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Assessing biomechanical corrections: A comparison between Corvis ST and ICare tonometer for intraocular pressure measurement

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ABSTRACT

This study aims to compare the accuracy of IOP measurements in pediatric patients using two different tonometers: ICare PRO and Corvis ST (CST). However, the choice of tonometers may vary between screening centers, depending on patient suitability. To address this, we enrolled 30 patients with retinopathy of prematurity over a period of 33 days for experimentation. A head-to-head comparison revealed a strong correlation between the Corvis ST (CST) and ICare PRO tonometers ($r = 0.867$). Furthermore, no significant difference was observed in IOP values obtained with the Corvis ST (CST) and ICare PRO tonometers ($P > 0.05$). However, it is worth noting that the Corvis ST (CST) measurements were significantly higher than those obtained from the ICare PRO tonometers ($P < 0.05$). In conclusion, this study demonstrates that the Corvis ST (CST) tonometer exhibits a high correlation coefficient comparable to that of the ICare PRO tonometer, making it a reliable tool for assessing IOP in pediatric patients. These findings are crucial for enhancing our understanding of the physiological function of melatonin in the eye and its potential to target melatonin receptors and their complexes for addressing various eye pathologies.

1. Introduction

While it is particularly important to determine IOP in ocular diseases, especially in patients who have undergone surgical procedures, measuring intraocular pressure (IOP) can sometimes be difficult and inaccurate (Hong et al., 2013). Tonometers are designed to provide accurate IOP measurements. Applanation tonometry is considered the gold standard for measuring IOP in adults. Several attempts have been made to improve the accuracy of IOP assessments in pediatric patients; however, the use of an applanation tonometer is not always feasible in children (Brazuna et al., 2022).

Elevated IOP has been identified as the primary risk factor for the development and progression of glaucoma. Therefore, the availability of accurate, reliable, reproducible, non-invasive, easy-to-use, and efficient methods for determining this parameter is of paramount importance for the clinical assessment of patients with glaucoma or suspected glaucoma. Currently, Goldmann applanation tonometry (GAT) remains the most commonly used method for measuring IOP. However, several studies have highlighted the limitations of this technique, particularly its reliance on corneal biomechanical properties. In recent years, several new tonometers have been developed with the aim of overcoming the limitations of GAT, including its dependence on corneal central thickness and other morphometric characteristics of the cornea.

However, to date, there is no tonometer available that provides measurements completely independent of corneal properties (Garcia-Feijoo et al., 2015; Smedowski et al., 2014). In this study, IOP was measured twice immediately after anesthesia induction using both the ICare PRO tonometer (ICare) and the Corvis ST (CST) in one eye, while two different operators used both devices to measure IOP in the fellow eye (Eliasy et al., 2018).

A recent development in tonometry is the Corvis ST (CST), which combines a Scheimpflug camera with a tonometer and provides various parameters related to corneal deformability based on the cornea's response to an air puff. Corneal thickness not only influences IOP measurements by tonometers but also acts as an independent risk factor for the development and progression of glaucoma. However, many studies focus solely on central corneal thickness, without considering the entire cornea (Lanza et al., 2018; Serafino et al., 2020).

The Corvis ST tonometer, similar to the ICare PRO tonometer, is a portable instrument based on similar principles. The Corvis ST tonometer features a liquid crystal display with markings of *s5%, 10%, 20%, and >20%, which indicate the coefficient of variation of the averaged readings. The corneal contact area for the Corvis ST tonometer is 2.72 mm^2, whereas for the ICare PRO tonometer, it is 3.06 mm^2. Since obtaining accurate IOP measurements in both adults

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Fig. 1. Corvis ST tonometer.

and children is challenging, we deemed it necessary to conduct a comparative study to assess the accuracy of IOP measurements using the ICare PRO and Corvis ST tonometers. In this study, we utilized the ICare PRO tonometer as our standard applanation tonometer (Halim, 2017; Samy et al., 2021).

The primary focus of this work is to compare the intraocular pressure measurements obtained by the Corvis ST and ICare PRO tonometers (ICare) in patients, as well as to explore the relationship between each tonometer and central corneal thickness. Proper measurement of IOP is one of the tools for glaucoma patient follow-up; however, many factors can influence the measurement accuracy. The factors that influence IOP measurements are mostly central corneal thickness (CCT), biomechanical properties of the cornea (tissue elasticity derivatives), and corneal astigmatism. The remaining sections of this paper are structured as follows: Section 2 provides details about the materials and methods employed in this study. In Section 3, we present and discuss the experimental results. Finally, Section 4 offers the conclusion and outlines future directions for this study.

2. Materials and methods

A cross-sectional study was conducted, following the approval of the study protocol and methods by the ethical committee at Alnahreen Clinical Center. A total of 30 volunteers were prospectively selected for the study, with their eyes chosen from the general ophthalmology service of the clinic. The data collection period spanned from August 2022 onwards. Informed consent was obtained from all participants, and one eye per patient was randomly selected for inclusion in the study, using a software called www.Randomization.com. If only one eye was eligible, it was included in the study (Hong et al., 2013; Brazuna et al., 2022; Giavarina, 2015).

Each eye underwent corneal curvature examination using the topography pentacam. Two sets of measurements with good quality were taken, adhering to the instrument's scale, and the average of these values was selected for statistical analysis. The comparison between the two tonometer types, namely ICare PRO and Corvis ST, was performed using the paired t-student test for paired data, and Bland–Altman plots were generated.

The microanatomy of the cornea forms the basis of corneal biomechanics, with collagen serving as the primary structural component and ground substance of both the cornea and sclera (Garcia-Feijoo et al., 2015; Giavarina, 2015). Collagen provides high tensile strength and a protective coating for the globe. Fibril packing anisotropy within the cornea may impact tissue transparency and refractive index. From a biomechanical perspective, the higher packing density of stress-bearing collagen fibrils in the stromal tissue of the parapapillary cornea may be essential for maintaining corneal strength and curvature in a region of reduced tissue thickness. This section will provide an overview of the tonometer types highlighted in this study and describe the collection and analysis of patients' data.

2.1. Specimen preparation

In this section, we will describe the two types of tonometers used for measuring corneal deformation response. The first one is the Corvis ST (CST), which is a novel non-contact tonometer designed to investigate the dynamic reaction of the cornea to an air impulse. The CST combines a non-contact tonometer with a high-speed camera that captures a series of horizontal Scheimpflug images during corneal deformation caused by an air puff jet. A high-speed Scheimpflug camera records the deformation process with full corneal cross-sections, which are then displayed in slow motion on a control panel (see Fig. 1). The camera captures 4330 images per second, covering a horizontal distance of 8.5 mm. The image resolution can reach up to 640 × 480 pixels. Fig. 2 illustrates a representative output from the Corvis ST, displaying several parameters related to the corneal deformation process.

During the corneal deformation response, a precisely metered air pulse causes the cornea to applanate, resulting in the first applanation. The cornea continues to move inward until it reaches the point of highest concavity. As the cornea is viscoelastic, it rebounds from this concavity to another point of applanation, known as the second applanation, and then returns to its normal convex curvature. Additionally, an air tonometer and pachymeter were used in this study to provide measurements of corneal biomechanical properties, as shown in Fig. 1.

During corneal deformation in response to the air impulse, the cornea undergoes a process of first and second flattening. The tonometer apparatus measures various parameters related to corneal deformability, including the time, speed, and amplitude of the first and second applanations, as well as the maximum concavity and the amplitude of the deformation.

Furthermore, this tonometer is equipped with an ultra-fast speed Scheimpflug camera that collects 4330 frames per second. It provides real-time video footage of the anterior chamber during the corneal deformation process, as depicted in Fig. 2. This camera allows for a detailed visualization of the dynamic changes occurring within the cornea during the measurement.

The Icare PRO tonometer is an upgraded version of the original Icare tonometer, employing the induction rebound principle to provide more precise and rapid measurements. Unlike the original model, the Icare PRO is disposable and requires minimal contact with the corneal surface, eliminating the need for anesthesia. For enhanced accuracy, it is recommended to take a sequence of seven IOP readings, with the mean value calculated as the final measurement. After each individual reading, the result is displayed, accompanied by an indicator

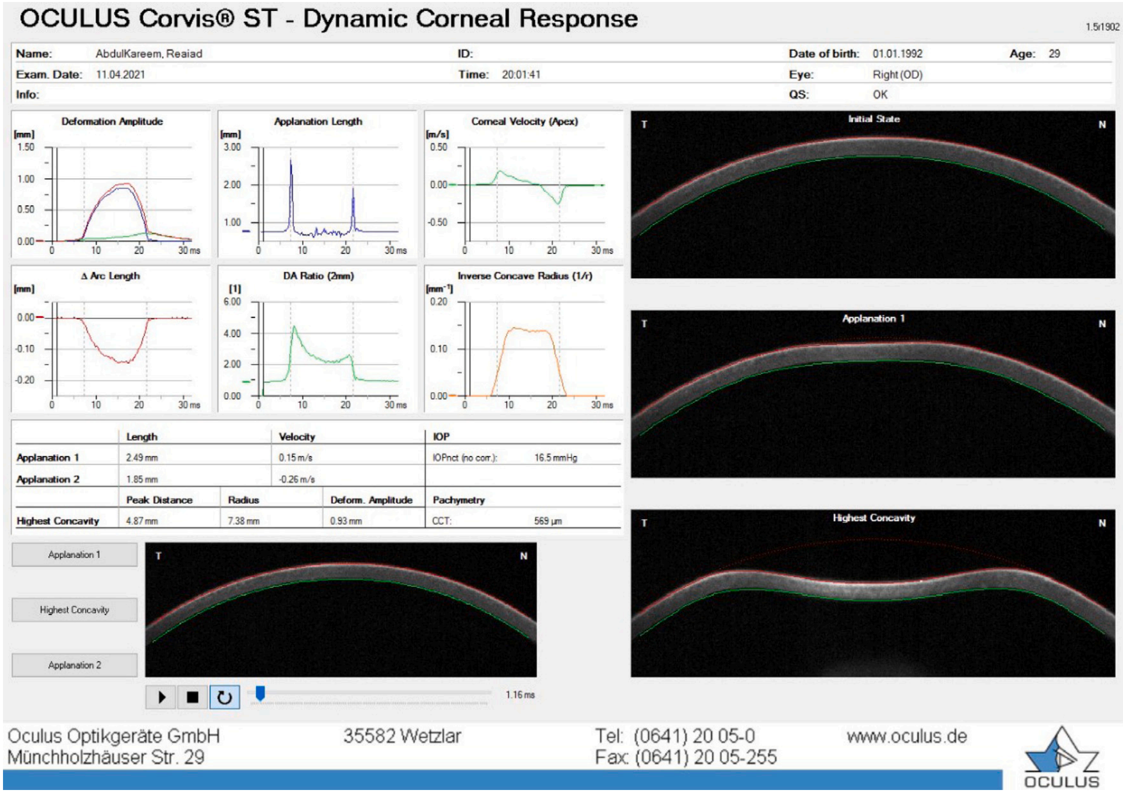

Fig. 2. Corvis STC tonometer results chart. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

Table 1
Demographic characteristics of cases that used in this study.

Patient (n = 30)	Age	ICare Pro	Corvis STC	IOP
M = 50% F = 50%	Mean = 45.9 Min = 27 Max = 64	SD = 0.025 Upper = 0.852 Lower = −0.802	SD = 2.43 Upper = 19.06 Lower = −14.20	Max IOP = 23.5 Min IOP = 10.5

of measurement reliability. If the variation among measurements is within normal limits, the numerical deviation is shown in green. However, if the variation is somewhat high, it is displayed in red. The tonometer automatically records and stores all measurements, which can be accessed directly or transferred to a computer device via a USB port. Fig. 3 illustrates the first type of Icare PRO tonometer. Due to its portability, ease of use, ability to perform tonometry in multiple positions, good reliability, and anesthesia-free operation, the Icare tonometer is increasingly employed in eye clinics worldwide. It is particularly valuable for patients who cannot tolerate Goldmann applanation tonometry (GAT). In cases where IOP measurement is challenging in a clinical setting, the Icare PRO tonometer can provide a reasonable estimate of IOP in patients with known or suspected glaucoma.

2.2. Patient data

A total of 60 eyes were included in the examined group of patients, who were recruited from the Ophthalmology Clinic of Alnahrain Center in Ramadi, Anbar, western Iraq. The selection of patients and the analytical approaches employed in this study were aligned with the research objectives and the inter-ocular correlation of the study variables. The Icare PRO rebound tonometer typically consists of a handheld device with a display screen and control buttons. The device is designed to be held in the hand during the measurement process. where, the screen is used to show the measurement results and other relevant information.

Regarding the agreement of IOP measurements between tonometers, the specific variables related to each eye were not the focus of interest. Therefore, the most appropriate statistical analysis was conducted at the individual eye level. Consequently, both eyes were included in the analysis to assess the agreement between the tonometers used. It is worth noting that the cohort of diseased eyes exhibited predominantly asymmetrical characteristics.

The available data used for this study can be found in Table 2, which is provided in the Appendix.

3. Results comparison and discussion

For this study, informed consent was obtained from all patients included in the research. A total of 60 eyes belonging to 30 volunteer patients met the inclusion criteria and did not meet any of the exclusion criteria. The demographic characteristics of the patients included in the study are summarized in Table 1.

The sample consisted of an equal distribution of men and women, with 50% of the sample representing each gender among the 30 patients. The mean age of the patients included in this study was 45.96 years. Importantly, measurements could be successfully obtained with the different devices for all patients, ensuring complete data collection.

Fig. 3. Show the image take from Icare PRO rebound tonometer manual of the correct device layout for a successful measurement.

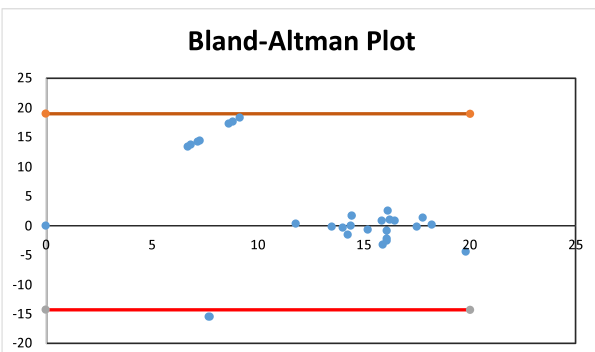

Fig. 4. Bland and Altman plot for data from the Table 1, with the representation equation from −1.96 to +1.96.

Table 2
Patient data for this study.

Patient	Sex	Age	Icare S.E		Corvis CCT			
			R	L	R		L	
					Cor	No	Cor	No
P1	M	53	0.25	0.50	14.3	15.5	17.5	19.5
P2	F	52	0.25	0.75	14.3	15.5	0.0	15.0
P3	M	36	0.75	−0.25	13.4	12.5	13.6	13.0
P4	M	34	0.50	−0.25	14.9	17.0	15.5	17.5
P5	F	50	−1.00	−0.25	15.7	16.5	16.5	18.0
P6	F	48	0.50	−0.00	13.8	13.5	14.2	13.5
P7	F	45	0.50	0.25	15.0	17.0	17.2	19.5
P8	M	60	0.50	1.00	16.8	18.5	15.7	17.5
P9	F	55	−0.00	0.00	16.3	15.0	15.4	14.0
P10	F	55	−0.00	0.50	17.4	19.5	14.9	16.5
P11	F	35	−0.25	−0.75	14.4	14.5	14.4	15.0
P12	M	64	−4.00	−3.75	17.6	19.0	22.0	23.5
P13	M	52	0.50	0.75	12.0	10.5	11.6	10.5
P14	F	42	0.25	0.50	17.6	18.5	0.0	16.0
P15	F	32	−1.00	−0.75	17.4	17.0	17.6	17.5
P16	F	51	−1.75	−1.50	18.5	18.5	17.1	18.0
P17	F	48	0.25	0.50	15.3	15.0	13.6	13.5
P18	M	45	−0.00	0.25	0.00	16.0	15.4	16.0
P19	F	27	−0.75	−1.00	0.00	18.0	15.5	16.5
P20	M	48	−0.75	−0.75	18.3	20.0	0.0	21.5
P21	M	55	−0.75	−0.75	16.9	18.0	16.0	17.0
P22	M	45	−0.00	0.25	13.4	13.5	0.0	14.5
P23	M	27	0.25	0.25	13.5	11.0	15.0	12.5
P24	M	50	0.25	0.25	13.7	16.5	0.0	19.0
P25	M	36	0.25	0.25	14.8	15.0	17.4	17.5
P26	F	54	0.50	0.25	14.5	13.5	0.0	16.0
P27	M	29	1.75	1.75	0.0	16.0	0.0	14.0
P28	F	58	−1.75	−2.25	17.3	18.5	0.0	35.5
P29	F	44	−0.50	−1.00	18.3	19.0	18.1	19.0
P30	M	49	0.50	−0.25	15.3	15.0	13.6	13.5

In this study, the p-value was found to be less than 0.05, indicating statistical significance. The regression model used in this analysis is represented by the equation: Upper = Mean Differences − (1.96 × SD), Lower = Mean Differences + (1.96 × SD), and Bias = AVERAGE(Differences). The SD refers to the standard deviation, which is a measure of variability used in this work.

Fig. 4 displays the Bland–Altman Plot depicting the agreement between Corvis CTS measurements for both the right (R) and left (L) eyes of all the correct eyes of the patients. It is important to note that the plot itself does not provide information about the sufficiency or suitability of the agreement between the methods. Further statistical analysis is required to determine whether these limits are exceeded or not.

In Fig. 5, the Bland–Altman Plot illustrates the agreement between Corvis CTS measurements for both the right (R) and left (L) eyes of all the patients whose eyes were not considered correct. Similar to the previous plot, the Bland–Altman plot itself does not provide information about the sufficiency or suitability of the agreement between the methods. Further statistical analysis is required to determine whether the limits of agreement are exceeded or not, using appropriate statistical tests or methods.

IOP measurements were obtained using the Icare tonometer and the STC by two experienced clinicians. The obtained IOP values were then compared. To assess the intraobserver variability and interobserver variability, the coefficient of variation and intraclass correlation coefficient were calculated. Furthermore, the agreement between the two devices was determined using Bland–Altman analysis. Where Fig. 6, show the Blan Altman Plot between Icare PRO for (R & L) eyes for all the patients.

Finally, Fig. 7 displays a regression line of the differences, which can aid in identifying any proportional difference between the measurements. By visually examining the plot, we can assess the overall agreement between the Icare PRO and Corvis STC measurements. It is important to verify the normal distribution of the differences. If the line of equality is not within the interval, it indicates a significant systematic difference between the measurements.

4. Statistical analysis

In this study, the normality of the distribution of the study population was assessed using the Kolmogorov–Smirnov test. Since some data did not meet the normality standards, non-parametric tests were used for the analysis of differences and correlations. The Friedman test,

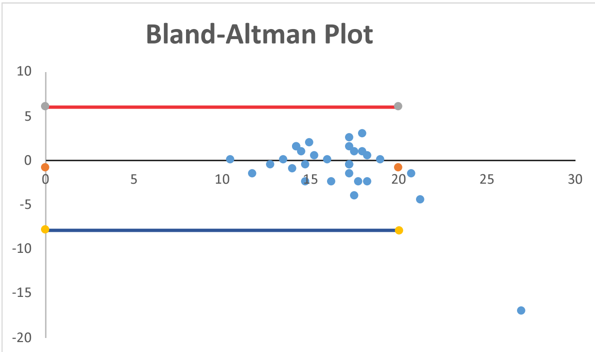

Fig. 5. Bland and Altman plot for data from the Table 1, with the representation equation from −1.96 to +1.96, for patient not correct eyes.

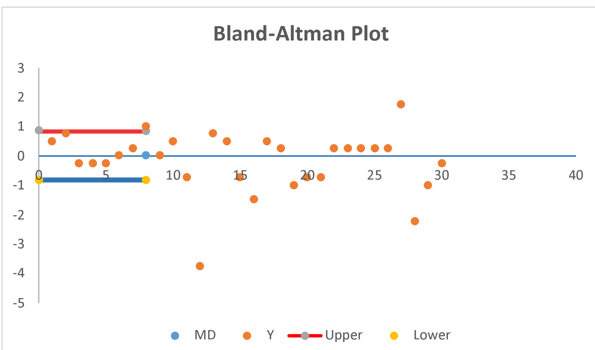

Fig. 6. Bland and Altman plot for data patient eyes from the Table 1, for the Icare PRO.

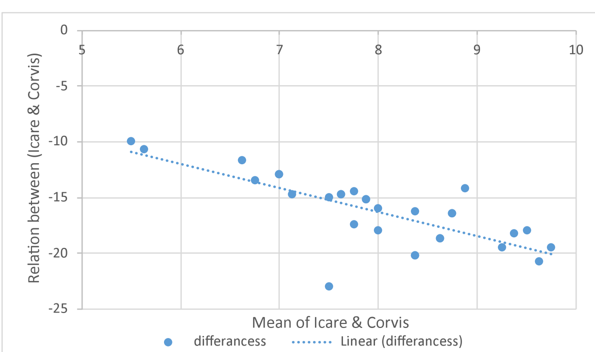

Fig. 7. Regression line between hypothetical measurements between Icare PRO and Corvis.

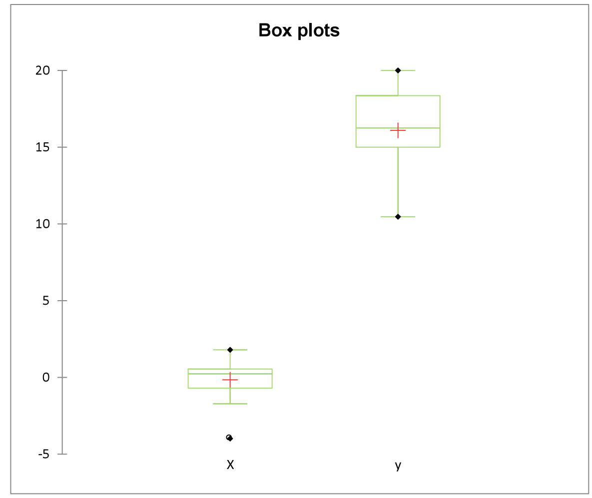

Fig. 8. Boxplot of Corvis STC (X), and Icare PRO (Y), river flow the dataset that used.

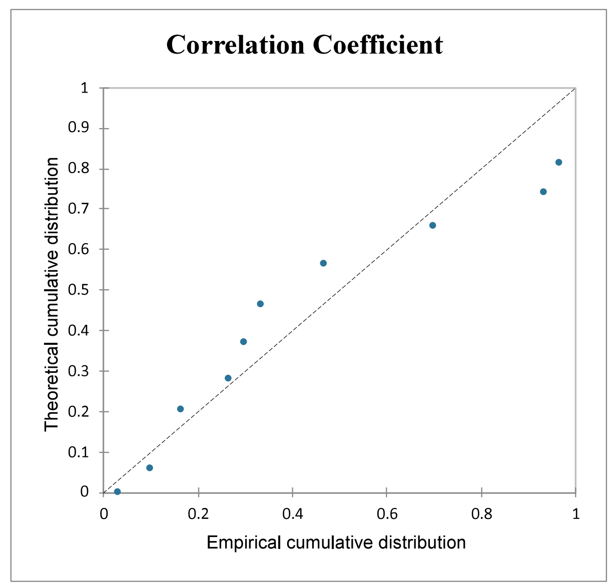

Fig. 9. Correlation Coefficient (Regression line) between Corvis STC and Icare PRO.

a non-parametric alternative to ANOVA, was conducted to compare values obtained from different instruments, followed by a post-hoc Wilcoxon signed rank test for pairwise comparisons. The p-values of each comparison were adjusted using the Bonferroni method.

Furthermore, the correlations between central corneal thickness (CCT) and spherical equivalent (SE) with IOP values obtained from the tested devices were evaluated using non-parametric Spearman tests. The significance level for all statistical tests was set at $p < 0.05$.

Statistical analysis was performed using SPSS software. The Wilcoxon signed ranks test was employed to determine whether there was a significant difference between the Corvis STC and Icare PRO tonometers. The p-values obtained for all instances indicated a significance level of $p < 0.0001$.

The distribution of the obtained solutions is illustrated in the box plot shown in Fig. 8. The box plot provides a visual representation of the data distribution and highlights the lower value for the Corvis STC, indicating its superior performance compared to the Icare PRO tonometer.

Fig. 9 displays the regression line between the Corvis STC and Icare PRO tonometers. The Y-axis represents the Corvis STC values, while the X-axis represents the Icare PRO values. The regression analysis was performed to assess the relationship between these variables.

The effect size of the regression analysis is indicated by the Adjusted R^2 value, which represents the proportion of the variance in the dependent variable (Corvis STC) that can be explained by the independent variable (Icare PRO) while adjusting for other variables in the model. In this case, the Adjusted R^2 value is 0.526, indicating that approximately 52.6% of the variance in Corvis STC can be explained by the Icare PRO measurements.

The unstandardized coefficient, B, represents the change in the Corvis STC value for each unit change in the Icare PRO measurement. The standardized coefficient, Beta (β), provides a standardized measure of the relationship between the variables. These values were calculated and presented in the analysis, although the specific values were not provided in the description.

Overall, the regression line and the calculated R^2 value indicate a moderate relationship between the Corvis STC and Icare PRO tonometers, with Icare PRO measurements accounting for a significant proportion of the variability in Corvis STC values.

The justification for analyzing data from one or both eyes in this study was based on the research objectives and the inter-ocular correlation of the study variables. Since the focus of the study was on assessing the agreement of IOP measurements between tonometers, specific eye variables were not the primary interest. Therefore, it was deemed appropriate to analyze the data at the level of each individual eye.

Including data from both eyes in the analysis of inter-method agreement between the tonometers employed allows for a comprehensive evaluation of the agreement between the two devices. This approach provides a more accurate representation of the overall performance and reliability of the tonometers in measuring IOP.

Furthermore, in cases where the study cohort consists of individuals with asymmetric eye diseases such as glaucoma and keratoconus, it is acceptable to include data from both eyes. Asymmetry in eye diseases can result in differences in IOP measurements between the two eyes, and analyzing data from both eyes allows for a better understanding of the overall agreement between the tonometers in a population with such characteristics.

In conclusion, the decision to include data from both eyes in the analysis was justified based on the research objectives, the inter-ocular correlation of the study variables, and the nature of the diseased eyes in the study cohort.

5. Conclusions

In conclusion, this study found that the Corvis CST tonometer demonstrated excellent consistency in measuring IOP and may be less influenced by corneal properties compared to the Icare PRO tonometer. The study emphasizes the importance of evaluating the differences between measurements rather than focusing solely on agreement when assessing the significance of differences between two methods. The correlation between the Corvis CST and Icare PRO should not be relied upon for evaluating the comparability of the two methods. Instead, the analysis of the mean differences and estimation of an agreement interval between the two methods, as shown in the plot analysis, provides a more accurate assessment of their agreement.

The study results suggest that the IOP measurements obtained with the Corvis CST tonometer are more comparable to those obtained with the Icare PRO tonometer. However, it should be noted that the Icare PRO tonometer tends to provide higher IOP values compared to the other techniques used in the study. Despite this difference, the Icare PRO tonometer can still be used interchangeably with pentacam and ultrasound pachymetry for central corneal thickness (CCT) measurement. These findings highlight the importance of selecting the appropriate tonometer based on the specific requirements of the study or clinical setting, taking into account factors such as corneal properties and the desired level of agreement in IOP measurements.

CRediT authorship contribution statement

Zeina M. Alsabti: Conceptualization, Methodology, Software. **Kawther A. Ahmed:** Data curation, Writing, original draft, Conceptualization, Methodology, Software. **Thakir M. Mohsin:** Data curation, Writing – original draft.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data are included in the manuscript.

Appendix

See Table 2.

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