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Technical Note

Comparison of the IOPen® and iCare® rebound tonometers with the Goldmann tonometer in a normal population

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Abstract

This study proposes to evaluate the level of accuracy of intraocular pressure (IOP) measurements of a second generation rebound tonometer (IOPen®), taking as references the Goldmann Applanation Tonometer (GAT) and the iCare® rebound tonometer. The right eyes of 101 consecutive clinical patients were assessed with the three tonometers. The IOPen® and iCare® measurements were taken by two different optometrists and the GAT by an ophthalmologist. In this study, statistically significant differences were found when comparing the IOPen® tonometer with the other two tonometers ($p < 0.001$). The IOPen® underestimated the IOP value when compared to the GAT and the iCare® (mean differences were 2.94 ± 4.65 mmHg and 3.20 ± 4.72 mmHg (mean ± S.D.), respectively). The frequency distribution of differences demonstrated that in more than 55% of measurements the IOP readings differed by more than 3 mmHg between the IOPen® and the GAT. Based on the present population study, these results suggest that IOPen® measurements should be interpreted with caution.

Keywords: applanation tonometry, iCare®, impact tonometry, induction, intraocular pressure, IOPen®, rebound tonometer

Introduction

Accurate estimation of intraocular pressure (IOP) is an important part of the ocular examination. The GAT is the 'gold standard' in clinical practice, against which all other types of tonometers are compared. However, for some, it is not the instrument of choice. In the majority of European countries, optometrists use pneumatic tonometers. Reasons include access to sterilisation and limited licensing of the use of topical anaesthetic.

In the last decade, there has been an interest in to the development of new methods and instruments to measure IOP with minimally invasive and non-anaesthetic procedures. Dynamic tonometry, also known as impact or rebound tonometry, was first described more than 70 years ago, and recently developed by Kontiola. The basic mechanism uses a solenoid and magnetised probe which is launched towards the cornea (Dekking and Coster, 1967; Kontiola, 2000; Fernandes *et al*., 2005). The probe which consists of a magnetized steel wire shaft covered with a round plastic tip at the end, hits the cornea and bounces back. The solenoid, inside which the probe moves, is used to detect the motion and impact when the probe collides with the eye and bounces back. The probe slows down faster as the IOP increases and, consequently, the higher the IOP, the shorter is the duration of the impact.

Recently, IOPen® (Medicel AG, Swiss Technology for Surgery, Luchten, Switzerland) has been introduced. The main innovations of this second generation tonometer, in comparison to the first generation (iCare®), was the introduction of a fixation light for the patient, and a target beam which allows the

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examiner to obtain a clearer visualization of the corneal centre. An automatic measurement system was also introduced which allows the operator to know the distance between the cornea and the tonometer; an automatic angle control with on-screen display; and an automatic calibration system which performs a new calibration after the introduction of a new measurement tip.

The iCare® tonometer was introduced quickly onto the market, being used not only in screening programs but also in clinical practice. The IOPen® is being marketed as an alternative to, and an evolution of, the iCare®, so it seems interesting to compare the tonometers to each other. For this reason the aim of this study was not only to evaluate the level of accuracy of measurements of intraocular pressure (IOP) of a new induction/impact rebound tonometer (IOPen®) taking as reference the GAT, but also to compare with the iCare® rebound tonometer.

Subjects and methods

One hundred and one consecutive clinical patients (41 males, 60 females), with ages from 19 to 84 years (53.2 ± 17.49 years), composed the study group. Right and left eyes were measured; however, only measurements from the right eye were considered for statistical analysis. All subjects were selected according to the inclusion criteria, which required good general and ocular health; no history of corneal surgery; and corneal astigmatism not more than 3.00 D or irregular. Informed consent for participation was obtained from each subject after the nature of the experimental procedures had been explained. All procedures followed the Declaration of Helsinki rules and were reviewed and approved by the Scientific Committee of the School of Sciences of Minho University (Portugal).

An optometrist with experience in handling the rebound tonometer evaluated IOP with the IOPen® tonometer. Measurements were carried out as recommended by the manufacturer. The subject was asked to look straight ahead to a far point while the examiner brought the tonometer near to the subject's eye. Once the tonometer was correctly adjusted, six IOP readings were acquired by lightly pressing the tonometer button. The instrument automatically averaged the six measurements, so the mean IOP was shown on the display. Two measurement series of six measurements were obtained, and the average value was recorded.

After 1 min the IOP was measured with the iCare®. The same procedure was performed by another experienced optometrist for the measurement of the IOP with the iCare® tonometer. The clinical procedure used to obtain the IOP with iCare® was explained in detail in previous papers (Jorge *et al*., 2008).

After 5 min, IOP was measured with GAT by an experienced ophthalmologist. Each of the tonometers had its own examiner, who recorded the measurement without knowing the other examiner's measurements.

The measurements with the iCare® and IOPen® tonometers were performed in random order, and the measurements with the GAT were made last.

Applanation tonometry obtains IOP values by applying different amounts of mechanical pressure to flatten a known corneal surface area, following topical corneal anaesthesia (2.5 mg mL^{-1} oxybuprocaine and 4 mg mL^{-1} fluorescein) (Alcon, Fort Worth, TX, USA). The drum was reset to 10 mmHg after each reading, and the biprism was disinfected with 3% hydrogen peroxide between subjects. For the GAT, a magnification of 10× was used in the slit-lamp in conjunction with a cobalt blue filter to detect the applanation end-point. For the GAT, two readings were obtained, and the average was recorded. All measurements were taken between 14:00 and 16:00 in order to minimize the effect of diurnal variations in IOP.

In this work, data were analysed using the statistical package SPSS (Version 17.0; SPSS Inc, Chicago, IL, USA). 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 ranks test. The 95% limits of agreement (mean of the difference ± 1.96 × S.D.) were also calculated, as recommended by Bland and Altman (1986).

Results

Data obtained from both eyes were initially analysed and no significant differences were found between the left and the right eye. However, only right eye measurements were submitted to analysis.

Table 1 displays the minimum and maximum, as well as the mean and the standard deviation of IOP measurements obtained with the three tonometers. These values reflect an underestimation by IOPen® when compared with the other two tonometers, −2.94 ± 4.65 mmHg and −3.20 ± 4.72 mmHg (mean ± S.D.), when compared with the GAT and the iCare®, respectively.

Table 1. Descriptive statistics (mean, S.D.) for IOPen®, iCare® and GAT. The values are in mmHg

	***n* = 101**			
	Minimum	**Maximum**	**Mean**	**S.D.**
GAT	8.0	29.0	15.69	4.12
IOPen®	6.5	24.0	12.76	3.72
iCare®	5.0	30.0	15.96	4.57

Table 2. Mean difference, significance level and 95% confidence interval limits between the three tonometers. The values are in mmHg

	Mean	S.D.	p*	Limits of agreement	
				Mean – 1.96*S.D.	Mean + 1.96*S.D.
IOPen® – GAT	−2.94	4.65	$p < 0.001$	−12.05	6.17
IOPen® – iCare®	−3.20	4.72	$p < 0.001$	−12.45	6.05
iCare® – GAT	0.27	3.16	$p = 0.310$	−5.92	6.46

*Wilcoxon signed ranks test.

Table 2 presents the mean difference, level of statistical significance, as well as the limits of agreement between the three tonometers at the 95% confidence level.

In order to graphically analyse the agreement between measurements obtained with different instruments, plots of differences as a function of the mean for the three instruments are displayed in *Figure 1*. It showed a systematic underestimation of the IOP by the IOPen® tonometer when compared with the iCare® and with the GAT. We also verified a moderate trend for an increase in the differences between IOPen® and GAT, and IOPen and iCare®, as IOP increases ($r^2 = 0.012$ and $r^2 = 0.048$ for GAT and iCare®, respectively). The plot of difference vs mean shows that this is greater at higher IOP values (for example for the comparison IOPen® vs iCare® (*Figure 1*), for a subject with IOP of 20.0 mmHg, the difference was −5.0 mmHg, and for another subject with IOP of 10.0 mmHg, the difference was −2.0 mmHg.

Figure 2 presents the percentage of subjects whose results for the mean differences between the tonometers are equal to or less than 1 mmHg (≤1); between 1 and 3 mmHg (>1 to ≤3); between 3 and 5 mmHg (>3 to ≤5); and greater than 5 mmHg (>5). It can be seen that for more than half the population (55.4% of cases), the mean difference between IOPen® and GAT is greater than 3 mmHg, but for the iCare® and GAT only in 24.7% of the population is the difference greater than 3 mmHg.

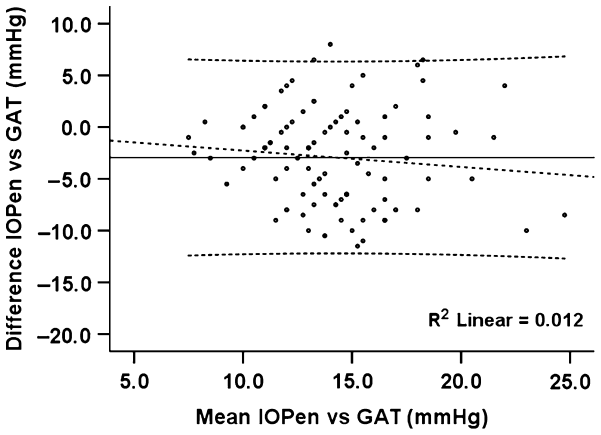
Discussion

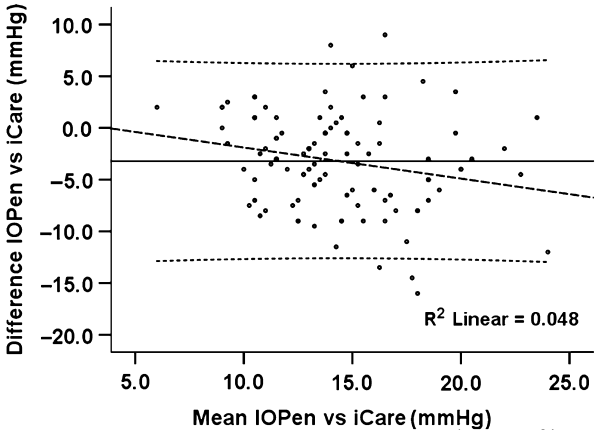
IOP evaluation has become a routine exam performed by optometrists from developed and developing countries. The prohibition to use diagnostic drugs imposed to the optometrists almost all over the world has led to the development of new IOP measurement systems during the past century, namely the non-contact tonometer (NCT) (Walby *et al*., 1975; Wittenberg, 1977; Shields, 1980). Recent studies have demonstrated how the improvements in NCT have turned this technique into a reliable and accurate method to determine IOP in a healthy population (Jorge *et al*., 2002; Queiros *et al*., 2006) and in glaucomatous patients (Jorge *et al*., 2003). Nowadays, non-contact tonometers are the instrument of choice for the optometric clinical practice due to their improvements and accuracy. However, even with the improvements introduced during recent decades, there is still a need for a low-cost, accurate and easy to use tonometer that allows measurements in people with special needs, such as persons confined to bed or in a paediatric population.

The first studies conducted with the rebound tonometer iCare® were performed in animals by Kontiola, which allowed him to conclude that the rebound tonometer is a reliable and accurate instrument for non-invasive IOP measurements in rat eyes. (Kontiola, 2000; Kontiola *et al*., 2001). The first study conducted by an independent team, intended to compare iCare® with the GAT, was performed by Fernandes *et al*. (2005). This study displayed the mean differences for IOP measured with two tonometers (GAT and iCare®), which were of 1.34 ± 2.03 mmHg (mean ± S.D.).

In the past 3 years, many other researchers have analyzed the iCare® tonometer. (Gonzalez-Meijome *et al*., 2006; Queiros *et al*., 2007). Garcia-Resua *et al*. (2006) found that the iCare® and Tono-Pen XL significantly overestimate IOP when compared with Perkins applanation tonometry. The mean difference between Perkins and iCare®, and Perkins and Tono-Pen XL, was 3.35 ± 2.28 mmHg and 2.78 ± 2.53 mmHg (mean ± S.D.), respectively (Garcia-Resua *et al*., 2006). Rehnman and Martin (2008) found an overestimation of the iCare® of 1.5 ± 3 mmHg (mean ± S.D.) when compared with GAT. In addition, for a glaucomatous population, Diaz *et al*. (2008) found an overestimation of the iCare® in relation to Perkins tonometer of 3.57 ± 2.98 mmHg. In accordance with previous studies, the present paper confirms the tendency for an overestimation of iCare® when compared to GAT. However, the average difference found is lower than that in previous studies, being 0.27 ± 3.16 mmHg (mean ± S.D.).

On the contrary, it can be observed that IOPen® not only underestimates IOP when compared with the GAT, but also shows a tendency to underestimate it to a greater extent when IOPs were higher than 14 mmHg. This is particularly important, since, in cases of higher IOP, with a higher glaucoma risk, tonometers need to have a higher accuracy and precision. This is also not achieved with the iCare® tonometer, since for higher values of IOP, iCare® measured values are even higher.





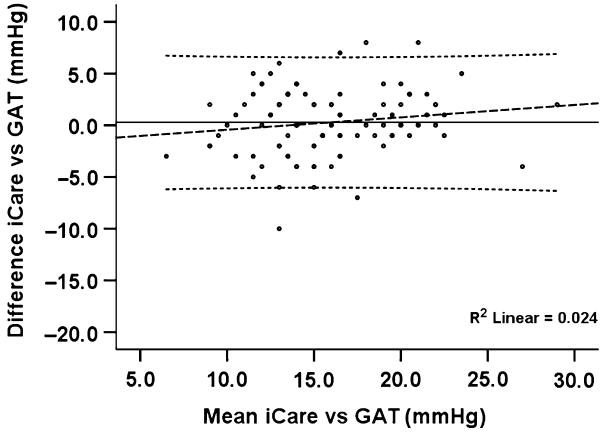
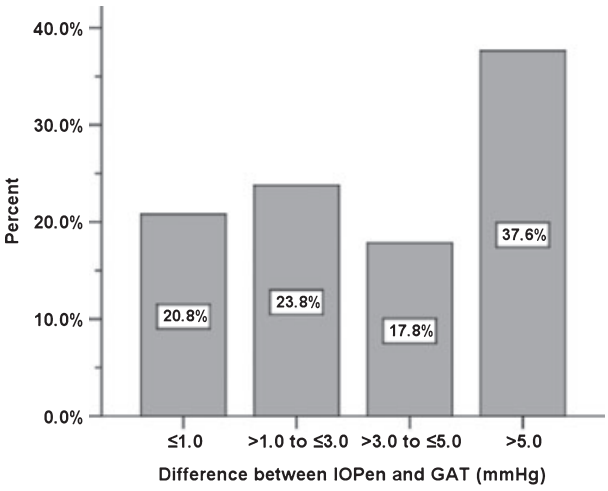
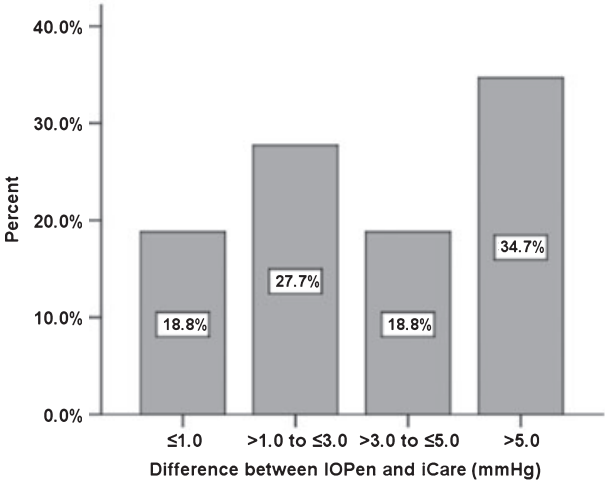


Figure 1. Plots of difference vs mean of IOP values obtained with IOPen®, iCare® and GAT. (The solid line represents the mean bias, the small dashed lines represent 95% limits of agreement and the large dashed line represents the linear regression).





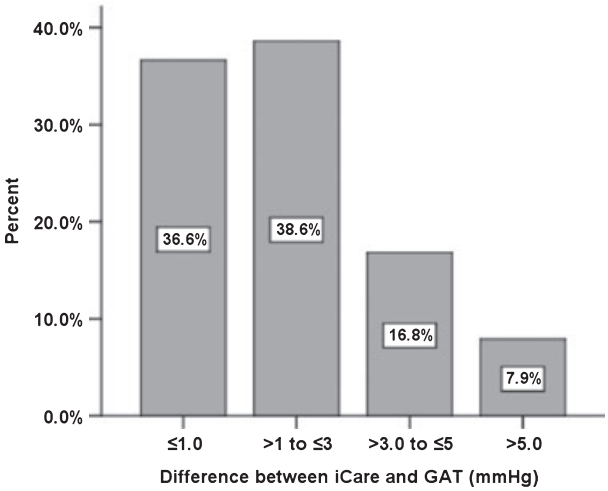


Figure 2. Frequency distribution of differences between IOPen®, iCare® and GAT measurements.

Both underestimation and overestimation are to be avoided, particularly underestimation, which can lead to diagnostic errors with severe consequences to patients' ocular health.

Figure 2 shows that for more than half the population (55.4% of cases), the mean difference between IOPen® and GAT is greater than 3 mmHg. This potentially increases the possibility of incurring a diagnostic error when measuring IOP in borderline patients (i.e. for patients with IOP around 20 mmHg, one in two could

potentially be identified as having ocular hypertension). Conversely, for the iCare®, only one in four patients will be affected by the same bias if they have an IOP arround 20 mmHg as measured with GAT.

Taking these results all together, we conclude that for the majority of patients within a normal range of IOP values, iCare® is able to measure this parameter with an absolute bias less than 1 mmHg, which is clinically acceptable for a screening method. On the other hand, IOPen® can only obtain clinically comparable results to GAT in less than half the cases.

Possible limitations of this work was the non-inclusion of a clinical population affected with increased IOP. It will also be interesting to study the influence of central corneal thickness and the biomechanical properties of the cornea on the measurements.

In summary, results from the present study have shown that, concerning this population, when compared to GAT, IOPen® significantly underestimated IOP, this difference was clinically relevant in the evaluation of IOP. This study showed that iCare® could be used as a screening instrument for IOP evaluation, but IOPen® must be used with extreme caution, since it underestimated IOP values to a clinically significant degree in more than half the population studied. The risk of false negatives induced by IOP underestimation with IOPen® implies that IOPs within a suspicious range (values above 14–16 mmHg) should be re-assessed or referred for GAT evaluation.

Statement

The authors state that they have no proprietary or commercial interest in any of the equipment used in this study.

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