratio to the total variation.

3. Results

The right eye CCT mean was 537 ± 28 μm with Sirius and 550 ± 35 μm with USP (Table 1). The correlation between measures was significant ($r = 0.92$ $p < 0.001$) and linear regression showed a good correlation between measures ($R^2 = 0.84$; Fig. 1).

Bland–Altman plot shows that the difference between instruments decreased significantly ($r = -0.48$ $p < 0.01$) moving to higher corneal thickness (proportional bias) (Fig. 2). The mean difference

Table 1
Corneal central thickness (CCT) and reliability coefficients. CP: coefficient of precision; CR: coefficient of repeatability; CV: coefficient of variation; ICC: intraclass correlation coefficient.

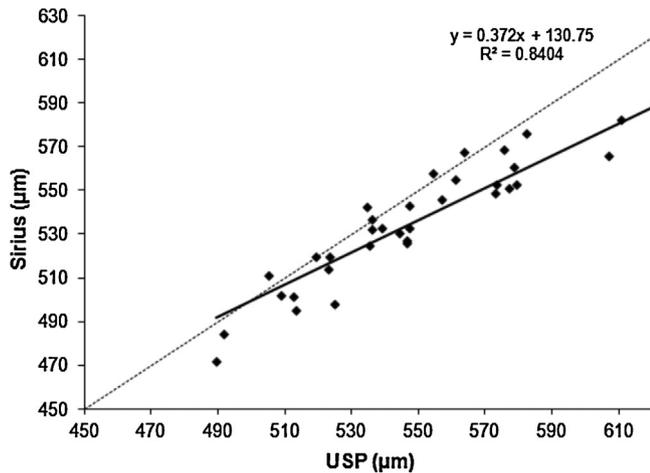|	CCT (μm)	CP (μm)	CR (μm)	CV (%)	ICC
Sirius	537 ± 28	9.4	13.3	0.9	0.97
USP	551 ± 33	15.9	22.4	1.5	0.95

Fig. 1. Plotting of correlation between USP and Sirius measures. Black line shows linear regression. Dashed line shows perfect correlation.
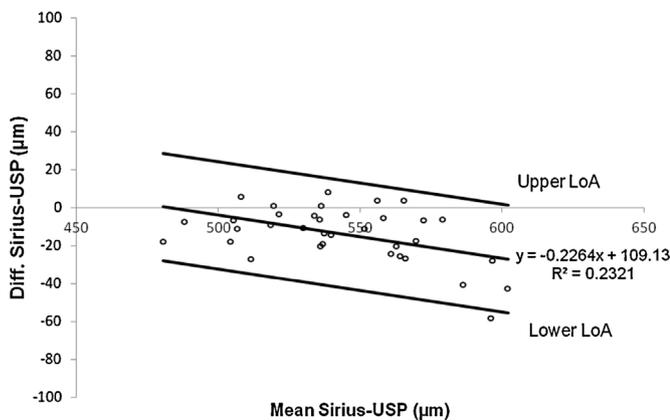

Fig. 2. Bland–Altman plot of the differences between Sirius and USP in CCT measures plotted against mean of the two instruments measures. Limits of Agreement are calculated as mean difference ± 1.96 SD of differences, CI at 95% calculated as Bland and Altman [18].

(Sirius minus USP) was −13.9 μm and the limits of agreement (LoA) were −42.2 μm and +14.4 μm. A significant difference between the two measures was found (t-test = 5.7; $p < 0.00001$) (fixed bias).

Standard deviation of each subject measure did not depend on measure size for both instruments (Figs. 3 and 4) (Kendall's τ; n.s.).

CP was 9.4 μm and 15.9 μm for Sirius and for USP, respectively. CR was 13.3 μm for Sirius and 22.4 μm for USP. CV was 0.9% for Sirius and 1.5% for USP. ICC was 0.97 and 0.95 for Sirius and USP, respectively (Table 1).

4. Discussion

In this experimental study, the agreement between the central corneal thickness (CCT) measurements obtained with two different technologies (Sirius SCS and USP) has been compared. Reliability of the two instruments was also investigated. Measurements were taken on a sample free of ocular pathology and corneal opacities.
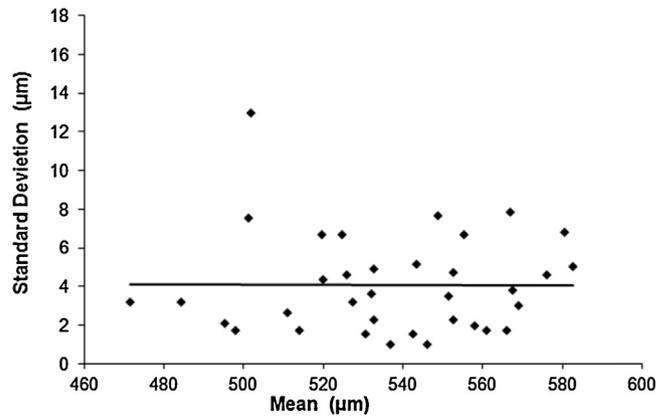

Fig. 3. Measure error of Sirius plotted as standard deviation in function of measure values.

For what concern the agreement between the two instruments studied, Sirius showed lower CCT measures compared to the USP. The mean difference (Sirius minus USP) was −13.9 μm and the limits of agreement (LoA) were −42.2 μm and +14.4 μm. Lower CCT measures compared to the USP have been already found in several studies referring to other kind of SCS instruments [13,22,23]. Also Orbscan and OCT have mostly showed a lower CCT measure compared to USP [13,24]. A reason to explain USP overestimation compared with optical instrument can be ascribed to the drug effect (topical anaesthetics) on corneal thickness. In fact it was reported that 1 drop of oxybuprocaine 0.4% provokes corneal oedema [25], although other studies have shown no significant difference in corneal thickness following instillation of 2 drops of oxybuprocaine 0.4% [26,27].

Differently, some other studies have shown that measures obtained by optical instruments are higher than ultrasound pachymeter ones [28–31]. Among these, in two studies the optical instrument used in comparison with the USP was the Sirius SCS [30,31]. Huang et al. [30] found a statistically significant difference of 6.88 μm (Sirius minus USP) with a range of agreement (LoA −6.4 to 20.1 μm) narrower compared to this study. More recently Jorge et al. [31], in a similar study, found a not statistically difference of 4.68 (Sirius minus USP) and a narrower range of agreement (LoA −15.8 to 25.20 μm). The differences between the present study and the latter two could be due to different models of USP used and also to the corneal position of measuring. For example Huang et al. [30] measured the CCT at corneal apex with Sirius and at pupil centre with the USP; in this study CCT measures were obtained at the pupil centre with both instruments. Jorge et al. [31] did not
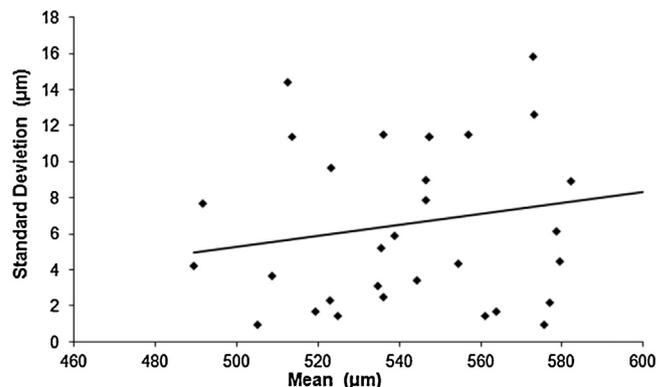

Fig. 4. Measure error of USP plotted as standard deviation in function of measure values.

report in which corneal location measures for both instruments were effectuated.

Reliability of the instruments was the second aspect investigated in this study. Sirius SCS measure error was evaluated as CP (9.4 μm), CR (13.3 μm), CV (0.9%) and ICC (0.97). Other studies have investigated the Sirius's precision with similar results. Milla et al. [32] found a CP of 6.1 μm, a CR of 8.6 μm, a CV of 0.6% and ICC of 0.92. Savini et al. [33], measures the CCT at the thinnest corneal point and at the geometric centre founding a CR of 7.4 μm and 6.6 μm, a CV of 0.48% and 0.43%, and a ICC of 0.992 and 0.994 respectively. Chen et al. [34] reported a CR of 9.18 μm but the location on the cornea where CCT was measured was unknown as in the study of Montalban et al. [35] that reported measures of precision better than ours (CP of 5.49 μm; CV of 0.52% and ICC 0.997). Huang et al. [30] found a CR of 9.06 μm and 8.96 μm a CV of 0.64% and 0.61% and an ICC of 0.991 and 0.991 at the geometric centre and at thinnest corneal thickness, respectively. In a different study Huang et al. [36] reported good repeatability of Sirius measures that were effectuated by two different examiners at the corneal apex (CCT) and at the thinnest point (TCT).

The differences in the results between the present study and the studies described above may be due to several reasons: the different size of the sample, the different position of the CCT measure (for example in this study CCT was measured at pupil centre, whilst in the Milla's study [32] at the corneal geometric centre), the procedure of acquiring the measure (for example in this study it consisted of a quality analysis of images but it was not clear if Milla and co-workers did it) and finally the experience of the operators that might affect measure precision.

If the reliability of Sirius and USP found in the present study is compared, it is possible to argue that Sirius's precision was far better than USP. This result suggests two different evidences. On one hand Sirius repeatability results were quite good, at the same level of previous study with the same instrument [31–33,35] and with other kind of SCS [28,34], even if in this study the examiner was not experienced. On the other hand USP precision was quite lower compared to other studies e.g. [28,35]. For example Nam et al. [28] found a better repeatability (CR = 4.9 μm) for USP measure. Several factors may explain this difference in USP repeatability:

- Different USP model used;
- Different number of subjects (52 in Nam' study; 35 in this study);
- Nam et al. measured CCT of both the eyes; right and left eye CCT is often very similar, so that measure variance decreases and consequentially repeatability improves.
- In the present study a non-rigorous method of measuring CCT with USP (lacking of chinrest, the absence of any device to improve centre pupil alignment of system of USP probe) was used that might have affected the precision although the examiner was expert.

All that has been discussed above regarding agreement between Sirius SCS and USP and the reliability of the two instruments should be evaluated according to specific clinical evaluation needs. Generally speaking, a certain level of agreement between two instruments as well as their precision might be sufficient or excessive depending on clinical requirements [33].

The agreement between instruments should reveal if a specific clinical evaluation could be assessed indifferently with two different instruments. We found such a fixed bias between measures obtained with Sirius and the USP that it is not possible to consider the two instruments clinically interchangeable. For example if one wants to detect physiological oedema (about 3/4%) [37], for an average corneal thickness of 550 μm Sirius and USP would be not interchangeable because their difference (13.9 μm) is close to corneal thickness variation.

Looking at reliability, the present study found that Sirius was sufficiently precise for clinical use. For example to ponder the IOP value a 25 μm precision in corneal thickness is required [38]. Sirius was able to obtain the required precision whilst USP had too low precision to be used for this specific clinical evaluation. Also for the evaluation of physiological oedema reported above, that requires a better precision; Sirius has got a precision sufficient to reveal oedema: for an average corneal thickness of 550 μm Sirius was able to read about 2.5% variation in 95% of cases.

Finally, this study has limitations that warrant further investigation: only one US pachymetry device was evaluated, and thus the results might not be valid for other US pachymetry models. Moreover we measured normal eyes only and it is not possible to apply our findings to other conditions, such as keratoconus or post surgery corneas.

5. Conclusions

Until today USP has been the most popular method to measure corneal thickness. Clinical interest in corneal thickness measure is improving and in order to obtain more precise results many technologies have been developing: slit scanning corneal tomography, OCT and Scheimpflug camera systems. These new instrumentations are less invasive, are able to measure the thickness of whole cornea and they are easy to use.

The Scheimpflug system Sirius has a good intraobserver precision and repeatability even in the presence of an inexperienced examiner. However, the average difference between corneal thickness measured with Sirius and USP was small but clinically significant; this means that the two instruments cannot be used interchangeably. Sirius showed precision and repeatability almost twice that of USP. A confidence interval of 13 microns for Sirius can show variations in corneal thickness with an uncertainty value lower than 2.5% in 95% of cases. The simplicity of use, the ability to obtain pachymetric maps, and the lower invasiveness make this instrument potentially useful for CL practice.

Conflict of interest

Antonio Calossi is consultant to CSO, Florence. No other author has a financial or proprietary interest in any material or method mentioned.

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