

Short-term variation in central corneal thickness and intraocular pressure using the Tono-Pachymeter NT530P (Tonopachy™)

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Abstract

Measurements of central corneal thickness (CCT) and intra-ocular pressure (IOP) are important for both diagnostic and therapeutic purposes. The aim of this study was to investigate the short-term variation and intra-subject repeatability of CCT and IOP measurements made with the Tono-Pachymeter NT530P (Tonopachy™). Fifty one consecutive automatic measurements of CCT and IOP were taken for the right eyes of 15 subjects (11 females and 4 males) aged 20 to 57 years (mean = 32.3 ± 13.5 years). The measured values (CCT and IOP) were compared against each other to establish the intra-subject repeatability and bias of each individual measurement with respect to the means, standard deviations and variances. Three different statistical

tests of normality: Kolmogorov-Smirnov (K-S), Lilliefors and Shapiro-Wilks (SW) tests suggested that most of the data was normally distributed, with a few exceptions. The inter-subject or overall mean values and standard deviations for the CCT and IOP samples were $528.2 \pm 27.4 \mu\text{m}$ and $14.4 \pm 4.3 \text{ mmHg}$ respectively. Although possible outliers increased the variability of the measurements of both parameters (CCT and IOP), the data generally showed good repeatability. The results of this study suggest that over short periods of time, the Tonopachy™ gives precise and repeatable measures of CCT and IOP. (*S Afr Optom* 2012 71(1) 12-21)

Key Words: Tonopachy™, repeatability, univariate normality, central corneal thickness, intraocular pressure

Introduction

Central corneal thickness (CCT) is used primarily by corneal specialists, refractive surgeons, glaucoma specialists and optometrists for clinical assessment and patient management¹. Central corneal thickness is useful in identifying early corneal thickness changes, such as in early or *form fruste* keratoconus, and in the detection and management of contact lens related complications². Also, surgical procedures such as astigmatic keratectomy, LASIK, PRK and Intacs placement rely on the accurate assessment of corneal thickness². Several studies³⁻⁷ have shown the influence of corneal thickness measurements on intra-ocular

pressure (IOP) measurements and the usefulness of CCT in diagnosing corneal disorders and glaucoma. There are several techniques used to measure corneal thickness including optical and ultrasound pachymetry. Ultrasound pachymetry is commonly considered the optimal standard for routine measurement of CCT in refractive surgery, but various limitations in ultrasound pachymetry have been highlighted^{1, 8}. These deficiencies include lack of precision, differences in pressure applied to the cornea during measurement, the notion that the velocity of sound varies between different layers of the cornea, possible spread of infection and epithelial disruption, and the need for anesthetic^{1, 8}. In an attempt to overcome these de-

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iciencies, efforts have been made to develop other rapid, non-invasive and accurate methods to measure CCT. Several new technologies such as combination tomography and topography (Orbscan), Scheimpflug imaging based (Pentacam, Precision), ultrasound based (Artemis) and optical coherence principle based (Visante) are now utilised for corneal thickness measurements and have greatly expanded our ability and precision for measurement of the cornea⁹⁻¹².

Tonometry is an essential test in routine eye examination as IOP is an important risk factor for glaucoma development and its progression^{13, 14}. Goldmann applanation tonometry (GAT) is universally accepted as the gold standard method for assessing IOP¹⁵. However, various deficiencies have been reported with GAT¹⁵. These include its dependence on factors such as CCT, curvature, corneal structure and axial length¹⁵. Goldmann applanation tonometry has also been reported to show greater variability and lower accuracy in keratoconus, high astigmatism and stromal scarring^{16, 17} and it is also not the instrument of choice among optometrists in certain countries due to limited licensing of the use of ophthalmic drugs such as topical anesthetics¹⁸. Recent advances in technology have led to the development of a number of non-invasive and non-anesthetic requiring procedures for measuring IOP^{19, 20}. A study by Kynigopoulos *et al*²¹ found that the Ocular Response Analyzer (ORA), a non-contact applanation tonometer, showed good short-term repeatability in normal volunteers. Sullivan-Mee *et al*²² evaluated and compared intra-examiner and inter-examiner repeatability and reproducibility for Dynamic Contour Rebound (DCT), ORA and GAT within the same group of subjects. The authors²² found that all three methods of IOP measurement demonstrated clinically acceptable repeatability and reproducibility. In a recent study of 100 participants; a mixture of glaucoma suspects and control volunteers, Kotecha *et al*²³ showed that the DCT showed the best repeatability when compared to the GAT and the Reichert ORA tonometer.

More recently, Nidek introduced a new simultaneous non-contact IOP and CCT measuring instrument, the Tono-Pachymeter NT530P (Tonopachy™)²⁴. Central corneal thickness measurement is determined by Scheimpflug camera principles that automatically detect the corneal apex. Mathematical software then allows for the detection of epithelial and endothelial

edges in order to provide a precise determination of the CCT²⁴. The determination of IOP by Tonopachy™ is based on an air puff that is ejected to the corneal surface²⁴. The force of the air puff on the cornea causes it to move inward and creates a slight concavity²⁴. During the transient deformity of the cornea, a light beam emitted by a diode bounces off it coaxially onto a sensor, allowing this device to provide an electronic measurement of the IOP²⁴. The instrument is simple, fast and easy to use and does not require ophthalmic medication and therefore measurements can be delegated to non-medical personnel.

When using a new instrument for ocular component measures, it is important to both clinicians and researchers that it gives repeatable and reliable measurements²⁵. Recent publications²⁵⁻²⁹ have reported good repeatability and reliability of various instruments for ocular component measures. For example, Mathebula and Rubin²⁶ showed that the Oculus Pentacam provides repeatable and reliable measures for CCT and axial anterior chamber depth in the eyes of young subjects. The aim of this study was to investigate the short-term variation and repeatability of multiple measurements of non-contact CCT and IOP using the Tono-Pachymeter NT530P.

Methods

In compliance with the Declaration of Helsinki, the study proposal was reviewed and approved by the University of KwaZulu-Natal Research and Ethics Committee before the commencement of the study. Fifteen subjects, ranging in age from 20 to 57 years participated in this study. All the subjects gave written informed consent after the nature and intent of the study had been fully explained to them. After a short case history, all subjects underwent ophthalmic tests which included uncompensated visual acuity, keratometry, slit lamp examination and direct ophthalmoscopy. Apart from one subject with glaucoma, none of the subjects included in this study had ocular abnormalities, any history of eye disease or prior refractive surgery and none were contact lens wearers. Each subject was seated and asked to keep both eyes open and to fixate on a fixation target within the instrument. Each subject underwent fifty-one CCT and fifty-one IOP consecutive automatic sets of measurements using the Tonopachy™. Both samples ($N_1 = 51$ and N_2

= 51) in each eye were obtained in approximately five to 10 minutes due to the auto-alignment function of the device. The testing environment had reasonably constant room illumination. All measurements were taken between 14h00 and 16h00 to minimize IOP fluctuations due to diurnal variations. All the subjects were measured on one day by the same operator with the eyes in their natural, undilated state.

CCT and IOP measurements were analyzed using the Statistica Ver8 software. The distributions for the samples of CCT and IOP measurements were plotted using box and whisker plots, histograms and normal probability plots. The ranges, means and standard deviations values were determined. The Kolmogorov-Smirnov (K-S), Lilliefors and Shapiro-Wilks (SW) tests were done to establish whether or not the two samples were normally distributed and thus whether parametric statistical tests were appropriate.

Results

The mean age of the subjects was 32.3 ± 13.5 years (range, 20 to 57 years). Seven (47%) of the subjects were Indian, five (33%) were Black, two (13%) were White and one (7%) was Coloured. Descriptive statistics for the CCT and IOP measurements for each of the 15 subjects is presented in Tables 1 and 2.

Table 1 Means, standard deviations (SD), maxima and minima, skewness and kurtosis for CCT measurements (in µm) for the right eyes of the 15 subjects are indicated. The skewness and kurtosis for the standard normal distribution should be zero. Positive values for the skewness indicate positive skewing and negative values for the skewness indicate data that is negatively skewed. Similarly, positive values for kurtosis indicate leptokurtosis and a negative value indicates platykurtosis. The individual or intra-subject means for CCT ranged from 486.8 µm to 581.3 µm while the overall inter-subject mean for all the 15 eyes was 528.2 µm.

Subject	Mean	Std. Deviation	Minimum	Maximum	Skewness	Kurtosis
1	537.4	3.5	529	546	-0.1	0.4
2	539.4	4.4	530	547	-0.2	-0.3
3	577.1	4.6	563	589	-0.3	1.2
4	488.7	4.3	478	499	0.0	0.4
5	533.9	4.4	523	543	0.1	-0.1
6	486.8	2.5	481	492	-0.1	-0.2
7	581.3	3.2	575	591	0.6	0.4
8	518.7	4.3	509	533	0.3	1.9
9	488.8	2.6	482	494	-0.3	0.4
10	525.9	4.9	518	542	1.2	2.1
11	526.8	2.5	522	535	0.6	1.5
12	532.1	3.9	523	542	0.0	0.6
13	519.2	3.9	513	525	0.3	-1.2
14	548.6	3.3	543	557	0.7	-0.1
15	517.4	1.4	515	523	1.3	4.6
Total	528.2	27.4	478	591	0.3	-0.3

Table 2 Descriptive statistics (sample means, SD, maxima and minima) for IOP measurements for the 15 subjects are indicated. The values are in mmHg. The intra-subject means for IOP ranged from 9.7 to 26.5 mmHg while the overall inter-subject mean was 14.4 mmHg.

Subject	Mean	Std. Deviation	Minimum	Maximum	Skewness	Kurtosis
1	16.1	1.1	14	19	0.6	0.6
2	15.0	1.2	12	17	-0.2	-0.3
3	16.6	1.1	15	20	0.5	0.5
4	10.8	1.2	9	14	0.4	-0.2
5	11.0	0.7	9	12	-0.3	0.3
6	15.6	0.9	14	17	-0.2	-0.5
7	18.0	1.1	16	21	0.1	-0.2
8	13.3	1.2	11	16	0.3	0.1
9	11.5	1.6	9	16	0.6	-0.1
10	26.5	2.6	22	32	0.4	-0.8
11	9.9	0.8	9	12	0.7	0.5
12	13.0	1.2	11	15	0.1	-0.7
13	14.5	1.1	13	16	0.1	-1.2
14	14.0	1.4	12	17	0.2	-0.9
15	10.0	0.7	8	11	0.2	-0.4
Total	14.4	4.3	8	32	1.6	3.2

Box and whisker plots are shown in Figures 1 and 2. The horizontal lines in the box are the means while the upper and lower ends of the box depict the standard deviations of the distribution. The whiskers are the minimum and maximum values for the subjects concerned.

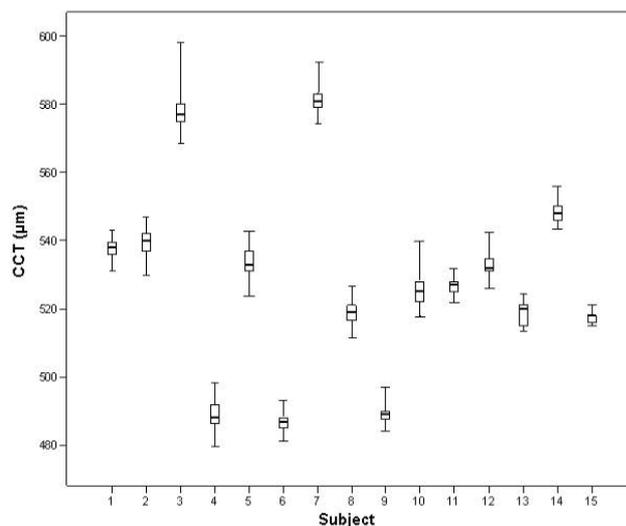


Figure 1 Box and whisker plots for CCT in micrometers (µm) on the y-axis and the subject number along the x-axis. The CCT means ranged from 478 µm and 591 µm and the standard deviations ranged from 1.4 µm to 4.9 µm.



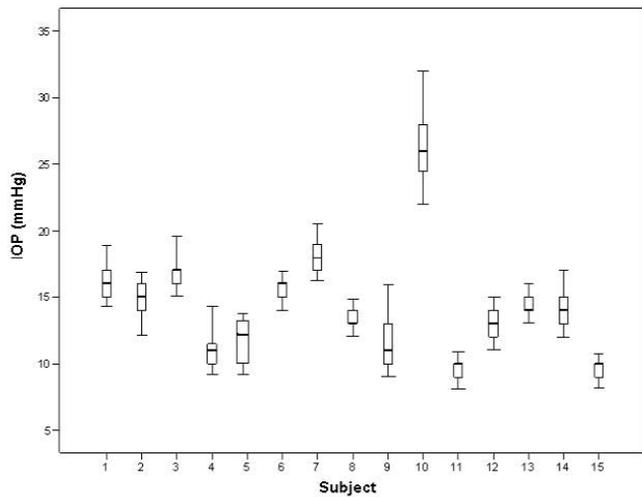


Figure 2 Box and whisker plots of IOP in mmHg (*y*-axis) for the right eyes of the 15 subjects. Subject numbers are shown on the *x*-axis.

profiles of CCT and IOP for all the subjects ($N = 51$ per sample) and they allow readers to inspect short-term repeatability and variation of CCT and IOP measurements.

Twelve out of fifteen subjects were normally distributed for CCT and IOP. However, significant skewness and/or kurtosis were seen in subjects 8, 11 and 15 for CCT measurements. Figures 5, 6 and 7 show histograms and normal probability plots for the samples of CCT and IOP for subjects 2 and 7. These subjects were randomly selected from the 12 subjects that were normally distributed. The histogram in Figure 5 shows the frequency distribution of the measurements and the curve on each figure indicates the normal distribution for CCT and IOP for the subjects 2 and 7. The normal probability plots are useful graphical tools for deciding to what extent the pattern of measurements concurs with a normal distribution.

Figures 3 and 4 of the 15 subjects include temporal

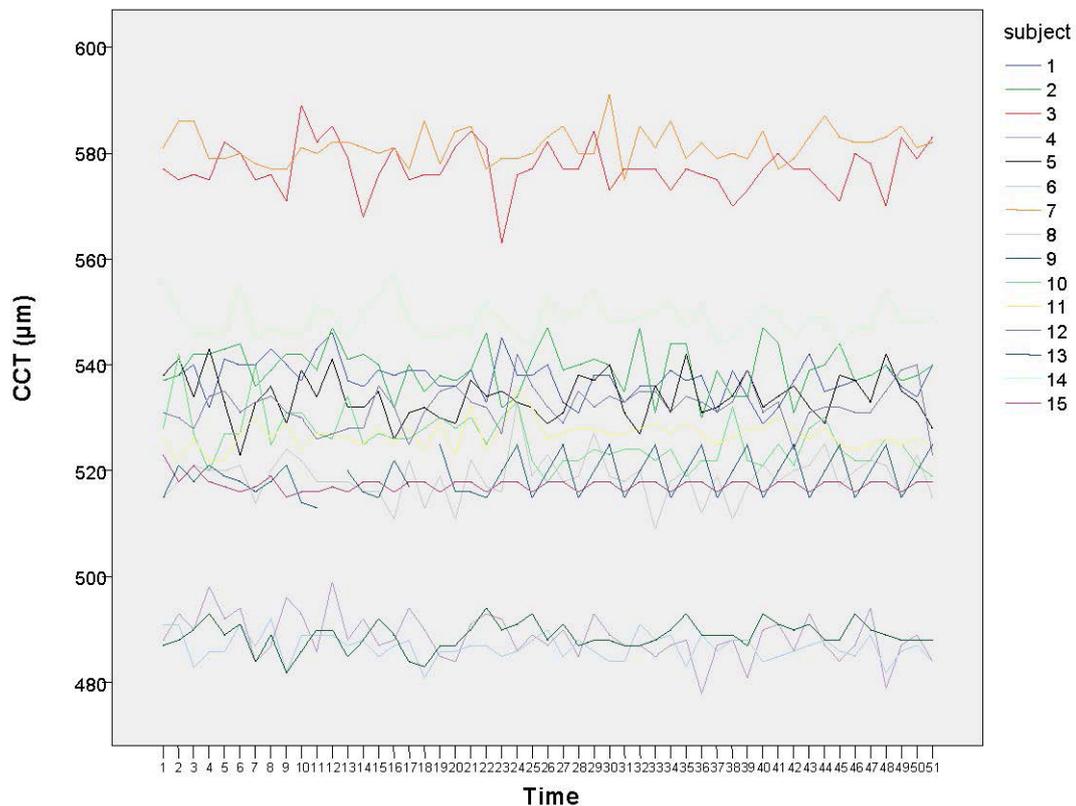


Figure 3 Line plots of temporal variation of fifty one measurements of CCT (μm) for the fifteen subjects are shown with different colours. These plots are useful in identifying atypical measurements or possible outliers in the sample.

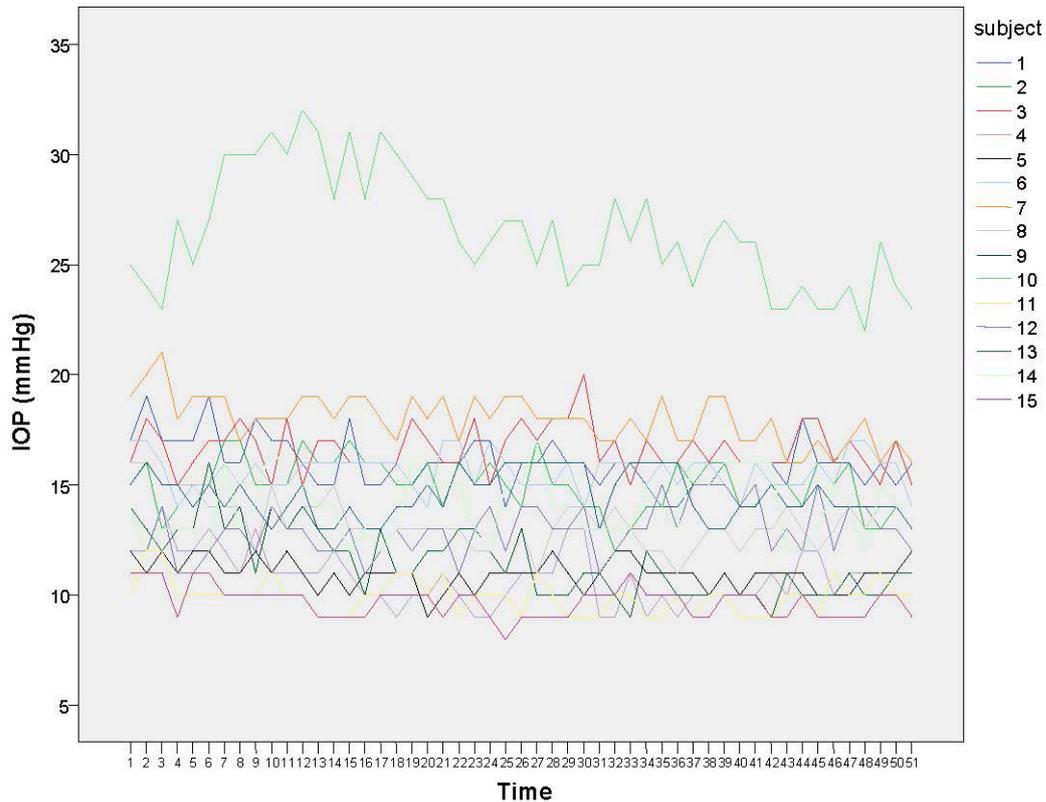


Figure 4 Temporal variation plots for samples of fifty one measurements of IOP (mmHg) for the right eyes of the fifteen subjects. The IOP profile of subject 10 (top green colour) appears to be more variable (22 to 32 mmHg) than the others. This is because the subject has chronic glaucoma.

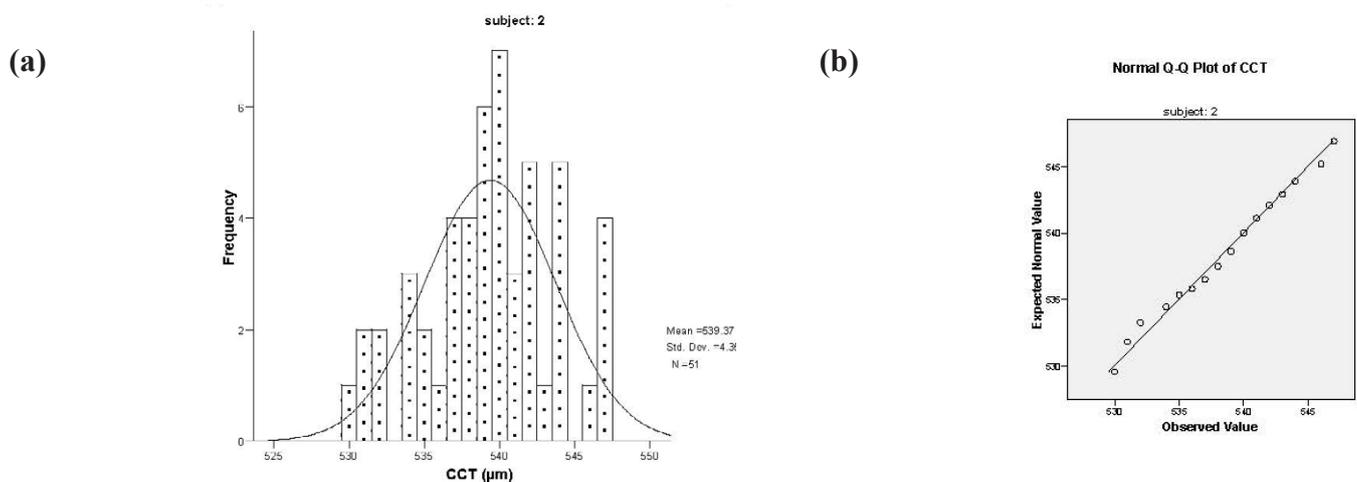


Figure 5 Histogram (a) and normal probability plot (b) for the CCT samples of subject 2. The CCT sample was approximately normally distributed although slight negative skewing and platykurtosis was present (see Table 1). The *x*-axis represents the frequency distribution for the CCT measurements and the bars show the CCT values that occur most frequently in the sample. The *p*-values for K-S, Lilliefors and SW tests were greater than 0.05, suggesting that the data showed a normal distribution. In the normal probability plot (b), the circles form a linear pattern near the diagonal solid line, suggesting that the sample is regarded as being obtained from a normally distributed population.

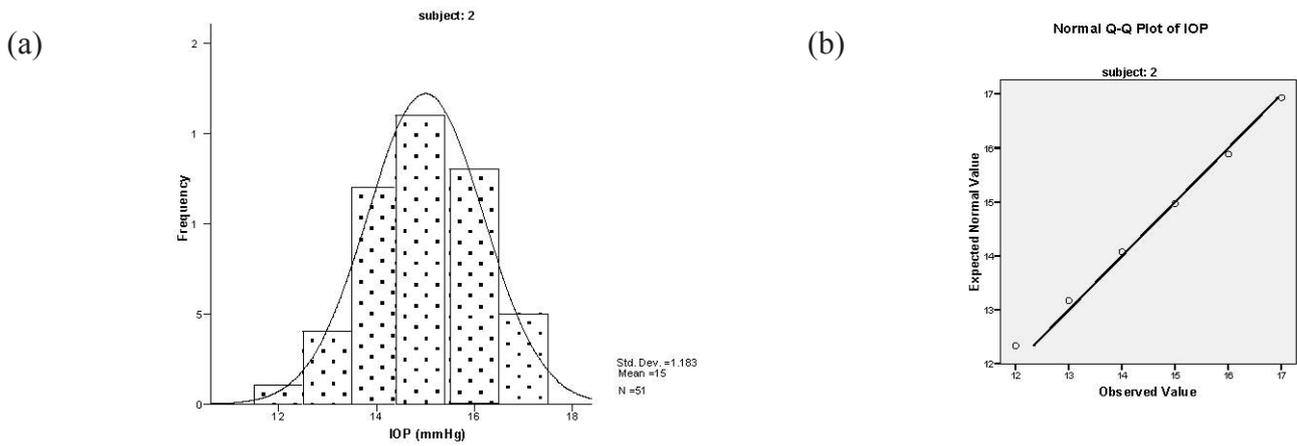


Figure 6 Histogram and normal probability plots for IOP samples of subject 2. As in Figure 5 above, the samples were normally distributed according to the *p*-values of K-S, Lilliefors and SW tests.

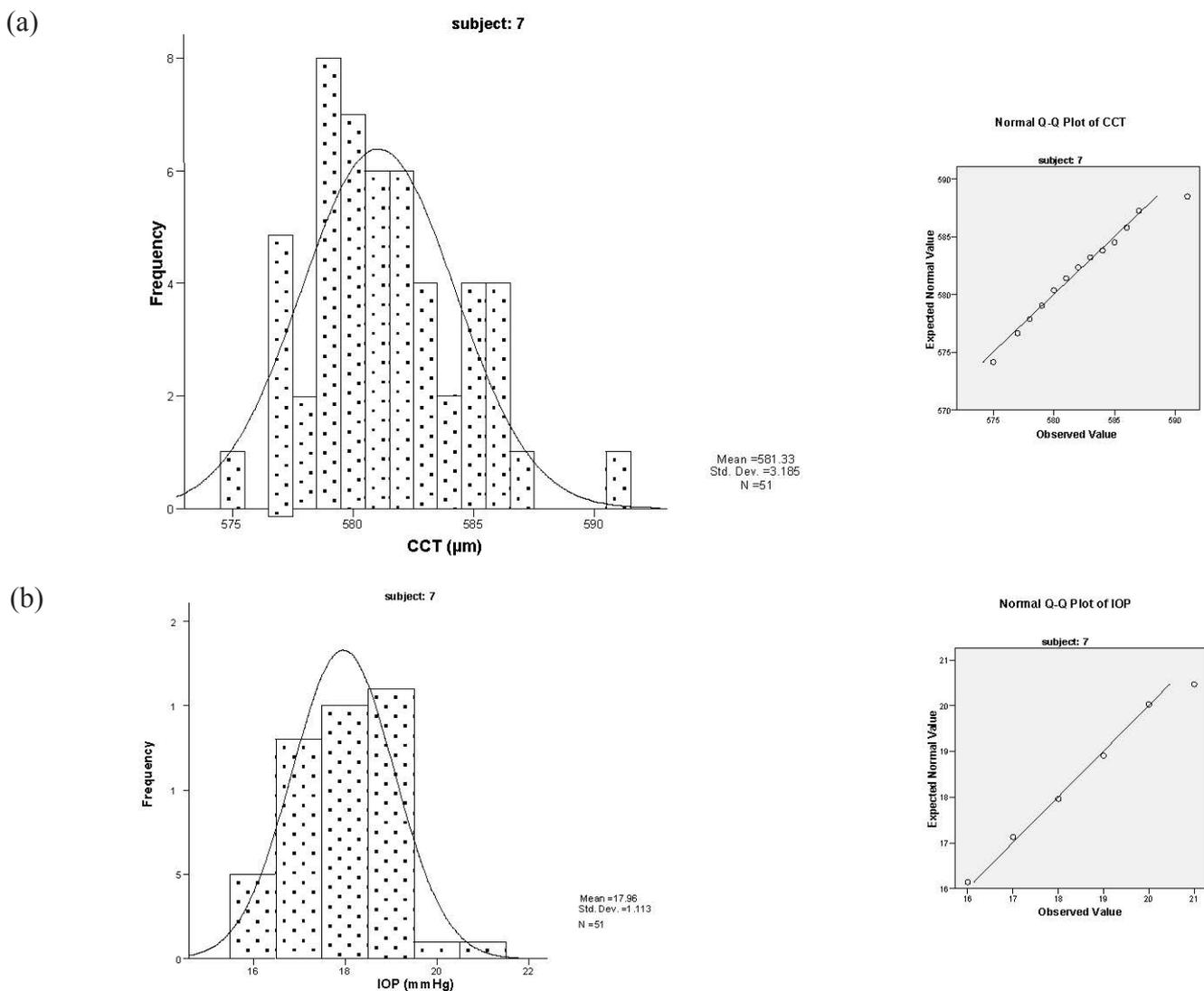


Figure 7 Histograms and normal probability plots for CCT (a) and IOP (b) samples of subject 7. Although a possible outlier for both CCT and IOP is seen at the top of the normal probability plots, the statistical analyses for normality showed *p*-values of greater than 0.05 for each of the K-S, Lilliefors and SW tests, suggesting that the data is essentially normal distributed.

Figure 8 shows an example of histograms and normal probability plots for subject 8 in the study that demonstrated departure from normality for CCT or

IOP samples. Other subjects that demonstrated departure from normality are subjects 11 and 15.

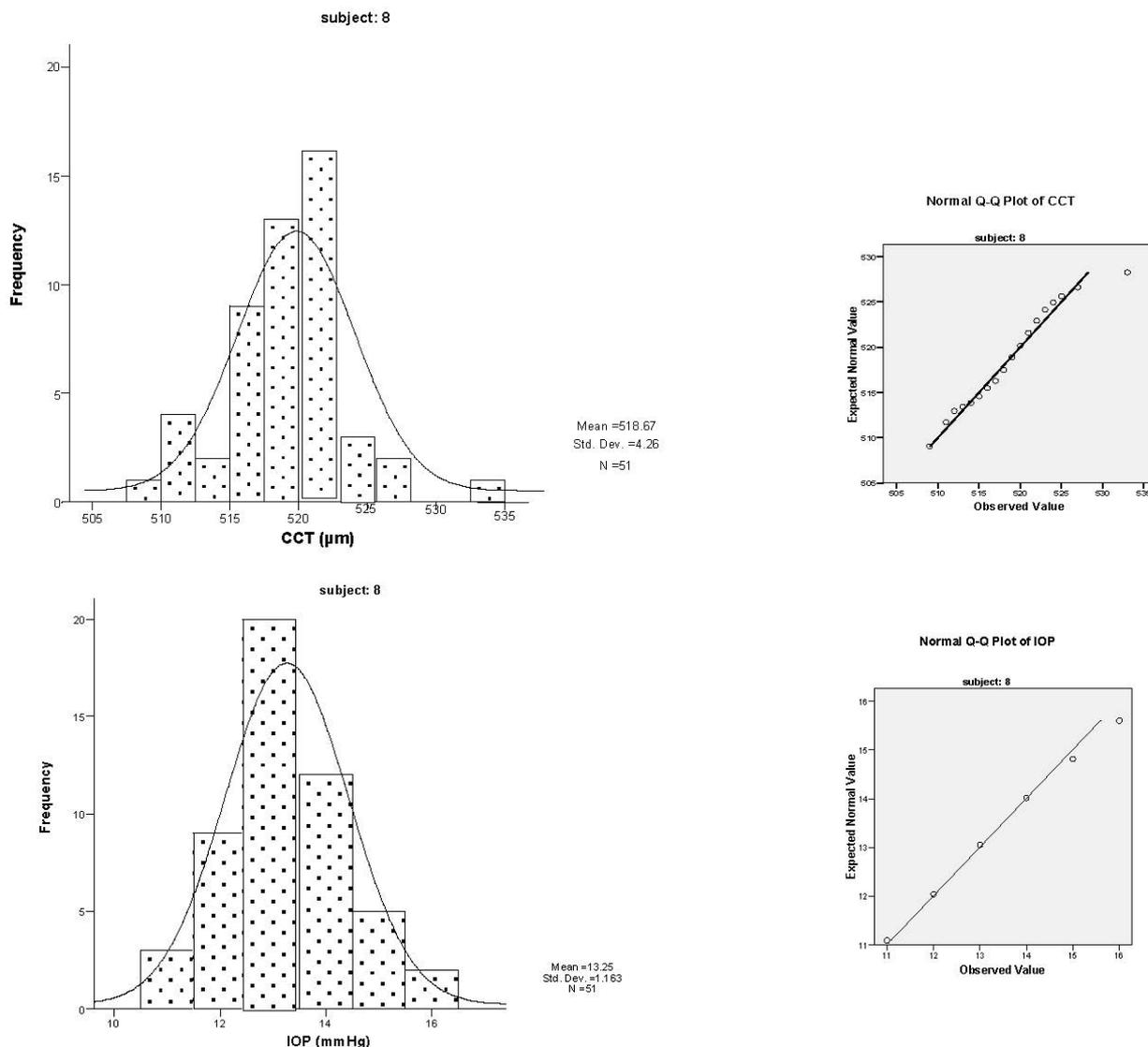


Figure 8 Histogram and normal probability plots for the CCT and IOP samples of subject 8. The CCT sample was normally distributed, the *p*-value was greater than 0.05, but less than 0.05 for the IOP in the SW test.

Discussion

Various automated pachymeters and tonometers are commonly used for the measurement of CCT and IOP and these parameters are sensitive indicators of corneal and ocular health. For example, timely detection of IOP changes contributes significantly to reduce the risks of blindness caused by glaucoma. When multiple measurements using various instruments are made, variations can be expected.

The mean values and standard deviations found in this study for the CCT of healthy human subjects are

consistent with those reported in the literature³⁰. For example, Mathebula and Rubin²⁶ found the inter-subject or overall means for CCT of 10 right eyes to be 0.55 ± 0.005 mm. The overall standard deviation for CCT (27.4 µm) seems high because the CCT values were measured in micrometres and not millimetres. As the standard deviations and maxima and minima suggest in Tables 1 and 2, CCT and IOP measurements showed minimal variation in the 15 eyes studied. Most do not show much in the way of either skewing or departure from mesokurtosis. If kurtosis is different from zero, the distribution displays

either leptokurtosis (indicated by positive signs) or platykurtosis (indicated by negative signs). For instance, the samples for CCT for subjects 10 and 15 had positive skewing (1.2 and 1.3) and leptokurtosis (2.1 and 4.6) and these samples should be inspected for some aspects of departure from univariate normality including outliers or atypical measurements in the sample, polymodal or multimodal distributions, *et cetera*. For CCT samples subjects 3, 8 and 11 showed leptokurtosis (Table 1) while subject 13 demonstrated a statistical measure that indicates a distribution that has a negative excess kurtosis (platykurtosis) for both CCT and IOP (-1.2 and -1.2).

Box and whisker plots are univariate data displays used to display graphically the mean and variability of data³¹. The box and whisker plots for the CCT and IOP (see Figures 1 and 2) showed that the standard deviations were small suggesting that multiple measurements of these parameters with the Tonopachy™ were similar for each of the subjects. The line plots for short-term variation shown in Figures 3 and 4 are mainly flat and the 51 measurements of each variable per subject took approximately 5 to 10 minutes, suggesting that there is minimal short-term variation in CCT and IOP measurements. Therefore, there appears to be good repeatability when using the instrument to measure either CCT or IOP. However, this may depend on the magnitude of the IOP; for example subject 10 in the data. Although the profiles of short-term variation for samples of 51 measurements of CCT and IOP showed good repeatability, there were some slight variability in the measurements over time (see Figures 2 and 3). Such variation has been observed in previous studies²⁶. The authors²⁶ suggested that this could be due to factors such as changes in the shape of the tear layer during blinking, eye movements, changes in IOP, heart rate, accommodation or iris position. We agree with the authors²⁶ that in order to confirm this, further studies would be needed. But the results of this study suggest that the Tonopachy™ provides repeatable measures of CCT and IOP, which are useful for clinical and research purposes.

Following the use of the K-S, Lilliefors and SW tests to calculate whether or not a randomly selected sample comes from a normal distribution, it was found that most of our data samples were normally distributed ($p > 0.05$; see Figures 5 to 7). The SW test

decides whether the null hypothesis (that a sample is from a normally distributed population) is rejected or not and has become the preferred method because of its good power properties³². Using the p -value of 0.05, the null hypothesis is rejected if p is less than 0.05 (and the data is not from normally distributed population)³². If the p -value is greater than 0.05, then one does not reject the null hypothesis that the data came from a normally distributed population. However, Figure 8 shows histograms and probability plots where the data was not normally distributed. Even though the distribution appears symmetric, significant skewness and/or kurtosis were seen in subjects 8, 11 and 15 for CCT measurements. The profile or line plots of temporal variations of the 51 measurements of the CCT and IOP were included because of the limitations of the tests for normality such as the K-S, Lilliefors and SW tests. These tests set the normal distribution as the null hypothesis and then see if the data gives a p -value low enough to reject but this sometimes creates a problem where there are many data points as it is easy to reject the null hypothesis³².

Previous studies^{7, 25-28, 33-35} have revealed variable results on the repeatability of the various instruments. The inconsistent findings in the previous studies could be due to different patient population, study designs and data analysis methods used in the studies. For example, few researchers^{25, 26} have taken multiple successive measurements per eye to investigate short-term variation of CCT in their studies. In accordance with Mathebula and Rubin²⁶, over short periods of time, we took 51 consecutive measurements per eye for each of the 15 subjects concerned. This should be an important part of the clinical assessment as it allows one to get a detailed statistical analyses (such as means, SD, variance) in order to understand the nature of the individual or intra-subject variation²⁶. For instance, subject 10 in this study was already on treatment after being diagnosed with chronic glaucoma three years prior to our collection of data. Table 2 and Figure 4 (see green colour at the top of the line plots) show that the IOP of the subject ranged from 22 to 32 mmHg with a mean of 26.5 mmHg and a standard deviation of 2.6 mmHg. We feel that this variation is of clinical significance and therefore warrants further attention (considering that the subject was already on treatment with timolol). It is therefore

possible that variations or fluctuations occurring in the short-term could be deleterious to the optic nerve. For example, Nouri-Mahdavi *et al*³⁶ reported that a 1 mmHg fluctuation in IOP was associated with a 30% increased risk for visual field loss in subjects with glaucoma. We therefore suggest to clinicians and researchers that caution should be taken when dilating a glaucoma subject as the IOP may be substantially elevated within a short time resulting in severe consequences to patients' eye health. Further investigation is recommended wherein repeated IOP measures are undertaken on multiple glaucoma subjects. Such a study could also investigate the impact of glaucoma medication use on the fluctuation and repeatability of IOP measurements.

Tonopachy™ provides sufficiently repeatable and reliable CCT and IOP measurements in eyes of healthy subjects over short periods of time. However, its variability in assessing and monitoring CCT and IOP in subjects with corneal disease or other ocular pathologies remains for future investigations. Also, we wish to highlight that the present study was done in a fairly small sample of 15 subjects; therefore further studies using the same instrument and with larger samples will help to confirm that the repeatability of these two parameters is good.

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