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A Cross sectional Study on Central Corneal Thickness in patients with Pseudo exfoliation syndrome and Normal Subjects.

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Abstract:
Background*: Pseudo exfoliation syndrome is one of the most common identifiable causes of open-angle glaucoma worldwide. Raised Intra ocular pressure (IOP) is the only known causal risk factor for glaucoma development, which can be therapeutically manipulated. The IOP measurement's accuracy can be affected by Central corneal thickness (CCT) as variations in corneal thickness can change the cornea's resistance to indentation. Therefore, a special emphasis must be given in the measurement of CCT in patients with pseudo exfoliation syndrome for early diagnosis of developing glaucoma.*
Materials and Methods*: In this hospital-based cross-sectional study, out of the 100 patients aged 50 years and above, 50 patients (100 eyes) diagnosed with Pseudo exfoliation syndrome and 50 normal subjects (100 eyes) were subjected to Pachymetry using DGH-550 Ultrasonic Pachymeter and Applanation Tonometry and values were analyzed.*
Results*: The mean central corneal thickness (in µm) was more in normal subjects (534.53±23.4) than Pseudo exfoliation syndrome group (508.40±13.99). There was high statistically significant difference between the means of intraocular pressure before and after central corneal thickness correction between the groups.*
Conclusion: *Significant underestimation of IOP was noted in PXF the group due to thinner corneas. Therefore, the central corneal thickness may influence the accuracy of applanation tonometry in the diagnosis, screening, and management of patients with glaucoma.*
Key words: *Central corneal thickness, Intraocular pressure, Pseudo exfoliation syndrome, Glaucoma, Normal subjects.*

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I. Introduction

Pseudo exfoliation syndrome (PXS) is a systemic microfibrillopathy, which targets ocular tissues through gradual deposition of proteinaceous material.[1] This fibrillar material produced by cells in the anterior segment of the eye in response to oxidative stress, when gets accumulated in the trabecular meshwork, it leads to elevated IOP, further leading to glaucoma.[2] The prevalence of glaucoma among subjects with PXS reported by recent population-based surveys from south India was 7.5% and 13%, respectively.[3,4]

Raised IOP is the only known causal risk factor for Glaucoma development; certainly, it is the only risk factor that can be therapeutically manipulated.[5] The IOP measurement's accuracy can be affected by Central corneal thickness (CCT) as variations in corneal thickness can change the cornea's resistance to indentation. Given the crucial role of CCT in the predilection of glaucoma development in pseudo exfoliation syndrome, this topic of interest substantiates its role in the study population.

II. Material And Methods

This hospital-based cross-sectional study was carried out on patients of Department of Ophthalmology, Sri Venkateshwara Medical College, and Sri Venkateshwara Ramnarayan Ruia Government General Hospital, Tirupati, A.P., India from February 2019 to March 2020. A total 100 adult subjects (both male and female) of aged ≥ 50, years were taken in this study.

Study Design: Hospital-based cross-sectional study

Study Location: This was a tertiary care teaching hospital-based study done in Department of Ophthalmology, Sri Venkateshwara Medical College, and Sri Venkateshwara Ramnarayan Ruia Government General Hospital, Tirupati, A.P., India.

Study Duration: February 2019 to March 2020.

Sample size: 100 patients.
Sample size calculation: The sample size was estimated based on a single proportion design. The target population from which we randomly selected our sample was considered 10,000, those who visited our outpatient department during the study period. We assumed that the confidence interval of 10% and confidence level of 95%.
Subjects & selection method: A total of 100 subjects, aged ≥ 50 years of which 50 subjects diagnosed with PXS and 50 normal subjects were selected based on the following criteria.

Inclusion criteria:
1. Subjects diagnosed with Pseudo exfoliation syndrome with white flakes or fibrillar granular material on the pupillary margin and anterior lens capsule.
2. Normal subjects include subjects with
    - Intraocular pressures < 21mm Hg in both the eyes measured by Goldman's applanation Tonometer.
    - Normal optic discs
    - Normal visual fields
    - Open angles on gonioscopy
    - No family history of glaucoma, no suspicion of any form of glaucoma, or any other eye disease.
3. Either sex
4. Aged ≥50 years,

Exclusion criteria:
1. Subjects with ocular diseases other than Pseudo exfoliation Syndrome.
2. Subjects with corneal pathologies.
3. Previous intraocular or corneal surgery
4. Diabetes mellitus, use of contact lenses, or any other conditions that may affect the corneal thickness
5. Ocular trauma

Procedure methodology
After written informed consent was obtained, all the subjects underwent a complete ophthalmic evaluation, which includes
1. Medical and ocular history
2. Best-corrected visual acuity
3. Slit lamp Bio microscopy to exclude corneal pathology using CARL ZEISS MEDITECH AG 07740 Jena Germany.
4. Applanation Tonometry (ZEISS AT 030 – CARL ZEISS, Jena Germany).
5. Indentation Gonioscopy with ZEISS 4 mirror handheld gonio lens.
6. Dilated fundus examination and stereoscopic examination of the optic discs and the nerve fiber layer using a +90D lens with the slit lamp.
7. Pachymetry using DGH-550 Ultrasonic Pachymeter (DGH Technology Inc. Exton, PA, USA)
8. Visual field examination with Humphrey Visual Field Analyzer (HUMPHREY FIELD ANALYSER MODEL-720i, CARL ZEISS MEDITEC Inc, Dublin, CA, USA).

Central corneal thickness was measured in both the eyes of all the patients using DGH-550 Ultrasonic Pachymeter (DGH Technology Inc. Exton, PA, USA). Topical proparacaine 0.5% was instilled in both eyes. The patients were seated, erect, and asked to look at a target fixed 3m away when the measurements were made. The tip of the handheld pachymeter probe was placed perpendicularly on the cornea and centered over the undilated pupil. and an average of the three consecutive readings for each eye was noted. IOP was measured using Goldmann applanation tonometer and the corrected IOP value was made using the pachymeter manufacturer's algorithm based on a cannulation study done by Ehlers et al.[6]

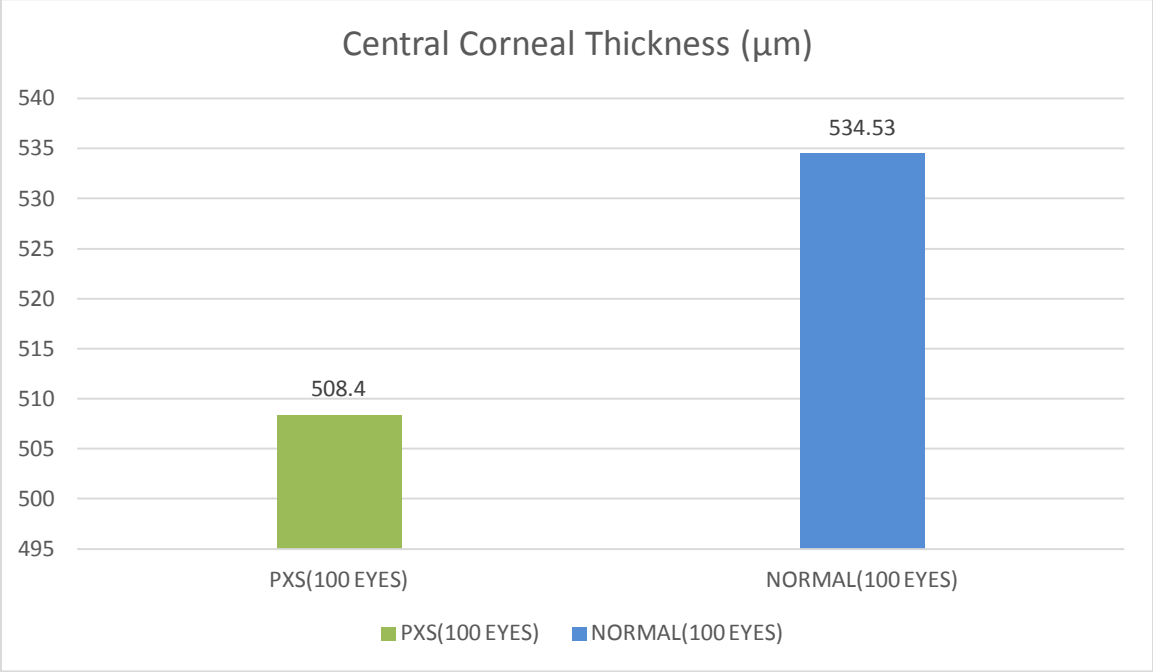
Statistical analysis
Data were entered into an excel sheet, and statistical analysis was done using SPSS version 22.0. Measurements of central corneal thickness, intraocular pressure was depicted in terms of mean and standard deviations. To compare the means between the groups T-test was used. P-value < 0.05 was considered as statistically significant.

III. Result

The following observations were made from measurements taken in the two study groups.

Table1: Distribution of Central Corneal Thickness among study groups

Group	No. of eyes	Mean (µm)	Std deviation (µm)
PXS	100	508.40	13.99
Normal subjects	100	534.53	22.82

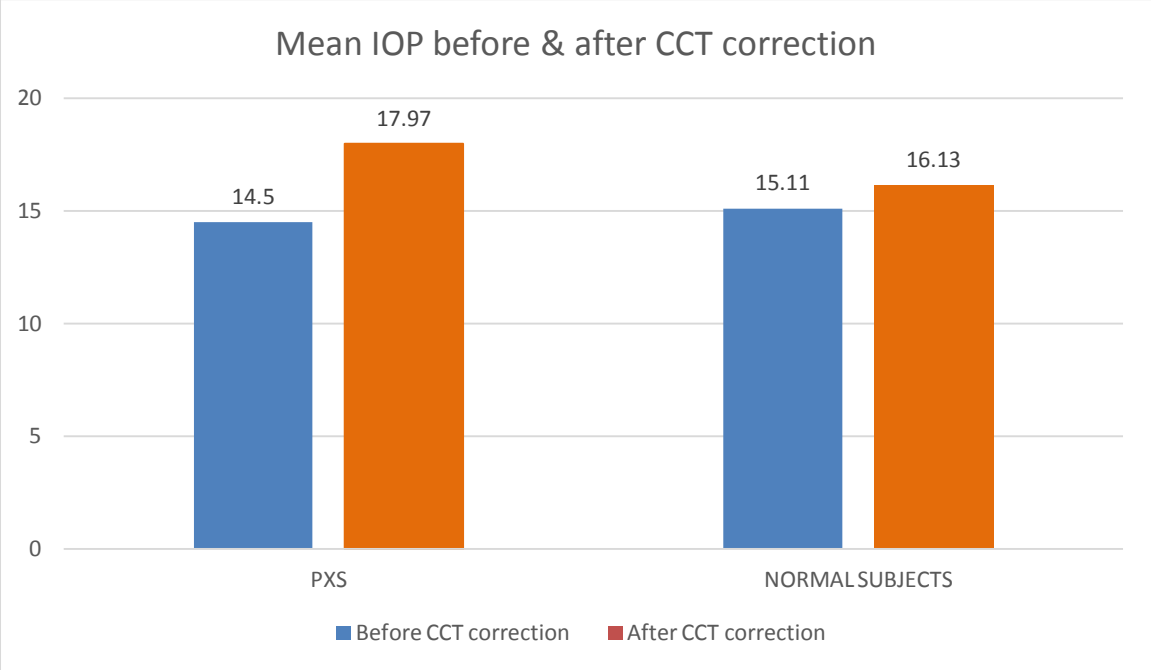


The mean central corneal thickness (in µm) was more in normal subjects (534.53±23.4) and in pseudo exfoliation syndrome group (508.40±13.99).

Table2: Mean intra ocular pressure before and after the CCT correction

Group	No.of eyes	Mean (±SD) IOP (mm of hg)		P value
		Before CCT correction	After CCT correction	
PXS	100	14.51±2.7	17.97±3.6	**<0.01***
Normal subjects	100	15.11±2.3	16.13±2.7	**<0.001***

***Statistically Significant**



There was high statistically significant difference between the means of intraocular pressure before and after central corneal thickness correction in both the groups.

Table3: Comparison of mean CCT in PXS group with Normal subjects

	Group	Number of eyes	Mean (µm)	SD (µm)	P Value
CCT	Normal subjects	100	534.53	22.82	**<0.001***
	PXS	100	508.40	13.99	

***Statistically Significant**

There was higher central corneal thickness (µm) in normal subjects (534.53±22.8) when compared to PXS group (508.40±13.99). The unpaired t test performed for mean central corneal thickness between normal and pseudo exfoliation syndrome subjects showed high statistical significance (P<0.001).

IV. Discussion

The measurement of central corneal thickness though perhaps not necessary in all suspected glaucoma patients may be of value in selected cases to improve clinical decision making, especially if the other clinical findings do not seem to correlate with the intraocular pressure.

Variability in CCT is a profound confounder of most tonometric techniques, especially the Goldmann Applanation tonometer. GAT tends to overestimate the IOP in thicker corneas, while in thinner corneas, it underestimates the IOP.[7] It helps the individuals with Pseudo Exfoliation Syndrome predict the risk of development of glaucoma, facilitate early diagnosis, and ensure the adequacy of treatment.

As the assessment of CCT has become an essential element in the clinical evaluation of a glaucoma patient, this study intends to analyze the CCT trends and to explore the relationship between CCT and IOP by GAT amongst these study groups. Lastly, this study aims to evaluate if CCT can be used as a useful tool for prognostication of disease progression in PXS and glaucoma diagnosis.

Pseudo exfoliation syndrome is the most common cause of secondary open angle glaucoma. Presence of PXF itself has a higher risk, which is independent of other risk factors including IOP. They are associated with a thinner CCT,[8] which leads to an underestimation of IOP and thereby delaying the diagnosis. Thinner CCT serves as another independent risk factor for development of glaucoma.[9] All these factors, place the individuals with PXS at a very high risk of advanced glaucomatous damage.

In the present study, the mean central corneal thickness of 508.40µm was noted in the PXS group and 534.53µm in normal subjects. CCT was thinner in the PXS group than the normal subjects. This difference proved to be statistically significant too. (P value <0.001). Other studies which showed the similar results are listed in the table below.

Table 10: Comparison of Mean CCT in PXS and Normal subjects with other studies

STUDY	CCT IN PXS (µm)	CCT IN NORMALS (µm)
PRESENT STUDY	508.40	534.53
Priya darshini et al[10]	501	517
Zare et al [8]	511.9±27.9	531.4±32.7
Kumar Nanda et al[11]	518	527
Inoue et al [12]	529±31	547±28

This shows that the presence of pseudo exfoliation is strongly associated with a significant thinning of the cornea. This is attributed to the apoptosis of the keratocytes of the anterior corneal stroma.[13]

In the PXS group, the average IOP before adjustment for CCT was 14.51±2.7mm of Hg. Following adjustment of CCT, the IOP value was 17.97±3.6mm of Hg. There was an increase of about 3.46 mm Hg in the IOP following adjustment of CCT. The increase in IOP was statistically significant. (P value<0.001). The underestimation in the IOP in the PXS group can be explained by the presence of pseudo exfoliation and the associated significant corneal thinning.

Both the normal subjects and the PXS groups had an almost similar IOP before CCT correction. There was a significant increase in the IOP following adjustment for CCT in both the groups. This shows that the IOP has been underestimated by GAT in both the normal subjects and the PXS group. But this increment in IOP was dissimilar in both the groups. (1.9 mm Hg in the normal subjects versus 3.1 mm Hg in the PXS group). The difference was also statistically significant. (P value<0.001).

This study has demonstrated that the CCT is thinner in PXS group and therefore emphasizes the measurement of CCT in all individuals for an accurate measurement of IOP. The PXS group exhibited a still more significant thinning of the central cornea and a significantly higher risk of underestimation of IOP compared with the normal subjects. The individuals with pseudo exfoliation are at greater risk of developing glaucoma than those without PXS. A thinner CCT itself may act as an additional risk factor for development of glaucoma and along with this, there is an underestimation of IOP resulting in a delay in diagnosis. All these factors lead to advanced disease at the time of presentation.

Measurement of CCT, therefore, is necessary in all cases of pseudo exfoliation for prediction of the risk of development and progression of glaucoma, for early diagnosis and to ensure adequacy of treatment.

V. Conclusion

The central corneal thickness may influence the accuracy of applanation tonometry in the diagnosis, screening, and management of patients with glaucoma. The measurement of CCT is therefore mandatory in the individuals with pseudo exfoliation syndrome to predict the risk of development of glaucoma, to facilitate early diagnosis, and ensure the adequacy of treatment.

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