

Comparison of ICare and IOPen vs Goldmann applanation tonometry according to international standards 8612 in glaucoma patients

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Abstract

• **AIM:** To compare IOPen and ICare rebound tonometry to Goldmann applanation tonometry (GAT) according to International Standards Organization (ISO) 8612 criteria.

• **METHODS:** Totally 191 eyes ($n=107$ individuals) were included. Criteria of ISO 8612 were fulfilled: 3 clusters of IOP, measured by GAT, were formed. The GAT results were given as mean±standard deviation.

• **RESULTS:** GAT (19.7 ± 0.5 mm Hg) showed a significant correlation to ICare (19.8 ± 0.5 mm Hg) ($r=0.547$, $P<0.001$) and IOPen (19.5 ± 0.5 mm Hg) ($r=0.526$, $P<0.001$). According to ISO 8612 criteria in all 3 IOP groups the number of outliers (of the 95% limits of agreement) exceeded 5% for ICare and IOPen vs GAT: No.1 ($n=68$) 29.4% and 22.1%, No.2 ($n=62$) 35.5% and 37.1%, No.3 ($n=61$) 26.2% and 42.6%, respectively.

• **CONCLUSION:** The strict requirements of the ISO 8612 are not fulfilled in a glaucoma collective by ICare and IOPen at present. As long as the Goldmann tonometry is applicable it should be used first of all for reproducible IOP readings. ICare and IOPen tonometry should be considered as an alternative tool, if application of Goldmann tonometry is not possible.

• **KEYWORDS:** ICare tonometry; IOPen tonometry; Goldmann applanation tonometry; glaucoma; intraocular pressure

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INTRODUCTION

Today many different tonometry devices are in use for the routine ophthalmological check-up. This points out the importance of creating an effective and reliable standard tool to measure the intraocular pressure (IOP) in an ophthalmologic examination.

A widely used standard in the clinical practice is Goldmann applanation tonometry (GAT). Limitations of GAT were primarily based on corneal structure alterations and examiner dependence^[1-2]. However, the most important shortcoming of GAT is the static nature of its measurement, which represents a single snapshot of an individual's IOP^[3]. A clinical instrument that directly measures the true gold standard of IOP is currently not available^[3]. Referring to other analysis systems of the IOP, the mechanism of the rebound tonometry gained high interest among glaucoma specialist as it showed a similar performance to the intracameral pressure of the eye^[4-6]. Rebound tonometry is one of the most recent approaches to create the optimum tonometer without the need of topical anaesthesia and thus minimising influencing parameters^[7-8]. In addition, it could be demonstrated that corneal pathologies did not mainly affect rebound tonometry^[7-8]. The international standards International Standards Organization (ISO) 8612 guidelines were developed to certify tonometers for the clinical use in healthy subjects and patients with raised IOP and served as guidelines to assess the rebound tonometry in our study design^[9].

The aim of the present study was to investigate the IOP distribution of the two rebound tonometers ICare and IOPen compared to the reference tonometry GAT according to ISO 8612 criteria in a glaucoma collective^[9].

SUBJECTS AND METHODS

Totally 191 eyes of 107 patients (62 women, 45 men) were included in this prospective study approved by the Ethics Committee Charite University Clinic Berlin from June 2012 to March 2013. The Declarations of Helsinki were followed at all times.

For each patient an ophthalmologic examination with medical history, best-corrected visual acuity, slit-lamp examination, gonioscopy, visual field examination (Humphrey Visual Field Analyzer, Carl Zeiss Meditec, Dublin, California, USA) and fundoscopy was performed. The study population included only patients diagnosed with primary open angle glaucoma (POAG), pseudoexfoliation glaucoma and pigmentary glaucoma. In all patients glaucomatous optic disc alterations and an open chamber angle in the gonioscopy could be demonstrated. The optic disc was described according to the diagnostic criteria by Jonas^[10]. Eyes, which were classified as glaucomatous had three consecutive abnormal visual field results [pattern standard deviation (PSD) outside the 95% confidence interval and/or glaucoma hemifield test outside normal limits]. Exclusion criteria of this study population were corneal pathologies like dystrophies, buphthalmus, corneal surgery and irregular astigmatism.

Two different rebound tonometers "ICare" and "IOPen" were investigated and compared to the reference method, which was "GAT" in the present study. The international standards ISO 8612 guidelines were developed to certify tonometers for the clinical use due to the European Union agreement of standardization of medical equipment and served as guidelines in our study design. To fulfill the ISO criteria we included 191 eyes of 107 persons. At least 150 eyes and at least 40 eyes for each of three pressure ranges, 7 to 16 mm Hg, >16 to <23 mm Hg, and ≥ 23 mm Hg, have to be examined.

IOP readings were received in the following order, all patients started with either IOPen or ICare followed by GAT evaluation in this sequence^[11-12]. We adjusted our study protocol according to the publications of Jorge *et al*^[11] and Fernandes *et al*^[12] to receive comparable data by reducing the bias of a different study set up. Additionally, we kept this sequence to reduce the bias of morphological alterations considering that the applanation initiated by GAT could introduce errors in the following IOP determinations.

For GAT three measurements were obtained: IOP readings were defined as the mean of three, including IOP measurements with a deviation of at most 3 mm Hg.

Methods

ICare rebound tonometry ICare rebound tonometry (Tiolat, Helsinki, Finland) uses a solenoid for producing its velocity to the central cornea; the probe uses a velocity of 0.2 m/s towards the cornea. Motion parameters are monitored by an induction based coil system. An advanced algorithm analyses deceleration and the contact time of the probe during corneal contact. Faster deceleration and shorter contact time of the probe are related to higher IOP measurements. Studies were composed a detailed description of this rebound tonometry principle^[13-14]. Topical anaesthesia and fluorescein application are not needed for measuring IOP.

IOPen rebound tonometry The IOPen rebound tonometry (Swiss Company Mediceal AG, Luchten, Wolfhaden, Switzerland) is using a similar principle compared to the ICare rebound tonometry, which is improved by an automatic measurement system for indicating the distance to cornea, an angle control for approaching the central cornea and a self calibrating system after changing the sanitary tip. The measure range reaches from 0-99 ± 2.8 mm Hg. Height, latitude, depth and weight are 294 mm \times 124 mm, 5 mm \times 29 mm, 6 mm, 212 g.

Studies extensively described the rebound tonometry technique^[13-15]. Advantages of the rebound tonometry in short, no topical anaesthesia, highly sanitary conditions by using a single use tip, fixation light for the patient and a target beam for the examiner^[13-15].

Goldmann applanation tonometry GAT (Haag Streit, Koeniz, Switzerland) is the widely used standard in ophthalmic slit-lamp examination; therefore it was used as the reference tonometer. Calibration of GAT is fulfilled according to ISO 8612. The GAT is based on the Imbert-Fick law to measure IOP^[16]. This law postulates that for an ideal sphere, the pressure within the sphere (P) is roughly equal to the force needed to flatten its surface (F), divided by the applanation area (A), that is $P = F/A$. IOP is proportional to the pressure applied to the cornea and to the thickness of the tissue. The diameter of the Goldmann probe is 3.06 mm which correlates to a contact area of 7.35 mm². Grams of force applied at the probe (3.06 mm) can be directly converted to mm Hg when multiplied by 10. The human cornea and its rigidity, however, do not behave as an ideal sphere. Corneal rigidity and tear film capillary attraction balance each other when the applanation area is set at 7.35 mm², which is the area of the GAT probe^[16].

The central corneal thickness (CCT) was measured by ultrasound pachymetry before the IOP measurements were taken (SP-3000, Tomey Corp. Nagoya, Japan). The CCT measurement was defined as the mean of five measurements. Measurements for all devices were taken by 1 ophthalmologist.

Assessment of statistical data was calculated by SPSS v20.0: linear regression analysis and descriptive statistics (mean, standard deviation, 95% limits of agreement and correlation quotients) were processed. Bland Altman plots were used to represent the analysis of the three tonometry devices.

To meet ISO 8612 criteria the difference method and total method of least squares were used for calculation of the regression line. The first method was the so called "difference method": the differences between the mean values of the test and reference tonometer were plotted against the mean values of the reference tonometer. At least 150 eyes for 3 IOP intervals (of which at least 40 eyes per IOP range) must be examined. For each IOP range the admissible tolerances of these differences are ± 5.0 mm Hg.

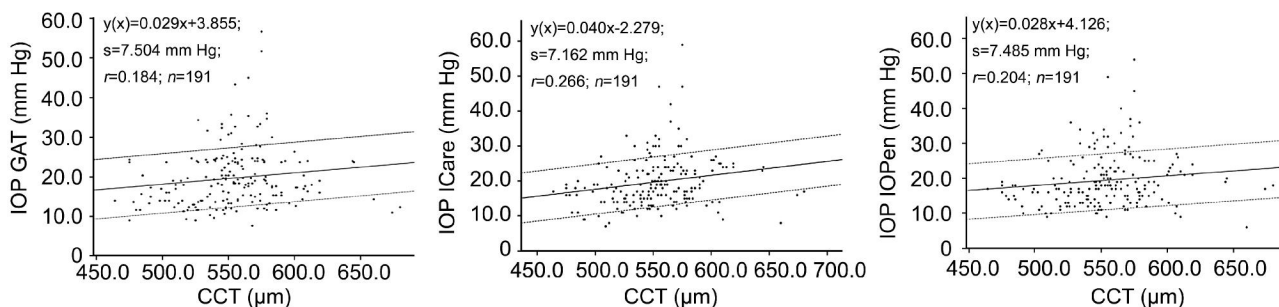


Figure 1 Linear regression analysis and confidence interval of the regression coefficient (slope) of ICare, IOPen and GAT vs CCT.

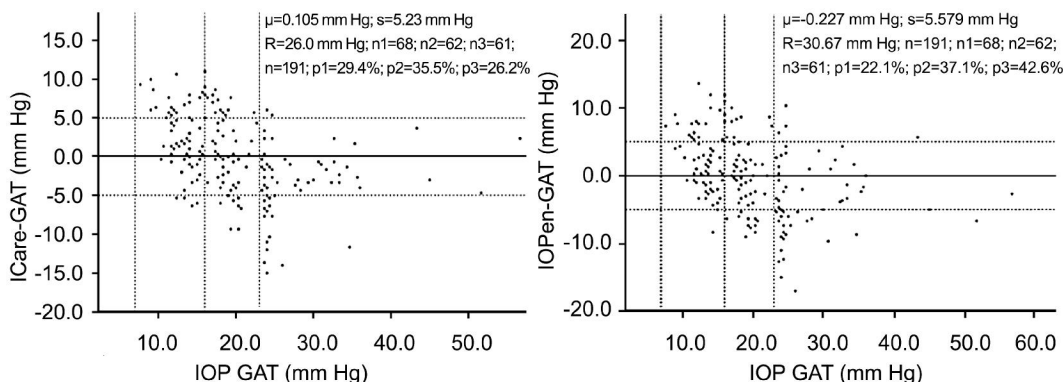


Figure 2 Difference of ICare–GAT and IOPen–GAT vs GAT. The comparison between IOP measurements taken with GAT, ICare and IOPen tonometers; mean difference±standard deviation, numbers of the IOP groups and outliers of the 95% limits of agreement in the three IOP groups were outlined.

The tolerance represents 1.96 times the standard deviation approved for the paired measurement, and so accounts for the permitted error of the tonometer under test and also for the unavoidable error associated with the reference tonometer. If the differences of mean values between the test tonometer and the reference tonometer are outside of the permissible tolerances ± 5.0 mm Hg, it implicates that these measurements on this specific eye are outliers. Only 5.0% outliers per IOP interval are permitted within a tolerance of ± 5.0 mm Hg. The second method of the analysis of this ISO standard is the "method of least squares". Slope, offset (interception) and the standard deviation of regression line are determined by this method. The maximum permissible errors for the three parameters can be derived from the outlier criterion of the difference method.

RESULTS

Mean IOP measured by GAT, ICare and IOPen were 19.7 mm Hg (± 0.5 mm Hg), 19.8 mm Hg (± 0.5 mm Hg) and 19.5 mm Hg (± 0.5 mm Hg), respectively (Table 1). Positive correlation $r=0.547/0.526$, $P<0.001$ was shown between GAT and ICare/IOPen, respectively. GAT measurements were similar to IOPen and ICare IOP analysis. Mean CCT was 553 ± 36.48 μm in this study population. Association of CCT and IOPen/ICare and GAT were calculated by linear regression analysis. GAT, IOPen and ICare tonometry showed following correlation to CCT (GAT: $r=0.184$, 95% CI $10.947 \leq \beta \leq 18.657$, $P=0.011$; IOPen: $r=0.204$, 95% CI $10.639 \leq \beta \leq 18.891$, $P=0.05$; ICare: $r=$

Table 1 Descriptive analysis of GAT, ICare and IOPen in the study population $n=191$ for each study

Value	GAT	ICare	IOPen
Mean	19.7	19.8	19.5
SD	0.5	0.5	0.5
Modus	18.3	18.0	18.0
Range	7.67-56.67	7.00-59.00	6.00-54.00

SD: Standard deviation.

0.266 , 95% CI $16.407 \leq \beta \leq 11.849$, $P<0.001$). The statistical data were represented in Figure 1.

The assessment of the study group included to split the population in three different IOP clusters: No.1 7 to 16 mm Hg ($n=68$), No.2 >16 to <23 mm Hg ($n=62$), No.3 ≥ 23 mm Hg ($n=61$).

Using the difference method statistics (IOPen-GAT vs GAT) and thus illustrating the comparison between IOP measurements (GAT and IOPen), a mean difference of $\mu=0.2 \pm 5.6$ mm Hg could be demonstrated. IOP outliers of the 95% limits of agreement in the three IOP groups were $p1=22.1\%$, $p2=37.1\%$, $p3=42.6\%$ (Figure 2). Further comparison of the IOP between GAT and ICare tonometry showed a mean difference of $\mu=0.1 \pm 5.2$ mm Hg. Outliers of the 95% limits of agreement in the three IOP groups were $p1=29.4\%$, $p2=35.5\%$, $p3=26.2\%$ respectively (Figure 2).

The ISO 8612 criteria could not be fulfilled by neither of the two test tonometers; limits were a standard deviation between test and reference tonometer <2 mm Hg and the number of outliers $<5\%$.

Linear regression analysis was performed between test tonometer ICare and reference tonometer GAT: $y=0.726x+5.501$, $s=4.815$ mm Hg, correlation quotient $r=0.547$, $P<0.05$. Linear regression analysis between test tonometer IOPen vs GAT showed following: $y=0.724x+5.197$, $s=5.189$ mm Hg, correlation quotient $r=0.526$, $P<0.05$.

DISCUSSION

The aim of the present study was to investigate the correlation between two rebound tonometers compared to GAT according to ISO 8612 criteria in glaucoma collective. Diagnosis and management of glaucoma is still highly dependent on the exact IOP measurements, although we know there are many different factors which lead to the optic nerve head neuropathy. As the IOP parameter is easy to assess and to influence by medication and surgery compared to vascular and genetic factors, new IOP devices were continuously developed to raise the accuracy of IOP analysis. In this study population the mean IOP measured by GAT, ICare and IOPen was very close in all three devices; significant correlations were shown between GAT and ICare/IOPen ($r=0.547$, $P<0.001$; $r=0.526$, $P<0.001$), respectively. Tamçelik *et al*^[17] reported about similar correlation coefficients of the GAT and ICare, and non-contact tonometer (NCT) and ICare measurements ($r=0.673$, 0.663 , $P<0.001$ respectively). Additionally in this study, ICare showed a slight overestimation and IOPen an underestimation of IOP compared to GAT. Jorge *et al*^[11] presented the only study comparing all three devices, ICare, IOPen and GAT, but in a cohort of healthy subjects ($n=101$); the study findings highlighted an underestimation of IOPen measurements compared to GAT and ICare and a difference of >3 mm Hg in $>55\%$ of IOP readings between IOPen and GAT. Other comparative studies (ICare vs GAT) reported about mean differences of IOP between $1.0-3.6$ mm Hg^[11,17-19]. Most of them presented an overestimation of ICare compared to GAT by $1.3-3.6$ mm Hg^[12,18-24]. Brusini *et al*^[25] demonstrated data of an underestimation of ICare vs GAT in a glaucomatous population by 1 mm Hg. Our findings showed a lower mean difference of 0.1 ± 5.2 mm Hg. Tamçelik *et al*^[17] reported on an overestimation of ICare analysis in the low GAT-measured IOPs, whereas ICare underestimated IOPs in high pressure ranges. The same trend was reported in our data of the glaucoma cohort. The agreement between ICare and GAT is higher in the IOP range of $9-22$ mm Hg, whereas significant discrepancies occur as the IOP deviates from normal values^[17].

Other studies compared IOPen and GAT: in a glaucomatous population ($n=60$) statistically significant mean differences of -4.8 ± 4.3 mm Hg and -4.8 ± 5.8 mm Hg for the right and left eye were found, which represented an underestimation by IOPen compared to GAT^[7,26]. Frequency distribution demonstrated that in $>71.6\%$ of the measurements the IOP readings differed by >3 mm Hg between the two tonometers^[26].

The present study confirmed an underestimation of IOPen, but presented smaller differences (0.2 ± 5.6 mm Hg) compared to Jorge *et al*^[11]. Accuracy of IOPen was comparable to GAT in patients with low or normal IOP but IOPen overestimated IOP at high pressure levels.

ICare and IOPen tonometry was investigated by fulfilling ISO 8612 criteria as the internationally accepted guidelines: The strict ISO 8612 criteria could not be fulfilled by neither of the two test tonometers in the present study. As ICare and IOPen failed this international guideline, Goldmann tonometry as the reference tonometer should be used first if available and applicable to the patient.

To minimize the influence of corneal architecture by measuring IOP the correlation of CCT, rigidity and hysteresis was tested with every newly developed device. Corneal hysteresis and corneal resistance factor were related to the corneal shape and thickness and showed a decrease of corneal hysteresis with age^[27]. Comparative studies showed no correlation of CCT to IOPen measurements ($P>0.05$)^[7-8]. Another comparative study showed that ICare tonometry was dependent on CCT, as well as ICare measurements increased by rising CCT^[18]. GAT, IOPen and ICare tonometry showed the following correlations with CCT (GAT: $r=0.184$, $P=0.011$; IOPen: $r=0.204$, $P=0.05$; ICare: $r=0.266$, $P<0.001$) in the present study. In addition for the clinical context, the variability of the ICare and GAT measurements over a wide range of CCT was minimal^[17]. There is a growing body of evidence that factors such as non-CCT could have an important influence on devices such as GAT and rebound tonometry^[28-30]. Asaoka *et al*^[28] suggested that the Corneal Visualization Scheimpflug Technology (Corvis ST tonometry) parameters were more influential for GAT than the CCT and average corneal curvature. Corvis parameters examined were the time of cornea movement inwards/outwards, maximum deformation amplitude and highest concavity curvature. The measured CST parameters were dependent on the level of IOP, but not significantly related to CCT^[28].

ICare tonometry could be a useful tool in patients with missing fixation and in paediatric cases, because the IOP measurements were not dependent on the exact position on the central cornea; the ICare measurements were also reliable if measured slightly peripheral to the central cornea, which is an advantage in handling handicapped patients and children^[20]. Another advantage is stated by Zeri *et al*^[31] who reliably performed rebound tonometry over silicone hydrogel contact lenses, whereas the agreement of GAT with or without contact lenses seems to be poor, especially for high intraocular pressure^[32].

In the present study, ICare and IOPen rebound tonometry could not meet the international standard for eye tonometer (ISO 8612) in a glaucoma population because the standard deviations between test and reference tonometer (<2 mm Hg) and the number of outliers ($<5\%$) exceeded the stated limits.

ICare, IOPen and GAT correlated significantly with CCT. ICare tonometry overestimated IOP compared to GAT, IOPen showed an underestimation of IOP. It seems to be advisable, that as long as the Goldmann tonometry is applicable, it should be used first for reproducible IOP readings. ICare and IOPen tonometry should be considered as an alternative tool, if application of Goldmann tonometry is not possible.

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