Original Article

A comparison of the corneal biomechanics in pseudoexfoliation syndrome, pseudoexfoliation glaucoma, and healthy controls using Corvis® Scheimpflug Technology

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Purpose: To compare the corneal biomechanical parameters among pseudoexfoliation syndrome (PXF), pseudoexfoliation glaucoma (PXG), and healthy controls using Corvis Scheimpflug Technology (ST). **Methods:** A prospective, cross-sectional study of 141 treatment-naïve eyes that underwent Corvis ST was conducted. These included 42 eyes with PXF, 17 eyes of PXF with ocular hypertension (PXF + OHT) defined as intraocular pressure (IOP) >21 mmHg without disc/field changes, 37 eyes with PXG, and 45 healthy controls. Corneal biomechanical parameters, which included corneal velocities, length of corneal applanated surface, deformation amplitude (DA), peak distance, and radius of curvature, were compared among the groups using analysis of variance models. **Results:** The four groups were demographically similar. The mean IOP was lower in the controls (15.6 ± 3 mmHg) and PXF group (16.0 ± 3 mmHg) compared to the other two groups (>24 mmHg). Corneal pachymetry was similar across the four groups. Mean DA was significantly lower ($P < 0.0001$) in the PXG group (0.91 ± 0.18 mm) and the PXF + OHT group (0.94 ± 0.13 mm) when compared to the PXF (1.10 ± 0.11 mm) and control groups (1.12 ± 0.14 mm). Corneal velocities were also found to be statistically significantly lower in PXG and PXF + OHT compared to the PXF and control groups. However, after adjusting for age and IOP, there was no difference in any of the biomechanical parameters among the four groups. **Conclusion:** Corneal biomechanical parameters measured on Corvis ST are not different between healthy controls and eyes with PXF and PXG. Since PXG is a high-pressure glaucoma, corneal biomechanics may not play an important role in its diagnosis and pathogenesis.

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The biomechanical properties of the cornea play an important role in the diagnosis of glaucoma. *In vivo* measurements have been performed using the ocular response analyzer (ORA) and the Corvis ST.[1-5] These devices have been extensively used to study the corneal biomechanics in primary open-angle glaucoma (POAG) and normal-tension glaucoma (NTG).[4-9] Parameters such as the corneal hysteresis (CH) on ORA and (DA) on Corvis ST were found to be lower in eyes with POAG compared to healthy controls.[4-7] In NTG eyes, corneas were noted to have a faster inward applanation velocity when compared to healthy controls on the Corvis ST, implying weaker corneal biomechanics.[8] However, there is limited literature on the corneal biomechanics of eyes with other subtypes of glaucoma.

Pseudoexfoliation syndrome (PXF) is a disease of the extracellular matrix, characterized by abnormal fibrillar deposits in the anterior segment of the eye, including the lens capsule, the iris, cornea, and trabecular meshwork. The deposition of this material in the trabecular meshwork, along with the accumulation of pigment may obstruct the aqueous outflow and result in a secondary glaucoma (pseudoexfoliation glaucoma, PXG). Although it is well established that eyes with PXF have an increased risk of developing glaucoma, there is insufficient data on the factors that confer this increased risk. We hypothesized that among eyes with pseudoexfoliation deposits, those with weak corneal biomechanics may be at a higher risk for glaucoma.

Therefore, the purpose of this study was to compare the corneal biomechanical parameters between eyes with PXF, PXG, and healthy controls using Corvis ST.

Methods

This was a prospective, observational study conducted at a tertiary eye care center between August 2015 and January 2019. The methodology adhered to the tenets of the Declaration of Helsinki for research involving human subjects. Written informed consent was obtained from all participants, and the study was approved by the institute's ethics committee.

The participants were patients with pseudoexfoliation deposits in the anterior segment of the eye (with and without glaucoma) and controls.

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For the purpose of the study, pseudoexfoliation deposits were defined as:[10-12]

- The presence of whitish flakes on the anterior lens capsule in a typical distribution of a partial/complete peripheral band with or without a central disc, or
- White material deposited on the pupillary border of the iris, or
- Uveal stage of pseudoexfoliation (pigments deposited on the anterior lens capsule in a distribution corresponding to the peripheral band with increased pigment in the anterior chamber angle).

Glaucoma was defined as characteristic optic disc changes as determined by glaucoma experts (rim notching, rim thinning, retinal nerve fiber layer defects, disc hemorrhages) with corresponding changes on optical coherence tomography (OCT) or visual fields (VF).

Based on these definitions, the study participants were divided into the following cohorts:

1. Control subjects had normal anterior segment examination (apart from cataract), absence of pseudoexfoliation deposits, intraocular pressure (IOP) ≤ 21 mmHg and normal posterior segment examination with non-glaucomatous optic discs, as assessed by glaucoma experts
2. PXF cohort had eyes with pseudoexfoliation deposits in the anterior segment, IOP ≤21 mmHg and normal posterior segment examination with non-glaucomatous optic discs, as assessed by glaucoma experts
3. PXF with ocular hypertension (PXF + OHT) cohort had eyes with pseudoexfoliation deposits in the anterior segment with IOP >21 mmHg, normal posterior segment examination and no evidence of glaucoma
4. PXG cohort had eyes with pseudoexfoliation deposits and glaucoma.

All participants underwent a comprehensive ocular examination, which included a detailed medical history, slit-lamp biomicroscopy (before and after pupillary dilatation), Goldmann applanation tonometry (GAT), gonioscopy, and a dilated fundus examination. Exclusion criteria were age less than 40 years, eyes with a history of trauma or intraocular inflammation. All eyes with the history of any ocular surgery were excluded except uncomplicated clear corneal phacoemulsification done more than 6 months prior to recruitment. Eyes with any corneal pathology, angle-closure disease, or retinal pathology were also excluded. Patients with a history of collagen vascular disorders or neurological diseases were not recruited. This was a study on treatment-naïve eyes and patients already on IOP-lowering therapy (eye drops/laser/surgery) were excluded from the analysis.

All participants underwent an examination with the Corvis ST (Oculus, Wetzlar, Germany) which is a non-contact device that records the entire dynamic reaction of the cornea to a fixed air-impulse. This is done using a high-speed Scheimpflug camera, the details of which have been described earlier.[1] Apart from measuring the IOP and the central corneal thickness (CCT), the Corvis ST provides several corneal biomechanical parameters based on the deformation response as shown in Fig. 1. The air puff first causes the cornea to move inwards and flatten. At this first applanation phase (A1), the length of the applanated cornea (A1 length in mm) and the velocity of the corneal apex (A1 velocity in m/s) are measured.

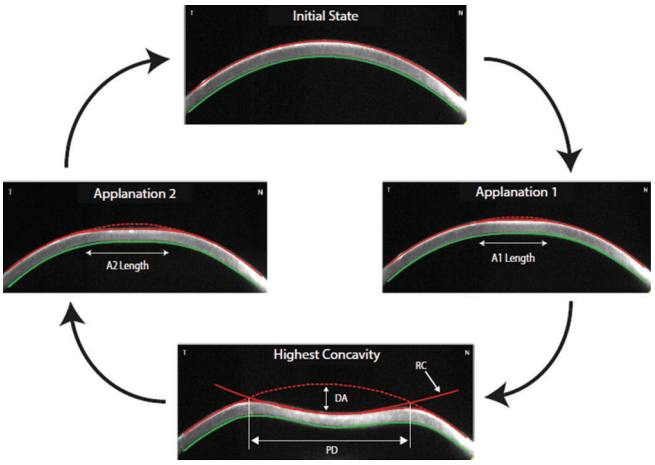

Figure 1: Scheimpflug images of the corneal deformation response on Corvis ST showing the biomechanical parameters derived at each stage. The fixed air puff causes the cornea to flatten (applanation point A1) and then move inwards to reach the point of highest concavity where the deformation amplitude (DA in mm), peak distance (PD in mm), and the radius of curvature (RC in mm) are measured. As the cornea begins to assume its normal, convex shape, it passes through the second applanation point (A2)

The cornea then continues to move inwards to reach a point of highest concavity. Three biomechanical parameters are measured here. The deformation amplitude (DA in mm) is the total displacement of the corneal apex from the start of deformation to the point of highest concavity. The peak distance (PD in mm) is the distance between the two bending points of the concave cornea. The radius of curvature (RC) is the curvature of the central concave cornea. As the cornea begins to assume its normal, convex shape, it passes through the second applanation point (A2) where again the length of the flattened cornea (A2L in mm) and velocity of the corneal apex (A2V m/s) are estimated.

All glaucoma patients and glaucoma suspects underwent a VF examination using Humphrey Field Analyzer II, model 720i (Zeiss Humphrey Systems, Dublin, CA), with the Swedish interactive threshold algorithm (SITA) standard 24-2 program. OCT imaging of the optic disc and peripapillary region was performed using Cirrus HD-OCT (Carl Zeiss Meditec Inc, Dublin, CA) if media clarity permitted good quality scans.

DA was the primary parameter considered for sample size calculation. Mean DAs in the control, PXF, PXF + OHT, and the PXG groups were considered to be 1.1, 1.0, 1.0, and 1.0, respectively. Sample sizes of the four groups (in an ANOVA [analysis of variance] design) were therefore calculated to detect a difference of 0.1 (effect size) in the DA between the control and the other three groups at a power of 80% with an alpha error of 5%. An unbalanced design was chosen with the group of PXF + OHT being half that of the other groups, as the number of eyes with PXF + OHT in a consecutive sample was expected to be less than that of the other groups. With these assumptions, the sample size determined for the control, PXF, PXF + OHT, and the PXG groups were 32, 32, 16, and 32, respectively.

Statistical analyses were performed using Stata version 14.2 (StataCorp, College Station, Tx) statistical software. Descriptive statistics included mean and standard deviation for continuous

variables and percentages for categorical variables. The analysis of variance (ANOVA statistic) was used to evaluate the difference in means among the four cohorts. The analysis of covariance (ANCOVA) was used to compare corneal biomechanical parameters among groups after adjusting for confounders. A P value of < 0.05 was considered statistically significant for the final analysis.

Results

141 eyes of 102 participants were included in the study. Table 1 shows that the 4 study groups were demographically similar. The clinical details are shown in Table 2. As expected, the IOP (measured on GAT and Corvis) was significantly lower in the PXF and control groups compared to the other two groups. The CCT was similar across the four groups. The VF parameters (mean deviation, pattern standard deviation, and VF index) were worse in the PXG group compared to the other three groups.

The corneal biomechanical parameters as measured on Corvis ST (Mean and SD) are shown in Table 3. These were compared among the four groups using the ANOVA statistic, and the DA, A1 velocity, and A2 velocity were found to be significantly different among the groups. The A1 velocity was higher in the control and PXF groups compared to the PXF + OHT and PXG groups suggesting that the former had more deformable corneas. The mean DA was less than

Table 1: Demographic data of study participants

	Control	PXF	PXF + OHT	PXG	*P*
No. of patients	32	29	14	27	
Mean age (SD)/years	66.0 (9)	67.8 (7)	68.2 (7)	69.0 (8)	0.52
No. of males (%)	21 (65)	19 (65)	7 (50)	16 (59)	0.74
No. of hypertensive patients (%)	12 (37.5)	13 (44.8)	5 (35.7)	12 (44.4)	0.89
No. of patients with diabetes	11 (34.4)	11 (37.9)	4 (28.6)	8 (29.6)	0.90

PXF: Pseudoexfoliation syndrome, PXF + OHT: Pseudoexfoliation with ocular hypertension, PXG: Pseudoexfoliation glaucoma, SD: Standard deviation

Table 2: Clinical data of eyes included in the study

	Control	PXF	PXF + OHT	PXG	*P*
No. of eyes	45	42	17	37	
Mean BCVA (SD)/LogMAR	0.19 (0.2)	0.31 (0.3)	0.37 (0.3)	0.41 (0.5)	0.05
Mean sphere (SD)/D	0.12 (2.1)	−0.04 (2.2)	−0.10 (1.6)	−0.32 (2.0)	0.84
Mean cylinder (SD)/D	−0.74 (0.7)	−0.70 (0.6)	−0.40 (0.5)	−0.75 (0.8)	0.31
Mean cup: disc ratio (SD)	0.46 (0.2)	0.43 (0.2)	0.44 (0.1)	0.78 (0.1)	<0.001
No. of pseudophakes (%)	6 (13%)	1 (2%)	0 (0%)	4 (10%)	0.14
Mean IOP GAT/mmHg	15.6 (3)	16.0 (3)	24.4 (3)	25.6 (7)	<0.001
Mean IOP Corvis/mmHg	16.7 (2)	17.2 (3)	22.4 (4)	24.2 (7)	<0.001
Mean IOP Corvis corneal compensated/mmHg	17.8 (3.2)	18.1 (4.1)	22.3 (4.4)	24.9 (7.4)	<0.001
Mean CCT (SD)/μ	532 (37)	531 (45)	546 (47)	532 (38)	0.53
Mean MD (SD)/dB	−3.3 (5.1)	−1.3 (1.6)	−3.2 (3.1)	−12.6 (10.0)	0.0003
Mean PSD (SD)/dB	2.8 (1.4)	2.6 (0.9)	3.4 (2.0)	6.4 (3.7)	0.0008
Mean VFI (SD)/%	93.7 (10)	97.3 (2)	93.4 (5)	65.7 (33)	0.0008

PXF: Pseudoexfoliation syndrome, PXF+OHT: Pseudoexfoliation with ocular hypertension, PXG: Pseudoexfoliation glaucoma, BCVA: Best-corrected visual acuity, SD: Standard deviation, IOP: Intraocular pressure, GAT: Goldmann applanation tonometry, CCT: Central corneal thickness, MD: Mean deviation, dB: Decibel, PSD: Pattern standard deviation, VFI: Visual field index

Table 3: Comparison of corneal biomechanical parameters derived from Corvis ST among the four groups using ANOVA (analysis of variance) statistics

	Control	PXF	PXF + OHT	PXG	*P*
A1 length/mm	1.87 (0.2)	1.82 (0.16)	1.90 (0.22)	1.92 (0.3)	0.33
A1 velocity/ms^{-1}	0.14 (0.02)	0.15 (0.02)	0.12 (0.02)	0.13 (0.03)	0.0001
DA/mm	1.12 (0.14)	1.10 (0.11)	0.94 (0.13)	0.91 (0.18)	<0.0001
Peak distance/mm	4.23 (1.2)	3.89 (1.2)	3.77 (1.0)	3.67 (1.1)	0.20
Radius of curvature/mm	7.13 (0.83)	6.98 (0.89)	7.37 (0.92)	7.50 (1.48)	0.16
A2 length/mm	1.81 (0.37)	1.83 (0.37)	1.81 (0.32)	1.91 (0.34)	0.61
A2 velocity/ms^{-1}	−0.37 (0.10)	−0.35 (0.17)	−0.28 (0.07)	−0.28 (0.10)	0.0015

All values represent means with standard deviations in parenthesis. PXF: Pseudoexfoliation syndrome, PXF + OHT: Pseudoexfoliation with ocular hypertension, PXG: Pseudoexfoliation glaucoma, A1: Applanation point 1, DA: Deformation amplitude, A2: Applanation point 2

1.0 in the PXG and PXF + OHT groups implying they had stiffer corneas and greater than 1.0 in the control and PXF groups. However, previous literature has shown that corneal biomechanics is affected by age, CCT, and IOP.[2,3,13] The data was hence reanalyzed after adjusting for IOP and age using the ANCOVA statistic. This revealed that there was no difference in any of the biomechanical parameters among the four groups as shown in Table 4.

Discussion

Corneal biomechanics in glaucoma has been studied extensively *in vivo* using the ORA and, more recently, the Corvis ST. Apart from using these devices to discern the effect of corneal biomechanics on IOP measurements, they have also been used to understand the role of biomechanics in glaucoma pathogenesis. Both devices measure the corneal response to a puff of air and generate data from the first and second applanation points; however, there are several differences between these devices that need to be recognized for a better interpretation of their measurements. The ORA measures the applanation of the cornea within the central 3 mm using an electro-optical infrared system while the Corvis ST uses a Scheimpflug camera to scan the entire cornea and measures the central applanation.[7] In the ORA system, an air-pulse is directed onto the cornea until an applanation event is reached and shuts off milliseconds after the first applanation, that is, the air pulse is not fixed and continues till the cornea just begins to indent.[4,14,15] In contrast, the Corvis ST has a fixed air puff and indentation of the cornea will not be possible for IOPs greater than 60 mmHg; hence, the machine will be unable to measure the IOP or biomechanical parameters in these situations.[13] However, this feature of a fixed load may be potentially useful in longitudinal studies to determine changes in corneal biomechanics over time. The parameters measured by the ORA and the Corvis ST are also different. The main biomechanical parameter of the ORA is the CH which is a measure of the area between the load-unload displacement curve and is calculated as the difference between the inward and outward applanation pressures (in mmHg).[14] The main biomechanical parameter of the Corvis ST is the DA, which is a measure of the strain response to a fixed load (the air puff) and is calculated as the displacement of the corneal apex at rest to the point of highest concavity (in mm).[13] Therefore, although both instruments provide measures of corneal biomechanics, it is imperative to understand that these are inherently different and not interchangeable.

The Corvis ST provides several biomechanical parameters unique to this system. A more deformable or weaker cornea is supposed to reach the first applanation point (A1) sooner and have a smaller A1L and a higher A1V; at the point of highest concavity, they have a higher DA, smaller PD and RC; and at the second applanation point they have a smaller A2L and lower A2V. Several studies have compared the corneal biomechanics of POAG and healthy controls using Corvis ST.[2,3,6,7,13] Although some have reported no difference between POAG and normal controls,[13] most studies (including a meta-analysis) have shown that POAG eyes have a significantly lesser A1V and a smaller DA suggesting that the corneas of POAG eyes are less deformable compared to healthy corneas.[2,6,7] This is contradictory to ORA studies which have shown that when compared to healthy controls, corneas of POAG eyes have a lower CH indicative of a weaker cornea.[4] This discrepancy is difficult to explain, but could be due to differences in the biomechanical property measured (viscosity vs elasticity), the higher IOP in the POAG group, or the inclusion of eyes on anti-glaucoma medication which may confound the results.

There is limited data on the corneal biomechanics (CH and corneal resistance factor [CRF]) in PXF and PXG using the ORA. Yazgan *et al.* found that the average CH value was 3.2 mmHg lower in PXG as compared to healthy controls, and was 1.9 mmHg lower in PXF compared with normal controls.[16] However, a limitation of this study was that the average CCT was significantly different between the groups which would have affected the corneal biomechanics. Another limitation was that most of the PXG patients were on prostaglandin analogues which have been shown to cause significant matrix metalloprotein upregulation in human sclera with subsequent extracellular matrix degradation.[17] It has been theorized that similar changes occur in the cornea as well, and clinical studies of glaucomatous eyes on long-term prostaglandin analogues have shown lower CH, lower CRF, and higher DA when compared with glaucomatous eyes not on prostaglandin analogues after adjusting for confounders such as IOP.[15,18] A study by Yenerel *et al.* also found that CH and CRF were lower in PXF eyes compared to normal controls despite similar IOP and CCT.[19] Cankaya *et al*. showed that the mean CH was significantly different between normal controls (9.4 ± 1.4 mmHg), PXF eyes (8.5 ± 1.5 mmHg), and PXG

Table 4: Comparison of corneal biomechanical parameters derived from Corvis ST among the four groups after adjusting for the difference in intraocular pressure and age using ANCOVA (analysis of covariance) statistic

	Control	PXF	PXF + OHT	PXG	*P*
A1 length/mm	1.92 (0.27)	1.87 (0.26)	1.82 (0.25)	1.83 (0.24)	0.39
A1 velocity/ms^{-1}	1.14 (0.02)	1.14 (0.02)	1.14 (0.02)	1.14 (0.02)	0.51
DA/mm	1.05 (0.13)	1.03 (0.13)	1.04 (0.12)	1.05 (0.12)	0.90
Peak distance/mm	3.99 (1.27)	3.70 (1.23)	4.09 (1.32)	4.05 (1.52)	0.58
Radius of curvature/mm	7.32 (1.34)	7.15 (1.30)	7.10 (1.24)	7.18 (1.22)	0.86
A2 length/mm	1.91 (0.40)	1.91 (0.32)	1.68 (0.37)	1.75 (0.42)	0.19
A2 velocity/ms^{-1}	−0.34 (0.13)	−0.33 (0.13)	−0.34 (0.12)	−0.33 (0.12)	0.93

All values represent means with standard deviations in parenthesis. PXF: Pseudoexfoliation syndrome, PXF + OHT: Pseudoexfoliation with ocular hypertension, PXG: Pseudoexfoliation glaucoma, A1: Applanation point 1; DA: Deformation amplitude, A2: Applanation point 2

eyes (6.9 ± 2.1 mmHg) with the CCT being similar in all three groups.[20] However, they did not find a significant difference in the CRF between the healthy controls and PXG groups.[20] A few studies have compared the corneal biomechanics between PXG and POAG and found that CH was significantly lower in PXG compared to POAG eyes.[21,22] There are no previous studies that have examined the corneal biomechanics in PXF and PXG using Corvis ST. The present study found no difference in the corneal biomechanical parameters among PXF, PXF + OHT, PXG, and healthy controls using the Corvis ST after adjusting for confounders. Again, the reasons for the different results on corneal biomechanics of PXG on ORA vs Corvis ST are not fully understood. It may be due to the differences in the biomechanical properties that these parameters represent as explained earlier.

PXG is inherently a high-pressure disease and because only treatment-naïve eyes were included in this study, it was inevitable that the IOP would be a confounder in our analysis. It is important to note that when IOP was not statistically adjusted for, the PXG and PXF + OHT groups (which had significantly higher IOP than the other groups) did show a reduced A1V, A2V, and DA suggesting these cohorts had stiffer corneas. However, the slower inward velocity and reduced amplitude of the deformation of the cornea in these eyes were most likely due to the increased IOP which resists the inward movement of the cornea. After adjusting for the age and IOP, there was no difference in the biomechanical parameters among control, PXF, PXF + OHT, and PXG eyes using Corvis ST. Other studies have also reported that IOP is the strongest predictor of DA, and hence it is imperative to account for it in all the analyses of corneal biomechanics using the Corvis ST.[18,23]

A strength of the present study was that only treatment-naïve patients were included and hence the effect of IOP-lowering medication has not confounded the results. The other important aspect of its methodology was the detailed phenotyping and classification of the pseudoexfoliation eyes. Apart from PXF and PXG, a separate group containing eyes with PXF whose IOP was >21 mmHg but which did not have any features of glaucomatous optic nerve damage (the PXF + OHT cohort) was included. The purpose of this was to improve our understanding of the pseudoexfoliation spectrum. If the corneas of this cohort were less deformable than the PXG eyes, it may have indicated that these eyes also had a stiffer lamina cribrosa which was protecting them from developing glaucoma. If the biomechanics of this cohort was different from the PXF group, it may have represented a biomarker for glaucoma development in eyes with PXF. The fact that the biomechanics of this PXF + OHT group was similar to the PXG group (both with high IOP) emphasizes the importance of IOP on Corvis ST biomechanical parameters, and that IOP remains the most important predictor for glaucoma in eyes with PXF.

A limitation of the present study is the inclusion of patients with diabetes, a disease known to affect the corneal biomechanics.[24] However, the distribution of diabetics was similar among the groups and hence may not have altered the results. Another drawback of the study design was that both eyes of patients were included if eligible which could be a potential confounder of the study results. However, this may also be viewed as a strength of the study since the two eyes of the same individual were often classified into different cohorts based on the specific phenotype and hence the cohorts were matched for systemic confounders. Another limitation is the inclusion of patients who had undergone clear corneal phacoemulsification, which alters the corneal structure. However, we only included eyes which had undergone cataract surgery more than 6 months prior to the study to ensure that the corneas were stable, and previous studies have shown that corneal biomechanics usually returns to baseline 1 month after cataract surgery.[25,26] Additionally, the distribution of pseudophakic eyes was not significantly different between the groups of our study, and hence, this is unlikely to affect our results.

Conclusion

To conclude, corneal biomechanical parameters measured on Corvis ST are not different between healthy controls and eyes with PXF and PXG. Since PXG is a high-pressure glaucoma, corneal biomechanics may not play an important role in its diagnosis and pathogenesis.

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Conflicts of interest

There are no conflicts of interest.

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