COMPARISON OF I-CARE TONOMETER WITH GOLDMANN APPLANATION TONOMETER IN GLAUCOMA PATIENTS

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ABSTRACT

PURPOSE: To compare the IOP readings obtained by the new tonometer iCare with those of Goldmann applanation tonometer (GAT), and to evaluate the influence of central corneal thickness (CCT) on the IOP measurements.

METHODS: One eye of 178 consecutive patients with primary open-angle glaucoma underwent ultrasonic CCT measurement, followed by IOP evaluation with the GAT and with the iCare tonometer. The deviation of the iCare readings from the GAT values, corrected according to the Doughty and Zaman formula, was calculated and correlated to the CCT by a linear regression model. The iCare readings were corrected on the basis of the CCT values. The agreement between the two devices was assessed using the Bland-Altman method.

RESULTS: The average CCT was 552±39 µm. The mean IOP and the mean corrected IOP with the GAT were 19.4±5.4 mmHg, and 18.5±5.7 mmHg, respectively. The mean iCare IOP reading was 18.4±5.2 mmHg. The deviations of the iCare readings from the corrected GAT values were highly correlated with the CCT values ($r = 0.63$, $P<0.01$). The linear regression indicated that a 10 µm CCT change resulted in a deviation of 0.7 mmHg. The mean iCare IOP reading corrected according to this linear regression model was 17.9±5.5 mmHg. The Bland-Altman scatter-plot showed a reasonable agreement between the two tonometers.

CONCLUSIONS: The iCare tonometer can be useful in routine clinical setting. The IOP readings are quite in accordance with those obtained by GAT. The measurements appeared to be influenced by CCT variations, and thus pachimetry should always be taken into consideration.

Introduction

Glaucoma is one of the major causes of blindness in the Western countries (1). It is well known that the major risk factors in the progression of glaucoma include increased intraocular pressure (IOP) levels and increased variation in IOP (2). Although the role of IOP in glaucoma is not fully understood, its lowering may halt or delay the progression of the disease (3).

Goldmann applanation tonometry (GAT) is widely accepted as the international gold standard for IOP measurements (4).

The accuracy of GAT measurements has proven to depend on many factors, including corneal thickness, curvature and structure, and axial length (5). Central corneal thickness (CCT) has especially been shown to have a substantial effect on IOP readings obtained by GAT. Godmann calibrated its tonometer considering the CCT to have a standard measurement of 520 μm (6), which means that IOP may be underestimated in eyes with thin corneas and overestimated in eyes with thick corneas (7-9). Under estimated and over estimated IOP readings can have a span that can be high as 12 mmHg (10), and thus CCT values may significantly affect the accuracy of IOP assessment. Considering the effect that corneal thickness has on GAT measurements, numerous correction factors have been proposed, ranging from 0.19 to 0.7 mmHg for each 10-μm difference in CCT compared to the mean values (7-14).

Several different methods have been proposed to overcome the disadvantages in GAT, which mainly include having to use a local anaesthesia, time consumption, the need of a slit lamp, and the influence of CCT. These alternative methods include new electronic applanation tonometers (15), non-contact tonometers (16), and Rebound tonometry (17,18).

Rebound tonometry, also called “impact” or “dynamic tonometry”, was introduced by Obbink more than 60 years ago (19), and later modified by Dekking and Coster in the sixties (17) and by Kontiola in 1997 (18). The method is based on measuring the impact duration of a probe colliding with the cornea: the higher the IOP, the shorter is the duration of the impact (17,18). The main advantages of this tonometric method are that it is quick and easy to use, the device is inexpensive, and above all, local anaesthesia is not required.

In 2000, Kontiola introduced a new and improved rebound tonometer, called induction-based impact tonometer (20), in which the device is of an easier construction, compared to the earlier versions (17,18). Kontiola’s prototype has given promising preliminary results (20-22) and became commercially available in 2003 under the name of iCare tonometer.

The purpose of our study was to compare IOP readings obtained using the iCare tonometer with those taken with GAT, in a fair sized group of glaucomatous subjects. The influence of CCT on the IOP measurements obtained with the iCare tonometer was also analyzed.

Methods

This prospective observational study included 178 consecutive patients affected with primary open-angle glaucoma (POAG), having a mean age of 67±13 years (range 30-93 years).

The study abided by the principles of the Declaration of Helsinki, and informed consent was obtained from all the patients.

All subjects underwent an ophthalmological examination including best-corrected visual acuity evaluation, slit-lamp examination, gonioscopy, and fundus biomicroscopy with a 90-diopter lens. One eye per patient was randomly selected for analysis, with exception to patients in which only one eye met our inclusion criteria.

The inclusion criteria included: BCVA ≥0.7; open anterior chamber angle; and, absence of ocular pathology other than glaucoma, mild nuclear sclerosis and rare drusen.

The exclusion criteria included: corneal astigmatism higher than 2 D; corneal diseases; microphthalmus; history of intraocular surgery within the last 3 months; ocular inflammation; and, contact lens wear.

The patients were classified as glaucomatous according to the EGS criteria (15), if at least one of the following was present: IOP >21 mmHg before medication; optic disc with typical glaucomatous findings or RNFL changes; and, reproducible glaucomatous SAP visual field defects.

All measurements were taken by the same examiner. CCT was measured with a central ultrasonic pachymetry (Altair pachymeter, Optikon 2000). The pachymeter probe was placed on the center of the cornea and the mean of three readings was calculated for each eye.

IOP was measured with GAT and iCare tonometer in random order. The GAT (Haag Streit, Koeniz, Switzerland) was performed with a slit lamp and the use of one drop of a local anaesthesia (0.4% oxybuprocain). GAT was calibrated according to the manufacturer's guidelines. The mean of three consecutive readings was recorded.

Rebound tonometry was performed using the new induction-based impact tonometer iCare (Tiolat Oy, Helsinki, Finland), which has been thoroughly described elsewhere (20). In brief, the tonometer is a light (250 g), small, handheld device, made up of a probe and a solenoid. The probe is composed of a stainless steel tube having a length of 50 mm and diameters of 1.4 mm/1.0 mm, and a fixed magnet is poisoned in the steel casing. In order to take IOP measurements, the device is positioned near the patient's eye, utilizing the forehead as a base support, and the tip of the probe is maintained at a distance of approximately 4-8 mm from the cornea. While pressing the measurement button, an electrical pulse is sent to the solenoid and creates a magnetic field, which in turn repels the magnet and the probe. The probe moves,

impacts and rebounds from the eye. The movement of the probe and of the fixed magnet induces a voltage in the solenoid, which is amplified and converted in a digital signal by a microprocessor. The voltage created is dependent on the speed of the probe. The software is pre-programmed for six measurements: the highest and the lowest readings are automatically discarded and the average IOP value is calculated from the rest of the readings. Local anaesthesia is not required. The probes are disposable, in order to avoid the risk of microbiological contaminations.

The mean CCT, GAT and iCare IOP values were taken for analysis.

The correction factor proposed by Doughty and Zaman (9) was used in considering the effect of CCT on GAT. The formula used was: corrected GAT = measured GAT – [(CCT-535) x (2.5/50)]. The corrected GAT was taken as the gold standard.

The deviation of the iCare tonometry readings from the corrected GAT value was calculated and correlated with the CCT variable, with the use of a linear regression model. This provided a formula which could be used to correct the iCare IOP readings based on CCT values.

The agreement between the corrected GAT and iCare tonometry values was assessed using the Bland-Altman method (23), which included the calculation of the mean difference between measurements (iCare tonometry minus GAT values), the standard deviation (SD) and the 95% confidence interval (CI) of the differences.

Statistical analysis was performed using the SPSS statistical software (ver. 11.0; SPSS Inc., Chicago, IL).

Results

The average CCT in our sample was 552±39 μm, ranging from 445 to 678 μm (95% confidence interval from 528 to 575 μm).

The mean IOP readings obtained by the GAT was 19.4±5.4 mmHg (range: 8-55 mmHg) (Tab.1).

The mean corrected GAT readings, calculated according to the Doughty and Zaman formula (9), was 18.5±5.7 mmHg (range: 6.6-51.7 mmHg) (Tab.1).

The mean IOP readings obtained by the iCare tonometry was 18.4±5.2 mmHg (range: 9-38 mmHg) (Tab.1).

The graph obtained by plotting the CCT values with the deviations of the iCare tonometry readings from the corrected GAT values is shown in Fig.1. The deviations of the iCare readings from the corrected GAT values were highly correlated with the CCT values ($r = 0.63$, $P<0.01$, Fig.1). Since the linear regression function was $y = 38.2 – (0.07 \times CCT)$ and the linear regression line intercepts the x-axis at the CCT value of 546μm (Fig.1), the following correction formula for the iCare readings can be used: iCare corrected IOP = measured iCare IOP – (CCT-546) x (0.07). According to this formula, 10 μm change in CCT resulted in an iCare value deviation of 0.7 mmHg.

The mean corrected iCare IOP value according to this formula was 17.9±5.5 mmHg (Tab.1).

The Bland-Altman scatter-plot comparing the corrected GAT and the corrected iCare tonometry readings (Fig.2) showed a reasonable agreement between the two methods. The differences between corresponding measures (iCare value minus GAT value) had a mean of -0.6 mmHg, a standard deviation of 3.4 mmHg, and a 95% confidence interval of -6.3 to 5.8 mmHg.

The differences between corrected iCare and corrected GAT measurements appear to be constant over the range of IOP measurements, as shown in the plot and the regression line (r = 0.08, p not significant) in Fig.2.

The corrected iCare readings were within ±3 mm Hg of the corrected GAT readings in 69.7% of eyes; within ±2 mmHg in the 51.7% of eyes; and, within ±1 mmHg in 26.4% of cases. In 10.6% of eyes, the difference was > ± 5 mm Hg.

After IOP readings were corrected on the basis of the CCT value, the iCare tonometer was adequately able to identify a high IOP in 31 out of 38 eyes with a corrected GAT IOP ≥21 mmHg, with a sensitivity of 81.6%.

Discussion

A precise measurement of the IOP is fundamental in any accurate ophthalmic examination, especially in dealing with patients with glaucoma and/or ocular hypertension.

Various methods to measure IOP have been utilized in the past, and new types of tonometry based on different principles are continuously being developed.

The Schiötz indentation tonometer, which was first proposed in 1906 (24), was until about 30 years ago, the method most used by general practitioners. This tonometry is still used today in some cases, especially in the bedridden elderly and when a microscope is not available, even if the IOP measurement is not very accurate and a local anaesthetic is required.

GAT (6), introduced in 1957, is the still to this day, the method currently most used by the majority of ophthalmologists, since this system has proven to be accurate, precise and easy to use, having a low intra- and inter-observer variability (25). GAT has been shown to be more

accurate than Schiötz tonometry, but does require a microscope and similarly, the use of an anaesthetic.

Most of the new electronic applanation tonometers available, such as the Tonopen (15), also require the administration of a local anaesthetic.

The non-contact tonometers (16) have the advantage of not requiring corneal anaesthetization, however, they are not accurate enough and are too expensive for clinical use in general practice.

The rebound tonometry (17,18) is characterized by the simplicity of the device construction and the possibility of measuring IOP without the use of a local anaesthetic.

The induction-based impact tonometry, proposed by Kontiola in 2000 (20), was the modification which has improved rebound tonometry: its prototype was tested in mice and rats, showing good correlation with the IOP measures manometrically obtained (21); it was also proposed for measuring IOP on rodents in glaucoma research (21), and tested in few clinical studies with satisfactory results (20,22).

The iCare tonometer is the first commercially available instrument based on the induction-based rebound method, and seems to have many advantages compared to other instruments: the device is small, lightweight and portable; a microscope is not required; it is easy to use; IOP is taken in a comfortable sitting position, and not lying down; anaesthetic or sedation is not required, and thus is even suitable for IOP self-monitoring at home; and, the rapid measurement enables monitoring in non-compliant subjects.

To the best of our knowledge, no other clinical studies regarding the use of this device in a clinical setting are available at the present time.

The purpose of our study was firstly, to compare the IOP readings taken with the new iCare tonometer with those of GAT, which is still taken as the gold standard for IOP measurements (4). In taking into consideration that several studies have shown that CCT is

essential in properly interpreting the IOP measurements obtained with GAT (7-9), we have corrected the GAT readings in relation to the CCT values (26).

There have been various CCT correction factors proposed in these current years, which aim at correcting IOP measurements obtained by GAT. Doughty and Zaman (9) did a meta-analysis, which took into consideration 600 articles over a 31-year span. In our study, the correction factor proposed in this thorough and extensive meta-analysis was used in considering the effect of CCT on GAT.

There have been a few published studies which have quantified the CCT-induced error in GAT measurements in relation to manometric readings (10), but as far we know, similar studies have never been performed in rebound tonometry.

The second purpose of our study was to evaluate the influence CCT had on the IOP measurements obtained with the new iCare tonometer and to calculate how these measurements could be corrected in accordance to CCT.

According to the method used by other authors (27), we used the corrected GAT values as the gold standard when evaluating the impact of CCT on the iCare tonometry measurements. The linear regression analysis showed that the iCare measurements were influenced by CCT; being overestimated in eyes with thick corneas and underestimated in eyes with thin corneas (Fig.1). The analysis precisely showed that a 10 μm change in CCT yielded a 0.7 mmHg deviation in the iCare readings (see Results). This value is comparable to those found with the same method in both non-contact tonometry and in ocular blood flow (OBF) tonometry (27).

This calculation method is obviously not as accurate as manometric studies, however, it does provide information which may prove to be more useful than correction factors which are simply derived the CCT values correlated with iCare IOP readings. Our findings may help clinicians better interpret IOP readings obtained with iCare, especially taking into account the increasing number of patients with a history of corneal refractive surgery. Howevre, the IOP

correction based on a linear correction factor is probably an oversimplification of a complex relationship between different corneal parameters and true IOP measurements. The accuracy of this method needs to be further investigated.

The actual iCare tonometry readings were corrected on the basis of CCT, and then compared to the corrected GAT measurements by means of the Bland-Altman method.

The Bland-Altman scatter-plot (Fig.2) showed a overall good agreement between the two corrected IOP measurements, suggested by the small observed absolute values in the mean and standard deviation of the differences between corresponding measures (-0.6 and 3.4 mmHg respectively). The graph in Fig. 2 also shows that the corrected iCare readings were within ±3 mm Hg of the corrected GAT readings in 69.7% of eyes.

The mean of the differences between the actual readings obtained with iCare and GAT was -1.0±3.5 mmHg (Tab.1). These results are: similar, to those found by Bandyopadhayay *et al.* (28) in which a comparison is made between GAT and Tonopen (the mean of the differences was 1.0±2.28); lower, than those reported by Meyer *et al.* who studied GAT and Digital Tonometer TGDc-01 'PRA'(29), and by Kaufmann *et al*. that compared GAT to dynamic contour tonometer (30); and higher, than those found in the studies between Pulsair 3000 and Rebound tonometer (22), between Tonosafe disposable tonometer and GAT (31), and between GAT and pressure phosphene self-tonometer (32).

In conclusion, the IOP readings obtained with the new iCare tonometer in our sample study have shown a reasonable concordance with IOP readings obtained by GAT, suggesting that iCare can be consider as an appropriate tonometry method for routine clinical use, especially in the screening of healthy patients. Because this tonometer can be used without an anesthetic, similarly to non-contact tonometry, it may also offer a possible affordable alternative for family doctors and optometrists, and could be used in taking self-measurements of IOP. Our findings suggest that iCare measurements are

affected by CCT. This indicates the importance of adjusting iCare IOP readings according to the individual corneal thickness in order to avoid overestimation or underestimation in IOP, which in some cases, can lead to diagnostic misclassification.

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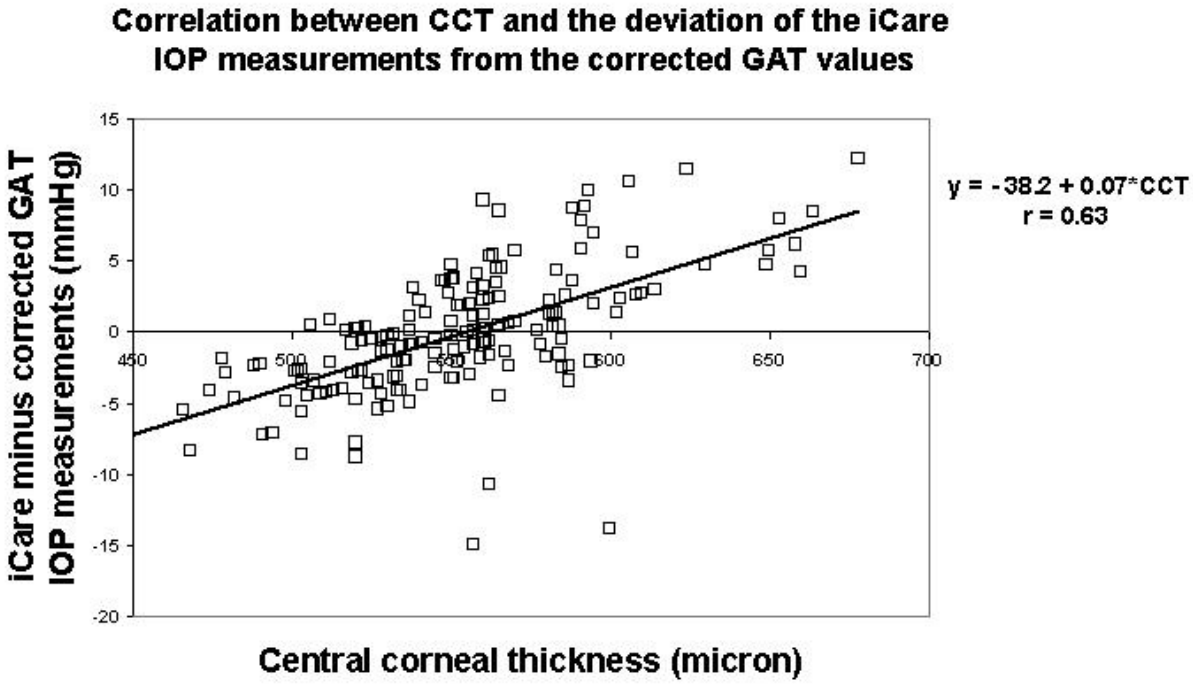
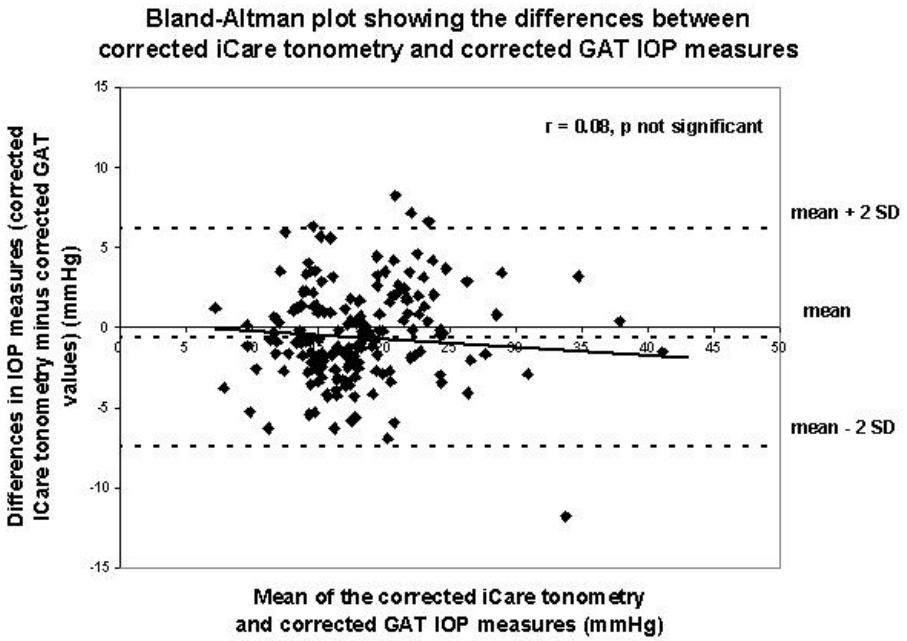
Legends for figures

Fig.1 Correlation between CCT and the deviation of the iCare measurements from the corrected GAT values calculated according to the formulae derived from the studies of Doughtly *et al*. (9)

Fig.2 Bland-Altman analysis showing the distribution of differences in IOP (corrected iCare tonometer value minus corrected GAT value, mmHg) (y-axis) and the mean IOP value of the tonometers (x-axis) for each eye measured.





Tab.1 Description of the IOP measurements results

	GAT readings (mmHg)	iCare readings (mmHg)	iCare - GAT (mmHg)	corrected* GAT readings (mmHg)	corrected** iCare readings (mmHg)	corrected iCare - GAT (mmHg)
mean	19.4	18.4	-1.0	18.5	17.9	-0.6
standard deviation	5.4	5.2	3.5	5.7	5.5	3.4
range	8 - 55	9 - 38	-17 - 8	6.6 - 51.7	6 - 40.4	-17.5 - 8.2
95% confidence level	12 - 31	11 - 31	-7 - 6.6	10.3 - 32.8	9.1 - 30.1	-6.3 - 5.8

IOP = intraocular pressure

GAT = Goldmann applanation tonometry

*** = correction formulae of Doughty *et al.* (9)**

**** = correction formulae obtained with our linear regression model (see Results)**