ORIGINAL RESEARCH PAPER VOLUME-6 | ISSUE-8 | AUGUST - 2017 | ISSN No 2277 - 8179 | IF : 4.176 | IC Value : 78.46

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

COMPARATIVE ANALYSIS OF CENTRAL CORNEAL THICKNESS MEASUREMENTS USING ULTRASOUND PACHYMETRY AND GALILEI DUAL SCHEIMPFLUG ANALYZER.

Ophthalmology

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ABSTRACT

Purpose: To assess comparability and interchangeability of central corneal thickness measurement by Ultrasound(US) Pachymetry and Galilei dual Scheimpflug Analyzer and to assess interobserver variation of Galilei dual Scheimpflug Analyser.

Materials and methods: In 130 healthy eyes of 65 subjects central corneal thickness (CCT) measurements were take with Galilei Dual Scheimpflug Analyser followed by ultrasound pachymetry. All the readings were taken by single operator. For calculating interobserver reproducibility, measurements were taken on Galilei Dual Scheimpflug Analyser by two observers at 5 mintues interval in another 50 healthy eyes.

Results: The mean corneal pachymetry (central corneal thickness) measured with US pachy was 530.99 ±26.32 micron (skewness 0.563kurtosis 0.530) and that measured by Galilei was 530.35±26.42 (skewness 0.538, kurtosis 0.84). There was no statistically significant difference between the CCT readings taken by Galilei and US pachy ($P < 0.001$). Interobserver reproducibility for the Galilei was 0.551%.

Conclusion: Pachymetry readings taken with Ultrasound pachymetry and Galilei have good concordance and high reproducibility, and can be delegated to non medical but trained person.

KEYWORDS:

corneal pachymetry, ultrasound pachymetry, galilei dual scheimpflug analyser.

Central corneal thickness holds an important place in refractive surgery practice. Precise measurement of CCT is critical as it dictates patient selection, amount of ablation and residual refractive error and risk of postoperative complications.[1-6]

Applanation Ultrasound pachymetry is the most commonly adopted method for corneal thickness measurement and is considered to be gold standard[8].It has high degree of interobserver and intraobserver reproducibility. Limitations of US pachy are poor fixation, chances of infection, epithelial damage due to direct contact, necessity for topical anesthesia, the risk of incorrect probe placement, and variations in sound wave speed due to different degrees of corneal hydration. Examiner's experience can affect the reliability of measurements as it requires perpendicular placement of the probe onto the corneal surface.[7-11]

The Galilei dual Scheimpflug analyzer (Ziemer, Switzerland), is a non contact instrument. It uses two rotating Scheimpflug cameras 180 degrees apart, in an effort to compensate for the errors associated with scans at an oblique angle. It has also a Placido disk to image the anterior segment of the eye. It provides point to point corneal pachymetry, anterior and posterior corneal cuvature, anterior chamber depth, lens densitometry, keratometry.

In our study we have compared central corneal thickness measured by US pachymetry and Galillei.

Materials and methods

Central Corneal thickness (CCT) measurements were compared between US pachymetry and Galilei dual Scheimpflug analyzer in 130 healthy eyes of 65 subjects. There were 26 females and 39 males. No subject had ocular abnormality or a history of refractive surgery, contact lens wear or ocular medication use. The study was approved by Instituitional Review Board and all participants were informed about the nature of study and written informed consent was taken from participants prior to study.

All measurements were taken in the undilated eyes and at the same time of day, between 11:00 am and 2:00 pm, at least three hours after awakening.

CCT measurements were first taken on the Galilei analyzer as it is a non contact procedure. Three readings were taken for each eye at an interval of 1 minute.

Galilei examinations were done as per the manufacturers' guidelines. The patient was seated with chin on the chin rest and forehead against the strap. Refractive error was entered before taking measurement. The patient looks at the target (red spot) and then asked to blink. The device was brought in focus by aligning the measurement head. Alignment was considered correct when the single red line touched the corneal epithelium. The patient was asked to blink again, open the eye and the reading was taken.

Following this, the cornea was anesthetized with topical 0.5% proparacaine and five readings were taken with US pachymetry. The 50 MHz probe was sterilised and applied as perpendicular on the central cornea. During scanning, subjects were asked to fix on the external fixation light with the other eye. The highest and lowest readings were excluded and the average of three readings was taken.

For calculating interobserver reproducibility of Galilei, two readings were taken by two different observers at an interval of 5 minutes in 50 healthy eyes of 25 subjects at the interval of 5 minutes.

Statistical analysis:

The values were entered in mean ± standard deviation (SD). Data was tested for normality using skewness (acceptable range of normality is between –1 and +1) and kurtosis (acceptable range of normality is between –1 and +1). In order to determine the clinical comparability, results were analyzed using the Bland and Altman analysis.[12] These plots are used to assess agreement between the various study methods and the 95% limits of agreement (LoA) for each comparison (mean difference ±1.96×SD), which describe the range where 95% of all differences can be expected to be, were calculated. A *P* value less than 0.05 was considered statistically significant. The SPSS professional statistics program was used for this purpose (SPSS for Window Version 11.5, Chicago, Illinois). CCT measurements were compared using paired t test.

The coefficient of interobserver reproducibility was defined as the SD of difference between the pairs of the measurements obtained by two observers, divided by the average of the means of each pair of observation.

Results:

The mean corneal pachymetry (Central Corneal Thickness) measured with US pachy was 530.99 ±26.32 micron (skewness 0.563 kurtosis 0.530) and that measured by Galilei was 530.35±26.42 (skewness 0.538, kurtosis 0.84). There was no statistically significant difference

between the CCT readings taken by Galilei and US ($P < 0.001$).

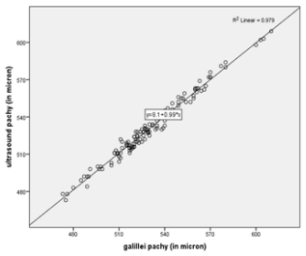


Figure1. Scatter plot to compare the CCT measurement by the two methods. X axis: measurement of CCT with Galilei in micrometers. Y axis: measurement of CCT with US pachymetry in micrometers

Fig.2 is a Bland–Altman plot and shows good agreement between Galilei and US. The 95% limits of agreement were –0.022 to +1.229. The plot indicates that there is no systematic bias between the two methods (P = 0.58 by linear regression method between difference and average by two methods.)

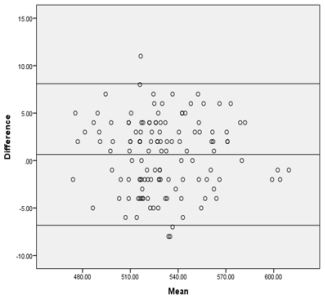


Fig. 2-Bland–Altman plot and shows good agreement between Galilei and US.

For measurement of interoperator reproducibility for Galilei, the mean CCT value taken in 50 eyes using the Galilei for observer 1 was 552.24 ± 28.791 µm, while it was 551.80 ± 29.40 µm for observer 2. There was no statistically significant difference between them. (P = 0.557). The 95%confidence interval of difference is -0.5516 to -0.3457. The coefficient of interoperator reproducibility for the Galilei was 0.551%. The scatter plot depicted in Fig.3 indicates good interobserver reproducibility. Bland - Altman plot shows good agreement between two observers. (Fig. 4)

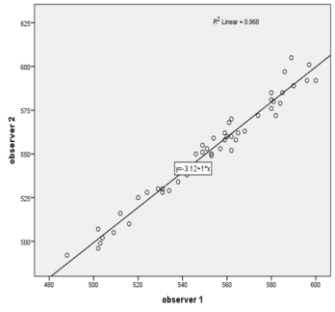


Figure 3. Scatter plot for comparing CCT between two observers. X and Y axes show CCT values measured by observer 1 and observer 2, respectively, in micrometers (either eye, n = 50)

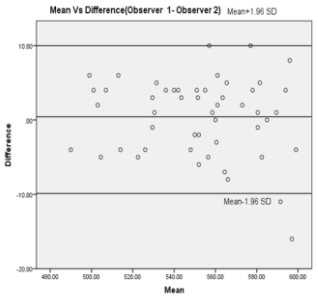


Fig. 4 Bland Altman plot showing good agreement between two observers.

Discussion:

Precise measurements of corneal thickness are important to evaluate the outcome of laser refractive surgical procedures, especially when considering enhancement surgery. Underestimation of corneal pachymetry may lead to exclusion of some of these patients and, in general, to an overly conservative treatment plan.13 Conversely, overestimation may increase the risk of corneal ectasia in ineligible patients.

Galilei is a non contact technique with simultaneously recording two rotating scheimpflug cameras, 180°apart. This helps to compensate for errors associated with scans at an oblique angle and increases the accuracy for measuring the central cornea and the peripheral cornea. Both anterior and posterior curvatures are assessed. Other major advantage of Galilei is that it measures the thinnest corneal thickness along with its location. In US pachy we are not aware of thinnest site of corneal thickness.

Several other technologies are available for CCT measurements. These include Pentacam, slit scan imaging, contact and noncontact specular microscopy, dual-beam partial coherence interferometry, Optical Coherence Tomography, Ultrasound Biomicroscopy.

In a study done by Jeevan Ladi et al[14] comparing central corneal thickness measurements with the Galilei dual Scheimpflug analyzer and ultrasound pachymetry, the mean CCT obtained by US pachymetry for 92 eyes was 541.83 ± 30.56 µm (skewness –0.417 and kurtosis –0.312). The mean CCT by Galilei for 92 eyes was 541.27 ±30.07 µm (skewness –0.3 and kurtosis –0.151). Mean difference between the two methods was 0.55 µm. There was no statistically significant difference between the CCT readings taken by Galilei and US ($P < 0.001$). Good agreement between Galilei and US was noted.

Karimian[15] et al concluded that Galilei measurements of CCT are well correlated with ultrasound pachymetry in normal eyes. After considering an acoustic coefficient equal to 0.98 for Galilei, its measurements will become equal to ultrasound values. In their study Mean CCT was 544.4 ± 33.4 µm, 546.7 ± 37.9 µm, and 555.8 ± 29.6 µm as measured by US pachymetry, Orbscan II, and Galilei systems, respectively. The mean difference of readings measured by US pachymetry with those measured by Orbscan II (acoustic coefficient 0.96) and Galilei were 2.3 µm and 10.2 µm, respectively. In spite of this discrepancy, the Galilei system had better agreement with US pachymetry than Orbscan II and US pachymetry (correlation coefficient 0.947 vs 0.817).

Park has conducted the study comparing pachymetry assessment using slit scanning imaging (Orbscan), rotating Scheimpflug imaging (Pentacam), dual Scheimpflug system (Galilei), and ultrasound pachymetry in normal and post-femtosecond (FS) laser in situ keratomileusis (LASIK) eyes[16]. He concluded that central corneal thicknesses obtained by all 4 measurement modalities might be acceptable before refractive surgery. However, in post-FS-LASIK eyes, measurements using Pentacam or Galilei were comparable with ultrasound pachymetry.

In a study by menassa et al[17] mean CCT readings by galillei (551.7 ± 36.6) and US (558.5 ± 38.4), with a mean difference of 6.8 micron, which is statically significant. However, the absolute difference (-12 to 26µm) was small and comparable to the reported range of +11 µm reported for the diurnal pachymetric variation of CCT.

The co efficient of interobserver repeatability is 0.551% in our study. In study conducted by jeevanladi it has been 0.377%[14]. It has been reported to be 1.10% for the pentacam, 0.59% for the OLCR and 0.18% for the OCT.

In previously performed studies, differences between readings of various methods have been noted. This disparity may be due to their distinct methodologies and principles.

Suzuki *et al* have reported CCT to be 548.1 ± 33 µm with US and 546.9 ± 35.4 µm with Orbscan (after application of correction factor).The measurements of both the instruments showed significant linear correlations with one another. They have suggested that orbscan

system measures the thickness between air – tear film interface and the posterior corneal surface. While in ultrasonic pachymetry, the posterior corneal surface is assumed to be located between Descemet's Membrane and the anterior chamber.[18] Also, it has been stated that US probe can displace upto 7- 40 µ of tear film and press the epithelium.19 Therefore scanning slit measurement are higher than ultrasound readings and may require application of acoustic equivalent correction factor. Orbscan manufacturers recommended incorporation of an acoustic factor of 0.92. This was calculated to compensate for the effect of tear film.

Various studies have been performed evaluating comparability of US pachy and pentacam scheimpflug imaging. Central corneal thickness values obtained with the Pentacam were similar to those obtained with US pachymeter (barkana)[13]. The Pentacam measured CCT values closer to ultrasound pachymetry and with less variability compared with Orbscan. The (interobserver) reproducibility with the Pentacam was highest of all 3 modalities[20].

In study conducted by Rainer et al[21] compared ultrasound pachymetry and partial coherence interferometry in the measurement of central corneal thickness. Their study concluded that Partial coherence interferometry was more precise method with better intraobserver variability. They suggested that repeated contact by a US pachymetry probe reduced corneal thickness by 1.3 microns.

However, as suggested by Ho *et al*[22] US pachy may also overestimate CCT due to the epithelial edema caused by analgesic eyedrops used before pachymetry. Chakrabatri et al[23] has reported the difference in mean CCT between ultrasound (538.0µm±36.7 SD) and orbscan (566.6µm±40.7SD). The orbscan measurement was approximately 28 µm higher than that of ultrasound pachymetry. These two modalities are not clinically interchangeably due to high degree of variability.

The major advantage of recently developed machines is to obtain additional corneal data such as thickness profile, elevation maps, anterior chamber depth etc.

For a new instrument to gain widespread use it must have high intraoperator and interoperator reproducibility, and readings must be having a clear correlation to currently established methods.

In conclusion, the Galilei analyzer can measure CCT with an excellent repeatability and reproducibility. This noncontact method of examination can thus be delegated to nonmedical personnel like technicians or optometrists in settings of busy OPDs. The pachymetry readings with Galilei showed good correlation with those of US pachymetry and there was no statistically significant difference between them.

Notes

The authors have no financial interest in any of the companies, products, or methods described in this article.

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