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Original Research Article

COMPARISON OF CENTRAL CORNEAL THICKNESS MEASUREMENT BETWEEN NONCONTACT PACHYMETRY AND ULTRASONIC PACHYMETRY

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ABSTRACT

Background: To compare CCT measurements between noncontact pachymetry (Topcon trk-2p) and ultrasonic pachymetry.

Materials and Methods: This study was undertaken in the Department of Ophthalmology of Lady Hardinge Medical College and Associated Hospitals from November 2017 to March 2019 after institutional ethical clearance. In this study, 100 cases from 16 year of age and above were enrolled as per inclusion and exclusion criteria after taking written informed consent.

Results: Mean age of study subjects was 43.09 ± 12.87 years. There were 33% male and 67% female patients in study. Overall mean CCT value obtained by noncontact pachymetry was 492.54 ± 28.08µm in right eye while mean CCT obtained by ultrasonic pachymetry showed value of 528.37 ± 28.80µm, in right eye. Mean CCT compared between two instruments showed statistically significant P value of < 0.001. Similarly mean CCT value in left eye obtained by noncontact pachymetry was 494.32 ± 27.71µm while mean CCT in left eye obtained by ultrasonic pachymetry showed value of 529.74 ± 29.10µm, which was statistically significant as P value obtained was < 0.001. Hence comparison of mean CCT between noncontact and ultrasonic pachymetry in our study was highly significant. Bland altman plot was in agreement with these results showing mean difference of 35.62µm and Limits of agreement (LOA) = 24.19 to 47.04µm. Hence it was found that noncontact pachymetry takes CCT values thinner by 35.62µm as compared to ultrasonic pachymetry. Mean CCT in right eye of male, by noncontact pachymetry was 497 ± 30.97µm and by ultrasonic pachymetry was 533.61 ± 31.74µm and results were significant P < 0.01. Similarly mean CCT in left eye of male, by noncontact pachymetry was 498.64 ± 30.29µm and by ultrasonic pachymetry was 534.42 ± 31.88µm and differences were significant P < 0.01. Similarly mean CCT in right eye of female, by noncontact pachymetry was 490.34 ± 26.52µm and by ultrasonic pachymetry was 525.79 ± 27.11µm and differences were significant P < 0.01. Similarly mean CCT in left eye of female, by noncontact pachymetry was 492.19 ± 26.32µm and by ultrasonic pachymetry was 527.43 ± 27.59µm and differences were significant P < 0.01. This signifies that difference of mean CCT obtained from both the instruments in male and in female is significant. Five patients(5%) had complaint of discomfort and seven patients(7%) had blurring of vision after ultrasonic pachymetry examination . There was no effect on the Snellen's visual acuity in all seven patients who had blurring. While no complaint was noticed in patients after taking measurements through noncontact pachymetry. No evidence of epithelial defect was seen after ultrasonic pachymetry examination.

Conclusion: Difference in mean CCT obtained by two instruments ultrasonic and noncontact pachymetry was significant. Noncontact pachymetry showed significantly thinner CCT value than ultrasonic pachymetry. Hence CCT value obtained by noncontact pachymetry is not as reliable as CCT obtained by gold standard ultrasonic pachymetry.
Keywords: Central corneal thickness, Noncontact pachymetry, ultrasonic pachymetry.

INTRODUCTION

The measurement of central corneal thickness (CCT) has a crucial role in both the diagnostic and therapeutic assessment of ocular pathologies therefore, it has become increasingly important in ophthalmic practice. This measurement is required for refractive surgery preoperative evaluations to prevent postoperative corneal ectasia, corneal edema and also is an indicator of corneal endothelial function.[1] It has a critical role in determining flap and residual stromal thickness and also optical zone in keratorefractive procedures.[2]

Central corneal thickness (CCT) has direct influence in intraocular pressure (IOP) measurement. It influences the measurement of IOP in many types of tonometry, including Goldmann Applanation Tonometry (GAT), and CCT has prognostic value for patients with ocular hypertension.[3] It is proven in various published studies, that for every 10 µm difference in the CCT from the population mean (approximately 542 µm), there is a 0.5 mm Hg difference between the actual IOP and the IOP measured with GAT.[3]

The pachymetry measurements must be prompt, precise, and reproducible.[4] To measure CCT, a wide range of advance devices like conventional ultrasonic pachymetry (US), confocal biomicroscopy, scheimpflug imaging, optical coherence tomography (OCT), and optical low-coherence reflectometry (OLCR) are available . Accurate measurement of CCT is of critical importance while evaluating ocular disorders. A new device or technique should therefore be compared with other standard technique, such as ultrasonic pachymetry, so that accuracy of new device could be known.

Currently, ultrasonic pachymetry is the most commonly used method for corneal thickness measurements. However, it has the disadvantage of direct contact of the probe with the cornea with use of topical anaesthesia, which may influence the CCT measurement. It may damage the corneal epithelium and increase the risk of infection. Nowadays, noncontact instruments have become more popular to overcome this disadvantage.

In our study noncontact pachymetry (Topcon trk-2p) automated optical pachymeter (Topcon, Tokyo, Japan) is used which is a modern instrument and provides corneal pachymetry data with other screening data, such as non-contact intraocular pressure (IOP) measurement, auto refraction, and keratometry.

The aim of this observational study was to compare CCT measurements between noncontact pachymetry (Topcon trk-2p) and ultrasonic pachymetry. Noncontact pachymetry is patient- friendly and time-saving, but it has not been well documented whether the CCT obtained from it is comparable to those derived from conventional ultrasonic pachymetry as the gold standard for measuring CCT. There are very few previous studies that evaluated this device, and the results are inconsistent, hence we did this study to prove reliability.

MATERIALS AND METHODS

This is a Hospital based, Observational, Cross sectional study which was conducted among patients presenting to Department of Ophthalmology, Lady Hardinge Medical College and Associated Hospitals, New Delhi, India (either as outpatient or requiring admission). Duration of study was November 2017 – March 2019.

Study Groups and Sample Size

A convenient sample size of 100 patients visiting to the Ophthalmology department of LHMC fitting into inclusion and exclusion criteria were enrolled for the purpose of this study.

Inclusion Criteria

- Patients in age group (16 year and above)
- Patients willing to give consent

Exclusion Criteria

- Patients with corneal pathology.
- Patients who wear contact lens.

Patients who underwent refractive or any other type of intraocular surgery within last 3 months.

Primary Outcome

- Comparison of central corneal thickness measurement by noncontact pachymetry and ultrasonic pachymetry.

Secondary Outcome

- Investigation of any discomfort, irritation, redness blurring of vision after pachymetry.
- Evaluation of any complications like corneal abrasion, corneal staining after pachymetry.

Methodology

Written informed consent was taken from patients and patients with age 16-18year consent from parent/ guardian was taken. Patients fulfilling the inclusion and exclusion criteria were taken for the study and a structured predesigned proforma was filled.

All patients were subjected to thorough history and ophthalmological examination which included

visual acuity assessment, best corrected visual acuity with cycloplegic refraction, torch light examination, Hirschberg test, pupillary reflex examination (direct/indirect), slit lamp evaluation, direct ophthalmoscopic examination.

Central corneal thickness readings from both eyes was taken by pachymetry. CCT readings was first evaluated by noncontact pachymetry followed by ultrasonic pachymetry. All the measurements were done by a single observer.

Noncontact Pachymetry (TOPCON TRK-2P)

The patient's face was accurately aligned to a fixed target within the device by keeping chin at chin rest and forehead at head rest. An image of the patient's eye was visible on the computer screen, with the machine marking the pupil edge and center, and the corneal apex.

The image was focused and centered manually. Five central corneal thickness readings from both eye were taken and mean value calculated.

ULTRASONIC PACHYMETRY (PACHETTE)

CCT was measured with the help of DGH 555 Ultrasonic Pachymeter (Pachette 3) which was caliberated with CAL box. The patient was laid in supine position looking the ceiling above and the probe was placed perpendicular to the centre of the cornea, after instillation of topical anesthesia 0.5% proparacaine hydrochloride ophthalmic solution. The measurements were performed after 60 seconds of drop application to avoid increase in corneal thickness due to the topical anesthesia. Proper precautions were taken to place the probe to the center of the cornea. Five consecutive measurements from both eyes were taken with ultrasonic pachymetry, and the mean value of these five measurements used as central corneal thickness reading.

A questionnaire was provided to the patient after taking central corneal thickness measurement for evaluation of discomfort, redness, blurring of vision and examination was done to look for corneal staining, abrasion.

Tools Used in Study

Tools (used for studying central corneal thickness mentioned in this study are enumerated below, all tests and tools are non-invasive and standard).

Pachymeter

1. Non contact pachymeter (Topcon TRK-2P)
2. Ultrasonic pachymeter (DGH 555 Pachette 3) Routine clinical examination list

Visual acuity charts, auto refractometer, direct ophthalmoscope, slit lamp examination.

Statistical Evaluation

- Tabulation of data with Microsoft excel spreadsheet and analysis of value by an open source freely available statistical software was done.
- Application of appropriate statistical tests like mean percentage. Student t-test, Mann-Whitney U test was used to compare (quantitative data) mean central corneal thickness values obtained from two instruments. Spearman correlation coefficient was used to see correlation between quantitative variables. Bland Altman plots, 95% limits of agreement was plotted to see agreement between noncontact and ultrasonic pachymetry.
- P value < 0.05 considered significant.

Ethical Issues

1. Ethical clearance was taken before the study from the thesis review board and the Institutional Ethics Committee.
2. All evaluation was performed by experts who would communicate the results of the same to the patients or to their parents/guardians.
3. All recruits were managed and followed up as per standards of practice (SOP)

Conflicts of Interest

No potential conflicts of interest relevant to this topic was reported.

Neither author has a proprietary or financial interest in any product mentioned.

Data Management

Individual files were allotted a unique serial number. All proforma was filled by the primary investigator after appropriate evaluation by the supervisor and co-supervisors. All records were managed by the primary investigator.

RESULTS

In this study, 100 cases from 16 year of age and above were enrolled as per inclusion and exclusion criteria after taking written informed consent.

Demographic Profile

Patients were taken from Department of Ophthalmology at Lady Hardinge Medical College and Associated Hospitals over the period of November 2017 to March 2019.

The age ranged from 16 year and above with mean age of 43.09 years with standard deviation of 12.87 years.

Table 1: Age Distribution of Study Subjects

Age (in years)	No.	%
16-30 years	17	17.0
31-45 years	43	43.0
46-60 years	32	32.0
>60 years	8	8.0

Table 2: Gender wise distribution of study subjects

Gender	No.	%
Male	33	33.0
Female	67	67.0

As depicted in Table 2 out of 100 patients enrolled 33 patients (33%) were male and 67 (67%) were female.

Table 3

This shows mean CCT compared between noncontact and ultrasonic pachymetry in right eye of 100 patients with P value obtained is <0.001 which is significant and mean CCT compared between noncontact and ultrasonic pachymetry in left eye of 100 patients with P value <0.001 which is also significant.

Table 3: Central corneal thickness by noncontact and ultrasonic pachymetry

	Noncontact pachymetry		Ultrasonic pachymetry		P value
	Mean	SD	Mean	SD	
Right CCT (µm)	492.54	28.08	528.37	28.80	<0.001
Left CCT (µm)	494.32	27.71	529.74	29.10	<0.001

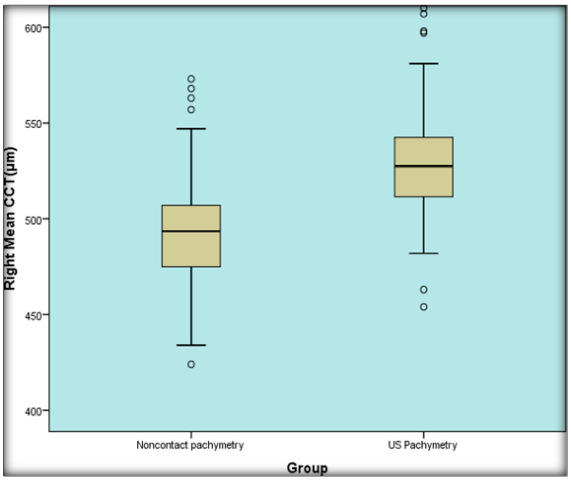

Figure 1a: Depicts mean value and maximum, minimum CCT value obtained from noncontact pachymetry and ultrasonic pachymetry in right eye.

Figure 1 a: Boxplot showing central corneal thickness by noncontact and ultrasonic(us) pachymetry in right eye

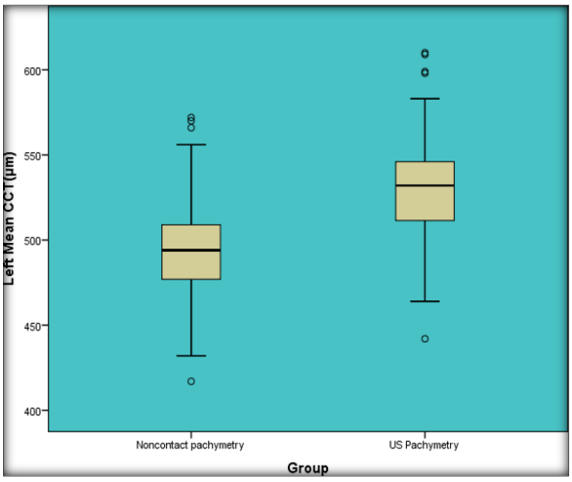

Figure 1b Depicts mean value and maximum, minimum CCT value obtained from noncontact pachymetry and ultrasonic pachymetry in left eye

Figure 1b: Boxplot showing central corneal thickness by noncontact and ultrasonic(us) pachymetry in left eye

This depicts mean difference in CCT between 2 instruments. The difference found showed significant P value < 0.001.

Table 4: Difference in CCT in both eye between noncontact and ultrasonic pachymetry

	Mean	SD
Difference in right eye CCT (µm)	35.83	5.88
Difference in left eye CCT (µm)	35.42	5.80

Figure 2 Bland-Altman analysis confirmed these results, noncontact pachymetry showed the lowest values when compared with ultrasonic pachymetry with the higher differences. The limits of agreement 95% is calculated as (LoA = mean of the difference ± 1.96 × SD of the differences).

Noncontact pachymetry underestimated mean CCT by 35.62 µm when compared with ultrasonic pachymetry, with 95% LoA ranging between 24.19 and 47.04 µm. The plot indicates that the difference between noncontact pachymetry and the ultrasonic pachymetry decreased significantly showing lower CCT for thinner corneas and moving to higher CCT when measuring thicker corneas.

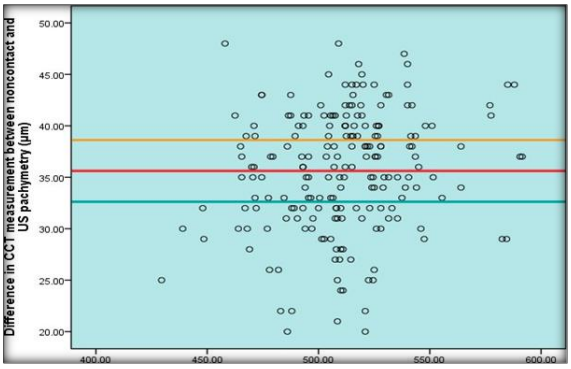

Figure 2: Bland–altman plot of noncontact pachymetry with ultrasonic pachymetry (us), showing a mean difference of 35.62 µm, LOA 24.19 TO 47.04 µm

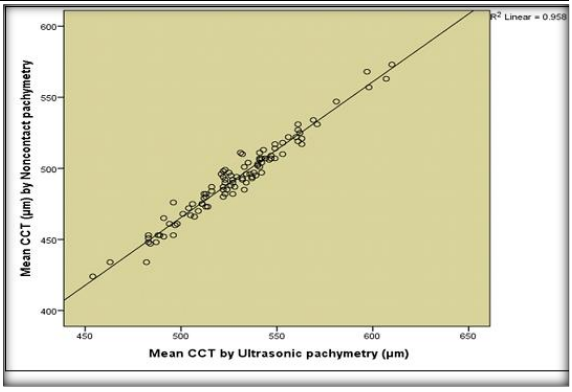

Figure 3: Scatterplot showing correlation between noncontact and ultrasonic pachymetry

Figure 3 shows that value of CCT obtained by noncontact and ultrasonic pachymetry is well correlated. Correlation was found with Spearman Correlation coefficient. r2 = 0.958, r = 0.978, P< 0.001. This shows positive correlation between mean CCT obtained from noncontact and ultrasonic pachymetry that is if CCT value is low in noncontact then ultrasonic pachymetry was also showing lower CCT value.

This shows mean CCT compared between noncontact and ultrasonic pachymetry in male patients with P value obtained < 0.01 and mean CCT compared between noncontact and ultrasonic pachymetry in female patients with P value obtained < 0.01.

Table 5: Central corneal thickness by noncontact and ultrasonic pachymetry in male and female

Sex		Noncontact pachymetry		Ultrasonic pachymetry		P value
		Mean	SD	Mean	SD	
Male	Right CCT (µm)	497.00	30.97	533.61	31.74	<0.01
	Left CCT (µm)	498.64	30.29	534.42	31.88	<0.01
Female	Right CCT (µm)	490.34	26.52	525.79	27.11	<0.01
	Left CCT (µm)	492.19	26.32	527.43	27.59	<0.01

This table shows mean CCT compared between male and female from noncontact pachymetry with P value 0.12 and mean CCT compared between male and female from ultrasonic pachymetry with P value 0.10 and showed insignificant results as P value is >0.05.

Table 6: Central corneal thickness compared between male and female by noncontact and ultrasonic pachymetry

	Male		Female		P value
	Mean	SD	Mean	SD	
Noncontact pachymetry	497.82	30.41	491.27	26.34	0.12
Ultrasonic pachymetry	534.02	31.57	526.61	27.26	0.10

Table 7: Complications after ultrasonic pachymetry in study subjects

Complications	No.	%
Discomfort	5	5.0
Pain	0	0.0
Blurring	7	7.0
Redness	0	0.0
Irritation	0	0.0
Corneal abrasion	0	0.0
Corneal stain	0	0.0

This shows that five patients (5%) had complaint of discomfort and seven patients (7%) had blurring of vision after ultrasonic pachymetry examination.

DISCUSSIONS

The measurement of central corneal thickness (CCT) has a crucial role in both the diagnostic and therapeutic assessment of ocular pathologies; therefore, it has become increasingly important in ophthalmic practice. It is measured by various ultrasonic and optical techniques, contact and noncontact techniques.

Noncontact pachymetry is patient-friendly and time-saving, but it has not been well documented whether the CCT obtained from it is comparable to those derived from conventional ultrasonic pachymetry as the gold standard for measuring CCT.

In our study we found that overall mean CCT value obtained by noncontact pachymetry was 492.54 ± 28.08µm in right eye while mean CCT obtained by ultrasonic pachymetry showed value of 528.37 ± 28.80µm, in right eye. Mean CCT compared between two instruments showed statistically significant P value of < 0.001. Similarly mean CCT value obtained by noncontact pachymetry was 494.32 ± 27.71µm in left eye while mean CCT in left eye obtained by ultrasonic pachymetry showed value of 529.74 ± 29.10µm, which was statistically significant as P value obtained was < 0.001, Hence the comparison of mean CCT between noncontact and ultrasonic pachymetry in our study was highly significant.

Mean CCT value obtained by noncontact pachymetry was 35.83 ± 5.88µm thinner in right eye & 35.42 ± 5.80µm thinner in left eye when compared to ultrasonic pachymetry and also showed significant P value < 0.001. The values obtained from noncontact & ultrasonic pachymetry were positively and strongly correlating with each other (r2 = 0.958,r = 0.978,P < 0.001) depicted in Figure 6 .Bland–Altman plot of noncontact pachymetry with ultrasonic pachymetry , showed a mean difference of 35.62 µm, with limits of agreement being (LOA) 24.19 to 47.04 µm,

Results obtained in our study were consistent with many other studies. Wells et al,[5] in their study found 29.7µm difference in CCT between ultrasonic & topcon trk-1p (noncontact pachymeter). The standard deviation was 40.7 µm with ultrasound and 42.3 µm with the topcon trk-1p measurements hence noted that these devices are not interchangeable in clinical practice. They related the reason for low CCT reading through trk-1p as the absence of corneal swelling due to instillation of local anesthetic and variations in the centration of the ultrasonic probe.

Perez et al,[6] found difference in CCT between ultrasound & tonopachymeter(ct-1p) by 33.1µm & concluded tonopachymeter measures thinner CCT than ultrasonic pachymeter.

Sagdik et al,[1] in their study found that difference found in CCT values between ultrasonic pachymetry & ct-1p tonopachymetry was of 28.43µm but there was high correlation in CCT readings between ultrasonic pachymetry and ct-1p tonopachymetry (r = 0.851, P< 0.001) .

Garcia rosua et al,[7] found differences between instruments was, 20.66±14.69µm (ultrasonic pachymeter & tonopachy(nt-530p)), hence found tonopachy underestimates CCT reading.

However the difference in CCT reading obtained in our study between ultrasonic pachymetry & noncontact pachymetry(trk-2p) showed slightly higher difference approximately 35.83 ±5.88µm in right eye & 35.42 ± 5.80µm in left eye as compared to above studies.

Hence the mean CCT value obtained through noncontact pachymetry showed thinner values as compared to ultrasonic pachymetry, which shows CCT values obtained by noncontact pachymetry is not as reliable as ultrasonic pachymetry values, as ultrasonic pachymetry is considered standard for taking CCT but the values from two instruments in our study showed good correlation with each other (r2 =0.958, r = 0.978, P < 0.001).

There are many possible reasons to explain these differences. Most of the studies1,5,6,8 give the reason for high value of CCT obtained through ultrasonic pachymetry as ultrasound probe decentration, oblique incidence of the probe to the cornea etc, but misalingment of the probe does not produce a significant error as the probe is quite sensitive to alignment errors. If the probe misaligns by 10º or more, the reading is not done because the echo is not captured by the receptor. It has been seen that the need for topical anesthesia, may influence CCT measurements. Nam SM et al,[9] in his study found that CCT after proparacaine increased by 8.6 µm (~4.5–12.6 µm, 95% CI) and then returned to baseline within 80 seconds hence topical anesthetics can influence CCT value by upto 12µm. Reliability of value may be influenced by variability of ultrasound speed in tissues of different hydration also.

Hence in our study also one of the reason for high value of CCT by ultrasonic pachymetry could be the use of topical anesthetic before CCT measurement.

The new noncontact pachymetry systems have recently become available. The comparison of a new measurement technique with an established one is often required to see whether the new one agrees sufficiently well with the old one, leading to replacement of the old or whether the two methods could be interchangeably used.

The main advantage of the noncontact measuring systems is that they avoid contact with the cornea, topical anesthetic is not required for measurement hence eliminating the risk of edema, epithelial damage, transmission of infection etc. Noncontact tonopachymeter (trk-2p) measures value by obtaining central fixation points which can be seen on the screen attached with it, while ultrasonic

pachymetry measurement is obtained by the clinician's judgement of placing probe on central cornea for making measurement. This also might bring bias in the study and explain the differences between noncontact pachymetry and ultrasonic pachymetry if the most central part of cornea is not measured in latter. In this study all precautions were taken to keep probe on central cornea, we used ultrasonic pachymetry as the gold standard method to measure central corneal thickness, because it is the most commonly used and accepted method, is a low cost technique, which can be easily used, and has good repeatability and reproducibility.

In our study we excluded patients with contact lens use as studies,[10] have proven that cornea experiences chronic edema due to extended lens wear which causes stromal thinning and hence alters CCT value. So only normal cornea without any pathologies, without history of contact lens use were chosen in our study.

In our study there were 33 (33%) male and 67 (67%) females in which we found that, Mean CCT in right eye of male, by noncontact pachymetry was 497 ± 30.97µm and by ultrasonic pachymetry was 533.61 ± 31.74µm and results were significant, $P < 0.01$. Similarly mean CCT in left eye of male, by noncontact pachymetry was 498.64 ± 30.29µm and by ultrasonic pachymetry was 534.42 ± 31.88µm and results were significant, $P < 0.01$.

Mean CCT in right eye of female, by noncontact pachymetry was 490.34 ± 26.52µm and by ultrasonic pachymetry was 525.79 ± 27.11µm and results were significant $P < 0.01$. Similarly mean CCT in left eye of female, by noncontact pachymetry was 492.19 ± 26.32µm and by ultrasonic pachymetry was 527.43 ± 27.59µm and results were significant $P < 0.01$ This signifies that mean CCT compared between both the instruments in male and in female is significant.

We also compared mean CCT values between male and female with both instrument to find any difference in CCT in the two sexes. We found males had thicker cornea than females. Mean CCT value in male by noncontact pachymetry was 497.82 ± 30.41µm and in females was 491.27 ± 26.34 µm depicted in Table 6 but P value was insignificant =0.12. Similarly mean CCT in male by ultrasonic pachymetry was 534.02 ± 31.57µm, and in females was 526.61 ± 27.26µm which also showed insignificant result P =0.10. Hence we conclude that CCT has no statistically significant differences in the two sexes.

Various studies showed that CCT is unrelated to gender. Ortiz et al,[11] analyzed the relationship between the CCT and the degree of myopia in 175 myopic eyes. They did not find statistically significant differences in CCT between the myopic groups in their study. Chen et al,[12] stated that CCT is not associated with refractive error, corneal curvature, anterior chamber depth and axial length. CCT is an independent factor unrelated to other ocular parameters

In our study five patients (5%) had complaint of discomfort and seven patients (7%) had blurring of vision after ultrasonic pachymetry examination,

This was evaluated in a questionnaire given to patients after examination. Reason for discomfort may be due to fear of instrument touching the cornea, blurring arose in seven patients after topical anesthetic. This may be due to effect on epithelial layer. There was no effect on the Snellen's visual acuity in all seven patients. While no complaint was noticed in patients after taking measurements through noncontact pachymetry.

The sample size of this study was small as compared to other population based comparative studies, hence future studies should be done on larger population group.

In conclusion, our data suggest that the clinician should be aware of significant differences of CCT values when measuring with different devices and noncontact pachymeter(trk-2p) gives lower CCT values than ultrasonic pachymeter as we consider ultrasonic pachymeter as gold standard for measurement of CCT.

CONCLUSION

This is concluded that difference in mean CCT obtained by two instruments ultrasonic and noncontact pachymetry was significant. Noncontact pachymetry showed significantly thinner CCT value than ultrasonic pachymetry. Hence CCT value obtained by noncontact pachymetry is not as reliable as CCT obtained by gold standard ultrasonic pachymetry.

The mean CCT values obtained by two instruments were strongly correlating with each other. Difference of mean CCT obtained in both male and female patients by noncontact and ultrasonic pachymetry is highly significant. No evidence of epithelial defect was seen after ultrasonic pachymetry examination so as such no complication was seen after pachymetry.

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