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A new rebound tonometer for home monitoring of intraocular pressure

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Abstract
Background To compare intraocular pressure (IOP) measurements obtained by the Icare ONE rebound tonometer (RTONE) and the Goldmann applanation tonometer (GAT) in healthy persons and glaucoma patients in a prospective study, and to investigate the influence of central corneal thickness (CCT).
Methods Measurements on 126 right eyes were obtained by three equally skilled ophthalmologists with each of the above-mentioned tonometers. In addition, patients measured their own IOP with the RTONE (RTONE(p)). The means and standard deviation for all tonometers were compared. Agreement between the tonometers was calculated using the Bland–Altman method.
Results A total of 95 (75.3%) patients were able to perform correct self-tonometry. Mean IOPs obtained were 17.1± 5.9 mmHg (RTONE performed by ophthalmologist: RTONE (o)), 17.3±5.6 mmHg (RTONE(p)) and 16.5± 5.1 mmHg (GAT). Correlation analysis indicated a good correlation between IOP readings obtained using RTONE (o) and RTONE(p) (ρ=0.916; p<0.001) and RTONE(o) and GAT (ρ=0.901; p<0.001). Bland–Altman analysis revealed a mean difference (bias) between RTONE(o) and RTONE(p), between RTONE(o) and GAT, and between RTONE(p) and GAT of −0.2, 0.6, and 0.8 mmHg, respectively, with 95% limits of agreement of −5.0 to 4.5, –4.4 to 5.6, and −4.6 to 6.1 mmHg, respectively. The difference between RTONE(o) and GAT significantly increased with increasing CCT (ρ= 0.004), with a 10% increase in CCT resulting in a 1.8% increase in the difference.
Conclusions Measurements obtained with the RTONE, either by an ophthalmologist or by the patient, showed an excellent correlation with those provided by applanation tonometry. RTONE generally tends to overestimate IOP compared to GAT readings and displays a dependence on CCT.

This study was registered with the DRKS (German Clinical Trials Register; www.germanctr.de; DRKS00000478).

Keywords Icare rebound tonometry · Goldmann applanation tonometry · Glaucoma · IOP home monitoring · Self-tonometry

Introduction

Elevated intraocular pressure (IOP) is a major risk factor for glaucoma, which causes visual impairment and blindness in millions of patients worldwide [1]. Accurate IOP estimation at various points in time is important to assess the risk for glaucoma and glaucoma progression. Goldmann applanation tonometry (GAT) is generally considered the "gold standard" for measuring IOP [2]. However, estimation with GAT has disadvantages: it requires a topical anesthetic, a slit lamp, and an experienced tonometrist. It is difficult in children, in patients who are bedridden, and in those with corneal abnormalities.

Icare tonometry is based on the principle of rebound tonometry [3, 4]. In rebound tonometry, a magnetized probe is launched against the eye, using a solenoid. This solenoid

The authors have full control of all primary data and agree to allow Graefes Archive for Clinical and Experimental Ophthalmology to review their data upon request.

Clinical trial registration: German Clinical Trials Register; number: DRKS00000478.

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detects the motion and impact when the probe collides with the eye and bounces back. The moving magnet in the probe induces voltage in the solenoid, and the motion parameters of the object are monitored. The simplicity of pressure measurement using the Icare rebound tonometer has been documented in a large number of studies. Moreover, Abraham et al. showed that inexperienced examiners are able to obtain valid values [5].

Additional studies have reported high intraobserver and interobserver reproducibility of measurement data [6, 7]. Measurement of IOP with rebound tonometry does not require topical anesthesia, minimizes corneal injury, and avoids the risk of cross infection through the use of disposable probes. Eventually, the technology of rebound tonometry could be a good alternative for self-measurement of intraocular pressure.

Recently, the Icare ONE tonometer (RTONE), which is also based on the principle of rebound tonometry, has become available for self-tonometry. The principle of self-tonometry will be of interest to patients requiring frequent monitoring of IOP. It provides the ophthalmologist with IOP measurements taken daily by the patient at routine intervals. Measurement of IOP at night and in supine position is an important diagnostic factor for glaucoma patients and is another possible application of the Icare ONE tonometer.

In our prospective study, we have compared IOP measurements obtained with the RTONE, either by an ophthalmologist or by the patient with GAT readings. Moreover, we also investigated the role of central corneal thickness (CCT) on rebound tonometry. After self-tonometry using the RTONE, patients were requested to complete a questionnaire using a visual analog scale to give their evaluation of the operability, safety, and comfort of the device.

Subjects and methods

This prospective trial included measurements at 126 right eyes (74 eyes with glaucoma disease and 52 eyes without glaucoma) of 126 patients of Caucasian ancestry who visited our department between July 2010 and November 2010 and had given signed and informed consent in writing. The study protocol conformed with the Declaration of Helsinki, and the trial was approved by the local ethics committee.

Measurements

Before measurement of intraocular pressure, all patients underwent a baseline examination, which included measurement of best-corrected visual acuity (EDTRS charts, Lighthouse, Long Island, NY, USA), visual field examination (30–2, Humphrey field analyzer, Carl Zeiss Meditec, Inc., Dublin, CA, USA), corneal pachymetry (optical low-coherence reflectometry pachymeter, Haag Streit, Koeniz, Switzerland), estimation of axial length (IOL Master, Carl Zeiss Meditec, Jena, Germany), and examination of the anterior and posterior segments of the eye.

Afterwards, all measurements of intraocular pressure were performed in upright position by three equally skilled ophthalmologists who had completed training in use of all the devices. The methods were always applied in the same order to avoid anomalies through a possible reduction in IOP induced by contact applanation tonometry: RTONE – GAT. Before the pressure measurements, the patients were instructed in self-tonometry and use of the RTONE tonometer. The RTONE used was a induction-based impact tonometer called Icare ONE (Icare Finland Oy, Espoo, Finland). After measurement of IOP by a skilled observer, using the RTONE, the patients measured their own IOP with the RTONE. The GAT was an AT900 Applanation Tonometer (Haag Streit, Koeniz, Switzerland). Measurements with the RTONE were performed without topical anesthesia, while subsequent measurements with GAT were taken after application of one drop of Conjuncain™ (oxybuprocaine 4 mg/ml, Bausch & Lomb, Berlin, Germany) and instillation of fluorescein (Haag Streit, Koeniz, Switzerland) in the tear film.

The IOP value obtained using the RTONE is the result of six consecutive measurements. The display on the device indicates 11 pressure zones between 5 and 50 mmHg (5–7, 7–10, 10–14, 14–18, 18–21, 21–24, 24–27, 27–30, 30–35, 35–40, and 40–50 mmHg). The precise values are stored in the tonometer's memory and can be transferred via USB cable to a computer using the Icare LINK software. Two adjustable support elements and an eye cup are provided for self-measurement of IOP. Invalid measurements due to a high standard deviation are indicated by a red LED signal, flashing "REPEAT".

To obtain patient views on general operability, safety, and comfort of IOP measurement with the Icare ONE tonometer, patients were requested to complete a questionnaire using a visual analog scale (range: 1 (excellent) – 5 (poor)) for different subitems (Fig. 1). To assess operability, a subgroup analysis was conducted to establish the patient's experience with contact lenses or with treatment involving application of eye drops, as recorded in the patient history, age of patient, and mean defect in the visual field.

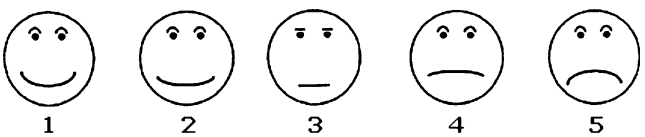

Fig. 1 Visual analog scale. Range: 1="excellent" to 5="poor"

Statistics

Three measurements were taken with each instrument, the mean of three valid measurements being used for statistical calculation [8]. According to the guidelines of the Icare ONE tonometer, only measurements were considered if those yielded maximum quality displayed automatically by the device.

Complete statistical analysis was performed using Prism software (version 5, GraphPad Software). Descriptive statistics were performed to establish the demographic characteristics of the study population. Descriptive analysis, including mean values and standard deviations of IOP measurements using the above-mentioned instruments, was also performed. As the IOP measurements were not normally distributed (calculated by D´Agostino-Pearson normality test), the differences between the tonometers were evaluated with the Mann–Whitney test, with p values of<0.05 being considered statistically significant. The calculated Spearman correlation coefficient ρ indicates a high correlation with ρ=0.7–0.99, a moderate correlation with ρ=0.4–0.69, and weak correlation with ρ<0.4. A Bland–Altman analysis was used to assess the bias and 95% limits of agreement between the instruments [9]. In the Bland–Altman analysis, the difference between each IOP measurement was plotted against the mean. Linear regression of the Bland–Altman analysis showed whether any over- or underestimation of IOP had arisen within the measured range. Linear regression of the difference between RTONE and GAT measurements against the estimated CCT showed whether CCT had led to any over- or underestimation of the IOP, as measured by the RTONE, in our study population.

Results

In our study, valid measurements were performed on 126 right eyes of 126 patients. Mean age of all patients, patients with glaucoma, and patients without glaucoma was 61.5± 15.2 years, 65.0±14.8 years, and 56.7±14.7 years, respectively. Ninety-five patients were able to perform correct self-tonometry of IOP, whereas 31 patients were not. For the entire series of 126 eyes, the mean IOP obtained was 16.5± 5.1 mmHg using the GAT. Measurements with the RTONE revealed a mean IOP of 17.1±5.9 mmHg when the measurement was performed by an ophthalmologist (RTONE (o)) and 17.3±5.6 mmHg when performed by the patient (RTONE (p)). A summary of all variables is given in Table 1.

Correlation analysis indicated an excellent correlation between RTONE(o) and RTONE(p) (ρ=0.916; $p<0.001$), RTONE(o) and GAT (ρ=0.901; $p<0.001$). In 58.7% of the eyes (74/126), IOPs provided by RTONE(o) were higher than GAT measurements. Differences of less than 1 mmHg (2 mmHg) [3 mmHg] with respect to GAT measurements were obtained in 39.7% (66.3%) [80.2%] of readings taken with the RTONE by an ophthalmologist.

Bland–Altman analysis revealed a mean difference (bias) between RTONE(o) and RTONE(p) and between RTONE (o) and GAT, of −0.2 and 0.6 mmHg, respectively, with 95% limits of agreement of −5.0 to 4.5 and −4.4 to 5.6 mmHg, respectively (Fig. 2). Linear regression of the comparisons revealed a proportional error over the range of pressures examined (RTONE(o) vs. RTONE(p): slope=0.08, $p=0.04$; RTONE(o) vs. GAT: slope=0.15, $p=0.003$) (Fig. 2).

The mean CCT for all eyes included in the study was 544.8±43.8 μm, ranging from 452.0 to 635.7 μm. Correlations between the measurements obtained with the

Table 1 Descriptive statistics for all eyes, eyes with glaucoma, and eyes without glaucoma. The mean and standard deviation are given. Additionally, the interquartile range and the median are presented in *square brackets*. As some patients were not able to perform Icare rebound tonometry by themselves, sample size of RTONE(p) is given in brackets

	All patients	Patients with glaucoma	Patients without glaucoma
n	126	74	52
IOP (RTONE(o))	17.1±5.9 mmHg	18.2±6.9 mmHg	15.5±3.5 mmHg
	[12.0–19.3; 16.0 mmHg]	[13.3–22.7; 16.3 mmHg]	[12.0–18.3; 15.3 mmHg]
IOP (RTONE(p))	17.3±5.6 mmHg	18.3±6.5 mmHg	15.9±3.4 mmHg
	[13.3–19.7; 16.0 mmHg] (n=95)	[13.3–22.7; 17.0 mmHg] (n=51)	[13.0–18.3; 16.0 mmHg] (n=44)
IOP (GAT)	16.5±5.1 mmHg	17.7±5.9 mmHg	14.7±2.8 mmHg
	[12.7–18.7; 15.7 mmHg]	[13.3–20.3; 16.0 mmHg]	[12.3–17.0; 14.7 mmHg]
Pachymetry	544.8±43.8 μm	536.3±42.6 μm	557.4±42.7 μm
	[505.0–564.0; 529.0 μm]	[509.0–570.3; 531.8 μm]	[525.3–585.3; 564.7 μm]
Axial length	24.0±1.7 mm	24.2±1.8 mm	23.8±1.6 mm
	[22.8–24.4; 23.8 mm]	[22.9–24.9; 23.9 mm]	[22.8–24.1; 23.6 mm]
Age	61.5±15.2 years	65.0±14.8 years	56.7±14.7 years
	[53.0–73.0; 63.0 years]	[57.0–76.0; 68.0 years]	[47.0–71.0; 58.0 years]

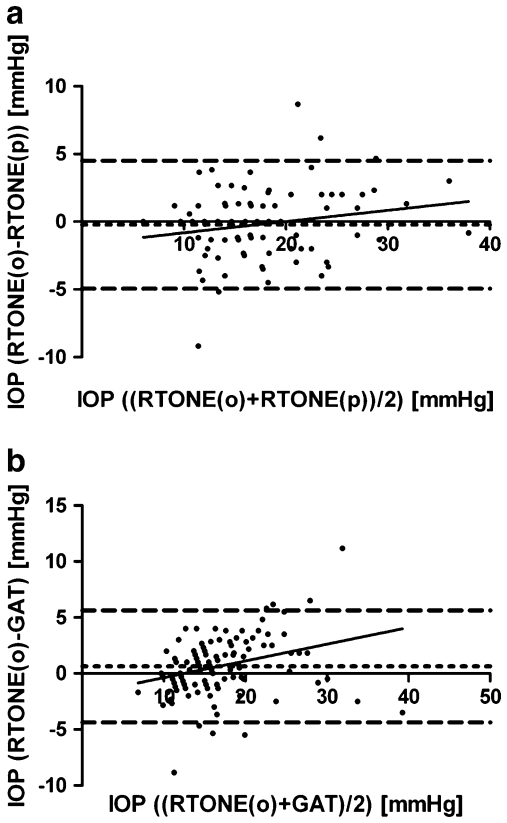

Fig. 2 Bland–Altman plots including linear regression for all included eyes. *X-axis* mean of IOP measurements of RTONE performed by an ophthalmologist (RTONE(o)) and RTONE performed by the patients themselves (RTONE(p)) (**a**) and RTONE(o) and GAT (**b**), respectively. *Y-axis* difference between IOP measurements of the RTONE(o) and RTONE(p) (**a**) and between RTONE(o) and GAT [**b**], respectively. *Dotted line* indicates bias [a: –0.2 mmHg; b: 0.6 mmHg]. *Dashed lines* indicate 95% limits of agreement [a: –5.0 to 4.5 mmHg; b: –4.4 to 5.6 mmHg]. *Solid line* indicates slope [a: 0.08 (p value = 0.04); b: 0.15 (p value = 0.0003)]

rebound tonometer and corneal thickness were weak but statistically significant (RTONE(o): ρ=0.264, p=0.009; RTONE(p): ρ=0.215, p=0.022). No correlation was detected between GAT and CCT. The difference between RTONE(o) and GAT significantly increased with increasing CCT (p=0.004), with a 10% increase in CCT resulting in a 1.8% increase in the difference (Fig. 3). Linear regression analysis disclosed that RTONE(o) overestimated IOP in comparison to GAT at higher CCT and underestimated pressure readings at lower CCT (X-intercept=509.6 μm) (Fig. 3).

Bland–Altman analysis revealed a mean difference (bias) between RTONE(p) and GAT of 0.8 mmHg, with 95% limits of agreement of −4.6 to 6.1 mmHg (Fig. 4). Linear regression of Bland–Altman data of RTONE(p) vs. GAT revealed no proportional error over the range of pressures examined. Other parameters, such as age, sex, or axial length, were not found to correlate with IOP or with the mean difference between tonometers.

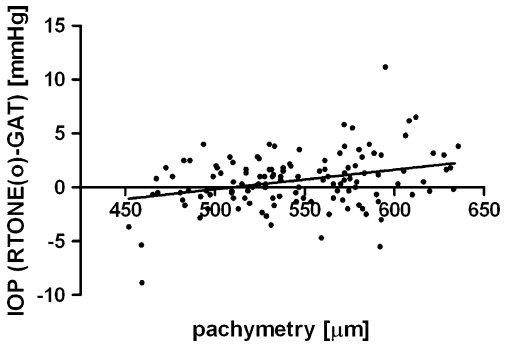

Fig. 3 Scatterplot comparing Icare ONE performed by an ophthalmologist (RTONE(o)) to Goldmann applanation tonometry (GAT) in relation to pachymetry results (CCT)

With regards to the items listed on the questionnaire, mean and standard deviation of general operability, sense of safety, and comfort of measurement with the Icare ONE tonometer when used by the patient were 2.1±1.0, 1.6±0.8, and 1.7±0.7, respectively. Subgroup analysis of general operability for patients aged 49 years or less, patients aged 50 to 69 years, and 70 or more years revealed a mean value of 1.9±0.7, 2.0±0.8, and 2.4±1.2, respectively. This analysis indicated a significant difference between the subgroups of patients aged 49 or less and those of 50 to 69 years of age, to those aged 70 or more (p=0.04 and p=0.02, respectively) (Fig. 5). Patients with experience in handling contact lenses gave higher rank for the general operability, though the difference was not significant (p=0.14) (Fig. 5). Subgroup analysis of patient experience with contact lenses, treatment involving application of eye drops, and mean defect in visual field revealed no significant differences.

Discussion

Several studies have analyzed the accuracy of rebound tonometry compared to applanation tonometry. Whereas

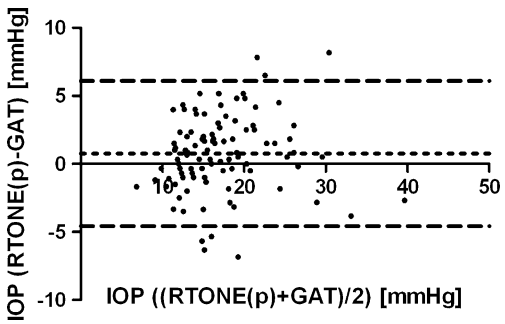

Fig. 4 Bland–Altman plot for all included eyes. *X-axis* mean of IOP measurements of RTONE performed by the patient (RTONE(p)) and GAT. *Y-axis* difference between IOP measurements with the RTONE(p) and GAT. *Dotted line* bias (0.8 mmHg). *Dashed line* 95% limits of agreement (−4.6 to 6.1 mmHg)

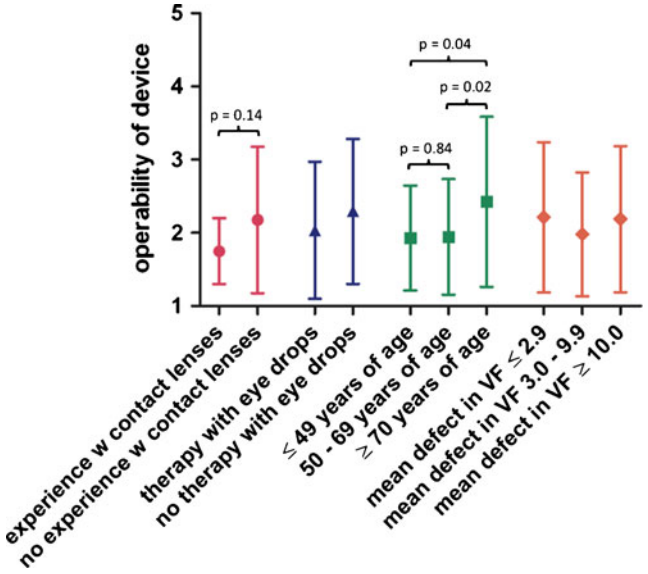

Fig. 5 Bar chart indicating the mean operability and standard deviation of the Icare ONE rebound tonometer separated into subgroups. *p* values of the Mann–Whitney test between subgroups are given

some studies report a very good agreement or only a slight difference between IOP values obtained by rebound tonometry and applanation tonometry [5, 10], other studies on different study populations indicate that rebound tonometry tends to overestimate IOP in comparison to measurements by applanation tonometry and particularly contour tonometry despite a very good correlation between the methods [11–16]. In the higher IOP range (GAT> 23 mmHg), rebound tonometry seems to provide more incorrect values than in the IOP range of 7–22 mmHg [15].

Our results indicate that IOP measurements obtained by an ophthalmologist using the Icare ONE tonometer (RTONE(o)) correlate extremely well with those provided by RTONE(p) (ρ=0.916; p<0.001) and GAT (ρ=0.901; p< 0.001). Nevertheless, on Bland–Altman analysis, the RTONE(o) showed a mean tendency to overestimate IOP in comparison to a GAT reading of 0.6 mmHg. In lower IOP ranges (<12 mmHg), the Icare ONE underestimated IOP in relation to the GAT reading, whereas Icare ONE showed an increasing overestimation of IOP in comparison to GAT in IOPs of>13 mmHg (slope=0.15, p=0.0003) (Fig. 2b). RTONE(p) showed a slight tendency to exceed the RTONE(o) readings at 0.2 mmHg.

The influence of CCT on IOP measurements is based on the assumption that thinner corneas will be more deformable and will therefore record artificially low pressures. Reductions in recorded IOP have been reported after LASIK using GAT and rebound tonometry, respectively [17, 18] and PRK using GAT [19]. In vivo studies in which human eyes are cannulated and the IOP set using a water column have demonstrated an error of between 0.4 and 0.7 mmHg per 10 μm difference in CCT with applanation tonometry [20–22]. Correlations between rebound tonometry readings and CCT have been observed in a number of studies [7, 11, 14, 16, 23–25]. Our study revealed a weak but significant correlation between the measurements obtained with the rebound tonometers and CCT (RTONE (o): ρ=0.264, p=0.009; RTONE(p): ρ=0.215, p=0.022). Further investigations indicated that the difference between RTONE(o) and GAT significantly increased with increasing CCT (p=0.004), with a 10% increase in CCT resulting in a 1.8% increase in the difference, and that RTONE(o) overestimated IOP values in relation to GAT readings at higher CCT and underestimated them at lower CCT (X-intercept=509.6 μm) (Fig. 3).

Bland–Altman analyses of IOP data obtained by measurement with the Icare ONE performed by the patient showed only slight and insignificant deviations from the readings obtained by an ophthalmologist with the Icare ONE in our study. Moreover, Bland–Altman analyses of readings obtained with RTONE(o) and RTONE(p) against GAT indicated only minimal deviations for bias and 95% limits of agreement (Figs. 2b and 4). Thus, the Icare ONE tonometer seems to be a precise and reliable tonometer when used by either an ophthalmologist or by a patient.

Self-tonometry has been proposed by many authors and could be of immense socio-economic efficacy in glaucoma management. At the moment, both the contact lens-embedded sensor for IOP monitoring and the Ocuton S self-tonometry device, as well as the hand-held applanation tonometer all have not yet reached clinical routine practice, despite promising preliminary results [26–31]. The potential usefulness of IOP home monitoring using the classic rebound tonometer (Icare) has been described in a few studies. For example, the ease of use and degree of accuracy of this device in inexperienced hands has already been shown [5, 32]. Inexperienced investigators were able to perform rebound tonometry appropriately and the rate of discrepancy was only slightly higher than that seen with experienced observers [5, 6]. Moreover, a high intra-observer and interobserver reproducibility has been shown in school children and adults [6, 7].

Patient evaluation, via our questionnaire, of general operability, sense of safety, and comfort of measurement with the Icare ONE rebound tonometer was excellent. Subgroup analysis of general operability of this device for patients of different age revealed that patients of 70 years or more of age considered the procedure more difficult than younger patients. Though not significant, patients with experience in handling contact lenses seem to be more skilled in using the Icare ONE rebound tonometer.

In conclusion, the Icare ONE tonometer provides pressure measurements that correlate well with those obtained by applanation tonometry. Whether measurements

are taken by an ophthalmologist or the patient, the readings obtained with Icare ONE tonometry can be expected to be higher than those determined by GAT, although the differences are relatively small. As in some previous studies on Icare rebound tonometry, the Icare ONE and CCT readings in our study indicated a dependency of Icare ONE tonometry on CCT, however, other trials did not detect a significant correlation between rebound tonometry and CCT [33].

Some theoretical limits of our study have to be taken in account. For practical reasons, the Icare ONE values and GAT were measured by the same investigators in an unmasked fashion. Besides, a pressure-reducing effect of repeated rebound tonometry on an eye can not be categorically ruled out. Moreover, it could be of interest to consider the corneal hysteresis and the corneal radius on the outcome of IOP measurement using the Icare ONE. Possible advantages of this new device are the numerous readings throughout the day, no need for eye drops, and a high acceptance by the patients. Disadvantages and reasons for impreciseness are a learning curve for using the device, possible self-induced corneal trauma, the possibility that IOP readings are not taken at the center of the cornea, and errors in taking the readings. All in all, Icare ONE self-tonometry appears to be a promising method, though its further relevance remains to be evaluated in future studies.

Competing interest for all authors None to declare.

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