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ORIGINAL PAPER

Accutome PachPen handheld ultrasonic pachymeter: intraobserver repeatability and interobserver reproducibility by personnel of different training grades

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Abstract To assess the intra-observer repeatability and inter-observer reproducibility of central corneal thickness (CCT) measurements of PachPen (Accutome, Inc., Pennsylvania, USA), a hand-held, portable ultrasonic pachymeter when used by an ophthalmic nurse compared to an ophthalmologist. Ophthalmology Clinic, University of Malaya Medical Center In this prospective study, CCT was measured in 184 eyes of 92 healthy subjects, first by a corneal surgeon experienced in ultrasound pachymetry (Observer 1) followed by an ophthalmic nurse new to the procedure (Observer 2). Nine measurements were obtained from each eye by each observer, independently. Measurements were compared between the observers. Coefficients of repeatability and reproducibility were calculated. The Bland–Altman plot was used to assess agreement between observers. Mean age of the study population was 54.3 ± 15.2 years old and consisted of 43.5 % male. Mean CCT as measured by Observers 1 and 2 were 528.3 ± 32.9 and 530.7 ± 33.3 μm, respectively. Observer 1 showed higher repeatability of measurements compared to that of Observer 2 (coefficient of repeatability 3.46 vs. 5.55 %). The measurements by both observers showed high correlation (0.96) and good agreement (mean difference −2.4 μm; 95 % limits of agreement −21.4, 16.7 μm). Coefficient of reproducibility of measurements between observers was 5.08 %. Accutome PachPen hand-held ultrasound pachymeters gives excellent intra-observer repeatability and inter-observer reproducibility by personnel of different training grades.

Keywords Central corneal thickness · Ultrasound pachymeter · Repeatability · Reproducibility · Different training grades

The finding of this study has not been presented in any previous meetings.

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Introduction

Central corneal thickness (CCT) is a clinically important parameter in ophthalmology for both diagnostic and therapeutic purposes. Reliable measurement of CCT is essential during preoperative assessment prior to refractive surgery to avoid iatrogenic keratectasia. It is also used to diagnose and monitor progression of various corneal pathologies as well as to monitor corneal changes in contact lens

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wearers. Furthermore, individual variation in CCT influences intraocular pressure measurement by applanation tonometry [1] and CCT is an independent risk factor for the progression of ocular hypertension to primary open-angle glaucoma [2].

Ultrasound pachymetry (UP) has been traditionally regarded as "gold standard" of CCT measurement. Thornton reported that certain ultrasonic pachymeters are reproducible with a low degree of bias and with little inter-observer variation [3]. Newer generation ultrasound pachymeters like PachPen (Accutome, Inc., Malven, Pennsylvania, USA) which uses a 10.5 MHz composite probe in a lithium battery operated hand-held device, has been shown to be comparable with other commercially available ultrasound pachymeters [4]. However, there are several limitations to the reliability of UP due to corneal indentation and misalignment of the probe. The latter is because the UP probe needs to be placed manually as perpendicularly as possible to the centre of the cornea. Furthermore, patient comfort is reduced by the need for topical anesthesia as well as the risk of epithelial abrasion and corneal infection. Nevertheless, UP is frequently and widely used because of its simplicity, portability, quick measurement time and low cost.

As UP is operator dependent, one needs to validate the reliability of CCT measurements by different trained personnel. Ingrid et al. established that optical biometry showed excellent repeatability using different examiners regardless of their medical training [5]. To date, there is no published study demonstrating good repeatability and reproducibility of CCT measurement using PachPen ultrasound pachymeter by personnel of varying medical training. In a busy ophthalmology practice, we believe trained ophthalmic nurses can perform reliable CCT measurement. Therefore, we conducted this present study to assess the intra-observer repeatability and inter-observer reproducibility of CCT measurements obtained by two observers with different training grades.

Materials and methods

The Institutional Ethics Committee approved this study. All subjects provided informed consent after receiving detailed information regarding the nature and purpose of this study. Prior to the investigations, all subjects underwent a complete ophthalmic examination including manifest refraction, slit lamp microscopy, and indirect ophthalmoscopy. Exclusion criteria included history of contact lens wear, ocular surgery or injury, corrected distance visual acuity worse than 20/40, active ocular pathologies other than cataract, and inability to cooperate with the examination.

184 eyes of 92 healthy subjects were recruited from the Ophthalmology Clinic, University of Malaya Medical Center. All CCT measurements were performed by a corneal surgeon experienced in UP (Observer 1) and were repeated by an ophthalmic nurse new to the procedure (Observer 2) at least 2 h after the first measurement. The pachymetry measurements were performed on the same day to evaluate inter-observer reproducibility. Nine consecutive measurements were taken as per the factory settings of the device. The ophthalmic nurse received a brief explanation on how to operate the instrument shortly before the first measurement.

The cornea was first anesthetized with one drop of 0.5 % topical proparacaine hydrochloride (Alcaine, Alcon, Belgium). The subject was seated and asked to fixate on a distant target. The CCT measurement technique involved lightly applying the hand-held probe perpendicularly on to the central corneal surface. The individual observer judged the probe alignment and placement on the central cornea surface. For central measurement, the subject's pupil was used as anatomical landmarks for the purposes of alignment. Using the pupil as an anatomical landmark ensures an identifiable zone for consistent measurements. After a measurement is taken, the subject was instructed to blink and a repeated measurement was obtained. The ultrasound probe was sterilized with alcohol after each subject.

Statistical analysis

Statistical analysis was performed using R software (version 2.14.0). Continuous measurements were summarized as mean ± standard deviation while categorical values were summarized as percentages. Coefficients of repeatability [6] and reproducibility of measurements were determined. The smaller the coefficient of repeatability and reproducibility means the higher the repeatability and reproducibility of measurements, respectively. Scatter plots were used to illustrate and to compare measurements by each

observer. Correlation of measurements by both observers was computed. The Bland–Altman plot was used to show the agreement of measurements between the observers.

Results

The mean age of the study population was 54.3 ± 15.2 years old (range 16–80 years) and consisted of 43.5 % male. Mean CCT as measured by Observers 1 and 2 were 528.3 ± 32.9 and 530.7 ± 33.3 μm, respectively as shown in Table 1. The mean measurement difference between observers was −2.38 μm [95 % limits of agreement (−21.41, 16.65)].

Repeatability study

Table 1 showed that Observer 1 (3.46 %) has higher repeatability compared to Observer 2 (5.55 %). All measurements appear to be normally distributed. There is one outlying reading by Observer 1 whereas there are two outliers by Observer 2 as shown in Fig. 1. All these outlying readings are from the same patient.

The overall standard deviation for Observer 2 is slightly higher than Observer 1 from Table 1. However, there is no obvious variation in standard deviation across the range of measurements with only a few inconsistencies for both observers as revealed in Fig. 2.

Inter-observer reproducibility study

Figure 3 shows high correlation (0.96) between the measurements by Observers 1 and 2. The solid line represents the regression line of measurements between observers whereas the dotted line is the line of equality of corresponding measurements by the two observers. From the proximity of the solid regression line to the dotted equality line, there is close agreement between measurements from Observers 1 and 2. The agreement between the observers is also examined using the Bland–Altman plot. From the Bland–Altman plot in Fig. 4, there is a good agreement between both observers with a difference of −2.4 μm and 95 % limits of agreement of (−21.4, 16.7) μm.

Table 1 Summary statistics and coefficient of repeatability of PachPen measurements by Observers 1 and 2 as well as coefficient of reproducibility between Observers 1 and 2

PachPen measurements	Observer 1 (Trained)	Observer 2 (Untrained)
Mean CCT (μm)	528.3	530.7
Standard deviation (μm)	32.9	33.3
Coefficient of repeatability (%) $(1.96\sqrt{2}s_W/\text{mean} \times 100\ \%)$[6]	3.46	5.55
Coefficient of reproducibility (%) $(1.96\sqrt{2}s_W/\text{mean} \times 100\ \%)$[6]	5.08	

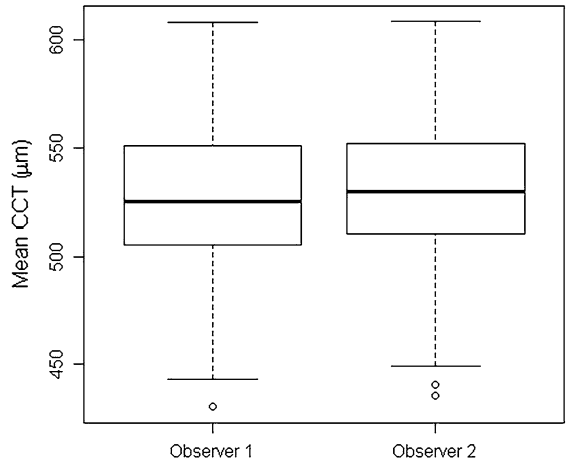

Fig. 1 Boxplot of means of CCT by two observers

Discussion

The results of the present study demonstrate that measurement of CCT using the PachPen hand-held pachymeter provides excellent intra-observer repeatability and inter-observer reproducibility regardless of background medical training. Gunvant et al. [7] demonstrated that ultrasonic pachymeter yielded excellent repeatability and inter-observer reliability. The technique was reported to be easy to operate and required minimal patient cooperation as compared to optical pachymetry devices. Miglior et al. [8] also showed that CCT measurement by means of ultrasonic pachymetry is highly reproducible and any well-trained operator should be able to make highly reliable measurements.

Although ultrasound has been reported to have good intra-observer repeatability [9], a higher degree

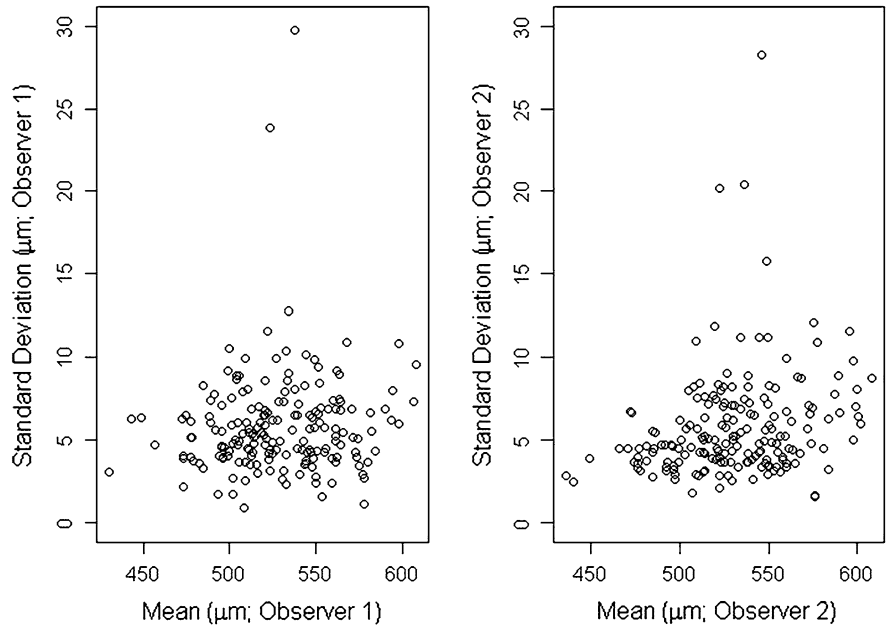

Fig. 2 Scatter plot of standard deviation against mean of CCT measurements by two observers

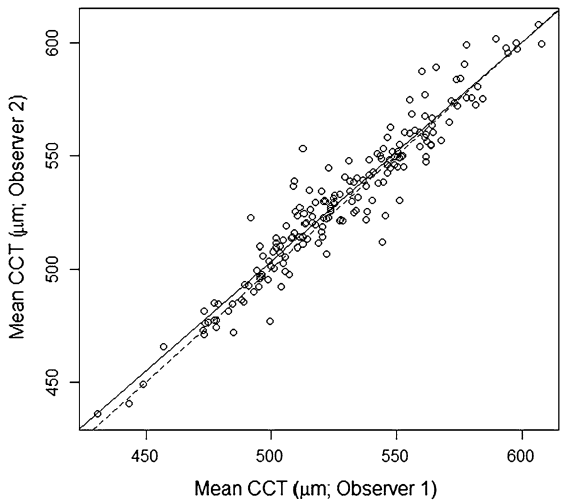

Fig. 3 Scatter plot to compare measurements from Observer 1 against Observer 2

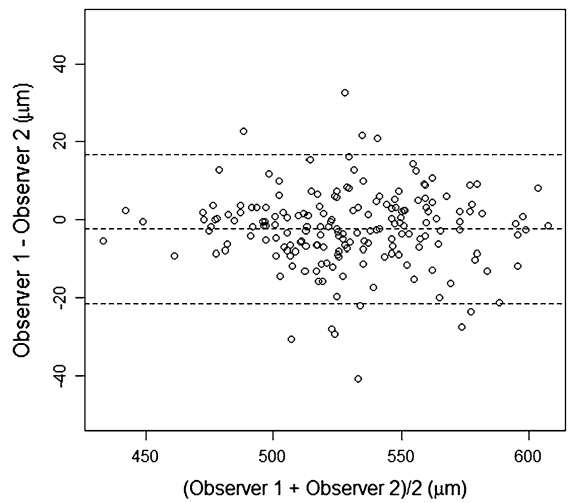

Fig. 4 Bland–Altman plot to assess agreement between Observers 1 and 2

of variation has been described between observers [10]. The mean inter-observer difference in CCT measurement of −2.4 µm in our study compared favorably with that obtained by Gordon et al. [11] who used a different ultrasonic pachymeter. The mean CCT measurement between two observers was highly similar, with a correlation coefficient of 0.96. This is in line with the measurement obtained with optical biometry [5, 12]. In our study, the intra-observer repeatability by the ophthalmologist was smaller than in ophthalmic nurse. It is attributable to the fact that repeatability of ultrasonic pachymetry mainly depends on examiner expertise.

In recent years, we have seen a growing range of new roles being created for nurses, often in areas previously considered to be performed solely by

doctors [13]. Lamirel et al. [14] reported that nurse practitioners in emergency departments were able to take quality non-mydriatic photographs. The training of ophthalmic nurses to carry out incision and curettage of chalazion have also been described [15, 16]. Our study showed that an ophthalmic nurse is capable of performing reliable pachymetry with minimal training. The main reason for this is because the PachPen hand-held device has a simple design which is easy to learn and use. Although the instrument involves contact with the cornea, a person can master the skill quickly compared to other ophthalmic tools like the Goldmann applanation tonometry which generally has a steeper learning curve [17].

However, our study has its limitation as only one ophthalmic nurse was evaluated. Further studies should be carried out to see if similar findings are observed when larger numbers of ophthalmic nurses are evaluated. Nonetheless, our findings of high intra-observer repeatability and inter-observer reproducibility of PachPen pachymeter support the role of ophthalmic nurses in performing such measurements.

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Conflicts of interest No authors have any financial or proprietary interest in any product, method, or material mentioned.

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