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Research Article

Assessment of the Biomechanical Properties of the Cornea and Biomechanically Corrected Intraocular Pressure Under Different Levels of Intraocular Pressure in Healthy Individuals and Primary Open-Angle Glaucoma Patients

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Abstract

Purpose: The study sought to analyze the intraocular pressure (IOP) dynamics as documented by the Corvis ST (CST), delving into the range of IOP fluctuations triggered by the water drink test (WDT) and juxtaposing these findings directly with Goldmann applanation tonometry (GAT) measurements. Simultaneously, the research aimed to probe into the corneal biomechanical characteristics portrayed by the CST amidst these varying IOP scenarios.

Methods: In a longitudinal, prospective study, IOP and corneal biomechanics were evaluated. Utilizing the CST, IOP dynamics induced by the WDT were juxtaposed with GAT measurements to discern the biomechanical disparities amidst varying IOP levels.

Results: 59 participants aged between 43 and 86 (59,97 ± 11,17) were evaluated. A consistent increase in IOP post-WDT was evident across all participants ($p < 0.0001$). There was no statistically significant difference between the baseline and peak measurements obtained with different IOP measurement techniques. Biomechanical parameters, specifically V1 (Applanation 1 velocity), V2 (Applanation 2 velocity), DA (Deflection amplitude) and SP-A1 (Stiffness parameter at first applanation), exhibited significant alterations post-WDT ($p < 0.0001$), especially when contrasting healthy individuals with primary open-angle glaucoma (POAG) patients. The measurements from CST bore a strong correlation with the GAT readings across both groups.

Conclusion: Our research accentuates the intricate interplay between corneal biomechanics and IOP. Notable shifts in corneal biomechanics, especially in parameters like V1, V2, DA and SP-A1, were observed in response to IOP variations induced by WDT, suggesting the corneal biomechanical structure's sensitivity to even transient IOP changes.

Keywords: *Corneal Biomechanics; Intraocular Pressure; Goldmann Applanation Tonometry; Scheimpflug Dynamic Analyzer; Primary Open-Angle Glaucoma; Water Drink Test*

Abbreviations

IOP: Intraocular Pressure; GAT: Goldmann Applanation Tonometry; WDT: Water Drink Test; CST: Corvis ST; CCT: Central Corneal Thickness; CEP: Research Ethics Committee; POAG: Primary Open-Angle Glaucoma; IOPnct: Uncorrected IOP; bIOP: Biomechanically Corrected IOP;

A1: Applanation 1 Time; A2: Applanation 2 Time; V1: Applanation 1 Velocity; V2: Applanation 2 Velocity; DA: Deflection Amplitude; SSI: Strain Stress Index; SP-A1: Stiffness Parameter at First Applanation; mm: Milimiters; VF: Visual Field; VA: Visual Acuity; OCT: Optical Coherence Tomography; ETDRS: Early Treatment Diabetic Retinopathy Study; log MAR: Logarithm of the Minimum Angle of Resolution

Introduction

Glaucoma stands as a leading cause of irreversible blindness, afflicting over 70 million individuals worldwide [1]. With demographic shifts, particularly in Asia and Africa, this number is projected to reach an unsettling 111.8 million by 2040 [1,2]. Despite its prevalence, glaucoma is its often-asymptomatic onset; estimates indicate that only 10% to 50% of those affected are aware of their condition during its early phases [3-5]. The disease is chiefly identified by optic neuropathy, characterized by symptoms such as neuroretinal rim thinning and increased excavation due to the death of retinal ganglion cells, with intraocular pressure (IOP) elevation being its principal risk factor [6-8].

Although the primary strategy for glaucoma management is IOP reduction, the tools for its assessment, particularly the Goldmann applanation tonometry (GAT), are not without their challenges [8]. The GAT, long regarded as the 'gold standard' for IOP measurement [9], is influenced by corneal factors like thickness, curvature, stiffness, and age. This underscores the necessity to comprehend the intricate dynamics between IOP and corneal biomechanics [10].

Recent research has brought to light the pivotal role of corneal biomechanics, particularly hysteresis, in both the onset and progression of glaucoma [11-13]. Advancements in diagnostic devices, such as the Scheimpflug dynamic analyzer (Corvis ST - CST, developed by OCULUS (Optikgeräte GmbH, Wetzlar, Germany), provide dynamic visualizations of corneal behavior, revealing invaluable data on its biomechanical attributes during deformation [14,15].

In our research, we explore the correlation between IOP variations as documented by the CST and diverse pressure levels induced by the water drink test (WDT), using the GAT as our benchmark for IOP evaluations. The choice of the WDT stems from its ability to indirectly measure the reserve potential for aqueous humor drainage from the eye and to estimate the peak ocular pressure [16-18].

Aim of the Study

This study primarily aims to:

(i) To analyze the IOP dynamics recorded by the CST across the diverse IOP thresholds induced by the WDT, juxtaposing these with GAT measurements, and

(ii) Assess the corneal biomechanical traits as outlined by the CST amidst these IOP variations.

Methods

This was a longitudinal, prospective, and observational study encompassing 59 patients aged between 43 and 86 years, consisting of 39 right eyes and 20 left eyes. We aimed to assess IOP and corneal biomechanical properties at different IOP levels in healthy individuals and POAG patients.

All participants underwent a thorough ophthalmologic examination, encompassing detailed personal, ophthalmologic, and familial histories. Diagnostic assessments encompassed slit-lamp biomicroscopy, IOP measurement, gonioscopy, dilated fundoscopy with a 78-diopter non-contact lens, stereoscopic disc photography, computerized perimetry for visual field (VF), and optical coherence tomography (OCT). Visual acuity (VA) was ascertained using the Early Treatment Diabetic Retinopathy Study (ETDRS) chart and

expressed via the logarithm of the minimum angle of resolution (logMAR). POAG diagnosis was predicated on two or more consecutive VF tests manifesting typical glaucomatous defects and corroborated with stereophotographs. The Humphrey II 750 (Carl Zeiss Meditec, Inc., Dublin, CA, EUA) perimeter and the CIRRUS 6000 (Carl Zeiss Meditec, Inc., Dublin, CA, EUA) were employed for VF and OCT examinations, respectively.

Study phases:

- Phase 1: Comprehensive assessment of both cohorts.
- Phase 2: Segmented analysis of phase 1 data. Phase 2A focused on healthy participants, while phase 2B was dedicated to untreated or post-washout POAG patients.

Inclusion and exclusion criteria

Healthy participants: Minimum age of 40 years, VA of at least 20/60 in each eye, IOP below 21 mmHg without previous episodes of elevated IOP, and absence of glaucomatous optic nerve damage or VF deficits. They also needed to be safe for water consumption and exhibit a minimum 2 mmHg rise in the WDT. Exclusion criteria included potential pregnancy, history of eye laser treatments, retinal disorders, uveitis, or non-glaucomatous optic neuropathies.

POAG participants: Criteria included a confirmed POAG diagnosis, characterized by optic nerve changes and/or consistent VF anomalies, with/without ongoing treatment. IOP above 21 mmHg without treatment or post-medication washout was required. Acceptable VF metrics included false negatives ≤ 33%, false positives ≤ 15%, and fixation losses ≤ 33%, with an open anterior chamber angle in gonioscopy. Exclusions were similar to the healthy cohort, with added exclusions for previous glaucoma surgeries, hemianopias, and advanced glaucoma (VF mean deviation < -12 dB).

Study protocol: A single trained ophthalmologist (MM) conducted all assessments. Preliminary evaluations used the CST for paquimetry, uncorrected IOP (IOPnct), biomechanically corrected IOP (bIOP), and other biomechanical metrics. This was followed by the GAT after anesthetic (Anestalcon, Alcon, Brazil) and fluorescein drop 1% (10 mg/ml, Allergan, Brazil) application. IOP Measurements were taken before and after an 800 ml water bolus, taken at 15-minute intervals. The eye with the highest IOP increase during the WDT was considered the study reference.

The study adhered to ethical guidelines, with approval from the Research Ethics Committee (CEP) and signed informed consent from all participants. The sample size was determined by convenience, totaling 59 participants.

The statistical analysis involved measures of central tendency and dispersion, such as mean and standard deviation. The eye with the highest IOP increase during the WDT was selected for statistical analysis. Comparisons between variables used paired t-tests for two variables and One-Way ANOVA for more than two groups. A significance level of 0.05 was adopted, with Bonferroni correction applied for multiple consecutive t-tests in biomechanical variables. Statistical analysis was performed using SPSS version 22.0 and GraphPad Prism 8.0.1

Results

Demographics and general findings: The study involved participants with an average age of 59.97 ± 11.17 years, spanning from 43 to 86 years. Females constituted 59.32% of the cohort with 35 participants. The central corneal thickness (CCT) across participants was observed to be 540.2 ± 43.19 microns on average (Table 1).

Intraocular pressure assessment: Across all sub-groups, a significant increase in IOP was observed post-test (Table 2). However, comparing the methods used to measure IOP at both baseline and peak, the differences weren't statistically significant (Graph 1A).

From a biomechanical perspective, when comparing biomechanical properties before and after WDT, neither A1 (Applanation 1 time) nor A2 (Applanation 2 time) showed any significant variations ($p = 0.76$ and $p = 0.53$, respectively). In contrast, parameters like V1 (Applanation 1 velocity), V2 (Applanation 2 velocity), and DA (Deflection amplitude) highlighted statistically significant variations ($p < 0.0001$). While the SSI (Strain stress index) demonstrated no meaningful deviations, the SP-A1 (Stiffness parameter at first applanation) parameter highlighted significant discrepancies with a p-value less than 0.0001 (Table 3).

CST analysis: A positive correlation was observed between IOPnct and bIOP concerning GAT-induced pressure elevation ($p < 0.0001$) (Graph 2A). The Bland-Altman analysis delineated the agreement between measurement techniques, notably between IOPnct and GAT, as well as between GAT and bIOP, for both initial and peak readings.

Phase-specific analysis

Healthy cohort (2A): This group comprised 29 eyes from 29 individuals, showing an average CCT of 531.0 ± 40.5 microns (Table 1). The IOP measurements revealed a significant increase compared to baseline readings (Table 2). However, the comparison of IOP measurement methods didn't present any significant differences (Graph 1). Following the initial analysis, we performed Pearson correlation with healthy subjects, revealing a positive correlation for both IOPnct and bIOP with the pressure increase assessed by GAT ($p < 0.0001$) (Graph 2B).

POAG cohort (2B): Including 30 individuals, this group displayed an average CCT of 549.1 ± 44.47 microns (Table 1). Like the 2A group, a significant rise in IOP was noted post-test across sub-groups (Table 2). The comparative analysis between GAT and both IOPnct and bIOP revealed notable differences, but such differences were absent between IOPnct and GAT (Graph 1). A close examination of biomechanical parameters found no significant differences for A1 and A2, but V1, V2, DA, and SP-A1 all showed significant variations with a p-value of less than 0.0001 (Table 3). As done in the previous groups, it was examined whether the increase in IOP after WDT was related to the values obtained with CST, using Pearson correlation. For both IOPnct and bIOP, the rise in pressure assessed by GAT showed a positive correlation, with $p < 0.0001$ (Graph 2C).

Description	All Participants (n = 59)	Healthy Participants (n = 29)	GPAA Participants (n = 30)
Number of participants	59	29	30
Eye (right/left)	39 (66.01%)/20 (33.89%)	21 (72.42%)/8 (27.58%)	18 (60%)/12 (40%)
Gender (female/male)	35 (59.32%)/24 (40.67%)	21 (72.42%)/8 (27.58%)	16 (53%)/14 (46.6%)
Age (years)	59.97 ± 11.17	59.97 ± 11.94	60.93 ± 10.49
Pachymetry (µm)	540.2 ± 43.19	531.2 ± 40.56	549.1 ± 44.47

Table 1: *Descriptive data of all participants, healthy participants, and those with POAG*

POAG = Primary Open-Angle Glaucoma.

Group	Measurement	Baseline IOP (mmHg)	Peak IOP (mmHg)	Difference (mmHg)	Significance
All patients (n = 59)	GAT	18,51 ± 5,03	23 ± 6,77	4,49	P < 0,0001
	IOPnct	18,95 ± 4,47	23,52 ± 6,91	4,57	P < 0,0001
	bIOP	17,64 ± 4,074	21,90 ± 6,06	4,26	P < 0,0001
Healthy patients (n = 29)	GAT	14,10 ± 3,08	17,03 ± 3,97	2,93	P < 0,0001
	IOPnct	14,84 ± 2,82	17,52 ± 4,15	2,68	P < 0,0001
	bIOP	14,13 ± 2,51	16,72 ± 3,75	2,58	P < 0,0001
POAG patients (n = 30)	GAT	22,77 ± 1,83	28,77 ± 2,56	6,00	p < 0,0001
	IOPnct	22,92 ± 2,04	29,31 ± 2,90	6,37	p < 0,0001
	bIOP	21,03 ± 1,69	26,92 ± 2,63	5,88	p < 0,0001

Table 2: *Intraocular pressure (IOP) assessment using GAT and CST at baseline and peak in different patient groups.*

GAT = Goldmann Applanation Tonometry; IOP = Intraocular Pressure; IOPnct = Uncorrected IOP; bIOP = Biomechanically Corrected IOP; POAG = Primary Open-Angle Glaucoma.

Parameter	Patient Group	Baseline	Peak	Difference	Significance*
A1 (mm)	All patients	2,37± 0,34	2,38 ± 0,31	0.01	p = 0,76
	Healthy	2,23± 0,34	2,31 ± 0,25	0.07	p = 0,32
	POAG	2,51 ± 0,29	2,46 ± 0,34	-0.04	p = 0,48
A2 (mm)	All patients	2,19 ± 0,41	2,22 ± 0,42	0,03	p = 0,53
	Healthy	1,98 ± 0,36	2,04 ± 0,32	0,06	p = 0,44
	POAG	2,39 ± 0,35	2,40 ± 0,44	0,008	p = 0,92
V1 (m/s)	All patients	0,16 ± 0,06	0,11 ± 0,02	-0,05	p < 0,0001
	Healthy	0,21 ± 0,05	0,12 ± 0,02	-0,09	p < 0,0001
	POAG	0,11 ± 0,01	0,09 ± 0,01	-0,01	p < 0,0001
V2 (m/s)	All patients	-0,29 ± 0,10	-0,19 ± 0,05	0,06	p < 0,0001
	Healthy	-0,37 ± 0,08	-0,23 ± 0,03	0,13	p < 0,0001
	POAG	-0,21 ± 0,04	-0,15 ± 0,03	0,03	p < 0,0001
DA (mm)	All patients	0,97 ± 0,13	0,86 ± 0,16	-0,11	p < 0,0001
	Healthy	1,07 ± 0,12	0,98 ± 0,13	-0,08	p < 0,0001
	POAG	0,88 ± 0,07	0,74 ± 0,08	-0,14	p < 0,0001
SSI	All patients	1,33 ± 0,33	1,33 ± 0,36	-0,009	P = 0,61
	Healthy	1,21 ± 0,17	1,24 ± 0,17	0,03	p < 0,0001
	POAG	1,46 ± 0,40	1,40 ± 0,47	-0,05	P = 0,12
SP-A1	All patients	118,3 ± 23,48	128,5 ± 24,96	10,21	p < 0,0001
	Healthy	106,5 ± 19,18	116,9 ± 22,06	10,39	p < 0,0001
	POAG	129,7 ± 21,75	139,8 ± 22,58	10,03	p < 0,0001

Table 3: *Biomechanical corneal parameters assessed by CST before (Baseline) and after TSH (Peak) in different patient groups.*

**Paired t-test for consecutive data. Corrected p-value (Bonferroni correction) considered significant if p < 0,0071.*

POAG: Primary Open-Angle Glaucoma; A1 = Applanation 1 Time; A2 = Applanation 2 Time; V1 = Applanation 1 Velocity; V2 = Applanation 2 Velocity; DA = Deflection Amplitude; SSI = Strain Stress Index; SP-A1 = Stiffness Parameter at First Applanation; mm = Milimeters.

Parameter	Patient Group	Baseline	Peak	Difference	Significance*
A1 (mm)	All patients	2,37± 0,34	2,38 ± 0,31	0.01	p = 0,76
	Healthy	2,23± 0,34	2,31 ± 0,25	0.07	p = 0,32
	POAG	2,51 ± 0,29	2,46 ± 0,34	-0.04	p = 0,48
A2 (mm)	All patients	2,19 ± 0,41	2,22 ± 0,42	0,03	p = 0,53
	Healthy	1,98 ± 0,36	2,04 ± 0,32	0,06	p = 0,44
	POAG	2,39 ± 0,35	2,40 ± 0,44	0,008	p = 0,92
V1 (m/s)	All patients	0,16 ± 0,06	0,11 ± 0,02	-0,05	p < 0,0001
	Healthy	0,21 ± 0,05	0,12 ± 0,02	-0,09	p < 0,0001
	POAG	0,11 ± 0,01	0,09 ± 0,01	-0,01	p < 0,0001
V2 (m/s)	All patients	-0,29 ± 0,10	-0,19 ± 0,05	0,06	p < 0,0001
	Healthy	-0,37 ± 0,08	-0,23 ± 0,03	0,13	p < 0,0001
	POAG	-0,21 ± 0,04	-0,15 ± 0,03	0,03	p < 0,0001
DA (mm)	All patients	0,97 ± 0,13	0,86 ± 0,16	-0,11	p < 0,0001
	Healthy	1,07 ± 0,12	0,98 ± 0,13	-0,08	p < 0,0001
	POAG	0,88 ± 0,07	0,74 ± 0,08	-0,14	p < 0,0001
SSI	All patients	1,33 ± 0,33	1,33 ± 0,36	-0,009	P = 0,61
	Healthy	1,21 ± 0,17	1,24 ± 0,17	0,03	p < 0,0001
	POAG	1,46 ± 0,40	1,40 ± 0,47	-0,05	P = 0,12
SP-A1	All patients	118,3 ± 23,48	128,5 ± 24,96	10,21	p < 0,0001
	Healthy	106,5 ± 19,18	116,9 ± 22,06	10,39	p < 0,0001
	POAG	129,7 ± 21,75	139,8 ± 22,58	10,03	p < 0,0001

Table 3: *Biomechanical corneal parameters assessed by CST before (Baseline) and after TSH (Peak) in different patient groups.*

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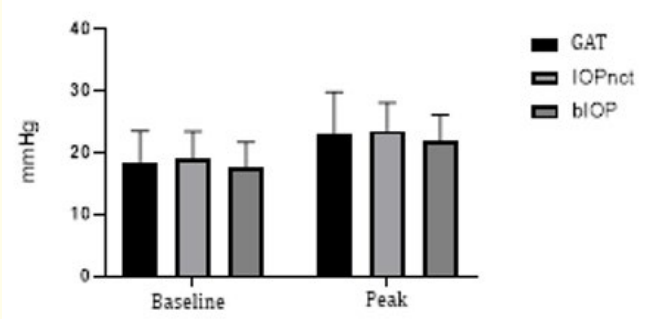
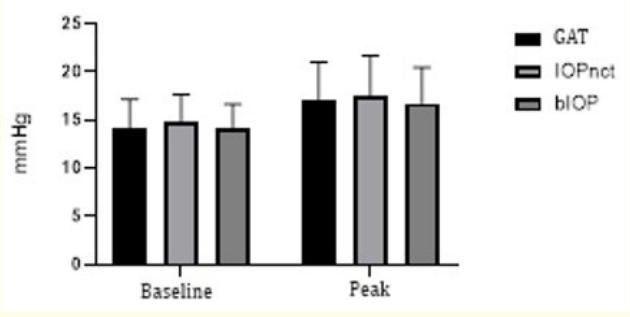
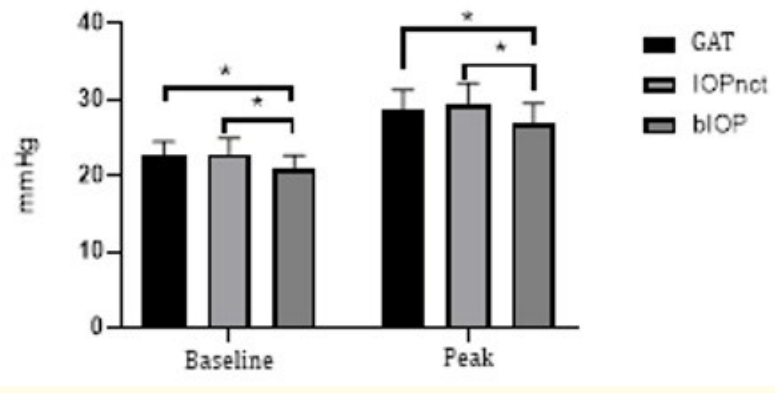
POAG: Primary Open-Angle Glaucoma; A1 = Applanation 1 Time; A2 = Applanation 2 Time; V1 = Applanation 1 Velocity; V2 = Applanation 2 Velocity; DA = Deflection Amplitude; SSI = Strain Stress Index; SP-A1 = Stiffness Parameter at First Applanation; mm = Milimeters.



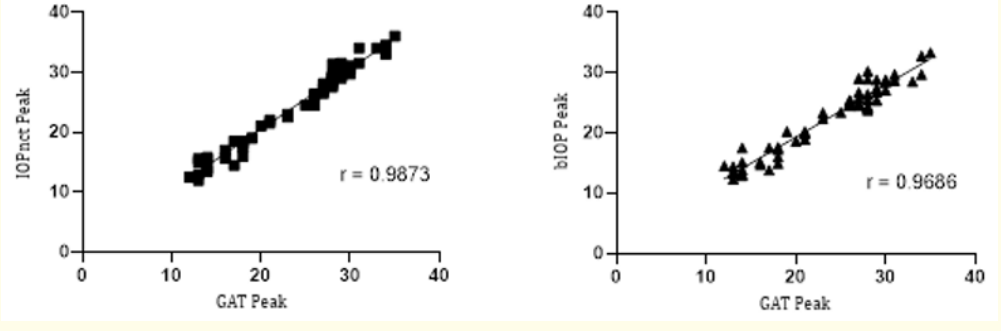
Graph 1A: *Comparison of the IOP measured before (baseline) and after (peak) TSH using GAT, uncorrected CST (IOPnct), and corrected (bIOP).*



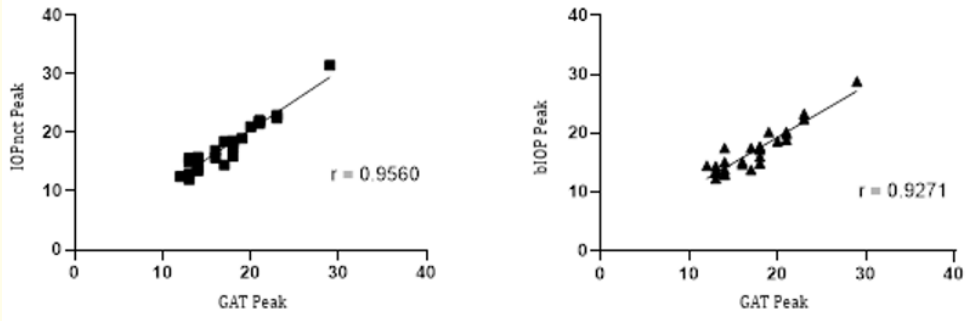
Graph 1B: *Comparison of the IOP measured before (baseline) and after (peak) TSH using GAT, uncorrected CST (IOPnct), and corrected (bIOP).*



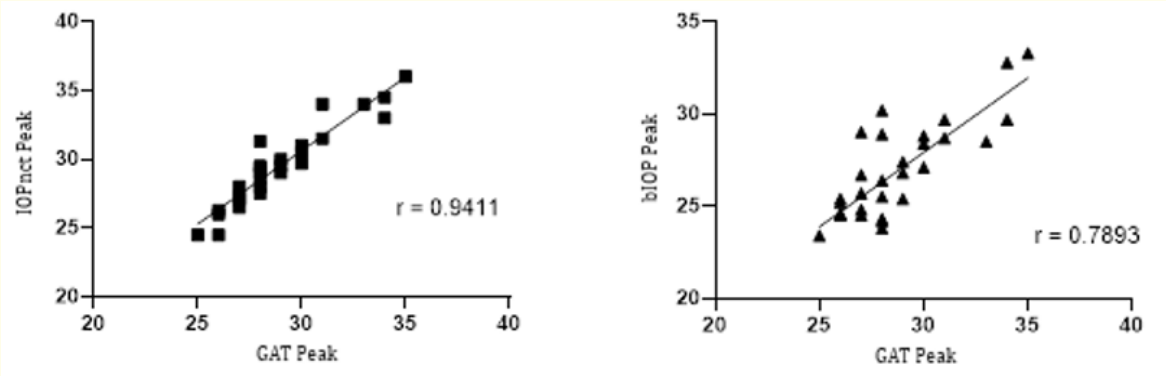
Graph 1C: *Comparison of baseline and peak IOP measurements before and after TSH using GAT, uncorrected CST (IOPnct), and corrected CST (bIOP). *Significant difference between groups ($p < 0.05$). While no statistically significant differences were observed between GAT and IOPnct for baseline IOP ($p = 0.99$; One-Way ANOVA), significant differences emerged in comparisons between GAT versus bIOP and IOPnct versus bIOP ($p = 0.049$ and $p = 0.024$, respectively). The comparison between GAT and IOPnct for the peak showed no significant difference ($p = 0.94$), but peak measurements by GAT, IOPnct and bIOP CST measurements were significantly different ($p = 0.02$ and $p = 0.014$, respectively).*



Graph 2A: *Graphic representation of the correlation between pressure peaks after WDT. The values expressed in mmHg obtained by GAT were compared with IOPnct and bIOP. r= Pearson correlation coefficient.*



Graph 2B: *Graphic representation of the correlation between pressure peaks after TSH. The values expressed in mmHg obtained by GAT were compared with IOPnct and bIOP. r = Pearson correlation coefficient.*



Graph 2C: *Graphic representation of the correlation between pressure peaks after TSH. The values expressed in mmHg obtained by GAT were compared with IOPnct and bIOP. r = Pearson correlation coefficient.*

Discussion

Our study magnifies the intricate relationship between IOP and the biomechanical properties of the cornea [11-13]. The prominence of IOP elevation as a leading risk factor for glaucoma is well-established [9]. Our findings provide an in-depth exploration into the ramifications of dynamic IOP levels on the biomechanical attributes of the cornea in the same eye, pointing towards significant avenues in glaucoma etiology comprehension.

Most tonometric techniques, whether contact-based or not, rely on tracking the corneal response to an applied mechanical force. As such, they are inherently influenced by the cornea's resistance to deformation, or in other words, its stiffness [19]. Liu and Roberts [20] have demonstrated that individual variations in corneal biomechanics can introduce larger errors in IOP measurement than those stemming from corneal thickness or curvature. This underscores the importance of adopting an IOP estimate that remains unaffected by material characteristics, age, or thickness. Considering this, the conventional GAT, a mainstay in IOP assessment, has shown tendencies to underestimate IOP, especially when juxtaposed against the advanced CST measurements. Such a discrepancy becomes crucial in clinical contexts, highlighting the imperative for clinicians to recognize these potential biomechanical discrepancies and adjust their assessment techniques accordingly [21,22].

Notably, biomechanical variances, particularly in parameters like V1, V2, and DA, between healthy and POAG cohorts were highly significant. These differences, potentially reflecting variations in corneal structure due to IOP fluctuations, accentuate the nuanced role of corneal biomechanics in glaucoma's pathophysiology [20,23]. The disparities in stiffness parameters, such as the indices SSI and SP-A1, coupled with variations in the CCT, bolster the hypothesis that corneal biomechanics might wield a pivotal role in glaucoma development and progression [24-26].

In the realm of tools and measurements, the observed strong correlation between IOP measurements using GAT and CST across both groups reinforces the credibility and potential of CST in clinical applications [22,27]. As technology advances, instruments like CST not only promise refined precision but also grant deeper insights into ocular biomechanics, catalyzing potential paradigm shifts in glaucoma management.

However, despite the robust findings, our study isn't without limitations. The convenience sampling method employed might have ushered in selection bias, potentially curtailing the generalizability of our results. The primary focus on IOP-induced biomechanical changes, although intensive, also mandates further investigations that integrate other potentially influential ocular or systemic factors. The reliance on the WDT as an artificial modality to induce IOP alterations might not completely reflect the complexities of natural IOP changes encountered daily. Furthermore, the study's cross-sectional design places constraints on extrapolating the long-term implications of these IOP variations on corneal biomechanics or the trajectory of glaucoma.

Conclusion

In conclusion, our research accentuates the multifaceted interplay between corneal biomechanics and intraocular pressure. We observed notable shifts in corneal biomechanics following IOP variations induced by WDT. This dynamic underscores that the corneal biomechanical structure is receptive to changes, even if transient, in IOP. The robust correlations and agreement between IOP measurements from CST and GAT highlight the reliability of CST. While GAT remains an essential tool, CST emerges as a promising alternative, offering more intricate biomechanical insights. As we progress in glaucoma research, integrating traditional tools like GAT with advanced technologies such as CST becomes pivotal to ensure a comprehensive and updated diagnostic and therapeutic approach.

Conflict of Interest

I declare that I have no financial interest or conflict of interest.

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