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ORIGINAL RESEARCH

Comparison of the precision of the Topcon SP-3000P specular microscope and an ultrasound pachymeter

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Aim: To compare the precision of the Topcon SP-3000P noncontact specular microscope (NCSM) and the DGH 500 ultrasound pachymeter (USP).

Methods: Triplicate measurements of central corneal thickness (CCT) for 100 eyes were taken with an NCSM and a USP in 2 visits separated by 1 week. Repeatability was assessed by computing the differences between all 3 readings from each subject. Coefficients of repeatability and reproducibility were computed.

Results: Mean CCT as measured by each instrument were: 518.53 ± 34.96 µm (range 417.33–592.67) and 516.94 ± 33.60 µm (range 431.67–582.67) for sessions 1 and 2 respectively, with the NCSM; 546.69 ± 36.62 µm (range 457.33–617.00) and 549.78 ± 35.26 µm (range 454.00–618.67) for sessions 1 and 2 respectively, with the USP. The ultrasound CCT measurements were consistently higher than those obtained with the NCSM in both sessions 28.17 ± 19.20 µm (mean ± SD, session 1) and 32.81 ± 14.04 (mean ± SD, session 2). The repeatability coefficient for the NCSM was better in both sessions than those for USP (±10 µm vs ± 12 µm in session 1 and ±8 µm vs ±10 µm in session 2). The reproducibility coefficient with the NCSM was half that with the USP (±21 µm vs ±41 µm).

Conclusion: The SP-3000P NCSM is a more precise and reproducible instrument for measurement of CCT than the USP, but both instruments are reliable, useful instruments for measuring CCT.

Keywords: cornea, Topcon SP-3000P, ultrasound pachymetry, repeatability coefficient, reproducibility coefficient

Introduction

The most common method for measuring corneal thickness is still ultrasound pachymetry (USP), because of the high degree of inter-observer and inter-instrument reproducibility of USP devices.[1,2] However, it requires corneal contact that may lead to false results due to indentation of the cornea.[3,4] The accurate measurement of corneal thickness with USPs is also dependent on the precise placement of the probe relative to the centre of the cornea which is often uncomfortable for the patient and may sometimes lead to damage of the corneal epithelium.[5]

Earlier studies[5–8] have shown that optical thickness determination, compared with specular microscopy and ultrasonic pachymetry, disclosed large inter-observer variation, less reproducibility, and greater subjectivity in measurements of central corneal thickness (CCT) in healthy subjects. One disadvantage in the use of USP is the need for topical anesthesia. Indeed one study reported thickness changes of ±10 µm (measured with USP) after the instillation of topical anesthesia.[9] Another study reported

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larger CCT values when 2 drops of proparacaine were instilled into the eye.[10]

An accurate measurement of CCT is important in a wide range of disorders, such as ectatic dystrophies,[11,12] contact lens-related complications, glaucoma, dry eyes, and diabetes mellitus.[13] The prediction of the outcome of refractive surgeries especially laser assisted in situ keratomileusis (LASIK) is also largely dependent on accuracy of pachymetry measurements.[13,14] Therefore, the availability of quick, accurate, noninvasive methods of CCT assessment is essential for the effective monitoring of corneal health and predicting success of refractive surgeries.

One such technique widely used is the new automated noncontact specular microscope (NCSM) Topcon SP-3000P (Topcon Corporation, Tokyo, Japan), which captures an image of the corneal endothelium and assesses corneal thickness simultaneously. It is also useful in corneal swelling measurements in contact lens wear.[15,16]

The purpose of this study was to compare the repeatability and reproducibility of the NCSM with those of a USP in measurement of CCT of healthy subjects.

Subjects and methods

The CCT of 114 healthy eyes of 57 subjects was measured with an NCSM (Topcon SP-3000P) and a USP (DGH 550, DGH Technology, Inc., San Diego, CA).

Inclusion criteria required that the subjects had no positive history for contact lens wear, no anterior segment disease or surgery, and no trauma or amblyopia.

Central corneal thickness readings of 7 subjects were excluded from the statistical analysis of this study because of previous history of hard contact lens wear due to keratoconus (2) and family history of glaucoma (5). Overall, CCT measurements were made of 100 eyes of 50 subjects (28 males and 22 females), of ages 20 to 25 years (mean ± SD, 22.4 ± 1.3 years). The subjects were randomly selected from student populations of different departments of the college of Applied Medical Sciences, King Saud University. After the purpose and procedures of the study were fully explained, each patient gave informed consent to participate in the study. The study was conducted in conformance with the tenets of the declaration of Helsinki and approved by the research ethics review board of the College of Applied Medical Sciences, King Saud University.

All measurements were carried out between 12.00 h and 14.00 h to avoid influence of diurnal variations in IOP.[17]

First, triplicate CCT measurements were obtained from both eyes of each subject with the NCSM and than with USP.

For the NCSM, CCT measurements were obtained using the automatic image capture, low-intensity mode of the specular microscope. Subjects were required to fixate on the central target, with chin on the chin rest and head on the forehead rest. The CCT was subsequently measured with a USP. The instrument was precalibrated for all measurements. The ultrasonic velocity was set at 1640 m/s. The cornea was anesthetized with 1 drop of 1% tetracaine. The probe was sterilized before CCT measurements were obtained for each subject by applying the probe perpendicularly to the surface of the central cornea. Measurements were taken 2 minutes after instillation of the tetracaine.

To establish reproducibility indices for both methods, subjects were required to visit the clinic for a second measurement session approximately 1 week from the first session measurement. The CCT measurements were carried out as in session 1.

All measurements with both techniques were carried out by the same examiner to eliminate the effects of inter-examiner bias on the variability of the CCT assessments.

Statistical analysis

The average corneal thickness of the right and left eye of each subject formed the data points. The level of significance for all comparisons was set at 5% and the paired *t*-test was performed for comparative data analysis. All statistical analyses were conducted with the graph-pad Instat Version 3 for windows program (Graphpad Software Inc., San Diego, CA).

Limits of agreement between techniques

Combined-session Bland–Altman plot of mean difference (USP – SP-3000P) in each session was plotted against the combined averages of CCT readings (USP + SP-3000P/2) for both sessions as a combined scatter plot. A paired *t*-test was conducted on the average CCTs of both techniques in both sessions (NCSM session 1 vs USP session 1; NCSM session 2 vs USP session 2).

Assessment of repeatability and reproducibility

For statistical analysis, the average of triplicate readings per subject was used for each technique to assess repeatability in each session.

A paired *t*-test was conducted on the averages of the triplicate CCT measurements in each session for each technique. Bland–Altman[18] statistical analysis was employed to assess the limits of repeatability (LoR) between measurements of CCT using each technique. A combined plot (session 1 and session 2) of difference between the triplicate CCT measurements in each technique taken on same day visit was plotted against the mean of the CCT measurements for that session. Repeatability coefficient (1.96*SD of intra-session mean differences)[19] for each session using each technique was calculated for comparison of both session repeatabilities.

For assessment of reproducibility, average CCT measurements obtained with 1 technique in session 1 was compared with the average CCT obtained with the same technique in session 2. The coefficient of reproducibility was calculated as 1.96*SD of intersession mean differences for each technique. To graphically represent the findings, a Bland–Altman plot of mean difference in CCT (session 1 – session 2) as a function of average CCTs of both sessions (session 1 + session 2/2) with same technique was used.

Results

Average CCT measured with both pachymeters

There was no statistically significant difference ($P > 0.05$) between the CCT values returned for the right and left eyes by NCSM and USP; thus the data points for all the subjects were pooled together and analyzed.

The mean CCT ± SD measurements for NCSM and for USP for each of the 3 consecutive readings in sessions 1 and 2 are shown in Tables 1 and 2, respectively. The mean CCT measurement for SP-3000P NCSM was 518.53 ± 34.96 µm (range 417.33–592.67) and 516.94 ± 33.60 µm (range 431.67–582.67) sessions 1 and 2, respectively. For USP, average CCT measurement was 546.69 ± 36.62 µm (range 457.33–617.00) and 549.78 ± 35.26 µm (range 454.00–618.67) sessions 1 and 2, respectively.

There were statistically significant differences in CCT values (USP vs NCSM) measured in the first session ($P < 0.001$) and in the second session ($P < 0.001$).

Limits of agreement between techniques

The mean difference ±SD between the two techniques (USP – NCSM) for session 1 was 28.17 ± 19.20 µm and 32.81 ± 14.04 µm for session 2. The limits of agreement, LoA (95% confidence interval) between techniques are shown in Tables 1 and 2.

Table 1 Session 1 average central corneal thickness (CCT) (µm ± standard deviation [SD]) values obtained using SP-3000P noncontact specular microscope (NCSM) and ultrasound pachymetry (USP), difference between means (MD) of CCT readings (µm ± SD), difference between techniques, limits of repeatability/limits of agreement between techniques (mean ± 1.96 SD), and coefficients of repeatability (reproducibility) for each technique (CoR)

Session one	USP	SP-3000P NCSM	USP – SP-3000P
Mean CCT ± SD	546.69 ± 36.62	518.53 ± 34.96	532.61 ± 34.49
MD ± SD	1.02 ± 5.97	0.28 ± 5.15	28.17 ± 19.20
LoR (+1.96 SD)	13	10	66
LoR (–1.96 SD)	–11	–10	–9
Minimum	457.33	417.33	438.17
Maximum	617.00	592.67	600.50
CoR	12 (41)	10 (21)	38 (41)

Figure 1 is a Bland–Altman plot of agreement between techniques (USP – NCSM). This was done for sessions 1 and 2 differently and plotted as a combined scatter graph. The limits of agreement as shown in Figure 1 were –9 to 66 µm and –5 to 60 µm for sessions 1 and 2, respectively.

Assessment of repeatability and reproducibility coefficients

Within-session, the mean difference ±SD in CCT readings obtained using the NCSM and the USP in sessions 1 and 2 is shown in Tables 1 and 2.

The repeatability of each technique was also examined with a Bland–Altman plot as shown in Figures 2 and 3.

Table 2 Session 2 average central corneal thickness (CCT) (µm ± standard deviation [SD]) values obtained using SP-3000P noncontact specular microscope (NCSM) and ultrasound pachymetry (USP), difference between means (MD) of CCT readings (µm ± SD), difference between techniques, limits of repeatability/limits of agreement between techniques (mean ± 1.96 SD) and coefficients of repeatability (reproducibility) for each technique (CoR)

Session 2	USP	SP-3000P NCSM	USP – SP-3000P
Mean CCT ± SD	549.78 ± 35.26	516.94 ± 33.60	533.36 ± 33.72
MD ± SD	1.03 ± 5.19	–0.13 ± 4.08	32.81 ± 14.04
LoR (+1.96 SD)	9	8	60
LoR (–1.96 SD)	–11	–8	–5
Minimum	454.00	417.33	444.83
Maximum	618.67	592.67	600.67
CoR	12 (41)	10 (21)	28 (41)

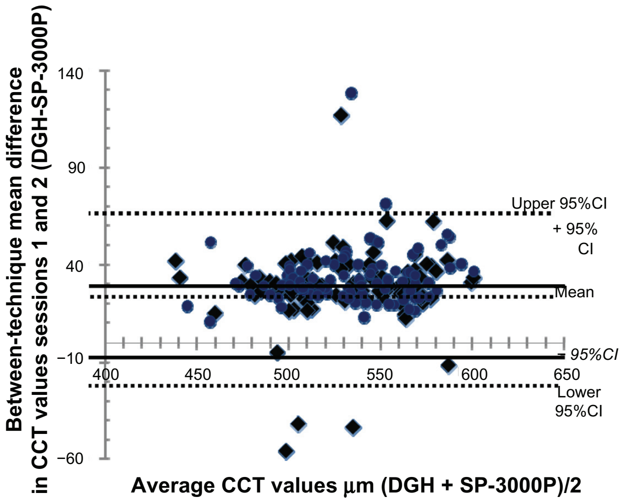

Figure 1 Combined Bland–Altman plots of mean difference between techniques in both sessions (ultrasound pachymetry session 1 – SP-3000P session 1; ultrasound pachymetry session 2 – SP-3000P section 2) against average central corneal thickness (CCT) of sessions 1 and 2. Plot also shows the 95% limits of confidence intervals (CI).

The repeatability coefficient (1.96*SD of intrasession mean differences) for the NCSM was better in both sessions than for the USP (±10 µm vs ±12 µm in session 1 and ±8 µm vs ± 10 µm in session 2).

CCT measurements obtained by the NCSM showed better reproducibility (±21 µm) than those by USP (±41 µm). A Bland–Altman reproducibility plot is shown in Figure 4.

Discussion

The NCSM underestimated CCT measurements by an average of 28.17 ± 19.20 µm and 32.81 ± 14.04 µm (sessions 1 and 2, respectively) compared with USP. These differences were statistically significant in each session (paired t-test:

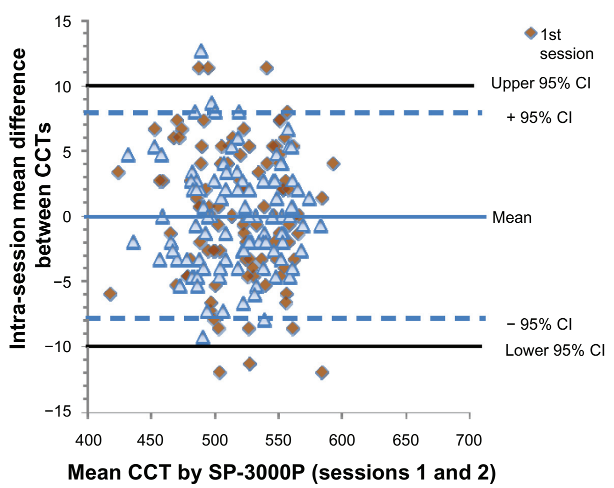

Figure 2 Combined Bland–Altman repeatability plots of mean difference (within sessions) of noncontact specular microscope (SP-3000P) against average central corneal thickness (CCT) of sessions 1 and 2, showing the 95% limits of confidence intervals (CI).

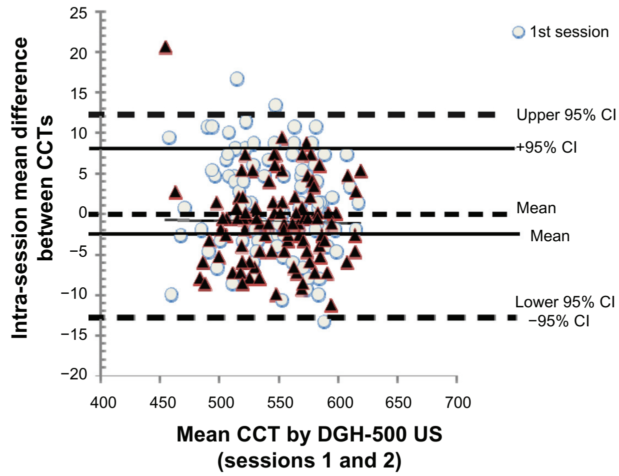

Figure 3 Combined Bland–Altman repeatability plots of mean difference (within sessions) of ultrasound pachymetry against average central corneal thickness (CCT) of sessions 1 and 2, showing the 95% limits of confidence intervals (CI).

$P < 0.001$) and between sessions (paired t-test: $P < 0.001$). Two previous studies reported 32 µm[2] and 33 µm[13] lower CCT values obtained with the NCSM compared with USP. This large variation is considerable and as such the devices cannot be used interchangeably. The agreement therefore is that each of these instruments is reliable in so far as it gives repeatable measurements.

The difference in their distinct operating principles may explain this variation: the NCSM measurements depend on the reflection of light, and the USP measurements depend on the reflection of sound from the anterior and posterior corneal surfaces. In USP, the posterior limit of the cornea is not exactly located, as the point measured could be located anywhere between Descement's membrane and the anterior chamber.[13]

The repeatability in the present study might appear to be slightly better than in some other reports[20,21] that have

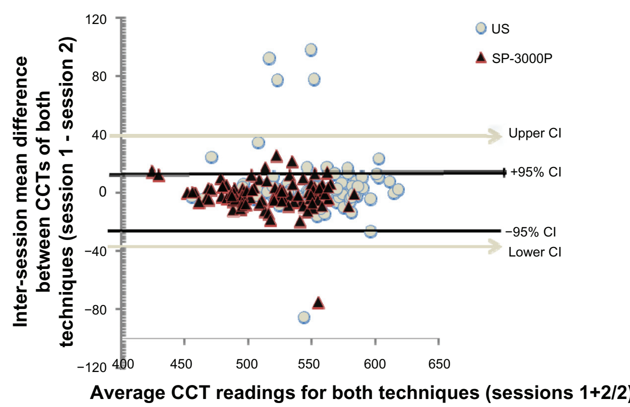

Figure 4 Combined Bland–Altman reproducibility plot of mean difference (between-sessions) in each technique against their average central corneal thicknesses (CCT) (sessions 1 + 2/2), showing limits of confidence intervals (CI) for both techniques.

assessed the repeatability of CCT measurements obtained by the older version of the NCSM device (SP-2000P) using 3 measures. In one of the studies,[20] the 95% LoR were between −15 and 17 μm, and –18 and 18 μm, first and second observer, respectively. LoR in our study for SP-3000P were −10 and 10 μm, and −8 and 8 μm, first and second session, respectively, indicating a possible improvement in precision of the newer design of this device.

A few other studies[14,22,23] have shown the coefficient of repeatability, expressed as a percentage, for Ocular Coherence Tomography, Galilei Scheimpflug Analyzer (Clarion Medical Technologies), Pentacam (Oculus Optikgerate GmbH), optical low-coherence reflectometer pachymeter, and different USP to be 2%, 0.43%, 0.84%, 0.33%, and 0.71%, respectively. When we tried to express our coefficient of repeatability as a percentage of the mean in our study, the coefficient of repeatability turned out to be 1.93% and 1.55%, sessions 1 and 2 for NCSM, and 2.14% and 1.86% for USP, sessions 1 and 2. Unfortunately, because the cited papers did not provide the method of calculating the repeatability coefficient, it is impossible to make a direct comparison.

The NCSM appears to have better repeatability in comparison with other reported studies[20,21,24,25] on available CCT measuring techniques. Mathew and Mark[24] a decade ago had concluded that the Orbscan system (Bausch and Lomb) is the most repeatable technique for measuring CCT. Mean CCT obtained by Orbscan in their study was 596 ± 40 μm (LoR of −10 to 17). In our study, mean CCT was 518.53 ± 34.96 μm (LoR −10 to 10 μm) and 516.94 ± 33.60 μm (−8 to 8 μm) in sessions 1 and 2, respectively of NCSM. On applying an acoustic correction factor to Orbscan CCT values obtained on 24 normal subjects with varying refractive errors in a recent study,[25] estimate of repeatability was within ±10 μm, similar to that obtained in our study (±8 and ±10).

Overall, the coefficient of reproducibilities for our study were ±21 μm and ±41 μm and when expressed as a percentage of the mean were 4.07% and 7.48% for NCSM and USP, respectively. This is comparable to those found in other studies.[14,22,23] A study has also shown the reproducibility by Pentacam to be higher than that by both Orbscan and USP, [26] but not as high as that found in our study with SP-3000P NCSM.

Our findings also agree with other studies[2,13,27–29] that have documented a significant difference between the NCSM CCT values and those of USP. In these recent papers, SP-2000P NCSM CCT measurements were found to be thinner than USP by 32 μm,[2] 28 μm,[13] 0.98 μm,[27] 19.4 μm,[28] and 21.4 μm.[29] Two other studies[2,30] also found SP-2000P NCSM CCT values to be 33 μm and 31.6 μm thinner than the USP values; however, these studies did not state subject ages. In contrast, Chaudhry[29] found no significant difference in the average values of CCT taken with NCSM and USP while the Pentacam CCT values were 19.3 μm and 8.2 μm higher than the USP values in normal eyes.

Another study[13] comparing SP-2000P NCSM and contact specular microscopy (EM-1000; Tomey) with USP showed that these instruments were not comparable in their thickness values in the same cornea, the thinnest average value being obtained with the NCSM, followed by USP, and contact specular microscopic pachymetry.

Importantly, we also found that values obtained in a given eye in each session by the same examiner were more consistent for the NCSM than for the USP unit in each session and between sessions. The repeatability and reproducibility coefficients of the NCSM were consistently higher than those of USP in each session and between sessions. The larger variability in measurements obtained with the USP could further be explained by the fact that the ultrasound pachymeter is a hand-held device and requires the placement of the probe perpendicular to the cornea. As such, operational errors are more likely to occur with this device.

This can be seen by comparing the distribution of data points and the upper and lower 95% CI on the Bland–Altman[19] scatter graph of the NCSM (Figures 2 and 4) and those of the USP (Figures 3 and 4) and their coefficients of reproducibility (±21 and ±41) for SP-3000P NCSM and USP, respectively. This study thereby shows that multiple readings taken with the SP-3000P NCSM would be more useful for comparisons over time in situations where a patient needs to be followed up over a period of time,[12] because patient fixation is used to determine the center of the cornea, ruling out the investigator bias with placement of the probe introduced by the USP. It would also allow examinations to be delegated to nonmedical personnel.

Nevertheless, in conditions of cornea cloudiness or media opacities, the USP is the method of choice in measurement of CCT over optically based pachymeters.

This study is limited to normal subjects of a very narrow age range and small sample size, which do not represent the entire population in whom CCT measurements are required. A study on a larger sample size of a wider age range and in subjects with different corneal anomalies is needed to verify the results of this study. Results from such a study will be more applicable in various situations in which CCT measurements must be obtained.

In conclusion and in agreement with a study by Chaudry,[29] despite the variation in CCT values obtained, both of these devices are useful for assessing CCT. They are reliable and repeatable but should not be used interchangeably. Therefore for refractive procedures and for long-term patient follow-up, consistent use of one device is recommended.

Disclosure

The authors report no conflicts of interest in this work.

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