

A comparison of intraocular pressure values obtained with the Tono-Pachymeter NT530P, iCare[®] rebound tonometer and Goldmann applanation tonometer

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Abstract

The purpose of this study was to compare the intraocular pressure (IOP) values measured with the Tono-Pachymeter NT530P (Tonopachy[™]) and the iCare[®] rebound tonometer (iCare[®]) with those obtained by the Goldmann applanation tonometer (GAT). The right eyes of 105 subjects aged 18 to 82 years (mean age = 29.27 ± 14.67 years) were assessed with the three tonometers. Central corneal thickness (CCT) was measured first using the Tonopachy[™] and then IOP was measured by Tonopachy[™], iCare[®] and GAT. The data was analyzed with descriptive statistics, paired *t*-test, correlation and regression analysis. The Bland-Altman method of analysis was used to evaluate agreements between the sets of data from the three devices. The CCT values ranged from 440 µm to 606 µm (mean = 518.49 ± 33.01 µm). There was little or no correlation between CCT and IOP for any of the instruments used in this study (*r* = 0.29 for Tonopachy[™], *r* = 0.22 for iCare[®], *r* = 0.17 for GAT). The mean IOP measured with the Tonopachy[™] was 14.31 ± 3.57 mmHg (range 8.7 mmHg to 31 mmHg) and 16.64 ± 4.38 mmHg (range 8 mmHg to 32 mmHg)

using the iCare[®]. The mean IOP measured with the GAT was 14.79 ± 3.09 mmHg (range 8.7 mmHg to 29.7 mmHg). Using the Bland-Altman method, the upper and lower limits of agreement between the Tonopachy[™] and GAT, iCare[®] and GAT, iCare[®] and Tonopachy[™] were 5.1 mmHg and -4.2 mmHg, 8.6 mmHg and -4.9 mmHg, 7.5 mmHg and -2.8 mmHg respectively. In 79.1% of the eyes studied, the mean IOP difference between Tonopachy[™] and GAT was less than 3 mmHg and in 20.9% of the eyes, the difference was greater than 3 mmHg. However, mean IOP differences of greater than 3 mmHg were obtained by iCare[®] in comparison with GAT (40%) and Tonopachy[™] (34.3%) respectively. Findings of this study suggest that the Tonopachy[™] yielded IOP readings that were consistent with those of GAT values while iCare[®] yielded higher IOP values compared to both GAT and Tonopachy[™]. (*S Afr Optom* 2011 70(3) 109-116)

Key words: Tono-Pachymeter NT530P, iCare[®] rebound tonometer, Goldmann applanation tonometer, intraocular pressure, central corneal thickness

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Introduction

The accurate measurement of IOP is a vital part of visual examinations and particularly for those diagnosed with glaucoma or those at risk of vision loss secondary to high IOP¹. Glaucoma has been reported to be the most important cause of irreversible blindness worldwide². The assessment of IOP is one of the clinical tests used in the diagnosis and management of glaucoma². To date the most accurate method for the determination of IOP is manometry³. This technique involves the insertion of a cannula into the anterior chamber of the eye³. Due to its invasive nature, manometry is not the method of choice for the clinical assessment of IOP³. Goldmann applanation tonometry is a form of contact tonometry and is considered to be the gold standard method of measuring IOP with low intra- and inter-observer variability¹. However, since there are biomechanical differences between individuals of different ages, the accuracy of GAT is affected by factors such as corneal thickness and curvature and GAT has been reported⁴⁻⁶ to be more precise in patients having an average CCT of 500 to 525 μm . De Moraes⁴ reported that GAT tends to underestimate IOP in eyes with thinner corneas (<525 μm) and overestimates IOP in eyes with thicker corneas (>555 μm).

There has always been a need to develop and introduce other different instruments to determine IOP⁷. This could be due to the GAT requiring the use of a topical anaesthetic agent. Previous studies^{8,9} have shown that the use of such agents can cause some level of discomfort and potential allergic reactions. Goldmann applanation tonometry also requires an intact anterior surface of the eye. The number of post-Lasik patients presenting for ophthalmic examinations is increasing and GAT has been found to be inaccurate in subjects who have undergone Lasik¹⁰. Further, GAT cannot be performed on bedridden patients, on younger children and in situations outside the limits of a consulting room¹¹.

iCare[®] rebound tonometry which is based on rebound principle involves analyzing the rebound motion of the instrument probe after it has interacted with the anterior surface of the eye^{7,12,13}. The probe in the iCare[®] tonometer is disposable and structured such that a rounded plastic tip covers the steel wire shaft to reduce the risk of corneal injury^{12,13}. When

the IOP is being measured, the small probe hits the anterior corneal surface and bounces back such that this interaction does not cause a corneal or a blink reflex^{12,13}. The movement of the probe after it has interacted with the anterior surface of the eye causes a small induction current which allows for the duration of the impact to be measured^{12,13}. The resultant deceleration of the probe is then determined and used to obtain the IOP reading. Corneal thickness could affect the duration of the impact of the rebound tonometer, causing an overestimation of IOP in eyes with thicker corneas¹². The iCare[®] rebound tonometer compares reasonably with GAT in some studies^{14,15} while others^{7,16} have suggested that it should be used as a screening device. For example, Abraham *et al*¹⁴, found that iCare[®] produced IOP values that agreed well with those obtained with GAT while Lopez-Cabarello *et al*¹⁶, in their study found that 84.6% of the IOP measured with the iCare[®] was greater than that measured with the GAT, with a mean difference of 3.4 ± 3.6 mmHg.

The Tonopachy[™] (Nidek, Japan) combines non-contact tonometry and pachymetry in one unit¹⁷. Using the principle of Scheimpflug camera, Tonopachy[™] provides non-contact measurements of the subjects' CCT and the automatic calculation function of the compensated IOP based on the CCT¹⁷. We considered it of interest to assess the IOP values obtained with Tonopachy[™] in detail, comparing it with two other well-established devices of IOP assessment. The aim of this study is therefore to compare the IOP values measured with the Tonopachy[™] and the iCare[®] with those obtained by the GAT.

Methods

The study was carried out on a sample of one hundred and five (29 males and 76 females) volunteers, attending the University of KwaZulu-Natal's Eye Clinic. Their ages ranged from 18 to 82 years with a mean of 29.27 ± 14.67 years. Measurements were made only on the right eyes over a 12 week period. The study proposal was approved by the University of KwaZulu-Natal Ethics Committee. Each participant gave written consent to participate in the study after the nature of the experimental procedures had been explained to them. All information relating to the study was treated as confidential as participants



were identified by their reference numbers, the key to which was known to the researchers. All individuals underwent a complete ocular examination, which also included a short case history, autorefractometry and assessment of keratometry. All participants had no histories of contact lens wear, corneal surface disease or intraocular surgeries. All participants taking any ocular or systemic medication likely to induce corneal changes were excluded. Participants exhibiting corneal astigmatism of greater than 3 D or irregular astigmatism were excluded from the study.

In accordance with previous studies^{7, 11, 14, 16, 18}, the non-contact method was performed first followed by rebound tonometry and then by the GAT. The reason given for this order was to avoid possible reduction in IOP induced by GAT as a result of aqueous massage^{7, 11, 14, 16, 18}. Central corneal thickness was measured for the purpose of establishing any relationship with any of the set of values from any of the tonometers. Previous studies^{19, 20} have shown that IOP measurement is influenced by CCT.

One of the authors (NR) with experience in using the Tonopachy™ evaluated CCT and IOP measurements. The subject was asked to keep the forehead against the forehead rest and look at the fixation target. Following appropriate adjustment of the patient on the instrument, three CCT and three IOP readings were taken and the instrument automatically averaged each of the three CCT and three IOP measurements. These series of measurements and their means were shown on the display and printed out for recording.

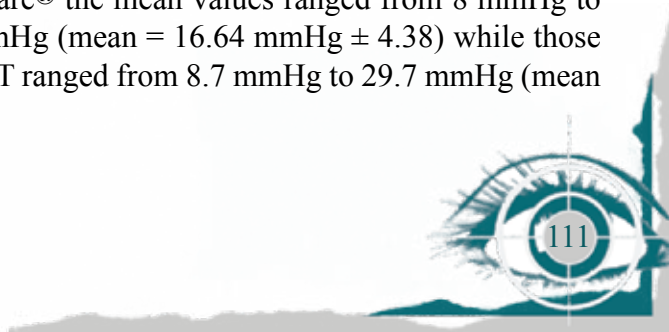
After one minute, IOP was measured with the iCare® rebound tonometer by another experienced optometrist (SJ), who was familiar with the use of the device. The subject was seated and looked straight to the fixation target. The tonometer was then brought closer to the subject's right eye with the central groove in a horizontal position. The software of the iCare® instrument is designed for six automatic consecutive measurements. The output is determined by automatically determining the mean pressure and standard deviation⁴. This value is then displayed on the digital screen and was recorded as the IOP. If a faulty measurement is obtained, it is automatically discarded by the software.

After five minutes, IOP was measured with the slit-lamp mounted GAT by an optometric staff member who had received formal training and was vali-

dated in GAT. The examiner taking the intraocular pressure with each tonometer was not aware of the results obtained by the other examiners. The GAT probe was sterilized with hydrogen peroxide and air dried, and the eye was stained with wetted fluorescein strip. A magnification of 10X in the slit lamp was used with cobalt blue filter to detect end points. The drum dial was set between 10 and 20 mmHg and the examiner applanated, by applying varying amounts of mechanical pressure to obtain the end point and recorded it. Three IOP readings were measured this way for the right eyes. All instrumentations utilized in data collection were calibrated prior to data collection. All measurements of CCT and IOP were taken between 14:00 and 16:00 to minimize the effects of diurnal variation and instability¹⁷. The data was captured and analyzed using the Statistical Package of Social Sciences (SPSS version 15.0). The Kolmogorov-Smirnov test was used to check whether the data was normally distributed or not and the paired t-test was used to compare IOP measurements. In order to assess the degree of concordance between Tonopachy™, iCare® and GAT values, the Bland-Altman plots were used^{21, 22}. The bias was statistically assessed as the mean of the differences compared to zero. The hypothesis of zero bias was examined by the non-parametric test Wilcoxon signed rank test. The 95% limits of agreement (mean of the difference $\pm 1.96 \times S.D$) were also calculated, as recommended by Bland and Altman^{21, 22}. The impact of CCT on the IOPs obtained through each method was determined by analyzing the correlation between the pachymetry and IOP values.

Results

The study included 105 right eyes of 105 subjects that included 43.8% Blacks, 47.6% Indians, 5.7% Coloureds and 2.9% Whites. The mean value for CCT = $518.49 \pm 33.01 \mu\text{m}$, with a range of 440 μm to 606 μm . However, there was little or no correlation between CCT and IOP values obtained with Tonopachy™ ($r = 0.29$), iCare® ($r = 0.22$) and GAT ($r = 0.17$). The mean values obtained by the Tonopachy™ ranged from 8.7 mmHg to 31 mmHg (mean = $14.31 \text{ mmHg} \pm 3.57$) and for iCare® the mean values ranged from 8 mmHg to 32 mmHg (mean = $16.64 \text{ mmHg} \pm 4.38$) while those of GAT ranged from 8.7 mmHg to 29.7 mmHg (mean



= 14.79 ± 3.09 mmHg). The difference between the mean Tonopachy™ and GAT values was statistically significant ($p = 0.037$). There was a statistically significant difference between mean values obtained with iCare® and GAT ($p = 0.000$). Also, the difference between the mean values obtained with iCare® and Tonopachy™ was statistically significant ($p = 0.000$). Using the Bland-Altman analysis between the Tonopachy™ and GAT, the limits of agreement (-4.2 mmHg, 5.1 mmHg) contain 98% (103/105) of the difference scores. The mean difference (bias) of the measurements between Tonopachy™ and GAT methods is 0.5 mmHg (see Figure 1). The mean bias between the iCare® and GAT is 1.9 mmHg and the limits of agreement are -4.9 mmHg (lower limit) and 8.6 mmHg (upper limit), which include 96% (101/105) of the difference scores (see Figure 2). The limits of agreement between the iCare® and Tonopachy™ measurements are from -2.8 mmHg to 7.5 mmHg, which includes 95% (100/105) of all difference data (see Figure 3).

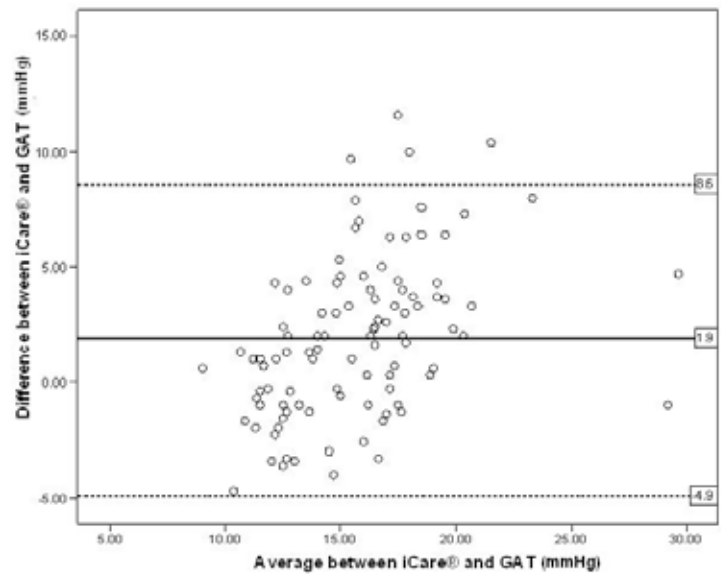


Figure 2: The Bland-Altman plot showing the difference between the means against the average of the means for iCare® and GAT measurements. Again, the solid line shows the mean difference (bias) and the small dashed lines represent 95% limits of agreement.

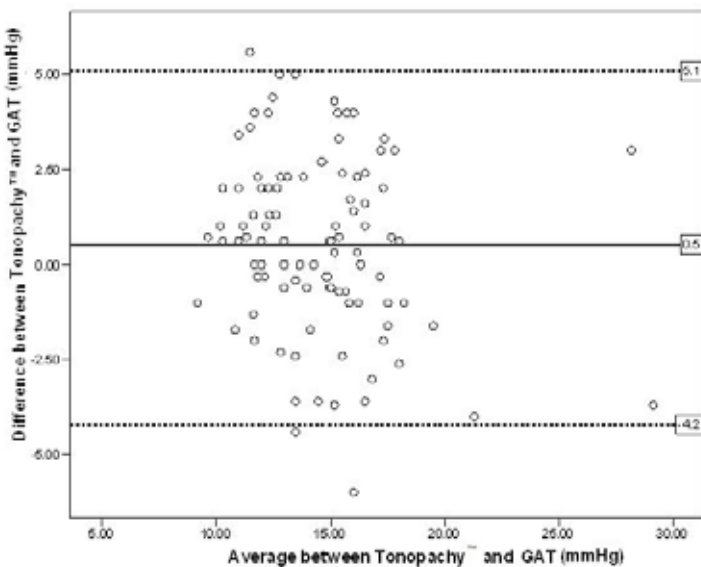


Figure 1: Bland-Altman plot of the difference between Tonopachy™ and GAT against the mean of Tonopachy™ and GAT in the 105 measurements in the study. The solid line in the Bland-Altman plot shows the mean difference (bias) and the small dashed lines represent 95% limits of agreement.

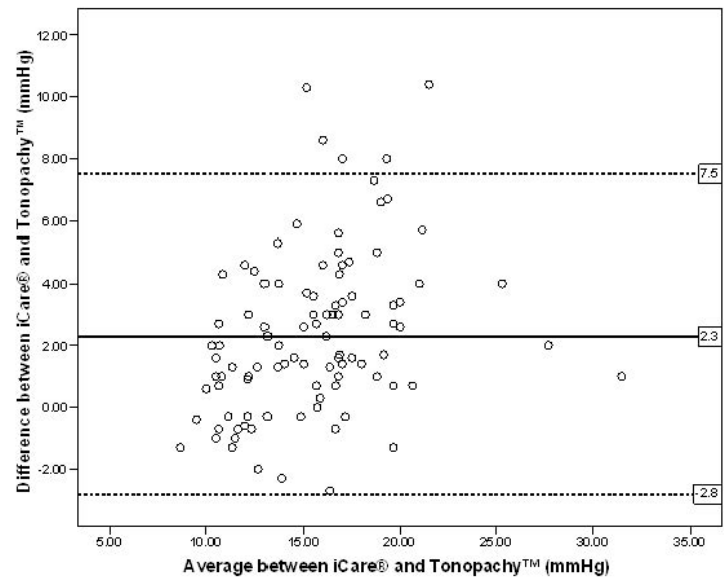


Figure 3: Bland-Altman plot of the difference between iCare® and Tonopachy™ plotted against their means in the 105 measurements in the study. As in Figures 1 and 2, the solid line is the mean difference (bias) and the small dashed lines represent 95% limits of agreement.

The frequency distribution of differences between Tonopachy™ and GAT readings differed by a value of 1 mmHg or less in 42.9% of the eyes studied and by a value of greater than 5 mmHg in 1.9% of the eyes (see Figure 4). The IOP readings, when comparing iCare® and GAT, differed by a value of between 1 mmHg and 3 mmHg in 34.3% and by more than 5 mmHg in 14.3% of the eyes studied (see Figure 5). The frequency distribution of IOP differences showed that in 38.1% of the eyes studied, the readings differed by a value of between 1 mmHg and 3 mmHg between iCare® and Tonopachy™ and in 11.4% of the eyes, the difference was greater than 5 mmHg (see Figure 6).

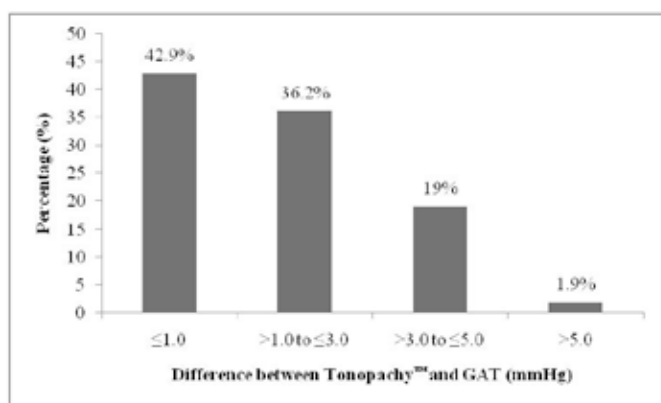


Figure 4: Frequency distribution of the difference between Tonopachy™ and GAT measurements.

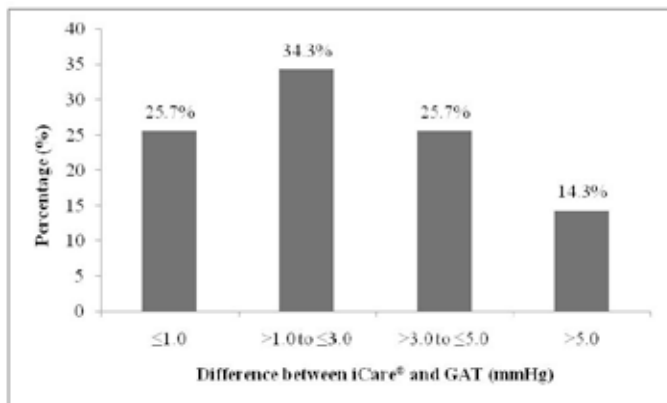


Figure 5: Frequency distribution of the difference between iCare® and GAT measurements.

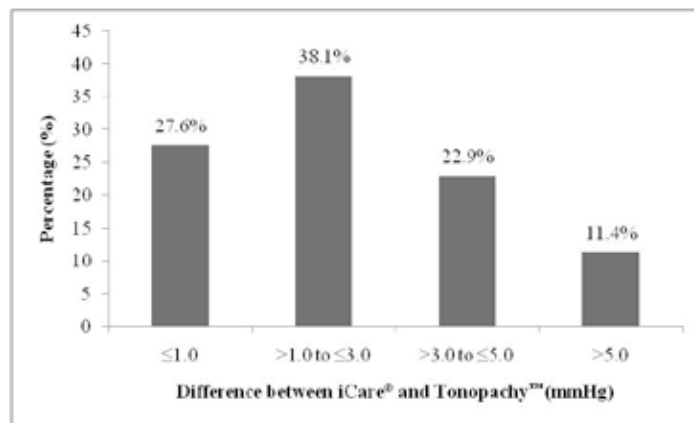


Figure 6: Frequency distribution of the difference between iCare® and Tonopachy™ measurements.

Discussion

It is important to compare measuring devices so that we know whether the devices yield comparable values. This study was therefore carried out to compare IOP values obtained from Tonopachy™ and iCare® with those obtained by GAT. Tonopachy™ values were similar to those of GAT while iCare® yielded IOP readings that were significantly higher than those of Tonopachy™ and GAT.

In this study no relationship was found between CCT and average IOP measurements for any of the three devices ($r = 0.29$ for Tonopachy™, $r = 0.22$ for iCare® and $r = 0.17$ for GAT). This could be due to the fact that measurements were performed only in eyes with normal corneas, with mean CCT values between 440 μm and 606 μm . The lack of relationship between CCT and IOP in this study are similar to those reported by Vandewalle *et al*²³ in 2009, who found no correlation between IOP measurements and CCT for the four instruments used (iCare®, dynamic contour rebound tonometer, ocular response analyzer and GAT). The authors²³ did not provide an explanation for the finding. However, differences may be encountered when IOP values are measured in eyes with corneal diseases such as keratoconus and those who have undergone keratorefractive surgery²⁴. However,

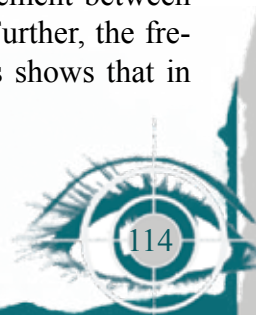
these results are different from those of Eballe *et al*¹⁹ who found that a rise in CCT by 100 μm was followed by an increase in IOP of about 2.9 mmHg.

Although the mean values obtained from Tonopachy™ and GAT are 14.31 mmHg and 14.79 mmHg respectively, the *p*-value from the paired *t*-test showed that the difference was statistically significant ($p < 0.05$). Presumably, the reason why this small difference was statistically significant is because the standard error of the difference was very small (0.23 mmHg) and the sample size relatively large ($N = 105$), thus providing high statistical power to detect small differences as statistically significant. We used the Bland-Altman analysis in the comparisons of values in this study because it assesses agreement rather than correlations only, which is the mean difference between the two variables^{21, 22}. This concept is important in the measurement and comparison of IOP because correlations coefficients are usually inappropriate and as a result, the conclusions drawn from such research are misleading^{21, 22}. The lower limit of agreement (Mean = $-1.96 \times \text{SD}$) in this study was -4.2 mmHg, the upper limit of agreement (Mean = $1.96 \times \text{SD}$) was 5.1 mmHg and the absolute range between the two limits is 0.9 mmHg suggesting closer agreement between the values obtained by the two instruments. Tonopachy™ consistently produced IOP values that were lower than those of GAT. The mean difference of 0.5 mmHg between Tonopachy™ and GAT readings shows that there is a good agreement (Figure 1). This means that on average, the Tonopachy™ underestimated IOP values compared with GAT by 0.5 mmHg. Lomoriello *et al*²⁵, reported that a mean difference of up to 1.3 mmHg were considered “clinically acceptable” and therefore the results of this study indicate that IOP measurements with the Tonopachy™ and GAT are comparable. Further, the frequency distribution of the differences (Figure 4) showed that in more than three-quarters (79.1%) of measurements, the IOP differed by less than 3 mmHg between the Tonopachy™ and GAT while in 20.9%, the difference was more than 3 mmHg. Where the difference between Tonopachy™ and GAT was more than 3 mmHg, there was a greater tendency for the Tonopachy™ to produce lower IOP values compared to GAT. Other studies^{26, 27} have shown that although several non-contact tonometers yielded higher IOP values compared to GAT, their values were within 2

to 4 mmHg of GAT readings in approximately 80% of the eyes studied. Based on the mean difference of greater than 3 mmHg used in the previous study⁷ to judge the potential of incurring a diagnostic error, in terms of underestimating and overestimating IOP, our results show that the possibility of incurring an error when measuring IOP is less than one in four eyes when using the Tonopachy™ compared with GAT.

The difference between the mean values for iCare® (16.64 mmHg \pm 4.38) and GAT (14.79 mmHg \pm 3.09) was statistically significant ($p < 0.05$). The lower limit of agreement (Mean $- 1.96 \times \text{SD}$) in this study was -4.9 mmHg, upper limit of agreement (Mean $+ 1.96 \times \text{SD}$) was 8.6 mmHg, and the absolute range between the two limits is 3.7 mmHg suggesting poor agreement between the values obtained by the two instruments. The mean difference of 1.9 mmHg between iCare® and GAT readings shows that there is a poor agreement. Therefore, on average, the iCare® overestimated the IOP values compared to GAT by 1.9 mmHg. Recent studies^{7, 15, 28-31} have reported that the iCare® significantly overestimated IOP when compared with GAT. In accordance with numerous other studies^{12, 16, 32, 33}, our study also showed that the overestimation was greater as the IOP values increased. This overestimation can lead to diagnostic errors since with higher IOPs, with a higher glaucoma risk, tonometers need to have a higher accuracy and precision⁷. Further, the frequency distribution of the differences showed that in 40% of the measurements, the IOP differed by more than 3 mmHg (Figure 5). Of these, there was a greater tendency for iCare® to overestimate IOP compared to GAT. Therefore, as reported by Jorge *et al*⁷, the iCare® may only be suitable as a screening device in subjects with a normal range of IOPs.

The iCare® values were consistently higher than those of Tonopachy™ and the difference between the mean values obtained by these two devices was statistically significant ($p < 0.05$). With the Bland-Altman method, the range between lower and upper limits of agreement between these two instruments was -2.8 mmHg to 7.5 mmHg, with a mean difference of 2.3 mmHg, suggesting that on average, iCare® overestimated IOP values compared to Tonopachy™ by 2.3 mmHg. Therefore, there is poor agreement between values obtained by the two devices. Further, the frequency distribution of the differences shows that in



34.3% of the eyes studied, the difference between iCare® and Tonopachy™ was greater than 3 mmHg, which is considered to be clinically significant as reported by Jorge *et al*⁷. Of these, the iCare® consistently produced higher IOP values in all of the cases compared to Tonopachy™. Therefore, in patients with a higher glaucoma risk due to elevated IOP, eye care practitioners should be aware that IOP measurements taken by the iCare® may be inaccurate (in comparison with those of Tonopachy™). This is important because it can lead to diagnostic errors and inappropriate management protocols. This implies that iCare® values cannot be used as a substitute for Tonopachy™ values where accurate comparison is necessary.

Subject selection only included eyes without corneal pathologies. A review by De Moraes *et al*⁴ has shown that although many new non-invasive technologies are getting closer to a precise estimation of the true IOP, none of these devices are highly accurate in determining IOP in eyes that have corneal pathologies and those that have undergone corneal surgical procedures. Similarly, other studies³⁴⁻³⁸ have reported that GAT underestimated IOP and showed greater variability and lower accuracy in keratoconus, high astigmatism and stromal scarring following refractive surgery. Therefore, the level of agreement of these three tonometers in cases of abnormal corneal thicknesses and corneal pathologies such as keratoconus, corneal scarring, corneal ectasia, post-refractive surgery remains for future investigations.

Conclusion

Tonopachy™ values agree sufficiently well with the established gold standard method of GAT and therefore the values obtained with the two devices can be used interchangeably and reliably in the assessment of IOP (at least in eyes without corneal pathologies). The statistical analysis in this study shows that the iCare® yielded values that are significantly higher than those yielded by the GAT. The iCare® also yielded significantly higher IOP values compared to those of Tonopachy™. Therefore, IOP values obtained with the iCare® rebound tonometer should be interpreted with caution.

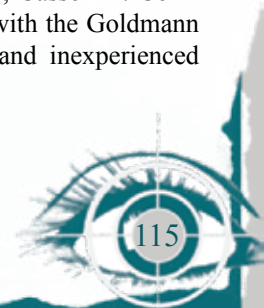
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