A comparison of Icare PRO and Perkins tonometers in anesthetized children

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ABSTRACT

Aim: To compare intraocular pressure (IOP) measurements obtained with the Perkins applanation tonometer (PAT) and Icare PRO (ICP) rebound tonometer in anesthetized aphakic or strabismus children. Furthermore, intra-operator and inter-operator correlation have been evaluated, along with the effects of Central Corneal Thickness (CCT) on IOP measurements.

Methods: Seventy children undergoing examination under anesthesia with sevofluorane for aphakic patients and for surgery for strabismus were included. IOP have been measured twice immediately after anesthesia induction with both PAT and ICP in one eye, and by two different operators with both devices in the fellow eye. Furthermore, CCT was measured with ultrasound pachymetry Pacline (Optikon). Agreement between the devices measuremente has been evaluated using Bland-Altman analyses. Repeatability and reproducibility of the device have been evaluated with Intraclass Correlation Coefficient (ICC) with a value >0.75 associated with excellent reliability. The relationship between IOP and CCT has been evaluated with Spearman's correlation coefficient r and determination coefficient r^2.

Results: Mean difference in IOP measurements between ICP and PAT was 1.97 mmHg ± 1.23 mmHg ($p < 0.05$). This difference appeared to be higher in aphakic patients (mean difference 2.15 ± 1.35) than in patients undergoing strabismus surgery (mean difference 1.83 mmHg ± 1.12). ICC Intraclass Correlation Coefficient is used to evaluate repeatability and reproducibility, that are both high for PAT (repeatability 0.96, reproducibility 0.76) compared with ICP (repeatability 0.81, reproducibility 0.70). Correlation coefficient between CCT and IOP is 0.66 for both ICP and PAT.

Conclusion: ICP tends to overestimate IOP compared to PAT. Repeatability and reproducibility are both high for PAT as compared to ICP. A significant correlation between IOP and CCT for both instruments has been demonstrated.

Key Words: intraocular pressure, pediatric glaucoma, tonometer, Perkins, Icare

INTRODUCTION

Intraocular Pressure (IOP) measurement is fundamental in the diagnosis of aphakic glaucoma, occurring in up to 45% of children after surgery for congenital cataract (1,2). Goldmann applanation tonometer (Haag-Streit, Switzerland - GAT) is the gold standard in IOP measurement, yet its application is not always feasible in children due to lack of cooperation associated with the discomfort from the contact of the probe with the corneal surface and the need of using it in sitting position. Perkins applanation tonometer (Kowa Company, Japan - PAT) is a portable device that shares the same applanation principle used in GAT; it requires topical anesthesia and can be used both in sitting and supine position. It is the portable device providing the most accurate IOP measurement (also if compared to GAT) (3,4).

Icare PRO (ICP) is a tonometer based on the rebound principle, as a small probe ejected onto the corneal surface, after an instant impact, undergoes a deceleration whose value is used by a software to calculate the IOP. ICP has been shown to provide IOP measurements generally higher than those obtained with GAT (5).

In clinical practice, various tonometers can be used, and we have to switch the tonometer depending on the situation (e.g., in children, bed-ridden patients, and poorly compliant patients). Agreement and repeatability among devices have been reported previously but direct comparison between ICP and PAT are poor in literature, especially in pediatric patients.

The aim of the present study is to compare IOP measurements obtained with ICP and PAT. According our opinion this comparison can be useful because of the lack of standardization in IOP measurement in children under anesthesia. The IOP measurement in some clinical situation (for example in aphakic children) it's very critical and few variation of IOP value could influence clinical decision.

In addition, the correlation between Central Corneal Thickness (CCT) and IOP measurements obtained with both devices has been analyzed.

MATERIALS AND METHODS

This prospective observational study has been held between December 2016 and June 2017 at the University Eye Clinic of the San Giuseppe Hospital (Milan, Italy). Patients were recruited from those referred to our Clinic for scheduled surgery for strabismus and for examination under anesthesia after phacoaspiration for congenital cataract. All patients enrolled were aged under 10 years of age. The youngest child is 2 months aged. Exclusion criteria were: corneal astigmatism ≥ 2 D (to avoid any cases of corneal ectasia) and infectious-inflammatory diseases evaluated during pre-operatory examination. Participation to the study has been proposed to parents/tutors during pre-operatory examination. Our study has been approved from the local ethic committee and abides by the tenets laid down in the declaration of Helsinki.

IOP measurements were obtained immediately after anesthesia induction with sevofluorane. The measurement were taken by P.N. and M.S. two pediatric ophthalmologist with more than 30 year experience. In the first eye, a single operator took measurements using both PAT and ICP to evaluate intra-operator repeatability. In the second eye, two different operators took independent measurements using PAT and ICP respectively to evaluate inter-operator reproducibility. In order to avoid confounding factors the order of devices, the operators and the eyes was randomized.

PAT and ICP were calibrated according to the manufacturer's instruction. For PAT, one IOP measurements was recorded. For ICP, only measurements resulting as "deviation: ok" in the device's display were recorded, in order to evaluate just the measurements whose deviation was < 15%, as resulting from the manufacturer's instructions. Ultimately, before surgery, CCT has been measured with ultrasound pachymeter Pacline (Optikon); three different measurements have been recorded, along with their mean.

The main variable of our measurements is the difference between the measurements with both PAT and ICP. Agreement between the devices has been evaluated using Bland-Altman analyses, with 95% limits of agreement (7). Repeatability and reproducibility have been evaluated with Intraclass Correlation Coefficient (ICC) in a causal effects regression model (8). ICC <0.40 is conventionally

considered to indicate poor reliability, while ICC >0.75 is associated with excellent reliability of the device. The relationship between IOP and CCT has been evaluated with Spearman's correlation coefficient *r* and determination coefficient r^2.

All statistical analyses were performed using Microsoft Excel 14.0.0 and GraphPad Prism 7. A $p< 0.005$ has been considered statistically significative.

RESULTS

A total of 70 patients aged from 2 months to 10 years were recruited, 41 (58.57%) of them undergoing strabismus surgery (S), 29 (41.43%) of them undergoing examination under sedation after phacoaspiration for congenital cataract (A). Mean age of enrolled patients was 4.30 ±4.41 (range 0-10) years. Mean IOP was 13.40 ± 1.74 mmHg (range: 9.8 – 22.1) using ICP and 11.43 ± 1.72 mmHg (8 -16) using PAT. Results in patients suffering from strabismus and from congenital cataract are shown in table 1.

Table 1. Mean IOP measurements obtained with Icare PRO (ICP) and Perkins Applanation Tonometer (PAT).

	Total	**S**	**A**
ICP (*mmHg*)	13.40 ± 1.74	13.35 ± 1.62	13.45 ± 1.90
Range	9.8 – 22.1	9.8 – 17.7	9.9 – 22.1
PAT (*mmHg*)	11.43 ± 1.72	11.52 ± 1.78	11.29 ± 1.64
Range	8 – 16	8 - 16	8 – 15

S: patients undergoing surgery for strabismus. A: aphakic patients undergoing examination.

Difference between measurements carried with ICP and PAT is 1.97 (SD ± 1.23 mmHg, upper LoA 4.38 , lower LOA -0.44). The difference is lightly lower in patients undergoing strabismus surgery (1.83 ± 1.12 mmHg, , upper LoA 4.03 , lower LOA -0.37), higher in aphakic patients undergoing examination under sedation (2.16 ± 1.35 mmHg, upper LoA 4.80 , lower LOA -0.49) (table 2).

Table 2. Mean difference between IOP measurements obtained with ICP and PAT. LoA Limits of Agreement.

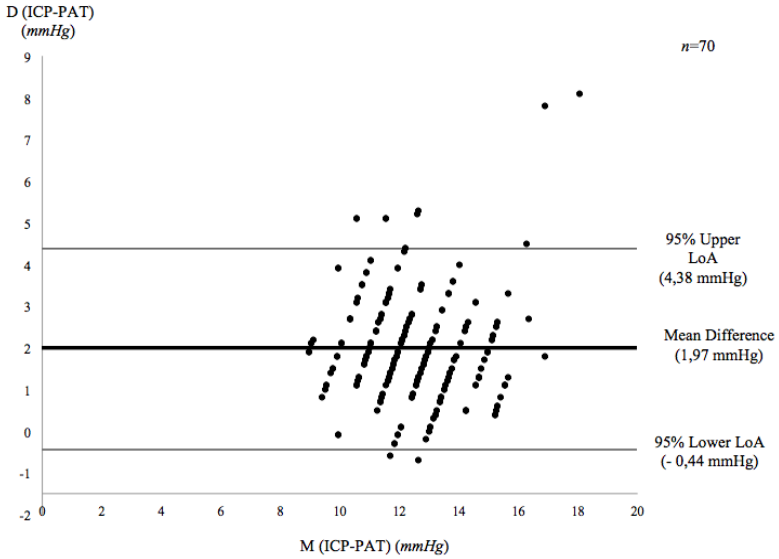
	Total	**S**	**A**
Difference ICP-PAT (*mmHG*)	1.97 ± 1.23 *p < 0.05*	1.83 ± 1.12 *p < 0.05*	2.16 ± 1.35 *p < 0.05*
95% LoA (*mmHg*)			
Upper LoA	4.38	4.03	4.80
Lower LoA	-0.44	-0.37	-0.49

S patients suffering from strabismus. A aphakic patients undergoing examination under sedation.

Mean difference between measurements, along with 95% confidence interval. Limits of Agreement (LoA) as evaluated with Bland-Altmann plot (figure 1, figure 2, figure 3).

Figure 1.

Bland-Altmann plot. Agreement between IOP measurements with ICP and PAT in overall



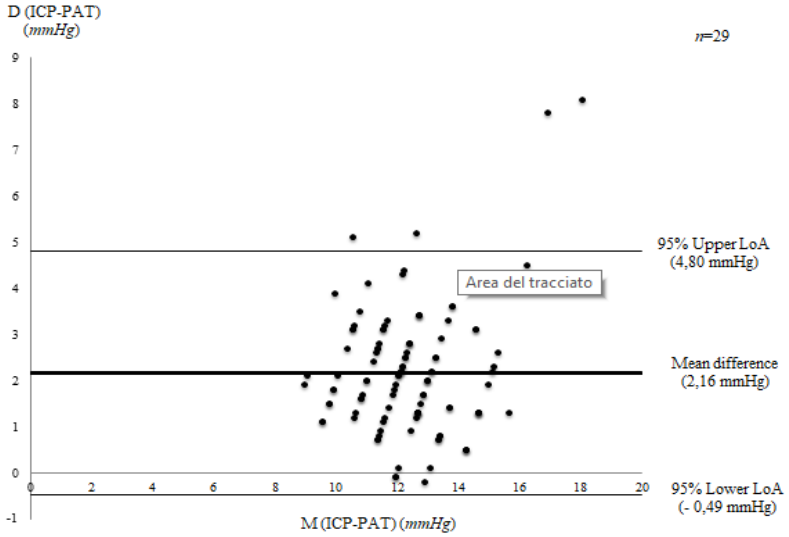
136 cases

137 *D difference, M mean.*

138

139 Figure 2

140 Bland-Altmann plot. Agreement between IOP measurements with ICP and PAT in aphakic patients



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142 *D difference, M mean.*

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144

145 Figure 3

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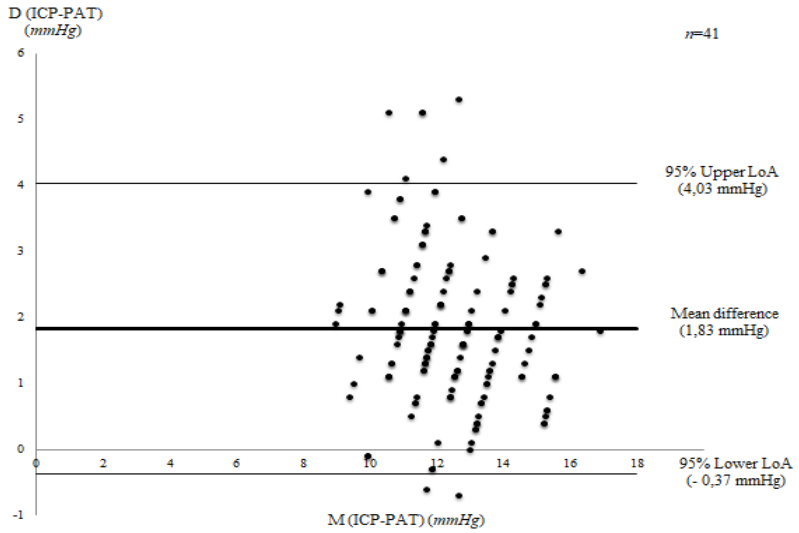
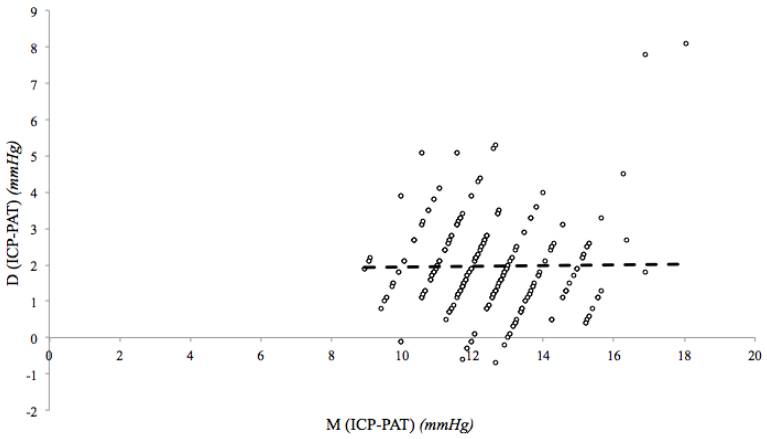
147 Bland-Altmann plot.Agreement between IOP measurements with ICP and PAT in strabismus group



D difference, M mean.

Linear regression analysis of the difference between IOP measurements of both devices shows a non-statistically significant (p=0.8273) tendency to having an increase in measurements' difference with increase of mean value of IOP obtained with both devices, with regression line $y = 0.0098x + 1,8443$, and $r^2 = 0.0002$. Results are shown in figure 4.

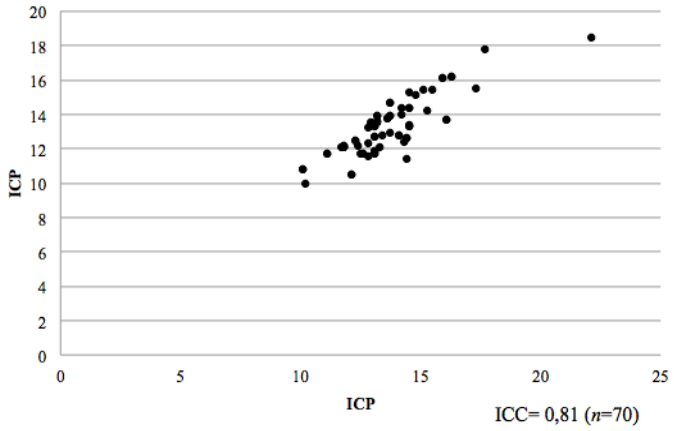
Figure 4. Regression analysis of mean IOP measurements and their difference



$r^2 = 0.00017$
r=0.013
P=0.8273

Intra-operator repeatability of measurements obtained with ICP is characterized by ICC = 0.81 (figure 5), while using PAT ICC = 0.96 (figure 6). For what concerns inter-operator reproducibility, ICC = 0.70 (figure 7) with ICP and ICC = 0.76 with PAT (figure 8).

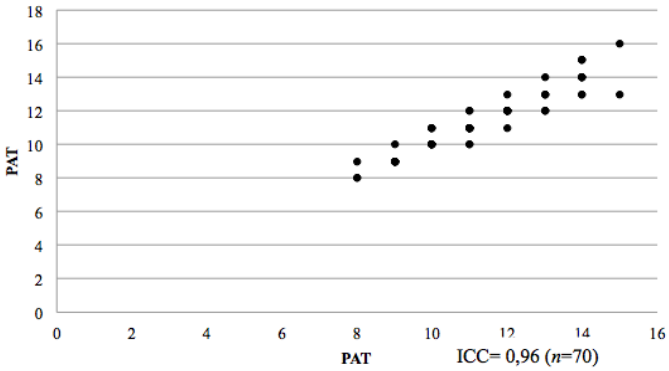
Figure 5. Intra-operator repeatability with ICP.



x axis: first measurement using ICP, y axis: second measurement using ICP

ICP: I Care PRO, ICC: Intraclass Correlation Coefficient

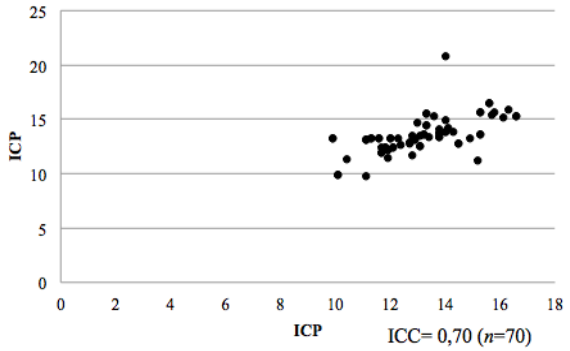
Figure 6. Intra-operator repeatability with PAT.



x axis: first measurement using PAT, y axis: second measurement using PAT

PAT: Perkins applanation tonometer, ICC: Intraclass Correlation Coefficient

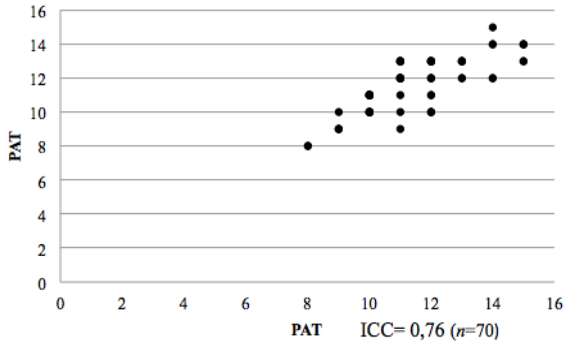
Figure 7. Inter-operator reproducibility with ICP.



x axis: first measurement using ICP, y axis: second measurement using ICP

ICP: I Care PRO, ICC: Intraclass Correlation Coefficient

Figure 8. Inter-operator reproducibility with PAT.



x axis: first measurement using PAT, y axis: second measurement using PAT

PAT: Perkins applanation tonometer, ICC: Intraclass Correlation Coefficient

Table 3 shows the difference of ICC for both devices in patients suffering from strabismus and in aphakic patients.

Table 3.

	Total	**S**	**A**
Repeatability (*ICC*)			
ICP	0.81 *(p<0,001)*	0.77 *(p<0,001)*	0.80 *(p<0,001)*
PAT	0.96 *(p<0,001)*	0.97 *(p<0,001)*	0.95 *(p<0,001)*
Reproducibility (*ICC*)			
ICP	0.70 *(p<0,001)*	0.72 *(p<0,001)*	0.64 *(p<0,001)*
PAT	0.76 *(p<0,001)*	0.83 *(p<0,001)*	0.63 *(p<0,001)*

Table 3. Repeatability and reproducibility evaluated with ICC for ICP and PAT. S, patients suffering from strabismus. A, aphakic patients undergoing examination under sedation.

Spearman correlation coefficient *r* between measurements obtained with ICP and CCT is $r = 0.66$; the same value has been observed in measurements obtained with PAT ($r = 0.66$). Data concerning *r* in patients' subgroups are shown in table 4, along with determination coefficient r^2.

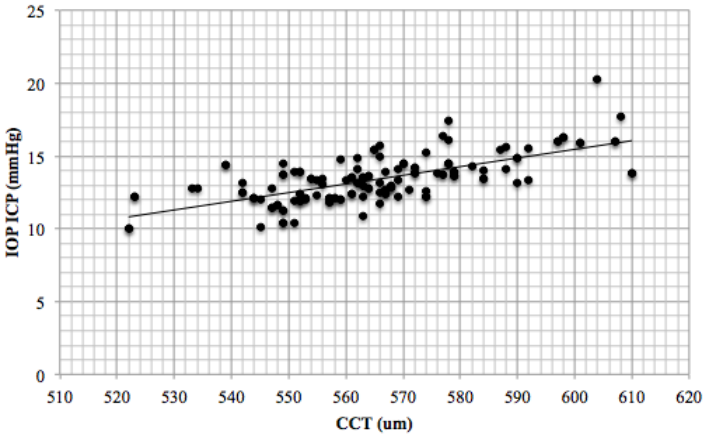
Table 4.

	Total	**S**	**A**
CCT-ICP			
r	0.66	0.64	0.67
r^2	0.43	0.41	0.45
	p<0.001	*p<0.001*	*p<0.001*
CCT-PAT			
r	0.66	0.70	0.62
r^2	0.44	0.48	0.38
	p<0.001	*p<0.001*	*p<0.001*

Table 4. Correlation between tonometric measurements obtained with ICP and PAT and central corneal thickness. S, patients undergoing surgery for strabismus; A, aphakic patients undergoing examination under sedation.

Correlation between measurements obtained with both devices and CCT are graphically shown in figure 9-10.

Figure 9. Correlation between tonometric measurements obtained with ICP and CCT

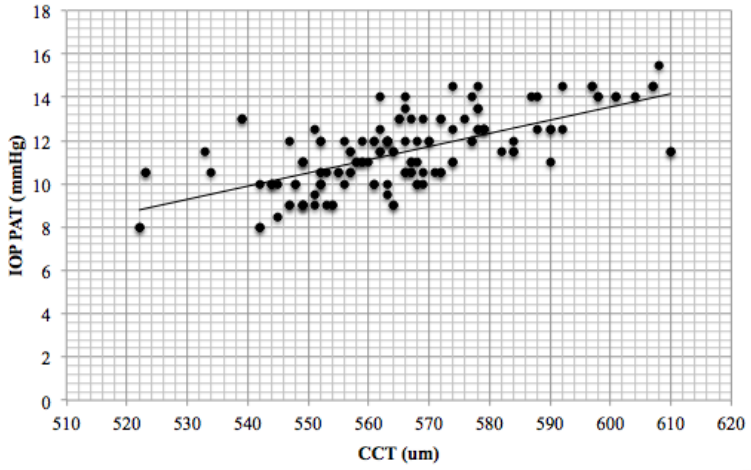


r=0.66

r^2=0.43

ICP: I Care PRO, CCT: Central Corneal Thickness

Figure 10. Correlation between tonometric measurements obtained with PAT and CCT.



r= 0.66

r^2= 0.44

PAT: Perkins applanation tonometer, CCT: Central Corneal Thickness

DISCUSSION

There are few studies on the direct comparison between different portable tonometers, since the performance of portable tonometers was more frequently compared to a non-portable Goldmann (GAT) tonometer, which is nowadays the gold standard for measuring the IOP. Shortly after its development, during the '70s and' 90s, the tonometric values detected with PAT were compared with those obtained with GAT in numerous studies (3,7). All these studies have established a good correlation between the pressure values detected with these two instruments, with a coefficient of correlation r which is near 0.91. In 2014 Arora R. et al. have established that the mean difference between the tonometric values measured with GAT and PAT is near 0.22 ± 0.44 mmHg (8). This good correlation has also been demonstrated in patients with edematous cornea (9).

Reports that compare the tonometric values obtained with ICP compared to those obtained with GAT are also numerous. These studies have been performed mainly on the adult population, and they are quite consistent in underline the tendency of ICP to overestimate the IOP compared to GAT (10, 11). In general, the mean difference between the two instruments is

around 1.0 ± 2.5 mmHg. On the other hand, it has been shown that ICP tends to underestimate the values of IOP compared to GAT in some cases of high pressure value (12, 13).

Furthermore, Icare TA01i has been shown to be less reliable than Icare PRO in comparison with GAT. Moreno-Montanes J. et al. showed that 79% of patients whose IOP had been evaluated with ICP had values with a difference less than 3 mmHg compared to GAT, while only 67% of patients whose IOP had been evaluated with Icare TA01i had values less than 3 mmHg (14).

In evaluation of these data, PAT is a closer tool to GAT precision, if compared to ICP, but is more difficult to use as a portable tonometer in awake children. In fact, the use of PAT requires as supplements fluorescein and local anesthetic, because of the contact between the measuring cone and the cornea. These aspects make PAT an instrument that can create discomfort in pediatric patients. All in all, ICP is the easiest tonometer because it is easy to use in pediatric patient. For these reason a comparison between the two devices is very useful.

In our patients' group, mean IOP values of 13.40 ± 1.74 mmHg and 11.43 ± 1.72 mmHg were established with ICP and with PAT.

The mean difference between the tonometric values measured with ICP and PAT is statistically significant ($p < 0.05$) and is equal to 1.97 ± 1.23 mmHg. This is in agreement with the known literature about the comparison between applanation tonometry and rebound tonometry, even if there are few works about this. The first study comparing the portable tonometers was written in 2006 by Garcia-Resua C. et al.: they measured the tonometric values in a population of 65 subjects of young adult with PAT and with Icare TA01i, a device that can't be used in a supine position. In these subjects, a tendency of Icare TA01i to overestimate the IOP values detected with PAT (9) was observed.

In 2013 Li Y. et al. observed an average difference of 2.0 ± 1.8 mmHg in the tonometric values measured with Icare TA01i and PAT. They found that 95% limit of the agreement between the 2 methods distributed between -1.6 to 5.6 mm Hg (4). The first comparative evaluation between ICP and PAT was carried out by Jablonski KS. et al. in 2013: an average difference between the pressure

values measured in the supine with ICP and with PAT of 0.1 with 95% limits of agreement of -3.6 to 3.8 mm Hg (16). In 2015, Nakakura S. et al. confirmed these results, demonstrating a mean difference between these two instruments of 0.43 ± 2.28 mm Hg with 95% limits of agreement -4.04 to 4.90 mm Hg (3). More recently, Borrego-Sanz L. et al. showed a difference near to 0.42 ± 3.69 mmHg with 95% limits of agreement 7.7 to -6.8 mm Hg between the pressure values measured with ICP and with PAT in subjects with congenital glaucoma (5).

Clinical evaluation in our patients shows that the difference between tonometric values measured with ICP and PAT is significantly higher in aphakic patients (2.16 ± 1.35 mmHg) than those with strabismus (1.83 ± 1.12 mmHg). This indicates a tendency of ICP to provide significantly higher tonometric values in aphakic patients than in patients with strabismus.

Determination of IOP is influenced by several corneal properties including elasticity, rigidity and central thickness (17). Surgical intervention on corneal tissue induces tissue structural changes and alter the corneal biomechanical properties. It is well known that central corneal thickness (CCT) increased after congenital cataract surgery (18, 19, 20). In contrast, limited information is available on corneal biomechanical properties. According to Faramarzi et al (21) Corneal Hysteresis (CH) decreased permanently after lensectomy. Simsek et al reported that CH was lower in aphakic eyes but there is no difference in Corneal Resistence Factor (CRF) among normal and aphakic eyes (19).

To our knowledge, there are studies that analyse difference in terms of agreement between ICP and PAT in of post-surgical aphakia. Probably, the difference that we found is due to the different response modality of the rebound tonometer on aphakic eye, in which the cornea has surgical alterations (change in CCT, CH and CRF), compared to a patient suffering from strabismus, in which the cornea has no post surgical changes.

Jorge et (22) found CH to be correlated with rebound tonometer IOP value. Also Chui and colleagues (23) found rebound tonometry measurement to be affected by CH and CRF; The same results were reported by Shin et al. (24) in a study including patients with glaucoma. To our

knowledge the only study that compare the effect of CH and CCT on IOP value obtained with rebound tonometry and applanation tonometry was conducted by Brown et al. (25).

According to their result thinner CCT was significantly associated with lower value of IOP using both Icare and GAT but GAT measurement are affected greater. Moreover lower CH was associated with higher IOP using Icare and GAT but GAT was more affected by CH than Icare. Then the difference between GAT and Icare was greatest with higher CCT and lower CH.

Despite few studies and sometimes controversial results these data could explain the greater difference between ICP and PAT in our study and the tendency to have higher IOP value with ICP in aphakic eye.

Our study shows the repeatability and reproducibility of ICP and PAT, with ICC values ranging from 0.63 to 0.97. . These results confirm the previously reported good repeatability and reproducibility data of the ICare systems.(26, 27).

However, most of the published studies report IOP values obtained in a sitting position.

In 2015 Nakakura S. et al. shown that correlation values tend to be lower in the supine position (3).

Finally, there is a statistically significant positive correlation between the tonometric values measured with both the ICP and PAT methods, and the central corneal thickness values, with a coefficients of correlation r variable in a range from 0.62 to 0.70. This indicates that the measured tonometric values tend to increase as the CCT increases.

Lots of papers analyzed the correlation between the corneal characteristics and the IOP values measured by the various instruments, reporting very heterogeneous results. Nakakura S. et al. (3) and Jablonski KS. et al. (16) did not demonstrate a correlation between CCT and IOP values measured with PAT and ICP, either supine or in a sitting position . Also Borrego-Sanz L. et al. (5), in the comparison between PAT and ICP in a pediatric population with congenital glaucoma, did not report a significant correlation between tonometric values measured with the two instruments and the CCT. Li Y. et al. (4) has established that both instruments can give higher IOP values with increasing corneal thickness, with an increase that tends to be higher for Icare TA01i compared to

PAT. In the patients of our study, there are no statistically significant differences related to the correlation between CCT and IOP using ICP rather than PAT.

The result of this study is very difficult to generalise to clinic sitting tonometry because the IOP is measured in supine position and under gas anaesthesia, both these condition affect IOP value. It is accepted that IOP increase in supine vs sitting position (28). It would have been interesting a comparison between supine and sitting IOP but patient in this study were undergoing sedated because ophthalmic examination could not be conducted while they were awake. A limit of this study is the influence of sevofluorane on IOP values. It is known that sovofluorane affects IOP value with a reduction up to 15% in 8 minutes following induction of anesthesia (6). We can't rule out IOP change because of anesthetic, although the measurements were made immediately after induction in order to limit as much as possible the effects of sevofluorane on the IOP.

CONCLUSION

The results obtained demonstrate that ICP can overestimate IOP values, with a statistical significant difference compared to PAT. This higher measurement was already known in previous works, and tends to be higher with higher IOP values and in patients with post-surgical aphachia after congenital cataract aspiration. Both devices show good repeatability and reproducibility of measurements, ensuring a high reliability of the measured values. It should be considered, although IOP values obtained tend to be on average 1.97 mmHg higher than PAT, which is known to be similar to GAT, the current gold standard for measuring IOP.

We also demonstrated a statistically significant correlation between the CCT values and IOP value, with a direct proportionality between the two parameters. Nowadays, in our knowledge, some data about this are extremely heterogeneous, probably due to the various visco-elastic properties of the cornea, which may influence IOP value. Further analyzes are necessary in order to be able to correctly interpret the various corneal parameters and their influence on tonometry.

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Table 1. Mean IOP measurements obtained with Icare PRO (ICP) and Perkins Applanation Tonometer (PAT).

	Total	**S**	**A**
ICP (*mmHg*)	13.40 ± 1.74	13.35 ± 1.62	13.45 ± 1.90
Range	9.8 – 22.1	9.8 – 17.7	9.9 – 22.1
PAT (*mmHg*)	11.43 ± 1.72	11.52 ± 1.78	11.29 ± 1.64
Range	8 – 16	8 - 16	8 - 15

S: patients undergoing surgery for strabismus. A: aphakic patients undergoing examination under sedation.

Table 2. Mean difference between IOP measurements obtained with ICP and PAT. LoA Limits of Agreement.

	Total	**S**	**A**
Difference ICP-PAT (*mmHG*)	1.97 ± 1.23 *p < 0.05*	1.83 ± 1.12 *p < 0.05*	2.16 ± 1.35 *p < 0.05*
95% LoA (*mmHg*)			
Upper LoA	4.38	4.03	4.80
Lower LoA	-0.44	-0.37	-0.49

S patients suffering from strabismus. A aphakic patients undergoing examination under sedation.

Table 3.

	Total	**S**	**A**
Repeatability (*ICC*)			
ICP	0.81 *(p<0.001)*	0.77 *(p<0.001)*	0.80 *(p<0.001)*
PAT	0.96 *(p<0.001)*	0.97 *(p<0.001)*	0.95 *(p<0.001)*
Reproducibility (*ICC*)			
ICP	0.70 *(p<0.001)*	0.72 *(p<0.001)*	0.64 *(p<0.001)*
PAT	0.76 *(p<0.001)*	0.83 *(p<0.001)*	0.63 *(p<0.001)*

Table 3. Repeatability and reproducibility evaluated with ICC for ICP and PAT. S, patients suffering from strabismus. A, aphakic patients undergoing examination under sedation.

Table 4.

	Total	**S**	**A**
CCT-ICP			
r	0.66	0.64	0.67
r^2	0.43	0.41	0.45
	p<0.001	*p<0.001*	*p<0.001*
CCT-PAT			
r	0.66	0.70	0.62
r^2	0.44	0.48	0.38
	p<0.001	*p<0.001*	*p<0.001*

Table 4. Correlation between tonometric measurements obtained with ICP and PAT and central corneal thickness. S, patients undergoing surgery for strabismus; A, aphakic patients undergoing