MAK HILL Publications Research Journal of Medical Sciences

Research Article
doi: 10.36478/makrjms.2024.2.409.413

Ophthalmological Study of Repeatability and Reproducibility of CCT Measurement by Ultrasonic Pachymeter at a Tertiary Hospital

[1]Sangeeta Vivek Patil, [2]Pranesh Kulkarni, [3]Abhishek Kulkarni and [4]Afreen

[1-4]Department of Ophthalmology, Khaja Banda Nawaz University-Faculty of Medical Sciences, Kalaburagi, Karnataka, India

OPEN ACCESS

Key Words
Central corneal thickness (CCT), ultrasonic pachymeter, inter observer reproducibility, intra observer reproducibility

Corresponding Author
Afreen,
Department of Ophthalmology, Khaja Banda Nawaz University-Faculty of Medical Sciences, Kalaburagi, Karnataka, India

Author Designation
[1,3]Associate Professor
[2]Professor
[4]Senior Resident

Received: 20 February 2024
Accepted: 15 March 2024
Published: 16 March 2024

Citation: Sangeeta Vivek Patil, Pranesh Kulkarni, Abhishek Kulkarni and Afreen, 2024. Ophthalmological Study of Repeatability and Reproducibility of CCT Measurement by Ultrasonic Pachymeter at a Tertiary Hospital. Res. J. Med. Sci., 18: 409-413, doi: 10.36478/makrjms.2024.2.409.413

Abstract
Assessment of central corneal thickness (CCT) has assumed considerable clinical importance in relation to the planning of corneal refractive surgery, management after refractive surgery, etc. Present study was aimed to study of repeatability and reproducibility of CCT measurement by the commercial available ultrasonic Pachymeter PACSCAN 300AP of Sonomed at a tertiary hospital. Present study was single-center, prospective, observational study, conducted in cases of age group 40-80 years, attending glaucoma clinic (irrespective of whether they have glaucoma or not). PACSCAN 300AP of Sonomed, an ultrasonic pachymeter is used for this study. 40 subjects underwent pachymetry in both of their eyes, thus a total of 80 eyes were included in the study. The mean CCT of observer A, observer B and observer C was 532.8µm, 528.3µm and 530.1µm respectively. There is no significant difference between the three mean CCT measurements (p=0.7). The mean measurement difference between observers was 2.91µm and the mean expected inter observer measurement was within ±1.00% and the largest observed value was <±1.1%. The ICC for reproducibility study was 0.979 (p<0.0001) suggesting that there is significant correlation between mean of the observer A, Observer B and Observer C. To assess agreement between the observers, Bland-Altman plot was constructed, agreement are narrow with respect to the mean CCT, thus indicating excellent agreement. A variation of ≥15 mm between two repeated measurements occurred in 145 out of 720 (20.14%) test-retest Intra observer evaluations and in 668 out of2160 (30.93%) test-retest inter observer evaluations. A variation of ≥15 mm between two repeated measurements has been considered as a clinically relevant outcome, indicates that, despite the high reproducibility of the procedure.

INTRODUCTION

Assessment of central corneal thickness (CCT) has assumed considerable clinical importance in relation to the planning of corneal refractive surgery, management after refractive surgery, diagnosis and monitoring of corneal ectasia such as keratoconus and Fuchs' dystrophy and in the evaluation of corneal health in patients with contact lenses[1].

Ehlers[2] have shown that CCT affects applanation tonometry measurements. Recent studies have disclosed the effect of CCT on diagnosing glaucoma, as patients with ocular hypertension were found to have increased CCT, which can lead to falsely elevated intraocular pressure measurements, whereas patients with low tension glaucoma were noted to have decreased CCT, resulting in falsely low intraocular pressure[3,4].

The Ocular Hypertension Treatment Study (OHTS) demonstrated that subjects with ocular hypertension and with thin corneas had a significantly higher risk for developing glaucoma such that a decrease in CCT of 40 mm added a 70% increase in risk[5]. Similarly it has been reported that refractive surgeries such as excimer photorefractive keratectomy can lower applanation tonometry values, probably due to thinning of the central cornea[6].

With the recent heightened interest in refractive surgery and thus the need for more precise definition of corneal parameters, accurate measurement of CCT has become increasingly important. Therefore the measurement of central corneal thickness is an important step in ophthalmic evaluation. Present study was aimed to study of repeatability and reproducibility of CCT measurement by the commercial available ultrasonic Pachymeter PACSCAN 300AP of Sonomed at a tertiary hospital.

MATERIALS AND METHODS

Present study was single-center, prospective, observational study, conducted in department of Ophthalmology, Khaja Banda Nawaz University-Faculty of Medical Sciences, Kalaburagi, India. Study duration was of 2 years (January 2021-December 2022). Study approval was obtained from institutional ethical committee.

Inclusion Criteria:

- Cases of age group 40-80 years, attending glaucoma clinic (irrespective of whether they have glaucoma or not), willing to participate in present study

Exclusion criteria:

- Individuals with previous corneal surgery
- Individuals with previous or current corneal disease including pterygium.
- Any active ocular infection or inflammation.
- Contact lens wearers.
- Patients with astigmatism greater than 1.5 D.
- Pregnancy.

Study was explained to patients in local language and written consent was taken for participation and study. All patients were enquired about relevant clinical history and undergone slit lamp examination along with refraction to identify the presence of any exclusion criteria.

The steps of the procedure were explained to patient in his or her own language. Lignocaine 4% eye drop was used in all cases as the topical anaesthetic agent. Subjects were seated and asked to look forward and fixate on a distant target. The measurement technique involved placing the tip of the hand held probe perpendicular to the center of the cornea, using the center of the undilated pupil as the landmark.

PACSCAN 300AP of Sonomed, an ultrasonic pachymeter is used for this study. It is a portable device which consists of a pacscan unit which is attached to an ultrasonic probe. The ultrasonic probe automatically measures the time between two echoes from anterior and posterior surfaces of the cornea keeping the ultrasound velocity in the cornea preset to 1636 m/sec and from this time interval CCT value is calculated, which is displayed on the unit's liquid crystal display (LCD).

Measurement of CCT was explained to subject, that the probe should gently touch the surface of the cornea. An automatic reading will be taken by the pachymeter after pressing the 'START' button. Upon the completion of an acceptable measurement the average reading will be displayed on the top of the screen along with the standard deviations of the reading (Each reading consists of 256 individual measurements). Similarly another four readings are taken with the standard deviations. Eliminating the first and fifth reading the mean of second, third and fourth readings were calculated as mean CCT of an individual.

In order to reduce the possibility of ocular surface drying, one drop of artificial tear (Moisol eye drop) was instilled 30 seconds before each measurement. Each measurement was recorded by an assistant. The observers were masked for all CCT measurements. The probe was sterilized with alcohol after each subject.

All the subjects underwent pachymetry as described above by three observers (ophthalmic assistant, resident and glaucoma fellow) who had experience in the use of the instrument. The order in which the observers took the measurements was randomized. The time interval between each observer

was less than five minutes to reduce the effect of diurnal variation on CCT. Inter observer reproducibility was based on the analysis of the three independent series of measurements made by the three examiners (nine readings).

Intra observer reproducibility was calculated for each of the three observers on the basis of three consecutive measurements done by them for all the above 40 subjects in both eyes. The time interval between each measurement was less than five minutes.

All statistical analysis was done by using the software package SPSS version16.0 (SPSS Inc., USA). Statistical comparisons among groups were performed using ANOVA. The statistical comparisons between two groups were made using t-test. A $p<0.05$ was considered to be statistically significant. Agreement was also analyzed by the Bland-Altman plots.

RESULTS AND DISCUSSIONS

40 subjects underwent pachymetry in both of their eyes, thus a total of 80 eyes were included in the study. The mean age of the subjects was 56.8 years, with a range of 40-72 years (fig 7). Majority were from 51-60 years age group (42.5%) followed by 61-70 years age group (30%). We calculated age wise category mean CCT measurements by observer A, observer B and observer C. There is no significant difference between age category in observer A (p-value=0.23). There is no significant difference between age category in observer B (p-value=0.24). There is no significant difference between age category in observer C (p-value=0.37)

Among 40 subjects, 17 were female and 23 were male. The average CCT in males and females was 537.4 µ and 526.5 µ for observer A. Similarly for observer B was 532.6 µ and 522.6 µ respectively. For observer C, the average CCT in males and females was 532.2 µ and 527.2 µ respectively. There is no gender-related difference between CCT measurements in all 3 Observers

The mean value of the three CCT measurements and their standard deviations of all the three observers including minimum and maximum values were measured. The mean CCT of observer A, observer B and observer C was 532.8µm, 528.3µm and 530.1µm respectively. There is no significant difference between the three mean CCT measurements (p=0.7). The mean measurement difference between observers was 2.91µm and the mean expected inter observer measurement was within±1.00% and the largest observed value was <±1.1%.

The ICC for reproducibility study was 0.979 ($p<0.0001$) suggesting that there is significant correlation between mean of the observer A, Observer B and Observer C.

To assess agreement between the observers, Bland-Altman plot was constructed, agreement are narrow with respect to the mean CCT, thus indicating excellent agreement.

The differences between the test-retest and their confidence intervals along with ICC values for Intra observer were analysed. For the observer A, the ICC was calculated and found to be 0.967($p<0.0001$) suggesting there is a significant correlation between 3 CCT measurements. For the observer B, the ICC was calculated and found to be 0.97($p<0.0001$) suggesting there is a significant correlation between 3 CCT measurements. For the observer C, the ICC was calculated and found to be 0.93 ($p<0.0001$) suggesting there is a significant correlation between 3 CCT measurements. The mean ICC for Intra observer reproducibility was 0.956 (SD 0.022) and 95% CI was within 0.915-0.974. The mean expected Intra observer measurement was within±1.01% and the largest observed value was <±1.1%. The above all results indicated statistically excellent correlation.

A variation of ≥15 mm between two repeated measurements occurred in 145 out of 720 (20.14%) test-retest Intra observer evaluations and in 668 out of2160 (30.93%) test-retest inter observer evaluations.

Reliable and validated measurement of CCT is an important parameter in the planning of keratore-fractive surgery, diagnosis and follow-up of diseases such as endothelial failure and glaucoma. There are many studies in the literature that compare CCT values measured using different devices but with conflicting results. Newer technologies are being used by many clinicians, such as scanning slit topography, confocal microscopy, specular microscopy and spectral oscillation interferometry, all of which employ optical methods. The reliability and repeatability of these methods have been studied by many researchers yielding different results[7].

The mean inter observer difference in CCT measurement that P Gunvant[8] found was 0.7 mm, which compared favourably with that obtained by Gordon[9] who used a different ultrasonic pachymeter. Furthermore, the Intra observer level of agreement was excellent with a mean difference between measurements of only 0.9 mm. This was an excellent level of agreement amounting to a CCT variation of only around 0.17%, assuming an average CCT of 538 mm.

We investigated the intra- and inter observer reproducibility of CCT measurements made using an ultrasonic pachymeter. The mean expected Intra observer measurement was within±1.01% and the largest observed value was <±1.1%.The mean expected inter observer measurement was within±1.00% and the largest observed value was <±1.1%. The extent of variability between each test-retest did not depend on

Table 1: Age wise inter observer evaluations

Age	No. of patients (%)	Mean CCT of Obs A (mean 1)	Mean CCT of Obs B (mean 2)	Mean CCT of Obs C (mean 3)
40-50	10 (25%)	544.1	538.3	538.5
51-60	17 (42.5%)	529.1	523.2	527.9
61-70	12 (30%)	526.5	524.9	524.3
>70	1 (2.5%)	557.5	556	552.5
P value	--	0.23	0.24	0.37

Table 2: Gender wise inter observer evaluations

Mean CCT	Sex	No. of patients (%)	Mean ±Std. Deviation	Std. Error Mean	p-value
Obs A	Male	23 (57.5%)	537.39 ± 32.604	4.807	0.168
	Female	17 (42.5%)	526.53 ± 37.015	6.348	
Obs B	Male	23 (57.5%)	532.57 ± 32.482	4.789	0.184
	Female	17 (42.5%)	522.56 ± 33.725	5.784	
Obs C	Male	23 (57.5%)	532.24 ± 33.127	4.884	0.495
	Female	17 (42.5%)	527.18 ± 32.043	5.495	

Table 3: Inter observer reproducibility study results

	CCT A1	CCT A2	CCT A3	Mean A	CCT B1	CCT B2	CCT B3	Mean B	CCT C1	CCT C2	CCT C3	Mean C
Mean	533.24	533.71	531.22	532.78	527.92	528.79	528.38	528.31	529.65	529.31	529.98	530.09
Std. Deviation	34.317	35.433	35.431	34.742	33.509	35.201	32.961	33.179	33.515	35.554	32.764	32.563
Minimum	456	453	453	454	449	449	460	462	453	402	453	458
Maximum	601	601	614	605	592	601	591	592	601	601	601	601

Table 4: Intra observer repeatability study results

Test-retest	ICC	Mean	Difference	SD	95% CI	95% CI (%)
Intra observer						
obsA1-obsA2	0.963	533.48	0.48	5.51	528.05-538.9	1.02
obsA1-obsA3	0.964	532.23	2.01	5.51	526.8-537.66	1.02
obsA2-obsA3	0.974	532.47	2.49	5.6	526.95-537.95	1.04
obsB1-obsB2	0.972	528.36	0.86	5.43	523.0-533.7	1.01
obsB1-obsB3	0.965	528.15	0.45	5.26	522.98-533.32	0.98
obsB2-obsB3	0.972	528.58	0.41	5.39	523.27-533.89	1.00
obsC1-obsC2	0.924	529.48	0.34	5.46	524.10-534.86	1.02
obsC1-obsC3	0.957	529.81	0.33	5.24	524.65-534.97	0.97
obsC2-obsC3	0.915	529.64	0.66	5.41	524.32-534.97	1.00
Mean	0.956	530.24	0.89	5.42		1.01

the absolute CCT value in any comparison, both in the Intra observer and inter observer evaluations.

The average CCT in males and females was 537.4 µ and 526.5 µ for observer A. Similarly for observer B was 532.6 µ and 522.6 µ respectively. For observer C, the average CCT in males and females was 532.2 µ and 527.2 µ respectively. Our study showed that there is no gender-related difference between CCT measurements in 3 observers. There is also no significant difference between age-wise category in observer A (p=0.23), observer B (p=0.24) and observer C (p=0.37). All the above results indicate that both the Intra observer and inter observer reproducibility of CCT measurements is extremely high. Our results were consistent with the previous published studies[9-11].

As reported by Bland and Altman, comparison of new measurement techniques with established ones in clinical measurement is often needed to assess whether the results of the two methods agree sufficiently for the new technique to replace the old. If the new method agrees sufficiently well with the old, then the two methods may be used interchangeably and the old may be replaced. In order to know the extent of agreement between the techniques, assessing their repeatabilities is important, because repeatability limits the amount of agreement between techniques[12].

A review of literature revealed that both intra-examiner variability and inter-examiner variability with USP were extremely high due to the fact that USP does not have a fixation light, and the diameter of probe is only 1 mm (which may have induced some variation while positioning on the cornea manually[10]) In addition, further potential source of variability lies in the corneal touch technique. A variation of >15 µm is observed in 11.3% of intra-examiner evaluations and 22% of inter-examiner evaluations. This indicates that care should be taken in the interpretation of IOP measurement corrected for CCT obtained using USP. In fact, it is possible to expect 10% of the CCT measurements to induce an incorrect IOP estimate of about 1 mmHg, even when the same operator performs the CCT examinations[10].

This study shows that multiple readings taken with the NCSM would be more useful for comparisons over time in situations where a patient needs to be followed up over a period of time[13]. Nevertheless, in conditions of cornea cloudiness or media opacities, the USP is the method of choice in measurement of CCT over optically based pachymeters.

US pachymetry depends on the reflection of ultrasonic from the anterior and posterior corneal surfaces. In ultrasonic pachymetry, the exact posterior reflection point is not known., it may be located between Descemet's membrane and the anterior chamber. If the reflection point is located at the anterior chamber, this will cause overestimation of the corneal thickness[14].

Accurate measurement of CCT with the hand-held ultrasound pachymeter relies on placement of the probe as close as possible to the central cornea. Higher values will be obtained if the probe is not placed at 90 degrees to the corneal surface or if placed slightly off center[15]. With hand-held ultrasound pachymetry, the same place on the cornea is not measured on every occasion, and because the cornea varies in thickness according to location, this adds to some error.

CONCLUSION

A variation of ≥15 mm between two repeated measurements has been considered as a clinically relevant outcome (as it can induce an error in intraocular pressure assessment of about 1 mmHg according to the conversion factor of Ehlers and colleagues of 0.7 mmHg/10 mm^x) and the frequency with which these substantial changes occurred has been calculated. This indicates that, despite the high reproducibility of the procedure, care should be taken in the interpretation of IOP measurement corrected on the basis of CCT measurement.

REFERENCES

1. Osuagwu, U. and K. Ogbuehi, 2012. Repeatability and interobserver reproducibility of artemis-2 high-frequency ultrasound in determination of human corneal thickness. Clin. Ophthalmol., 6: 761-769.
2. Ehlers, N., T. Bramsen and S. Sperling, 1975. Applanation tonometry and central corneal thickness. Acta Ophthalmol., 53: 34-43.
3. Copt, R.P., 1999. Corneal thickness in ocular hypertension, primary open-angle glaucoma, and normal tension glaucoma. Arch. Ophthalmol., Vol. 117 .10.1001/archopht.117.1.14.
4. Herndon, L.W., 1997. Central corneal thickness in normal, glaucomatous, and ocular hypertensive eyes. Arch. Ophthalmol., 115: 1137-1147.
5. Gordon, M.O., J.A. Beiser and J.D. Brandt,et al 2002. The ocular hypertension treatment study. Arch. Ophthalmol., 120: 714-720.
6. Abbaso?lu, Ö.E., R.W. Bowman, H.D. Cavanagh and J.P. McCulley, 1998. Reliability of intraocular pressure measurements after myopic excimer photorefractive keratectomy11the authors have no proprietary interest in these or any other tonometers.. Ophthalmology, 105: 2193-2196.
7. Sadoughi, M., B. Einollahi, N. Einollahi, J. Rezaei, D. Roshandel,et al., 2015. Measurement of central corneal thickness using ultrasound pachymetry and orbscan ii in normal eyes. J. Ophth Vision Res., 10: 4-9.
8. Gunvant, P., D. Broadway and R. Watkins, 2003. Repeatability and reproducibility of the bvi ultrasonic pachymeter. Eye, 17: 825-828.
9. Gordon, A., E.A. Boggess and J.F. Molinari, 1990. Variability of ultrasonic pachometry. Optometry Vision Sci., 67: 162-165.
10. Miglior, S., E. Albe, M. Guareschi, G. Mandelli and S. Gomarasca,et al 2004. Intraobserver and interobserver reproducibility in the evaluation of ultrasonic pachymetry measurements of central corneal thickness. Br. J. Ophthalmol., 88: 174-177.
11. Kiddee, W. and O. Horattanareung, 2009. Reproducibility in the ultrasonic pachymetry measurements of central corneal thickness. J Med Assoc Thai., 95: 672-676.
12. Bland, J.M. and D.G. Altman, 1996. Measurement error. BMJ., 313-744.
13. Insler, M.S. and J.D. Baumann, 1986. Corneal thinning syndromes. Ann Ophthalmol., Vol. 18.
14. Mimouni, M., V. Flores, Y. Shapira, S. Graffi and S. Levartovsky et al., 2017. Correlation between central corneal thickness and myopia. Int. Ophthalmol., 38: 2547-2551.
15. Paul, T., M. Lim, C.E. Starr, H.O. Lloyd, J.D. Coleman,et al., 2008. Central corneal thickness measured by the orbscan ii system, contact ultrasound pachymetry, and the artemis 2 system. J. Catar Refra Surg., 34: 1906-1912.