Contact Lens & Anterior Eye 37 (2014) 442–446

Contents lists available at ScienceDirect

Contact Lens & Anterior Eye

journal homepage: www.elsevier.com/locate/clae

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

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ARTICLE INFO

Article history:
Received 13 October 2013
Received in revised form 20 June 2014
Accepted 21 July 2014

Keywords:
Scheimpflug corneal tomography
Ultrasound pachymetry
Central corneal thickness
Agreement
Reliability

ABSTRACT

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 ± 28 μm, and 550 ± 35 μm, 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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http://dx.doi.org/10.1016/j.clae.2014.07.009
1367-0484/

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