Evaluation of the ICare Rebound Tonometer as a Home Intraocular Pressure Monitoring Device

Sanjay Asrani, MD,* Ashmita Chatterjee, BSc,† David K. Wallace, MD, MPH,*
Cecilia Santiago-Turla, MD,* and Sandra Stinnett, DrPH*

Purpose: (a) To investigate whether the ICare rebound tonometer can provide accurate measurements of intraocular pressure (IOP) in the hands of an inexperienced user compared with ICare measurements and Goldmann tonometry by a trained technician and (b) to assess the intrauser reproducibility of IOP measurements and the learning curve among patients using the ICare rebound tonometer.

Methods: A trained technician used the ICare rebound tonometer to measure the IOP of the right eye of 100 glaucoma patients. The technician then instructed each patient on use of the ICare tonometer. Each patient then measured his/her own pressure using the ICare tonometer. Finally, a different technician, who was masked to both of the earlier readings, measured IOP by Goldmann applanation tonometry. Thirty patients repeated the ICare measurement 3 times (once every 5 min) 20 minutes after the initial IOP measurement.

Results: Of the 100 patients, 82 of patient ICare and the technician ICare readings were within 3 mm Hg of each other, and 75 of the patient ICare and Goldmann applanation tonometry measurements were within 3 mm Hg of each other. Intraclass correlations between self-administered ICare measurements 1 and 2, 1 and 3, and 2 and 3 were 0.69, 0.71 and 0.81, respectively.

Conclusion: In this study, the ICare rebound tonometer was accurate and reliable in the hands of patients. Patients can easily learn to self-administer this test, possibly allowing for home monitoring of IOP.

Key Words: Self-tonometry, intraocular pressure, rebound tonometer

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Raised intraocular pressure (IOP) is known to be a major risk factor for glaucoma development and progression. IOP measurements during the office hours have been shown to incorrectly identify IOP peaks and its range.[1–3] Recently some studies have shown that short-term IOP fluctuations and intervisit IOP variations are prognostic factors for glaucoma progression.[4–8] However, data on IOP fluctuations are limited owing to the impractical nature of measuring IOP in the office over several hours or days. A home tonometer would provide these data and could aid in the management of individual patients.

The ICare rebound tonometer measures IOP without need of a topical anesthetic. It was first used in animals,[9,10] and it is now available for use in humans.[11] Multiple studies have compared the ICare tonometer with the Goldmann applanation tonometer (GAT) or other instruments to measure intraocular pressure in human beings.[12–20] Abraham et al[21] noted that the measurements taken with the ICare tonometer by both experienced and inexperienced technicians were comparable with GAT measurements. None of these studies have reported any adverse events during ICare tonometry. However, the instrument has not been tested in the hands of patients.

To evaluate its potential as a home IOP measuring device, we compared IOP measurements of the ICare rebound tonometer by inexperienced users (patients) with ICare and Goldmann tonometry measurements by experienced technicians. In addition, intrauser reproducibility (patient) and learning effect were evaluated by repeating office IOP measurements in a subset of patients.

PATIENTS AND METHODS

One hundred consecutive willing patients at the Duke Eye Center were screened in accordance with inclusion and exclusion criteria below. Eligible patients were recruited to participate in the study. The study used a Duke Institutional Review Board-approved protocol, and informed consent was obtained on all enrolled patients. Patients were included, if they were 18 years or older and had open-angle glaucoma (patients with characteristic glaucomatous optic nerve changes and visual field changes) or were considered to be a glaucoma suspect (patients with raised IOP but no visual-field defect or glaucomatous optic nerve damage). Exclusion criteria were: severe arthritis affecting the upper extremity in the patient, any corneal abnormalities such as opacities, scars, Fuchs dystrophy, map-dot-fingerprint dystrophy, history of recurrent corneal abrasion, corneal surgery, history of any ongoing ocular symptoms, such as eye pain or redness or discharge, history of a filtering or tube surgery for glaucoma (to reduce risk of infection-associated complications), history of diabetes (to reduce risk of recurrent corneal abrasions), or monocular status.

The ICare rebound tonometer is a handheld portable instrument that uses an impact/induction principle to measure intraocular pressure.[9–11] When the instrument is held at a distance of 3 to 10 mm from the unanesthetized eye, a solenoid magnetized probe in the instrument is propelled against the eye, impacts, and then rebounds from

FIGURE 1. Patient shown testing own eye pressure with ICare tonometer.

the cornea. The probe on the ICare tonometer has a round plastic tip that minimizes the risk of corneal injury and is disposable eliminating the need for disinfection. The inbuilt software acquires 6 readings, of which 4 are averaged after the highest, and lowest readings are eliminated. An error bar is displayed, if reliable readings are not obtained.

The right eye of each patient was evaluated in this study. A trained technician, using the ICare rebound tonometer, initially measured the IOP (before any eye drops were instilled). The displayed (reliable) reading was documented. The technician then instructed each patient on use of the ICare rebound tonometer. Next, each patient measured his/her own pressure using the ICare tonometer under the supervision of the technician, and the reading was recorded by the technician (Fig. 1). Finally, anesthetic drops were instilled, and a different experienced technician, who was masked to both of the earlier readings, used the Goldmann applanation tonometer to measure the patient's IOP.

Thirty of the 100 patients participated in a second phase of the study to evaluate reproducibility and learning effect. Thirty consecutive willing patients were consented for this second phase of the study at the time of the initial consent (before beginning the first phase of the study). Each patient repeated the ICare measurement 3 times (once every 5 min) beginning 20 minutes after the initial IOP measurement.

Each of these readings was recorded by the observing technician after each measurement.

Other data, such as age, corneal thickness, refractive error, right- or left-handedness, contact lens wear history, and earlier history of the use of eye drops were recorded by chart abstraction and interview. The number of attempts needed to get an error-free reading was also recorded. Patients were given a questionnaire to assess comfort, ability, and willingness to use the ICare tonometer at home and to elicit suggestions in instrument design for improving ease of use.

Statistical Analysis

The difference in IOP measurements between patient and technician was computed. The proportion of patients for whom this difference was more than 3 mm Hg, which we consider to be a clinically relevant difference was calculated. Intraclass correlation coefficients and their confidence intervals were calculated[22] to assess interuser and intermethod agreement. Differences between the measurements obtained by the patient and the technician using the ICare tonometer, and those between the ICare tonometer and the GAT were evaluated using the Student's paired t test. Linear regression and Bland-Altman plots were used to determine, whether the average of measures was related to the difference between the measures.

Intraclass correlations between intrauser measurements were calculated to asses the intrauser reproducibility and the effect of learning curve among patients in the use of the ICare rebound tonometer.

A univariate analysis was done to study, whether associated factors, such as age, history of contact lens wear, history of eye drop use, perception in ease of use of the instrument, right or left handedness, were associated with differences between the measurements obtained by the patient's ICare and that by the Goldmann used by the technician. SAS Version 9.1.3 was used for all analyses.

RESULTS

The mean age of the patients was 63 years (range 23 to 90 y, median 65 y). Mean corneal thickness OD was 545 μm (482 to 642 μm). Mean spherical equivalent OD was − 0.89 diopters (range − 15 to + 4 diopters). The mean IOP OD
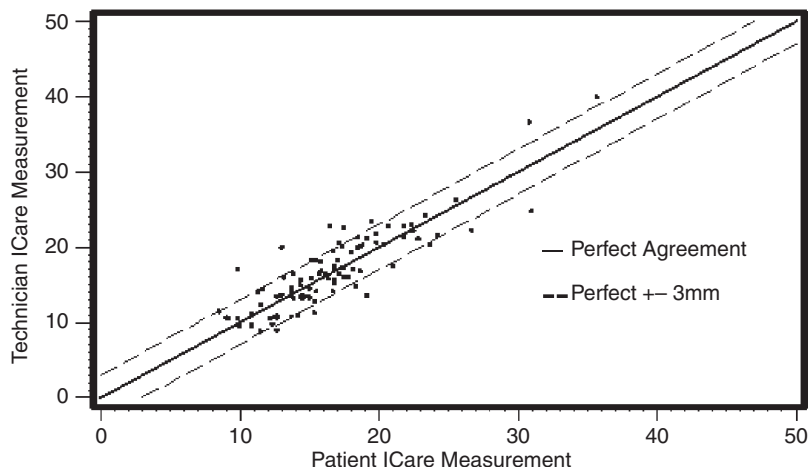

FIGURE 2. Agreement between the patient and the technician ICare tonometer measurements.
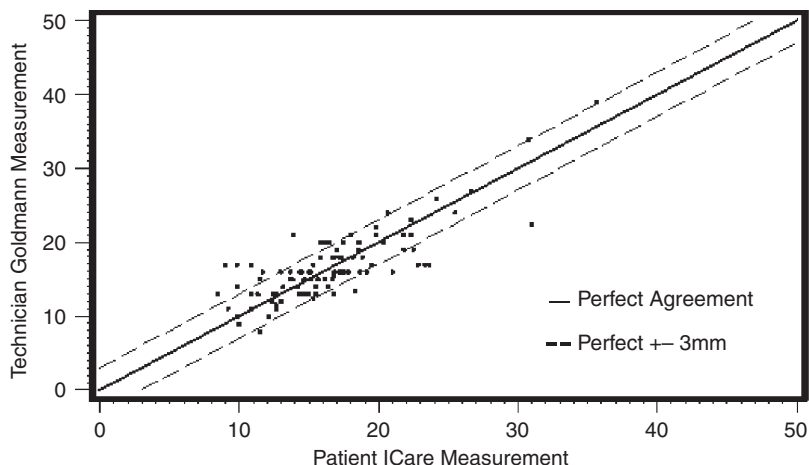
FIGURE 3. Agreement between the patient ICare tonometer measurement and the technician Goldmann applanation tonometer measurement.

was 16.7 mm Hg (range 8.8 to 40 mm Hg). Thirty- eight percent of the participants had a history of contact lens wear, 90% of the participants had a history of eye drop use, and 92% of participants were right-handed.

Eight-four percent of the study participants required just 1 attempt to achieve an error-free measurement using the ICare tonometer, and 13% required 2 attempts. Ninety-four percent of the participants agreed or strongly agreed that they learned to use the ICare tonometer quickly, and 93% agreed or strongly agreed that the instrument was simple and easy to use.

Comparisons Between IOP Measurement Methods

Figure 2 shows agreement between the patient ICare and the technician ICare measurements. Eighty-two percent of readings were within 3 mm Hg of each other. Figure 3 shows agreement between the patient ICare measurement and the technician Goldmann measurement. Seventy-five percent of these readings were within 3 mm Hg of each other.

Table 1 gives the mean IOP values and standard deviation for the group with each method of testing. Table 2 shows the intraclass correlations between different testers and methods. All correlations were greater than 0.8 indicating excellent agreement between all methods.

In the Bland-Altman plot shown in Figure 4, the slope of the regression line ($r^2 = 0.005$) was not significantly different from zero ($P = 0.469$) indicating that, when differences between measures were observed, they were not more likely to be associated with high or low IOP values.

Reproducibility of ICare Measurements

Sixty-three percent of the measurements between error-free attempts 1 and 3 and 80% of the measurements

between error-free attempts #2 and #3 were within ± 3 mm of perfect agreement. Table 3 shows the intraclass correlation between error-free attempt 1 and 2, 1 and 3, and 2 and 3. Correlations were reasonably good between all pairs and particularly good between attempts 2 and 3.

By univariate analysis, corneal thickness (slope = 0.028, $P = 0.007$, $R^2 = 0.08$) and level of IOP (slope = -0.157, $P = 0.013$, $R^2 = 0.07$) were associated with differences between IOP measured by patient ICare and technician Goldmann applanation tonometry measurements. ICare tended to measure slightly higher than Goldmann for thicker corneas and slightly lower than Goldmann for thinner corneas. ICare tended to measure slightly higher than Goldmann, when the IOP was low and slightly lower than Goldmann, when the IOP was high. However, the regression lines did not fit the data well, as indicated by the low values of R^2.

Age, history of contact lens wear, history of eye drop use, perception in ease of use of the instrument, and right or left handedness were not associated with differences between IOP measured by patient ICare and Goldmann applanation tonometry measurements.

DISCUSSION

IOP data from the patients' home environment is currently unavailable. The choices for home tonometry have been limited. The tonopen (Reichert Ophthalmic Instruments, NY), and other home tonometry devices are limited in their use as a home monitoring device owing to the need to dispense a topical anesthetic. The pressure phosphene tonometer was used for home tonometry, but its value was limited by poor correlation with Goldmann applanation tonometry.[23]

The ICare tonometer may have the potential to become a valuable tool for home IOP monitoring. Sahin et al[24]

TABLE 1. Mean IOP Values, Standard Deviation, Minimum, Maximum, and Median IOP Values With Each Method of Measuring IOP

Method	n	Mean	Std Dev	Minimum	Median	Maximum
Goldmann-Technician	100	16.67	4.58	8.00	16.00	39.00
ICare-patient	100	16.50	4.78	8.50	15.83	35.67
ICare-technician	100	16.73	5.27	8.83	16.17	40.00

TABLE 2. Intraclass Correlations Between Different Testers and Methods of IOP Measurement

Comparison	Intraclass Correlation	Confidence Interval	Mean Difference	Paired t test P	Repeatability Coefficient*	Limits of Agreement†
All	0.85	0.85-0.92				
Patient ICare-Goldmann	0.81	0.73-0.87	− 0.17	0.501	5.83	− 5.99, 5.66
Technician ICare-Patient ICare	0.88	0.82-0.92	0.06	0.497	5.42	− 5.37, 5.48
Technician ICare-Goldmann	0.85	0.79-0.90	0.23	0.671	5.00	− 4.77, 5.23

*Repeatability coefficient = twice the standard deviation of the differences.
†Limits of agreement = mean difference plus or minus 2 standard deviations.

showed that ICare tonometry could be used comfortably in schoolchildren (304 eyes) without use of topical anesthetics. Good intratechnician (correlation coefficients of 0.87 to 0.97) and intertechnician reproducibility (correlation coefficient of 0.82 to 0.85) of ICare measurements have been reported in different studies.[13,24] Some investigators have found that ICare rebound tonometry overestimates IOP compared with GAT, especially in eyes with thick corneas,[12,13,19] whereas others have reported highly comparable measurements with the GAT (84% of all readings were ± 3 mm Hg of GAT.[14,15,20,24] In this study, the technician-measured inter-method reliability between the ICare tonometer and the GAT, the intraclass correlation was 0.85 (confidence interval 0.79-0.90; P = 0.671) indicating excellent agreement between these techniques.

In this study, we compared the reliability of the readings obtained by an inexperienced user (patient) with a trained ophthalmic technician using the ICare tonometer and with the Goldmann tonometer. We found that the patient's measurement using the ICare compared well with that of the trained technician using the ICare (88% correlation). A high degree of corroboration (81%) between the IOP measurements taken by the patient using the ICare and the technician using GAT was also found.

The correlation of measurements between error-free attempts 2 and 3 was greater than the correlation between attempts 1 and 2 indicating the presence of a gentle learning curve in patients' use of the ICare tonometer. The differences in IOP measurements between attempts 1, 2, and 3 were not statistically significant (Table 2). The gentle learning curve implies that minimal time is required for training patients in the use of the ICare instrument. The strong intraclass correlation between attempts 2 and 3 indicates a high degree of reproducibility in ICare tonometer IOP measurements in the hands of the patient.

In a recent study on calibration error tolerance,[25] 28% of devices had a calibration error greater than ± 2 mm Hg at 20 mm Hg, and 21% remained with that error when rechecked within 4 months of recalibration. Differences between Goldmann tonometer readings and other methods of measurement (such as the patients' ICare readings) of ± 3 mm Hg are therefore probably acceptable.[26] A recent study on measurements by the Goldmann tonometer[27] did not find a one-to-one relationship between calibration error and clinical error in IOP measured, making it difficult to calculate a correction factor. They concluded that in certain circumstances in which resources are limited, it may be clinically acceptable to use tonometers with calibration errors of less than ± 3 mm Hg.

In a study comparing the Pascal dynamic contour tonometry and the tonopen with GAT, the mean of the differences in IOP measurements was 3.2 ± 2.4 mm Hg for Pascal DCT minus GAT readings, and 0.5 ± 4.5 mm Hg for TonoPen minus GAT readings. The 95% confidence interval of differences in IOP measurements was higher between TonoPen and GAT readings (− 6 to 7 mm Hg)
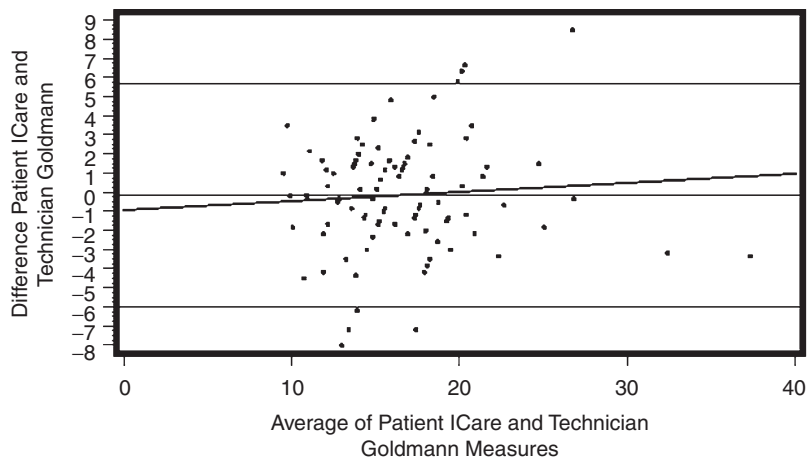

FIGURE 4. Bland-Altman plot of the average versus the difference between the patient ICare tonometer measurements and the technician Goldmann applanation tonometer measurements.

TABLE 3. Intraclass Correlations Between Intrauser Measurements of IOP by the Patient Using the ICare Tonometer

Attempt Comparison	Intraclass Correlation	Confidence Interval	Mean Difference	Paired *t* test *P*	Repeatability Coefficient*	Limits of Agreement†
1-2	0.69	0.45-0.84	− 0.05	0.614	7.36	− 7.4, 7.31
1-3	0.71	0.47-0.85	0.62	0.184	7.58	− 6.96, 8.20
2-3	0.81	0.64-0.90	0.67	0.333	5.97	− 5.31, 6.64

*Repeatability coefficient = twice the standard deviation of the differences.
†Limits of agreement = mean difference plus or minus 2 standard deviations.

than between Pascal and GAT readings (0.1 to 6.8 mm Hg).[28] In this study, 82% of the ICare readings of the patient's measurement versus that of the trained technician were within ± 3 mm Hg. Meanwhile, 75% of the patient ICare measurement and the technician Goldmann measurement readings were within 3 mm Hg of each other. The above rate of agreement implies that ICare can be used by patients to accurately measure their IOP at home.

Limitations

There are some limitations to this study. First, the ICare was being used by the patient under supervision of a trained technician. The reliability of the instrument readings may not be the same, when its use is unsupervised. Subsequent studies would be useful to evaluate this effect. Second, IOP measurements with ICare at home by a patient may not necessarily be from the central cornea. However, Chui et al[29] reported that the IOP measurements with ICare taken from the central cornea were similar to those obtained from the peripheral cornea.

The expense of the ICare tonometer (currently priced around $3900) may limit its widespread use as a home IOP monitoring device. However, as its use will primarily be for patients requiring aggressive monitoring, the instrument could be given on loan by glaucoma specialists to those that need it for a week at a time. Beside the cost of the instrument, there is a recurring cost of a new probe that is required for each patient. However, as the same patient uses the probe for home tonometry, this cost may be minimized, as it is possible to store the probe aseptically in the original capped container. It will be important to verify that the plastic tip at the end of the probe will remain intact with repeated use and that the probe remains clean, when used intermittently.

Though in this study we did not have any corneal abrasions or other adverse reactions from the use of the ICare tonometer, it is likely that use of the same in an unsupervised environment will result in some adverse reactions. It may also prompt undue worry on the part of the patient, if a falsely high or low reading is obtained. Additionally, some patients might use it more than the typical 5 times per day, and its overuse cannot be monitored.

There are many benefits of home monitoring. IOP data on a patient are typically collected for 2 to 4 seconds at a time, 3 to 5 times a year owing to the need for instruments that can be used by trained ophthalmic personnel and thus limited to those in physician offices. This leads to very limited IOP data available to eye physicians for the management of a chronic condition, such as glaucoma. Future advances in therapy and the better understanding of the role of IOP fluctuations may be possible with the availability of additional IOP data in the patient's own environment. This advance may be similar to the advent of home glucose monitoring devices for the management of diabetes. Future research will involve development of implantable continuous IOP monitoring devices.

In conclusion, IOP readings provided by the ICare tonometer are both reliable and reproducible. Its recent US FDA approval, its gentle learning curve and the absence of need for an anesthetic make it ideal for use by the patient. Thus, the ICare tonometer has the potential of providing IOP data in the patient's home environment, and may be of particular value for those patients requiring aggressive monitoring of IOP.

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