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Comparison of intraocular pressure measurements between Icare PRO Tonometer, Goldmann Applanation Tonometer and non-contact tonometer in healthy and glaucomatous eyes

Comparação da medição da pressão intraocular entre o tonômetro Icare PRO, o tonômetro de aplanação de Goldmann e o tonômetro de não-contacto em olhos saudáveis e olhos glaucomatosos

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Abstract

Purpose: *To validate the comparative measurements of intraocular pressure performed with IcarePRO tonometer (IPT) in relation to Goldmann applanation tonometer (GAT) and non-contact tonometer (NCT), as well as to evaluate the influence of central corneal thickness (CCT) on these values.* ***Methods:*** *This was a prospective and comparative study conducted during 6 months in the Department of Ophthalmology, Hospital de Braga, Portugal. The study population comprised two groups: healthy adults and adults with primary open angle glaucoma (POAG). The IOP values were obtained by the three tonometers and the order of execution was randomly selected. CCT values were obtained by ultrasonic pachymetry.* ***Results:*** *A total of 168 eyes (74 with diagnosis of POAG and 94 healthy) of 84 patients were included in this study. The mean IOP values obtained by IPT, GAT and NCT were 17.36±3.78 mmHg; 14.59±3.32 mmHg; and 17.04±4.01 mmHg, respectively. The comparison between IPT and NCT did not reveal statistically significant differences in the two groups studied. However, statistically significant differences were obtained between IPT and GAT values (p <0.001). The IOP values, recorded by all the tonometers, were significantly and positivily correlated with the CCT (p <0.001).* ***Conclusion:*** *IOP readings measured by IPT are comparable with those obtained by NCT, but higher than those obtained by the GAT. CCT values are correlated with IOP measurements with IPT, as it does in GAT and NCT, and should be always taken into consideration.*

Keywords: *Corneal pachymetry; Glaucoma; Glaucoma, open-angle; Intraocular Pressure; Tonometry, ocular*

Resumo

Objetivo: Validar os valores de pressão intraocular (IOP) realizados com o tonômetro IcarePRO (IPT) em relação ao tonômetro de aplanação de Goldmann (GAT) e tonômetro de sopro (NCP), assim como avaliar a influência da espessura central da córnea (CCT) nesses valores. **Métodos:** Estudo prospectivo e comparativo realizado durante 6 meses consecutivos no Departamento de Oftalmologia do Hospital de Braga, Portugal. A população estudada compreendeu dois grupos: adultos saudáveis e adultos com glaucoma primário de ângulo aberto (POAG). Os valores de IOP foram obtidos pelos três tonômetros e a ordem de execução foi selecionada aleatoriamente. Os valores de CCT foram obtidos por paquimetria ultrassônica. **Resultados:** Um total de 168 olhos (74 com diagnóstico de POAG e 94 saudáveis) de 84 pacientes foram incluídos neste estudo. Os valores médios de IOP obtidos pelo IPT, GAT e NCT foram de 17.36±3.78 mmHg; 14.59±3.32 mmHg; e 17.04±4.01 mmHg, respectivamente. A comparação entre IPT e NCT não revelou as diferenças estatisticamente significativas nos dois grupos estudados. No entanto, foram obtidas diferenças estatisticamente significativas entre os valores registados pelo IPT em comparação ao GAT (p <0.001). Os valores de IOP, medidos por todos os tonômetros, foram significativamente correlacionados com a CCT (p <0.001). **Conclusão:** As leituras de PIO medidas pelo IPT são comparáveis às obtidas pelo NCT, mas superiores às obtidas pelo GAT. Os valores de CCT estão correlacionados com medidas de IOP, tal como acontece com o GAT e NCT, pelo que devem ser levados em considerados.

Descritores: Paquimetria corneana; Glaucoma; Glaucoma de ângulo aberto; Pressão intraocular; Tonometria ocular

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Introduction

Glaucoma, a chronic and neurodegenerative optic neuropathy, is a main global cause of irreversible blindness. The disease management is directed to reduce intraocular pressure (IOP) by pharmacological or surgical means. Despite the serial monitoring and the different therapeutic options, some patients maintain a progressive visual field loss.[1,2] Routine evaluation of IOP is essential in the management of patients with glaucoma, since its reduction is the only proven method of slowing down disease progression.[3] To obtain accurate measurements of IOP, various diagnostic devices are available in clinical practice. Among them, the Goldmann applanation tonometer (GAT) is considered the gold standard in tonometry according to current references.[4-6] However, it presents disadvantages such as: being an operator-dependent method; requiring the use of topical anesthesia; and being difficult to perform in children and bedridden patients.[7-13] Among other alternatives, the Icare PRO tonometer (IPT) provides a new type of portable reading using the principle of impact or rebound to measure IOP. The calculation is made by parametric variation of the motion after a magnetic probe reaches the cornea. This probe uses a motion-and-impact detection solenoid that, at the time of collision, induces voltage and tension, allowing measurement of IOP.[6,7] The Non-Contact tonometer (NCT) is another form of flattening tonometry that uses a calibrated column of compressed air to flatten the cornea.[8,14,15]

The significance of central corneal thickness (CCT) in clinical diagnosis and management of glaucoma is well recognized, however its importance remains a matter of debate. Nevertheless, CCT should be taken into account for better interpretation of IOP values.[8,14,16-20] Another factor that may have an impact on the value recorded by tonometry, and which is currently the focus of much debate, is the position in which the measure is performed. Recently, several studies have shown that IOP is higher in the supine position compared to measurements in the sitting position, so these changes have been associated with an increase in nocturnal IOP and could be related to the progression of glaucoma.[7,10,11,21]

This is the first study that simultaneously compares the validity of IPT with respect to NCT and GAT in the measurement of IOP in healthy eyes and in eyes with diagnosis of primary open angle glaucoma (POAG), and that also compares its measures in different groups of CCT, evaluating its applicability in sitting and dorsal decubitus positions.

Methods

Design of the study and Population Study

The study was approved by the Ethics Committee from Hospital de Braga and School of Medicine - University of Minho. Signed informed consent was obtained from all patients prior to data collection.

This study follows a prospective and comparative design. The study was performed in Hospital of Braga and data was collected from individuals that attended the Ophthalmology and Glaucoma Department, from June to November 2017, and filled the inclusion criteria after ophthalmologic observation. The study population was divided into two different groups: a healthy adult population group (Healthy Group) and an adult population group with diagnosis of POAG (POAG Group). In the Healthy Group, we included adults with 18 years or more, while the POAG Group included adults with 18 years or more with diagnosis of unilateral or bilateral POAG. The following criteria were considered for POAG diagnosis: typical optic disc changes characterized as focal or diffuse thinning of the retinal nerve fibre layer with consistent glaucomatous visual field defects, and open angle on gonioscopy. Glaucomatous visual field defects will be confirmed if 2 of the following 3 conditions are met: presence of a cluster of 3 points on a pattern deviation probability plot with $P < 5\%$, 1 of which had $P < 1\%$; a pattern standard deviation with $P<5\%$; or a glaucoma hemifield test result outside normal limits. For both groups, we considered the following exclusion criteria: any pathological change detected in the anterior or posterior segment; family history of glaucoma (for the Healthy Group); previous history of trauma or eye surgery; eyelid/corneal changes that made measurements impossible to perform; and, no collaboration during measurements.

Prior to IOP measurement, all elected individuals that came to Ophthalmology appointment were submitted to an ophthalmologic observation by an Ophthalmologist, with baseline assessment and routine procedures performed, including best-corrected visual acuity evaluation, slit-lamp examination, gonioscopy, and fundus biomicroscopy with a 90-diopter lens.

CCT measurements

CCT values were obtained by ultrasonic pachymetry (Alcon® OcuScan RxP) before the IOP measurements. The pachymeter probe was placed on the center of the cornea, and the mean of 3 readings was calculated for each eye.

IOP measurements

The IOP values were obtained by the three tonometers (IPT, GAT and NCT), and the order of execution was randomly selected, with a 15-minute time interval between readings. The IOP measurements were conducted by independent observers. Each observer was responsible for using a single device. NCT (Topcon CT-80 Topcon corporation, Tokyo, Japan) automatically recorded three IOP readings, with their average per eye being recorded for the study. GAT (Haag Streit, Koeniz, Switzerland) values were recorded after 3 consecutive readings and a mean value was calculated for each eye observed. IPT (Tiolat Oy, Helsinki, Finland) was positioned near the patient's eye with the forehead being used as a base support. IOP measurements were taken with the tip of the probe maintained at a distance of approximately 3 to 7 mm from the center of the cornea, according to the manufacturer's instructions. The mean of six consecutive sets of acceptable final measurements was used for subsequent analyses. The measurements with IPT were made firstly in sitting position and after 15 minutes in dorsal decubitus.

Statistical analysis

Data analysis was performed with Statistical Practice for the Social Sciences (SPSS, version 23, IBM Corporation). Exploratory analysis for categorical variables are presented as frequencies and percentages. For quantitative variables, statistical analysis involved measures of descriptive statistics (absolute and relative frequencies, means, standard deviations and inferential statistics), after checking out for distribution's symmetry. The coefficient of flattening (kurtose) and skewness were also analyzed. The level of significance to reject the null hypothesis was set at $p<0.05$. Paired samples t-test was used for mean comparison between IPT and the other two instruments, including the comparison in each group

of CCT and for comparison of IPT measurements in siting position and dorsal decubitus position. Student's t-test for independent samples was used to compare CCT in healthy and POAG eyes. The Bland-Altman analysis was used to test the agreement between the measuring instruments. One-sample t-test was used previously to verify if we could proceed with the plot construction. In the Bland-Altman graphs, the difference between each IOP measurement (e.g. IPT-NCT) was plotted against the mean of the 2 measurements [(IPT-NCT)/2]. Linear Regression analysis was used to verify bias. Pearson's correlation coefficient was used to assess correlation between the tonometers for the IOP measurement.

Results

Descriptive Statistics

A total of 168 eyes (74 eyes with diagnosis of POAG and 94 healthy) were included in this study. Demographic characteristics of the sample population are shown in table 1. The sample consisted of 46 (54.8%) males and 38 (45.2%) females, with a mean age of 63.8 (±17.2 years).

Table 1
Demographic and clinical characteristics from 168 eyes.

	Subgroups	N (%)	Sex n(%)		Mean Age (years)
			Male (n=92)	Female (n=76)	
Cases					
(n=168)	**POAG Group**	74 (44%)	37 (50%)	37 (50%)	69.8
	Healthy Group	94 (56%)	55 (58.5%)	39 (41.5%)	62.6

n: sample size; POAG: primary open angle glaucoma.

Table 2
Descriptive statistics of IOP (mmHg) and CCT (μm) obtained in 168 eyes.

	Minimum	Maximum	M	SD
GAT	4.00	22.00	14.59	3.32
NCT	5.00	30.00	17.04	4.01
IPT sitting position	6.40	32.70	17.36	3.78
IPT dorsal decubitus	10.70	27.50	19.46	3.65
CCT	441.00	611.00	529.32	37.40

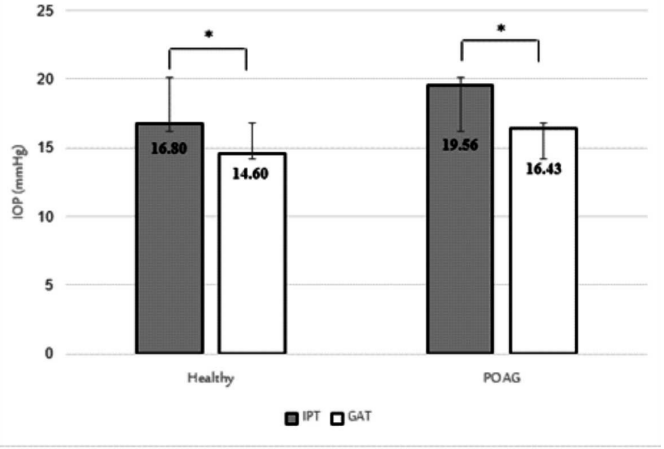
GAT: Goldmann Applanation Tonometer; NCT: Non-Contact Tonometer; IPT: Icare PRO Tonometer; CCT: Central Corneal Thickness; M: mean; SD: standard deviation.

Inter-device agreement: Agreement between IPT and GAT

Figure 1 presents the mean comparison between IPT and GAT in healthy and POAG eyes. Overall, we found a statistically significant difference in both healthy eyes [t(92)=10.942, p<0.001, d=0.320], and in eyes with POAG [t(72)=8.337, p<0.001, d=0.124]. Thus, there is no inter-device agreement between the two instruments.

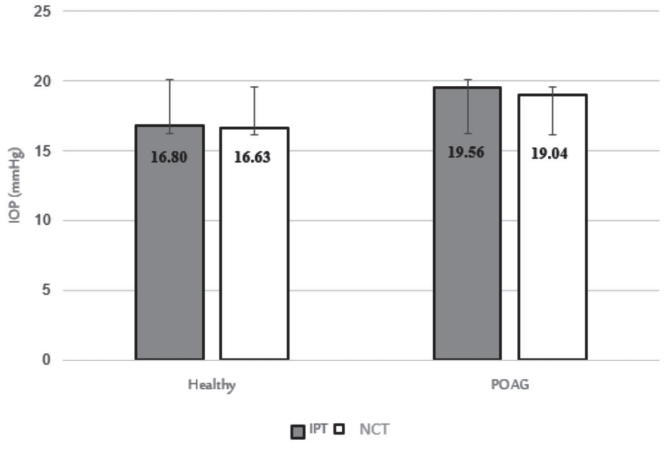
Inter-device agreement: Agreement between IPT and NCT

Figure 2 presents the mean comparison between IPT and NCT in healthy and POAG eyes. In our study, eyes with POAG had a higher mean IOP difference between IPT and the NCT than healthy eyes (0.52 and 0.17 mmHg, respectively). Statistical analysis between IPT and NCT revealed an agreement between IPT and NCT readings in healthy [t(92)=0.703, p=0.484, d=0.112] and glaucomatous eyes [t(72)=1.177,p=0.234, d=0.124]. The Bland-Altman plots showed an overall agreement between IPT and NCT measurements, in both healthy and POAG eyes (Figure 3). In Figures 3 we can see the plot for healthy and POAG eyes, respectively, performed by the IPT and NCT instruments. The group mean (red line) of the differences was 0.34 mmHg in healthy eyes and 1.05 mmHg in POAG eyes. Bland-Altman analysis revealed no biases between IPT and NCT with 95% limits of agreement of -4.46-4.80 in healthy eyes (Figure 3A) and -6.80-7.85 in glaucomatous eyes (Figure 3B). In table 3 we analyze the potential bias and as B unstandardized coefficient is close to 0 and we have no statistical significant results in both healthy and POAG eyes, we can conclude an inter-device agreement between the two instruments.



IOP: Intraocular Pressure; IPT: Icare PRO Tonometer; GAT: Goldmamn Applanation Tonometer. *p<0.001

Figure 1: Mean comparison between IPT and GAT in healthy (n=94) and POAG eyes (n=74).



IOP: Intraocular Pressure; IPT: Icare PRO Tonometer; NCT: Non Contact Tonometer

Figure 2: Mean comparison between IPT and NCT in healthy (n=94) and POAG eyes (n-74).

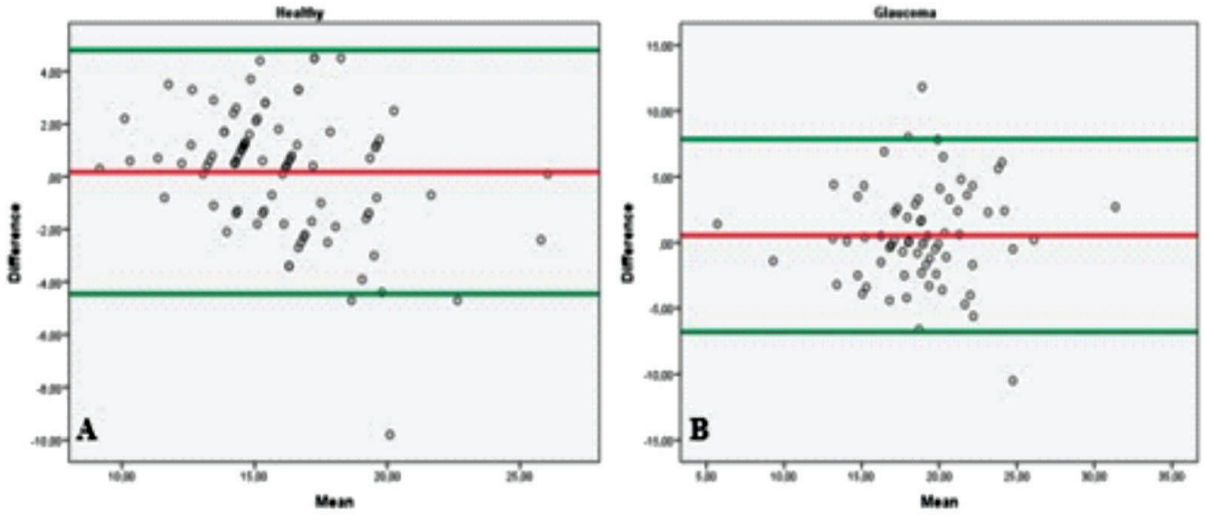


Figure 3: Bland-Altman plots showing the distribuition of differences in IOP (IPT value minus NCT value, mmHg) (y-axis) and the mean IOP value of tonometers (x-axis) for each eye measured in healthy (n=94) and |POAG eyes (n=74) in (A) and (B), respectively. The red line indicates the mean of the differences (identity line) and the green lines lower and upper bounds of agreement for a 95% confidence interval.

Table 3
Linear regression: analysis of bias

	Unstandardized coefficients		Standardized coefficients		
	B	Standard error	B	t	P
Healthy Group	-0.055	0.095	-0.064	-0.578	0.565
POAG Group	-0.175	0.116	-1.167	-1.156	0.134

POAG: Primary Open Angle Glaucoma Dependent variable: difference between IOP measurements from ICT and NCT. Independent variable: mean of the 2 measurements [(IPT-NCT)/2]

Sitting position vs. dorsal decubitus

Healthy eyes registered a mean IOP of 15.96±2.51 mmHg and 18.93±2.83 mmHg in sitting and dorsal decubitus position, respectively. In healthy patients, measurements of IOP obtained with IPT are significantly higher in dorsal decubitus [t(26)=4.155, p<0.001, cohen's d=1.110]. POAG eyes had higher measurements in both postures with IOP mean of 18.12±4.43 mmHg and 19.78±4.27 mmHg in sitting and dorsal decubitus positions, respectively. In this group, the values are also higher in dorsal decubitus although the difference is not statistically significant [t(13)=1.045, p=0.305, cohen's d=0.382].

Correlation with CCT values

In healthy eyes, the mean of CCT was 531.88±35.45 µm. In POAG eyes, the mean registered was 525.86±39.88 µm. The CCT is higher in healthy eyes, although the difference is not statistically significant [t(166)=1.102, p=0.313, cohen's d=0.160]. The linear regression analysis shows a positive correlation of IOP values measured with the three tonometers and CCT. The correlation coefficients between tonometers and CCT are all statistically significant, positive and moderate or low (Table 4).

Comparison of IPT in different groups of CCT

By grouping the CCT values into distinct categories (<470 µm; 470-550 µm; and ≥550 µm) and comparing IOP means by instrument in healthy and POAG eyes, we verified that for thin corneas (CCT<470 µm) there are no statistically significant differences between the IPT and the GAT (p=0.518 and p=0.971 for healthy and POAG eyes, respectively). However, we were able to find statistically significant differences between IPT and GAT, in the group of 470-550 µm and ≥550 µm, either in healthy eyes or with POAG (Table 5). The same analysis was applied for the comparison with the NCT and we found statistical significant differences between IPT and NCT in a CCT ranging from 470-550 in healthy eyes (Table 6).

Table 4
Pearson correlation between CCT and the three tonometers in study

	CCT	Equation of linear regression
IPT	r=0.363, p<0.001	3.5866xCCT+466.95
GAT	r=0.385, p<0.001	4.33xCCT+466.03
NCT	r=0.530, p<0.001	4.9198xCCT+445.47

GAT: Goldmann Applanation Tonometer; NCT: Non-Contact Tonometer; IPT: Icare PRO Tonometer; CCT: Central Corneal Thickness

Discussion

Tonometry is a fundamental procedure in routine ophthalmologic examination. Accurately measure IOP is essential when diagnosing and managing glaucoma. The IPT has gained much interest recently, due to its practical use, comparable measurements with other forms of tonometry, good reproducibility and a relatively more comfortable experience for the patients since it is minimally invasive and a non-anaesthetic procedure.[12, 14, 22, 23] The clinical necessity of such tonometer is justified in people who have difficulties in positioning their head on the slit lamp (children, wheelchair, obese) and in cases where eye drops need to be avoided.[14,24,25] However, doubts have arisen whether the IPT would produce comparable results with the GAT and NCT over a wide range of CCT.[18, 19, 26]

Table 5
Mean IOP comparison in healthy (n=94) and POAG eyes (n=74), between IPT and GAT, according to groups of CCT (μm)

		IPT			GAT		Statistics
		N	M	SD	M	SD	
CCT<470 μm	Healthy	3	13.69	3.84	11.40	4.08	t(92)=0.708, p=0.518, d=0.578
	POAG	7	17.63	3.67	17.56	3.42,	t(72)=0.037, p=0.971, d=0.019
CCT 470-550 μm	Healthy	84	16.63	3.45	13.90	3.10	t(92)=5.395, p<0.001, d=0.832
	POAG	54	19.29	3.96	16.41	3.20	t(72)=6.738, p<0.001, d=0.800
CCT≥550 μm	Healthy	7	16,67	3.44	14.01	3.14	t(92)=2.438, p=0.031, d=0.807
	POAG	13	19.37	4.04	16.30	3.26	t(72)=2.132, p=0.043 d=0.836

GAT: Goldmann Applanation Tonometer; IPT: Icare PRO Tonometer; CCT: Central Corneal Thickness; POAG: Primary Open Angle Glaucoma; M: mean; n: frequencies; SD: standard deviation.

Table 6
Mean IOP comparison in healthy (n=94) and POAG eyes (n=74), between IPT and NCT, according to groups of CCT (μm)

		IPT			NCT		Statistics
		N	M	SD	M	SD	
CCT<470 μm	Healthy	3	13.69	3.84	12.60	3.31	t(92)=0.372, p=0.728, d=0.305
	POAG	7	17.63	3.67	17.34	3.90	t(72)=0.143, p=0.889, d=0.077
CCT 470-550 μm	Healthy	84	16.63	3.45	15.87	3.32	t(92)=7.450, p<0.001, d=0.224
	POAG	54	19.29	3.96	20.00	4.17	t(72)=0.907, p=0.366, d=0.175
CCT≥550 μm	Healthy	7	16,67	3.44	15.96	3.34	t(92)=0.392, p=0.702, d=0.209
	POAG	13	19.38	4.04	20.02	4.31	t(72)=0.391, p=0.699, d=0.153

NCT: Non-Contact Tonometer; IPT: Icare PRO Tonometer; CCT: Central Corneal Thickness; POAG: Primary Open Angle Glaucoma; M: mean; n: frequencies; SD: standard deviation.

Most of the previous comparative studies between instruments have concluded that IPT would produce slightly higher readings than the GAT.[15, 16, 25, 27, 28] On the other hand, Brusini et al. found agreement for glaucomatous eyes between IPT and GAT, using as a comparison term the GAT values corrected for the CCT.[5] Additionally, Gao et al. considered IPT a reliable alternative to GAT for patients in a low to moderate IOP range but not in patients with high IOP values.[24] Another study conducted by Tamçelik et al. showed that IPT tends to overestimate in the low GAT-measured IOPs, whereas it underestimates in high GAT-measured IOPs.[8] Our findings indicate that although IPT values cannot be considered similar and interchangeable with IOP measures determined by GAT, the behaviour of this tonometer is more similar to that of the NCT. We found an overall agreement between IPT and NCT measurements, in both healthy and POAG eyes. These results were similar to those found by Martinez-de-la-Casa et al in health eyes.[15] The interest in developing a tonometer that minimizes the limitations of GAT and can be used in an easy and interchangeable way has increased over the years. Despite the use of NCTs in clinical routine for such purpose, there is a lack of consensus with respect to the correlation observed between measurements obtained using this instrument and GAT. Indeed, while some studies demonstrated sub-optimal correlation values,[16] others demonstrated that NCT present an excellent agreement with GAT measurements, both in normal subjects and patients with glaucoma.[26]

The main purpose of this study was to validate the use of IPT, not only comparing its agreement with NCT and GAT but also by assessing how body position could influence its measurements in both healthy and POAG eyes. The mechanisms underlying the changes in IOP induced by alterations of the body posture are not fully understood. Compression or altered geometry of neck vessels, changes in episcleral venous pressure, choroidal vascular congestion, gravity, and shift of body fluid have been suggested to play a role.[9-11, 29, 30] This is the first study which splits sitting and dorsal decubitus position simultaneously in healthy and glaucomatous eyes using IPT to measure IOP. We found higher IOP values in dorsal decubitus in both groups of eyes, although the differences were not statistically significant in POAG eyes. With this approach, we could verify similar results as those found by TE. Lee et al., although they compared IPT measures in supine and lateral decubitus body positions.[29, 30]

According to our results, CCT seems to influence IOP readings with IPT, as it does in GAT and NCT, and should be considered when interpreting measurements in clinical routine. This positive and significant correlation noted between the GAT, NCT and IPT measurements and CCT indicates that as the value of CCT increases, IOP increase with all tonometers in study, being this relation more relevant with NCT measurements. A possible explanation could be the viscoelastic property of the cornea, which is deformed over about eight milliseconds in NCT, resulting in relatively greater stiffness than the GAT, where IOP measurement is relatively static.[16, 20, 26]

This is the first study that introduces the comparative analysis of IPT values with the other two tonometers over different groups of CCT based on its reference values. We concluded that for thin corneas (CCT<470 µm) there are no statistically significant differences between the IPT and the GAT in both groups of eyes. However, this may be due to the reduced sample size, and thus further studies may be required to clarify this issue.

The comparison of IPT with NCT, under the same analysis, showed statistical significant differences between the instruments in CCT values from 470-550 µm in healthy eyes. There was a systematic trend of IPT to give higher readings, showing higher means of IOP over a wide range of CCT and this difference was more notorious in relation with GAT.

The main study limitation is related to the fact that only healthy subjects or individuals with POAG were included. Therefore, our findings may not be applicable to eyes with other forms of glaucoma or ocular hypertension or other ocular abnormalities that may cause an elevation in IOP. Besides, each instrument used in this study was performed by a single observer, which means that three observers were responsible for the measurements and could not switch between them for using other tonometer. As so, although we decreased the risk of influencing measurements according to the previous values observed, we could not control and avoid potential bias induced by the interobserver variability. Another factor that possibly affected IOP overestimation of measures in comparison with the other two tonometers may be the no use of topical anesthesia for IPT measurements and the sequential measurements with the other instruments in a random sequence. Although IPT does not require topical anesthesia, unfamiliarity or anxiety related with the measurements in two different body positions with this tonometer may induce eyelid squeezing and increase IOP values. However, we believe the possibility of such anxiety-related bias was reduced by obtaining the other measurements in a randomized sequence.

In future studies, larger sample sizes could improve our knowledge and allow comparison with other groups (e.g. different ages, patients with previous corneal surgeries or ocular pathologies, or different subtypes of glaucoma). Additionally, more investigation is required to access whether posture-induced IOP changes are related to the onset or progression of glaucoma damage. As so, large population studies and meta-analysis are necessary to validate the IPT and to enable its standardization.

In conclusion, in our analysis we compared three instruments of tonometry, using as main goal the validation of IPT. The comparison with the gold-standard tonometer, the GAT, showed no interchangeable measures and we could not establish an agreement between the instruments. However, we found that measurements taken with IPT are quite in accordance with those obtained by NCT and we demonstrated an inter-device agreement. The measurements differ according to CCT variations, and thus pachymetry should always be taken into consideration.

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