

# Comparison of Measurement of Intraocular Pressure by ICARE PRO® Tonometer and Goldmann Applanation Tonometer

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## SUMMARY

The paper compares a concordance in measuring the intraocular pressure (IOP) using two different tonometers, Goldman applanation tonometer (GAT) and ICARE PRO® tonometer. GAT is nowadays considered a standard device for measuring the IOP at the offices of ophthalmologists. Options of the measurements are however limited by necessary installation as well as use of a slit lamp where the evaluation is made subjectively by the examiner. The ICARE PRO® tonometer is a light and mobile device that allows to perform the measurement horizontally as well as vertically. The results are calculated automatically.

The data for the paper was collected by IOP measurements in right and left eye in 45 individuals at the age range of 8–84 years. They were all diagnosed for glaucoma or were suspected to have glaucoma. The measurements were carried out always at the same day time. The acquired data was compared by a double select paired t-test with a significance level  $p = 0.05$  and then analyzed by Bland-Altman method.

There was no statistically important difference ( $p > 0.26$ ) between the two devices. The average IOP measured by the ICARE PRO® tonometer was 18.19 mm Hg with standard deviation 3.70 mm Hg, whereas the average IOP measured by GAT was 17.94 mm Hg with standard deviation 3.66 mm Hg. It was observed that the difference in the measurements was not related to the IOP.

The results show an acceptable concordance of measurements performed by the two devices. The ICARE PRO® tonometer, in comparison with its predecessor ICARE® TA01 evaluated in the past, shows a much smaller average difference in collected values compared with GAT. Based on the analysis of the collected data it may be stated that measuring the IOP by ICARE PRO® tonometer is clinically acceptable alternative to the use of GAT.

**Key words:** intraocular pressure, Goldman applanation tonometer, ICARE PRO® tonometer, rebound tonometry, applanation tonometer

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## INTRODUCTION

Measurement of intraocular pressure (IOP) represents one of the basic methods for screening and monitoring of glaucoma or ocular hypertension. To date, the most widely used and internationally recognised method for measuring IOP is Goldmann applanation tonometry, frequently referred to as the gold standard in the measurement of IOP [1]. Upon the use of this method, IOP is determined on the basis of the “Imbert-Fick law”, modified for the requirements of calculation of the pressure of the real eye [2], in which IOP is calculated from the force necessary for applanation of the cornea by a blunted glass cone with a certain constant diameter. The corresponding instrument, a Goldmann applanati-

on tonometer (GAT), is placed on a slit lamp, the optical system of which is used simultaneously for measurement. Upon measurement of IOP using GAT, it is essential to apply local anaesthetics and fluorescein to the cornea. This is therefore an invasive examination, which places a certain burden on the patient. Further disadvantages are the immobility of the instrument connected to the slit lamp, subjective reading of the resulting values and the essential additional experience of the examiner.

A range of methods have been proposed and practically implemented for the measurement of IOP, based on various principles which attempt to eliminate the disadvantages of measurement on GAT. An overview is presented for example by the publication [3]. One of the possible alternatives

may be tonometry based on rebound, also known as dynamic or rebound tonometry, which does not require anaesthesia of the cornea or application of other pharmaceuticals, whilst at the same time providing a good concordance of measurement with the results of Goldmann applanation tonometry within the framework of the trials conducted to date [4, 5, 6]. In the Czech Republic this method is not yet widespread in clinical practice, and the original comparative trial conducted by Czech authors has not been published yet in professional periodicals. The method is based on the observation of the rebound of the moving probe of the instrument off the cornea of the eye, where a change of the movement parameters of the probe takes place depending on the level of IOP. The value of IOP is subsequently de-

terminated from the kinetic parameters of the probe. This method is practically used for example by instruments of the ICARE® type, in which the latest types of this device include the type ICARE PRO®. The first tonometer based on this method was presented in the year 2000, the first commercially available device was introduced onto the market in 2003 [7, 8]. The core advantages of this technique and thus also of the ICARE PRO® device include easy handling, speed of measurement, mobility of the instrument, possibility of measuring in vertical and horizontal position, determination of the final result by automatic averaging of a number of consecutively measured data, and the ability to conduct the measurement without the application of any pharmaceuticals.

The ICARE PRO® tonometer is a light, mobile instrument, which can be controlled easily with one hand, in which the measured data is displayed on an integrated display and saved in the memory. It is subsequently possible to export and back up the data in the supplied database software in a computer. The instrument is fed by an inbuilt accumulator and recharged in a separate docking station, which at the same time serves for connection to a computer. The actual measuring device is a measuring head, installed on an ergonomic handgrip with a main control button. The measuring head contains a coil into which a disposable probe is inserted horizontally – a light, magnetised metal rod with a rounded contact end. Before measurement, the contact end of the rod, inserted in the measuring head, is brought towards the cornea to a distance of approximately 4 to 8 mm. An adjustable head rest located in the upper part of the measuring head serves for maintaining the correct examination position. Upon pressing the main button, a magnetic field is triggered in the coil by an electrical impulse, launching the probe into movement at the cornea. Following rebound of the probe from the cornea and its backward movement voltage is induced in the coil, which is detected, amplified, converted into a digital signal and processed. The generated voltage is dependent on the movement parameters of the probe. The relevant IOP is determined from the obtained data by the integrated software. With regard to the potential variability of the results, the final result is determined as an average of a number (usually six)

of rapidly following consecutive partial measurements.

As has already been mentioned, previously published studies demonstrate a good concordance of the predecessors of the ICARE PRO® model with GAT [4, 5, 6]. The aim of this paper was to determine whether this new model also demonstrates a good concordance in comparison with GAT, and the extent to which it can therefore be substituted for GAT in routine clinical practice.

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## METHODOLOGY

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The study took place at the Department of Ophthalmology at the University Hospital of Palacký University in Olomouc. The study enrolled 45 subjects (28 women and 17 men) aged from 8 to 84 years, with an average age of 55 years and a standard deviation of 18 years, in whom glaucoma had been diagnosed, or who had been observed due to suspicion of glaucoma. For the purposes of the study, pressure was measured in both eyes of all the subjects, thus a total of 90 eyes were measured. The study was conducted in accordance with the provisions of the Helsinki Declaration. With regard to the possible influence of physiological changes on IOP during the course of the day, the measurement was conducted always between 8 a.m. and 12 p.m. The measurement was implemented within the framework of a complex ophthalmological examination. As a result, mydriatics were applied to both eyes of all subjects before initiation of the examination. For the purposes of the examination by Goldmann tonometer, anaesthetics and dye in the form of fluorescein strips were also applied. For reasons of maintaining the same physiological conditions upon measurement by both instruments and ensuring the minimum possible time delay between the individual measurements, all the stated substances were applied before initiation of measurement. Each subject was first of all measured using ICARE PRO® tonometer, always with a new disposable probe. IOP was determined first of all for the right and then the left eye. One measurement on the given eye consisted of a series of six rapidly performed consecutive partial measurements. In this process the software automatically evaluated whether a partial measurement had been erroneous, i.e. whether the speed of the probe was too low or high,

or whether its impact was too soft or hard. These errors can be caused by an inappropriate distance or incline of the instrument, or an undesirable rebound of the probe off the eyelid or non-central part of the cornea. If an error was detected, the measurement was not accepted and it was conducted again. The resulting value of intraocular pressure for the given eye, hereinafter indicated as IOPICARE, was obtained as an arithmetic average of the partial results. At an interval of five minutes after the end of the last measurement of the subject using the ICARE PRO® instrument, IOP was measured using GAT. The value from GAT is hereinafter indicated as IOPGAT. IOP was again first of all determined for the right and then the left eye, in which one measurement was conducted on each eye and the values were read on the scale by the examiner. Each of the compared devices was operated by a different examiner, with sufficient practical experience in handling of such a device. The examiners did not change throughout the entire study. The values determined with ICARE PRO® were not known to the examiner using GAT before the measurement.

The concordance of the data obtained by both instruments was tested by a double-sample pair t-test on a level of significance  $p = 0.05$ , and further analysed by the Bland-Altman method [8]. For the requirements of this analysis, the partial difference  $\Delta IOP$  was determined between the values measured by both instruments,  $\Delta IOP = IOPICARE - IOPGAT$ , as well as the arithmetical average of these partial values  $(IOPICARE + IOPGAT)/2$ . In addition, the overall average difference in pressure, the relevant standard deviation SD and 95% confidence interval were calculated for all the examined eyes. The upper and lower limits of the confidence interval were determined as  $\pm 1.96 \cdot SD$ . The analysis was conducted in the program MS Excel.

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## RESULTS

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No statistically significant difference ( $p > 0.26$ ) was found between the data from both tested instruments in a pair t-test. The overall average value of IOP from the data obtained with the ICARE PRO® tonometer was 18.19 mm Hg, the relevant standard deviation was 3.70 mm Hg. In the case of GAT, the overall average value was 17.94 mm Hg with a standard devi-

ation of 3.66 mm Hg. The measured values fluctuated within an interval from 10.00 mm Hg to 27.70 mm Hg for ICARE PRO® and from 11.00 mm Hg to 26.00 mm Hg for GAT.

A Bland-Altman analysis of the concordance between the results obtained from both instruments is graphically presented in Fig. 1. The difference  $\Delta IOP$  of the measured pressures, determined for each eye, is plotted depending on the arithmetical average of the values from both studied tonometers, in which the data determined for the individual eyes is illustrated by circles. The average difference, represented in the graph by a full horizontal line, was 0.25 mm Hg with standard deviation of 2.15 mm Hg. The scope of the relevant 95% confidence interval was from -3.97 mm Hg to +4.48 mm Hg. The limits of the interval are illustrated in the graph by means of horizontal dotted lines. The performed

correlation analysis implied that the dependence of the difference  $\Delta IOP$  on the average pressure is not significant for the observed sample ( $r = 0.018$ ,  $p > 0.86$ ).

The frequency of the values of size of the differences is illustrated by the histogram in Fig. 2. A difference in size of less than 3 mm Hg was determined in 84.4% of the studied eyes, of which the size of the difference in 65.5% of measurements was less than 2 mm Hg and in 34.4% of measurements less than 1 mm Hg. A difference in size of 3 mm Hg and more was determined in 15.6% of eyes, of which a difference of over 4 mm Hg was recorded in only 6.7% of cases.

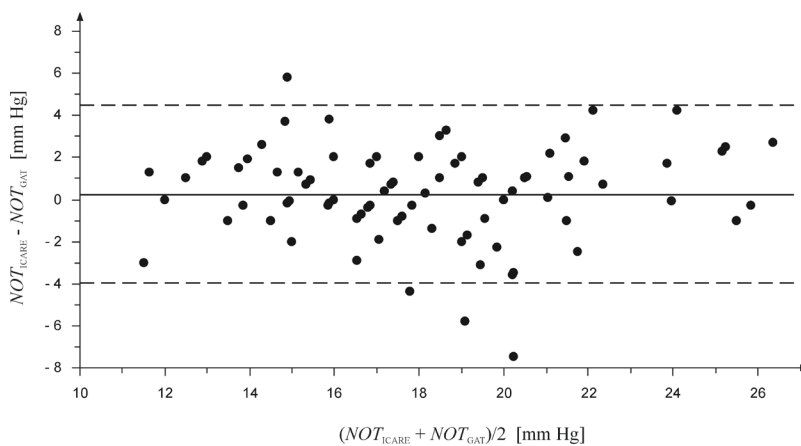
## DISCUSSION

In some cases (for example immobile patients, children), observation of intraocular pressure requires mobile,

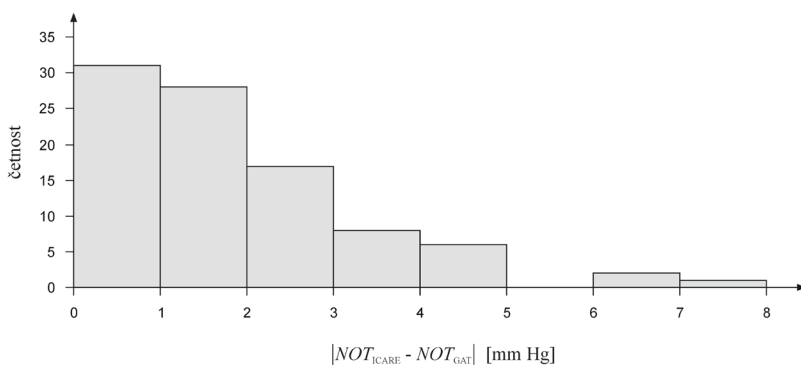
quick and simple measurement, if possible without placing any further burden on the examined patient. Mobility, simplicity and the ability to record quickly also plays a significant role in screening. Goldmann applanation tonometry, which usually requires a device firmly attached to a slit lamp, the necessity of application of pharmaceuticals to the eye and subjective reading of the resulting values, is not optimal for these purposes. As a result, alternative methods for measurement of IOP are being sought, which could eliminate these disadvantages to a considerable degree. The widespread techniques which do not require the application of pharmaceuticals include noncontact tonometry, which uses flattening of the cornea caused by an air jet. However, this method may cause considerable discomfort for some patients [10]. Tonometry based on the rebound method, specifically tonometry of the ICARE® type, represents one of the options which combine the required properties. An ICARE® tonometer, specifically type TA01, is one of the first commercially used tonometers of this type whose concordance with GAT has been studied in detail. The obtained results demonstrate clinically acceptable concordance.

In the study [4] conducted on glaucoma patients it was determined that in comparison with GAT, ICARE® TA01 produces values by  $1.00 \pm 3.50$  mm Hg lower (average  $\pm$  standard deviation), in which a difference of less than 3 mm Hg was determined in 74.1% of the measured eyes. As against this, a research presented in a publication [6] determined averagely higher values in the case of ICARE® TA01 in comparison with GAT, by  $1.40 \pm 2.19$  mm Hg. The study included patients with normal ocular pressure, hypertension and glaucoma. Similar conclusions are also presented in a publication [5] in which the values produced by ICARE® TA01 were by  $1.34 \pm 2.03$  mm Hg higher than in the case of GAT. 82.6% of measured eyes demonstrated a difference of less than 3 mm Hg. In all the above cases, concordance of the measurements by both of the observed instruments was evaluated as good on the basis of a Bland-Altman analysis, and the ICARE® TA01 instrument was thus confirmed as a suitable alternative to GAT.

In our study, on the basis of a comparison with GAT, we evaluated an ICARE PRO® tonometer, which represents



**Fig. 1** Graphical dependence of difference in pressures measured by ICARE PRO® and GAT on average value of measurement. The circles represent the values obtained for the individual eyes. The full horizontal line represents the average value of the difference; the dotted lines delineate the 95% confidence interval.



**Fig. 2** Histogram of absolute frequency of occurrence of size of differences in pressures measured by ICARE PRO® and GAT.

the latest commercially available model of an ICARE® type tonometer. In addition to the above-stated advantages of the previously verified type, it provides the additional advantage of simple transmission of the measured data into the relevant database software, which enables archiving and processing of it. The instrument differs from the previous model in a number of technical parameters (for example size of the used probe), and it is therefore impossible to take the results which were valid for the older model. On the basis of the data obtained within the framework of our study, a statistically insignificant ( $p > 0.26$ ) average difference of  $0.25 \pm 2.15$  mm Hg was determined between the values of IOP measured using ICARE PRO® and GAT. Taking into account the above-stated published results

[4, 5, 6], it is possible to state that in comparison with its predecessor, ICARE PRO® manifests a fundamentally smaller average difference in the measured values as against GAT. In this the 95% confidence interval of concordance in the Bland-Altman method (from -3.97 mm Hg to +4.48 mm Hg) is of a size analogous as in the previous studies (from -7.00 mm Hg to +6.6 mm Hg [4], from -2.89 mm Hg to +5.69 mm Hg [6] and from -2.64 mm Hg to +5.32 mm Hg [5]). At the same time it was determined that as much as 84.4% record a deviation of less than 3 mm Hg, which is a higher value than stated by the publications [4, 5] for the previous version of the instrument.

On the basis of the presented results, the ICARE PRO® instrument can be considered to be a clinically

acceptable alternative to GAT in the tested range of IOP values, in which a comparison with the previous model demonstrates a clearly smaller difference in the values in comparison with GAT. With regard to the fact that no dependence of the difference on the value of measured pressure was demonstrated, it is possible to state the hypothesis that an analogous concordance would also be recorded for lower and if applicable higher values of IOP than those of the group tested in this study. However, it is necessary to verify this in further studies. At the same time it shall be necessary to supplement information about the influence of central thickness of the cornea on the results of measurement, which was demonstrated in the case of the previous type [4, 6] and was not analysed in our study.

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