Intraoperator Repeatability and Interoperator Reproducibility in the Ultrasonic Pachymetry Measurements of Central Corneal Thickness

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Objective: *To assess the repeatability and reproducibility of central corneal thickness (CCT) measurement by the commercial available ultrasonic pachymeter in Songklanagarind Hospital.*
Material and Method: *Seventy eyes underwent two sessions of CCT measurements, each session consisting of two CCT measurements, performed by two different operators. The mean and standard deviation of the mean differences were calculated. The interoperator repeatability and interoperator reproducibility were calculated by means of intraclass correlation coefficient (ICC). Agreement was analyzed by means of Bland-Altman plots.*
Results: *The mean CCT for 70 eyes was 537.61 $\pm$ 26.66 mm. The intraoperator repeatability study of the first operator, the mean difference between the repeated measurements was 0.49 mm. The ICC was 0.985 ($p < 0.001$). For the second operator, the mean difference between the repeated measurements was 0.57 mm. The ICC was 0.935 ($p < 0.001$). A Bland-Altman plot of both operators showed narrow limits of agreement with respect to CCT for both operators. The mean measurement difference between operator was 0.96 mm and the ICC for reproducibility study was 0.979 ($p < 0.01$). The Bland-Altman plot showed narrow limits of agreement with respect to CCT.*
Conclusion: *The measurement of CCT using the ultrasonic pachymeter is highly repeatable and reproducible.*

Keywords: *Anthropometry, Cornea, Reproducibility of results, Ultrasonography*

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Central corneal thickness (CCT) is an important parameter in clinical practice. For example, the assessment and treatment of many corneal disorders, the management of patients with glaucoma as well as intraocular pressure (IOP) measurement.

It has been known that variation in CCT influences the IOP measurement by the applanation tonometry, the pressure is measured too high in non-edematous thick corneas, and too low in thin cornea[1,2]. The Ocular Hypertension Treatment Study (OHTS) found that CCT is an increasingly important factor in the assessment of patients with ocular hypertension (OHT)[3,4].

CCT measurements provide the valuable values in planning of refractive procedures, the safety and the amount of correction to avoid the postoperative complications such as cornea instability[5].

The measurement of corneal thickness, or pachymetry, can be measured using a number of methods including the contact system (optical and ultrasound pachymetry) and the noncontact system (laser interferometry and optical coherence tomography)[6-8]. The ultrasonic pachymetry have been the most widely used technique because of ease of use.

The ophthalmic biometries, as well as pachymetry, should have both accuracy and precision. In terms of precision, it should be high repeatability and reproducibility.

Many studies have reported the precision analysis of CCT measurement. Some studies analyzed the agreement between contact and noncontact techniques, comparison of ultrasound pachymetry, coherence interferometry, and optical coherence tomography[9-14]. Few recent studies have reported

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that measurement of CCT by means of ultrasonic pachymetry is highly repeatable and reproducible by the analysis of correlation and agreement[15-17].

The objective of the present study was to assess the repeatability and reproducibility of CCT measurement by the commercial available ultrasonic pachymeter in Songklanagarind Hospital.

Material and Method

A prospective analytical study between March and June 2007 was carried out after the Ethics Committee of Prince of Songkla University approved the present study. Written informed consent was obtained from each subject. The authors recruited 35 normal healthy volunteers that were medical personnel and patients at Songklanagarind Hospital.

The subjects who had previous or current corneal pathology (keratitis, corneal scar, keratoconus, or irregular corneal surface), previously underwent corneal refractive or intraocular surgery, and currently used a contact lens were excluded from the study.

For the CCT measurement, the hand-held probe of Tomey SP-3000 Pachymeter (Tomey Corp., Japan) was calibrated at the beginning of each session. After instillation of 1% tetracaine hydrochloride that was used for topical anesthetic. For central measurements, the subject that was in the supine position was asked to fix the eye at the distant target to reduce the convergence position of eyes. The pupil was used as an anatomical landmark for probe alignment. First and then second operator sequentially measured CCT of each subject. One drop of artificial tear (Tear Naturale Free, Alcon, USA) was applied during each session for reducing the effect of surface dryness to CCT. Time between measurements by each operator was limited no more than 4-5 minutes to reduce the effect of diurnal variation.

Corneal thickness was measured in 70 eyes of 35 healthy volunteers. Both eyes of each subject underwent pachymetry, as described above, performed by two operators who were experienced in the use of the instrument. Each eye underwent two sessions of CCT measurements, each session consisting of two CCT measurements, performed by two different operators. An assistant recorded each measurement. Both operators were masked to all CCT results.

The mean and standard deviation of the mean differences were calculated. The interoperator repeatability and interoperator reproducibility were calculated by means of intraclass correlation coefficient (ICC). Agreement was analyzed by the Bland-Altman plots. Statistical analysis was done by using the software package SPSS version 11 (SPSS Inc., USA) and MedCalc version 9, and a p-value < 0.05 was consi- dered to be significant.

Results

Among 35 subjects, 17 were female and 18 were male. The mean age of the subjects was 42 years, with a range of 10 to 78 years. All 70 eyes underwent pachymetry, as described above. The distribution of values followed a normal distribution. The mean CCT for 70 eyes was 537.61 ± 26.66 μm. For the mean CCT of each measurement by each operator are shown in Table 1.

Intraoperator repeatability study results

For the intraoperator repeatability study of the first operator, the mean difference between the repeated measurements was 0.49 μm. The ICC was calculated and found to be 0.985 ($p < 0.001$). For the second operator, the mean difference between the repeated measurements was 0.57 μm. The ICC was 0.935 ($p < 0.001$). The results indicated statistically excellent correlation.

To assess the agreement between each measurement, A Bland-Altman plot showed narrow limits of agreement for each measurement by operator A (Fig. 1). For operator B, Bland-Altman plot also showed narrow limits of agreement for each measurement by operator B (Fig. 2).

Interoperator reproducibility study results

Interoperator reproducibility study. The mean measurement difference between operators was 0.96 μm and the ICC for reproducibility study was 0.979 ($p < 0.01$). The Bland-Altman plot also showed narrow limits of agreement (Fig. 3).

Discussion

The objective of the present study was to assess the precision of CCT measurement by Tomey

Table 1. Mean central corneal thickness (CCT) measured by both operators

	Mean central corneal thickness (microns)
1st by Operator A	537.01 ± 26.99
2nd by Operator A	537.76 ± 26.51
1st by Operator B	538.11 ± 25.86
2nd by Operator B	537.54 ± 27.79

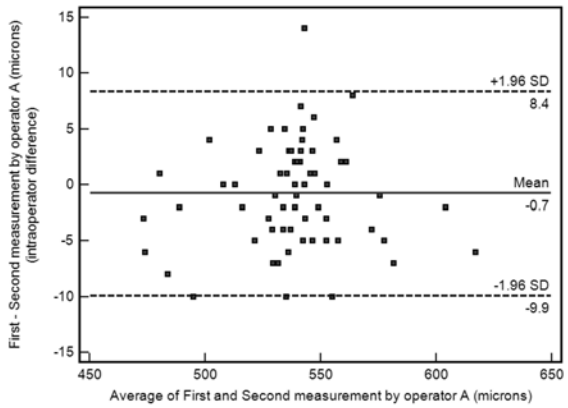

Fig. 1 A Bland- Altman plots of data from the intra-operator repeatability study results. Mean CCT of each measurement was plotted against the difference in CCT measurement between first and second measurement by operator A

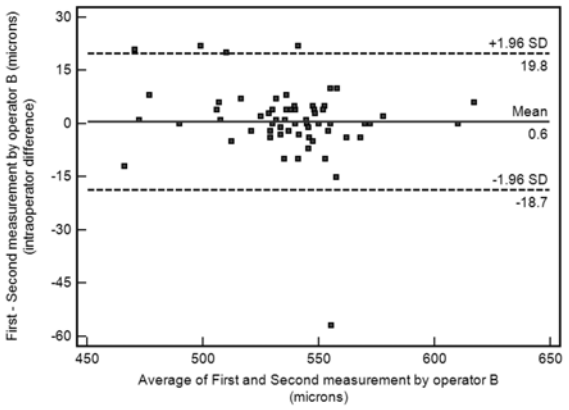

Fig. 2 A Bland-Altman plots of data from the intra-operator repeatability study results.Mean CCT of each measurement was plotted against the difference in CCT measurement between first and second measurement by operator B

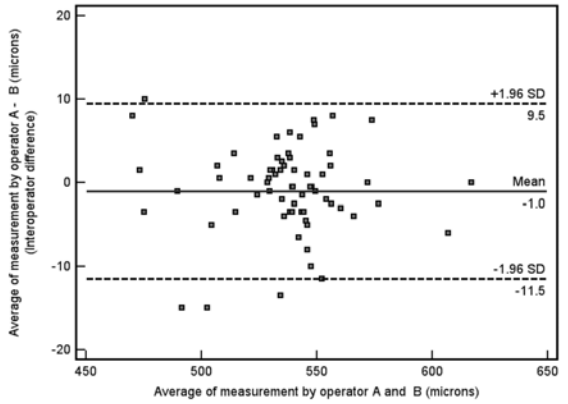

Fig. 3 A Bland- Altman plots of data from the intra-operator reproducibility study results. Mean CCT of measurement was plotted against the difference in mean CCT measurement between operator A and B

SP-3000 pachymeter in Songklanagarind Hospital. The authors investigated the precision in terms of the intraoperator repeatability and interoperator reproducibility.

The descriptive statistics show that, the study populations have nearly no sex difference. All age range population is included. The mean CCT of all subjects is 537.61 $\pm$ 26.66 μm. The analyses of intraoperator repeatability and interoperator reproducibility show almost perfect correlation (ICC being between 0.935 and 0.985). The strength of linear relationship that were more than 0.8 were considered "very strong correlation". The agreement shows narrow limits. The results indicate that both the intra- and inter-operator precision of CCT measurements is extremely high.

Consistent with previous study results, Gunvant P studied the precision of CCT by BVI ultrasonic pachymeter. The mean CCT of 72 subjects was 538 μm. (95% CI 528 -545). The ICC was 0.993 for intraoperator repeatability study and 0.996 for interoperator reproducibility study[10]. The results of the present study compared favorably with that obtained by Miglior S who used Altair ultrasonic pachymeter in CCT measurement. The mean CCT of 51 subjects was 568 $\pm$ 12 μm. The ICC was 0.966 for intraoperator repeatability study and 0.935 for interoperator reproducibility study[11]. Furthermore, the level of agreement was excellent.

The authors used the artificial tear eye drop for reducing the effect of corneal surface dryness cause error in CCT measurement. Blinding technique between each measurement prevented the bias of CCT measurement. The slightly small population in the present study cannot affect the analysis of correlation coefficient value and strength of linear relationship.

The sources of variability may be the cooperation of subject and the corneal touch technique. The results show that the CCT measurements make by different operator may be slightly different but still in narrow limit of agreement, as showed in Bland-Altman plot.

Conclusion

The results of the present study suggest that the measurement of CCT using the ultrasonic pachymeter is highly repeatable and reproducible.

References

1. Doughty MJ, Zaman ML. Human corneal thickness and its impact on intraocular pressure measures: a review and meta-analysis approach. Surv Ophthalmol 2000; 44: 367-408.
2. Bron AM, Creuzot-Garcher C, Goudeau-Boutillon S, d'Athis P. Falsely elevated intraocular pressure due to increased central corneal thickness. Graefes Arch Clin Exp Ophthalmol 1999; 237: 220-4.
3. Brandt JD, Beiser JA, Kass MA, Gordon MO. Central corneal thickness in the Ocular Hypertension Treatment Study (OHTS). Ophthalmology 2001; 108: 1779-88.
4. Brandt JD. Corneal thickness in glaucoma screening, diagnosis, and management. Curr Opin Ophthalmol 2004; 15: 85-9.
5. Carr J, Hersh P. Patient evaluation for refractive surgery. In: Azar DT, editor. Refractive surgery. Stanford: Appleton & Lange; 1997: 101-9.
6. Giasson C, Forthomme D. Comparison of central corneal thickness measurements between optical and ultrasound pachometers. Optom Vis Sci 1992; 69: 236-41.
7. Muscat S, McKay N, Parks S, Kemp E, Keating D. Repeatability and reproducibility of corneal thickness measurements by optical coherence tomo- graphy. Invest Ophthalmol Vis Sci 2002; 43: 1791-5.
8. Yaylali V, Kaufman SC, Thompson HW. Corneal thickness measurements with the Orbscan Topography System and ultrasonic pachymetry. J Cataract Refract Surg 1997; 23: 1345-50.
9. Marsich MW, Bullimore MA. The repeatability of corneal thickness measures. Cornea 2000; 19: 792-5.
10. Gunvant P, Broadway DC, Watkins RJ. Repeatability and reproducibility of the BVI ultrasonic Pachymeter. Eye 2003; 17: 825-8.
11. Miglior S, Albe E, Guareschi M, Mandelli G, Gomarasca S, Orzalesi N. Intraobserver and interobserver reproducibility in the evaluation of ultrasonic pachymetry measurements of central corneal thickness. Br J Ophthalmol 2004; 88: 174-7.
12. Pierro L, Conforto E, Resti AG, Lattanzio R. High-frequency ultrasound biomicroscopy versus ultrasound and optical pachymetry for the measurement of corneal thickness. Ophthalmologica 1998; 212 (Suppl 1): 1-3.
13. Wheeler NC, Morantes CM, Kristensen RM, Pettit TH, Lee DA. Reliability coefficients of three corneal pachymeters. Am J Ophthalmol 1992; 113: 645-51.
14. Rainer G, Petternel V, Findl O, Schmetterer L, Skorpik C, Luksch A, et al. Comparison of ultrasound pachymetry and partial coherence interferometry in the measurement of central corneal thickness. J Cataract Refract Surg 2002; 28: 2142-5.
15. Bechmann M, Thiel MJ, Neubauer AS, Ullrich S, Ludwig K, Kenyon KR, et al. Central corneal thickness measurement with a retinal optical cohe rence tomography device versus standard ultrasonic pachymetry. Cornea 2001; 20: 50-4.
16. Gordon A, Boggess EA, Molinari JF. Variability of ultrasonic pachometry. Optom Vis Sci 1990; 67: 162-5.
17. Realini T, Lovelace K. Measuring central corneal thickness with ultrasound pachymetry. Optom Vis Sci 2003; 80: 437-9.
18. Stucchi CA, Gennari G, Aimino G, di C, I, Bauchiero L. Systematic error in computerized pachymetry. Ophthalmologica 1993; 207: 208-14.
19. Harper CL, Boulton ME, Bennett D, Marcyniuk B, Jarvis-Evans JH, Tullo AB, et al. Diurnal variations in human corneal thickness. Br J Ophthalmol 1996; 80: 1068-72.
20. Lattimore MR Jr, Kaupp S, Schallhorn S, Lewis R. Orbscan pachymetry: implications of a repeated measures and diurnal variation analysis. Ophthalmology 1999; 106: 977-81.
21. Shah S, Spedding C, Bhojwani R, Kwartz J, Henson D, McLeod D. Assessment of the diurnal variation in central corneal thickness and intraocular pressure for patients with suspected glaucoma. Ophthalmology 2000; 107: 1191-3.

การทำซ้ำในผู้วัดและการผลิตซ้ำระหว่างผู้วัดในการวัดความหนาของส่วนกลางกระจกตา โดยเครื่องตรวจวัดความหนา ของ กระจกตาด้วยคลื่นเสียงความถี่สูง

วีระวัฒน์ คิดดี, อรสา ห่อรัตนาเรือง

วัตถุประสงค์: *เพื่อประเมินการทำซ้ำและการผลิตซ้ำในการวัดความหนาของส่วนกลางกระจกตาโดยเครื่องตรวจวัดความหนาของกระจกตาด้วยคลื่นเสียงความถี่สูง ณ โรงพยาบาลสงขลานครินทร์*

วัสดุและวิธีการ: *วัดความหนาของส่วนกลางกระจกตาจำนวน 70 ตา แบ่งเป็นสองวาระ แต่ละวาระวัดสองครั้งด้วยผู้วัดคนละคนคำนวณค่าเฉลี่ยและค่าเบี่ยงเบนมาตรฐานของความแตกต่างเฉลี่ยคำนวณการทำซ้ำในผู้วัดและการผลิตซ้ำระหว่างผู้วัดด้วยค่าเฉลี่ยของค่าสัมประสิทธิ์เกี่ยวพันระหว่างประเภทวิเคราะห์ ความเห็นพ้องด้วยค่าเฉลี่ยการกำหนดจุดแบบ Bland-Altman*

ผลการศึกษา: *ค่าเฉลี่ยความหนาส่วนกลางกระจกตาของ 70 ตา เท่ากับ 537.61 $\pm$ 26.66 ไมครอน การทำซ้ำในผู้วัดคนแรกและคนที่สองมีค่าเฉลี่ยความแตกต่างระหว่างการวัดซ้ำเท่ากับ 0.49 และ 0.57 ไมครอน ค่าสัมประสิทธิ์เกี่ยวพันระหว่างประเภทเท่ากับ 0.935 ($p < 0.001$) การกำหนดจุดแบบ Bland-Altman ของผู้วัดทั้งสองแสดงให้เห็นวงจำกัดแคบ ๆ ระหว่างผู้วัดทั้งสองความแตกต่างในการวัดเฉลี่ยระหว่างผู้วัดเท่ากับ 0.96 ไมครอน และค่าสัมประสิทธิ์เกี่ยวพันระหว่างประเภทเท่ากับ 0.979 ($p < 0.001$) การกำหนดจุดแบบ Bland-Altman แสดงให้เห็นวงจำกัดแคบ ๆ ของความเห็นพ้องกันในความหนาส่วนกลางกระจกตา*

สรุป: *การวัดความหนาของส่วนกลางกระจกตาโดยเครื่องตรวจวัดความหนาของกระจกตาด้วยคลื่นเสียงความถี่สูงสามารถทำซ้ำและผลิตซ้ำได้อย่างสูง*