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Repeatability and agreement of intraocular pressure measurement among three tonometers

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Background: Elevated intraocular pressure (IOP) is one of the causes of irreversible optic nerve head damage and visual field loss. It is often measured with applanation tonometers but the use of rebound tonometry devices has been proposed as an alternative to assess IOP. Rebound tonometers have also been proposed as a method for patients to measure their own intraocular pressure (that is, self-tonometry). The purpose of this study was to determine the intrasession repeatability and the agreement of the IOP measurement with two rebound measuring principle tonometers, ICare ic100 and ICare Home with Perkins tonometer.

Methods: This study involved 27 healthy volunteers (18 to 30 years old). We performed three consecutive IOP measurements with ICare Home, ICare ic100, and Perkins. The means of the three measurements from each device were calculated. Repeatability and agreement were defined according to the British Standards Institute and the International Organization for Standardization. The agreement was assessed using the method described by Bland and Altman, where 95 per cent of the differences or limits of agreement were between 1.96 standard deviations of the mean difference.

Results: All tonometers showed close measurements (Perkins 15.34 ± 3.45 mmHg, range 10.00–24.00; ICare ic100 15.40 ± 4.06 mmHg, range 9.67–23.33; and ICare Home 14.22 ± 4.72 mmHg, range 7.33–24.00). The co-efficient of variation (CV) and within-subject standard deviation (Sw) was low for ICare ic100 and Perkins (close to 6.30 per cent and one) with higher values for ICare Home (CV = 9.55% and Sw = 1.33). The intraclass correlation co-efficient showed values higher than 0.96 for all tonometers. The difference between both rebound tonometers was statistically significant (p = 0.03).

Conclusion: The ICare ic100 tonometer provides repeatable IOP measurements close to the measurements of the Perkins IOP (good agreement); however, ICare Home provides less repeatable values, showing worse agreement with the Perkins tonometer in healthy subjects.

Key words: agreement, intraocular pressure, repeatability, tonometer

Intraocular pressure (IOP) measurement (tonometry) is a common test included by eye-care practitioners in eye examinations particularly for patients diagnosed with, or at risk for, glaucoma,[1] and in care after eye surgery (for example, intraocular lens implantation,[2] vitrectomy,[3] and trabeculectomy[4]). An increase in IOP can cause irreversible optic nerve damage and visual field loss, and IOP is one of the parameters used as an indicator of glaucoma progression.[5]

In clinical and research practice, IOP is usually measured with applanation tonometers (Goldmann and Perkins) because their measurements are interchangeable,[6] although the Goldmann tonometer is considered the gold standard.[7] These devices require contact with the anterior corneal surface, so it is necessary to instil a topical anaesthetic. Moreover, the eye-care practitioner needs to be trained to conduct this procedure correctly to obtain an accurate IOP measurement. In recent years, non-invasive tonometers, such as pneumatonometers,[8] transpalpebral tonometers[8] and tonometers based on rebound measurements,[9] have been proposed for use in clinical practice, because they are minimally invasive devices. These minimally invasive tonometers could be of great utility in primary eye-care practice in the early detection of glaucoma.

IOP is affected by daily fluctuations (up to 5 mmHg)[10,11] and ocular factors, such as accommodation, corneal thickness, action of the extraocular muscles (convergence) or blinking, and corporal factors, such as body position, Valsalva manoeuvres and blood pressure, and external factors, such as tight neckties or atmospheric pressure,[10,12] and these IOP variations are related to optic disc damage.[13] Therefore, it could be important to know IOP variations throughout the day in glaucoma patients, and one single IOP measurement may not be enough for clinical decision-making.[1] Since 1958, different methods of IOP monitoring have been investigated for their applicability to improve glaucoma diagnosis and treatment, but their implementation in clinical practice is

challenging.[14–16] Currently, the use of non-invasive devices, such as self-tonometry devices, including ICare ic100 or ICare Home, has been proposed as an alternative for assessing IOP variations.[7]

Determination of the repeatability and agreement of measurements from a device are needed prior to introduction of the device into clinical practice; however, to the best of our knowledge, there have been no previous reports on the intrasubject repeatability of the ICare ic100 and ICare Home rebound tonometers in healthy subjects. Therefore, the purpose of this study was to determine the intrasession repeatability and the agreement of the IOP measurements of two tonometers, ICare ic100 and ICare Home, which function based on the rebound measurement principle, compared with the Perkins tonometer.

Methods

Subjects

The tenets of the Declaration of Helsinki were followed, and informed consent was obtained from all volunteers after they were fully informed of the nature of the study. The Human Sciences Ethics Committee of the University of Valladolid approved the study.

This study involved healthy volunteers between 18 and 30 years of age. A complete eye examination was carried out to verify ocular health. All subjects had a best-corrected visual acuity equal to or better than 20/25 measured at a distance to allow adequate fixation for tonometry. The exclusion criteria were previous ocular surgery (especially corneal refractive surgery), history of ocular pathology, corneal disease (such as dry eye with positive fluorescein staining) and systemic disease.

Instrumentation

IOP was measured in each subject's right eye with the ICare ic100 (ICare Finland Oy, Vantaa, Finland), ICare Home (ICare Finland Oy) and Perkins (Clement Clarke International, Harlow, UK) tonometers. The ICare rebound tonometer is a handheld, portable instrument that functions based on the impact/induction principle.[17] This tonometer requires no anaesthesia. When the device is held at a distance of 3–10 mm from the eye, a solenoid magnetised probe is launched toward the central cornea. The probe hits the eye and bounces back. The solenoid, inside which the probe moves, is used to detect the movement and impact of the probe because the moving magnet induces voltage in the solenoid. The probe has a plastic coating to avoid the risk of corneal damage and is disposable.

The ICare ic100 tonometer is a new version of the ICare tonometer with an automatic measuring sequence series and a single mode with one button. The software obtains six measurements, eliminating the highest and the lowest, and the final measurement is the average of the four remaining measurements. A colour signal indicates whether the measurements are reliable or if it is necessary to repeat the acquisition. Moreover, this version has an intelligent positioning assistant for perpendicular alignment of the tonometer relative to the cornea. The ICare ic100 tonometer has a measuring range from 7 mmHg to 50 mmHg, with an accuracy of $\pm$1.2 mmHg for measurements less than 20 mmHg and $\pm$2.2 mmHg for measurements greater than 20 mmHg, with a minimum unit of measurement of 1 mmHg, according to the manufacturer's information.

The ICare Home device includes the innovations found in the ICare ic100 device and has two points of support on the face (superior and inferior) to permit patient self-tonometry. The patient should be instructed on how to use this device and adjust it to his/her face to maintain good alignment.

The Perkins tonometer is a handheld portable device based on the Imbert–Fick law applied to applanation tonometry as in the Goldmann tonometer.[18] The Perkins tonometer has a measuring range of 2–52 mmHg with a minimum unit of measurement of 2 mmHg.

IOP measurement procedure

Three consecutive measurements were obtained for each subject's undilated right eye in a single session by the same experienced operator using the ICare ic100, ICare Home and Perkins tonometers. The ICare Home measurements were performed by the same experienced operator to avoid learning effects and dependence on operator skill. All IOP measurements were collected between 11:00 and 15:00 hours to minimise the effects of diurnal variations in IOP. The device order was randomised except for the Perkins tonometer, which was used at the end due to the need for topical anaesthesia. The time between measurements was minimised, with less than one minute between repeated measurements using the same device and approximately 15 minutes between measurements with different tonometers. Poor-quality measurements related to eye movements or blinking were discarded. Volunteers were repositioned by the operator between each of the three measurements to ensure correct alignment of the eye with the optical axis of the tonometer using the same protocol.

Statistical analysis

A minimum sample size of 21 subjects was determined to be necessary to detect a minimum difference of 2 mmHg in IOP measured with different tonometers with a power of 90 per cent, assuming a standard deviation of 5 mmHg in the IOP measurements. We finally included 27 volunteers to guarantee an adequate sample size for statistical analysis even if 20 per cent of the subjects dropped out of the study.

Statistical analysis was performed using SPSS for Windows software (version 15.0; SPSS Inc., Chicago, IL, USA). The mean of the three measurements from each device was calculated. The present study's definitions of repeatability and agreement were defined according to the British Standards Institute and the International Organization for Standardization.[19] The intrasession repeatability of the set of three consecutive measurements of each parameter was calculated as follows: within-subject standard deviation (Sw)[20] intrasubject precision (1.96 $\times$ Sw, which shows half of the expected range containing 95 per cent of the repeated measurements from an individual);[20] repeatability (2.77 $\times$ Sw, which is an estimate of half the range which contains 95 per cent of differences between observation pairs taken from individuals)[20] co-efficient of variation (CV); percentage of the measurement's variation, defined as the ratio of the Sw to the overall mean (CV = Sw/mean $\times$ 100 [%]);[20] and the intraclass correlation co-efficient (ICC), used to classify the agreement as poor (ICC less than 0.75), moderate (ICC from 0.75 to less than 0.90), or high (ICC 0.90 or greater).[21] The agreement was assessed using the method described by Bland and Altman, where 95 per cent of the difference or the limit of agreement (LoA) was between 1.96 standard deviation (SD) of the mean difference.[19,22] Exact parametric confidence intervals for limits of agreement were calculated.[23]

The non-parametric distribution of variables was verified using the Kolmogorov–Smirnov test, with $p > 0.05$ indicating that the data were normally distributed. Differences in IOP between devices for all calculated

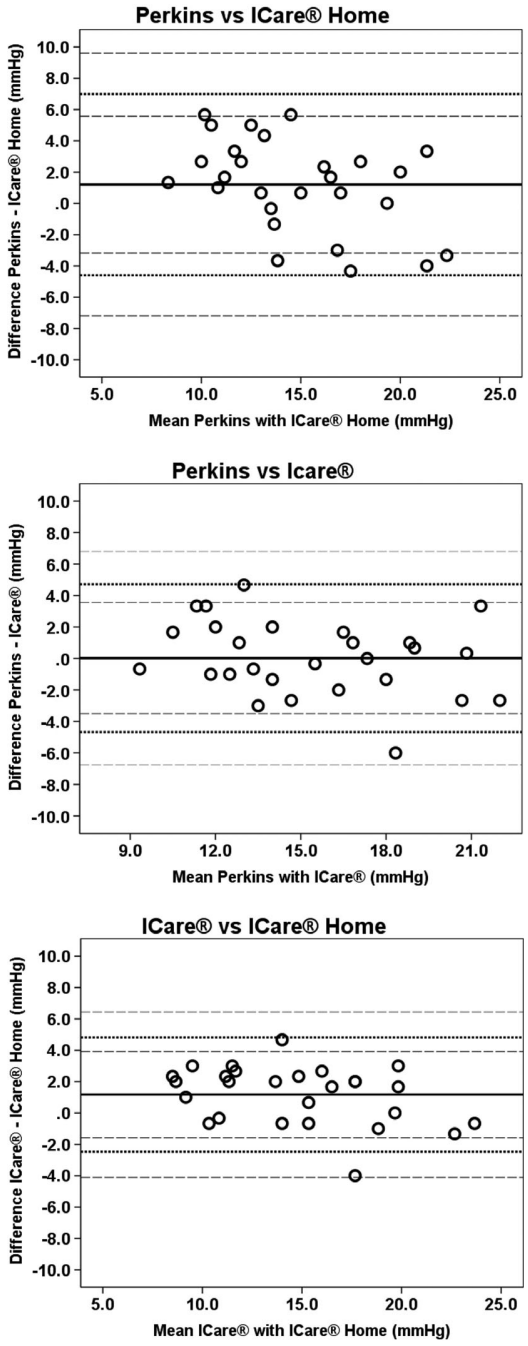

Figure 1. Bland and Altman plot of the intraocular pressure (IOP) agreement. Top: Perkins versus ICare Home (mean difference of 1.20 ± 2.96 mmHg, p = 0.05; limits of agreement [LoA] from 7.00 [95% CI from 9.60 to 5.58] to −4.60 [95% CI from −3.18 to −7.20]; R^2 = 0.21; p = 0.02). Centre: Perkins versus ICare ic100 (mean difference of 0.02 ± 2.39 mmHg, p = 0.86; LoA from 4.70 [95% CI from 6.80 to 3.55] to −4.66 [95% CI from −3.51 to −6.76]; R^2 = 0.07; p = 0.17). Bottom: ICare ic100 versus ICare Home (mean difference of 1.17 ± 1.86 mmHg, p = 0.03; LoA from 4.82 [95% CI from 6.45 to 3.92] to −2.48 [95% CI from −1.58 to −4.11]; R^2 = 0.13; p = 0.07). Mean: mean of the measurements performed by both tonometers. Difference: difference between the measurements performed by both tonometers. Exact confidence intervals for limits of agreement were plotted.

repeatability co-efficients (Sw, precision, repeatability, CV, and ICC) were compared using a Wilcoxon non-parametric paired test, with $p < 0.05$ considered significant.

Results

Twenty-seven eyes of 27 healthy patients (nine men, 18 women) who were 21.6 ± 3.6 years old (range 20 to 29 years) were included in this study.

All tonometers yielded similar measurements (Perkins 15.34 ± 3.45 mmHg, range 10.00 to 24.00; ICare ic100 15.40 ± 4.06 mmHg, range 9.67 to 23.33; and ICare Home 14.22 ± 4.72 mmHg, range 7.33 to 24.00) (Figure 1). However, the difference between the two rebound tonometers was statistically significant (p = 0.03). There was no significant difference between the Perkins and rebound tonometers (p > 0.05).

High intrasession repeatability was observed with all tonometers (especially the Perkins and ICare ic100 tonometers) in healthy eyes (Table 1). The CV for the three tonometers was less than 10 per cent, with a Sw close to 1 mmHg, which is the minimum unit of measurement for the ICare devices, and a Sw of 2 mmHg for the Perkins tonometer. The ICC showed values greater than 0.96 for all tonometers, thus showing high agreement.

The ICare ic100 tonometer showed slightly better agreement (LoA from 4.70 to −4.66 mmHg) with the Perkins tonometer than did the ICare Home tonometer (LoA from 7.00 to −4.60 mmHg), as shown in Figure 1.

Discussion

Daily IOP monitoring is a challenge to eye-care practitioners and patients. Non-invasive rebound tonometers (ICare ic100 and ICare Home) have been proposed as possible devices for the repeated measurement of IOP in patients with glaucoma or those suspected of having glaucoma. Our results suggest that the ICare ic100 tonometer provides repeatable IOP measurements (Sw 0.99; CV 6.28%; LoA 3.03 to −3.42), and these measurements were close to the measurements obtained with the Perkins tonometer in healthy subjects (p = 0.86). However, the ICare Home tonometer, used by an experienced operator, provided less repeatable values (Sw 1.33; CV 9.55%; LoA 4.94 to −4.69) than the ICare ic100 tonometer (Table 1) and showed poorer

Device	Mean ± SD	Range	Sw	Prec	Rep	CV	Range of 95% LoA	ICC
Perkins	15.34 + 3.45	(10.00–24.00)	0.98	1.93	2.73	6.44%	3.07 to −2.78	0.97
ICare ic100	15.40 ± 4.06	(9.67–23.33)	0.99	1.95	2.76	6.28%	3.03 to −3.42	0.97
ICare Home	14.22 ± 4.72	(7.33–24.00)	1.33	2.61	3.69	9.55%	4.94 to −4.69	0.96
p-value*	0.05	-	0.33	0.33	0.33	0.15	-	-
p-value**	0.86	-	0.81	0.81	0.81	0.86	-	-
p-value***	0.03	-	0.12	0.12	0.12	0.07	-	-

CV: co-efficient of variation, ICC: intraclass correlation co-efficient, LoA: limits of agreement, Prec: precision, Rep: repeatability, SD: standard deviation, Sw: within-subject standard deviation.

*p-value = difference ICare Home with Perkins tonometer (Wilcoxon test).

**p-value = difference ICare ic100 with Perkins tonometer (Wilcoxon test).

***p-value = difference ICare Home with ICare ic100 tonometer (Wilcoxon test).

Table 1. Intraobserver repeatability for intraocular pressure measured with Perkins, ICare ic100 and ICare Home

agreement (LoA 7.00 to −4.60) with the Perkins tonometer. These results could be associated with the reduced vertical dimension of the ICare Home tonometer, which could hinder alignment with the corneal apex and the maintenance of a perpendicular orientation with the corneal surface. These results suggest that the usefulness this instrument can offer for patient self-tonometry must be assessed with further research comparing patient self-measured IOP values with values obtained by experienced practitioners.

The repeatability of previous versions of the ICare device has been assessed.[9,24] For example, the ICare PRO device showed worse CV and ICC values than we found with the ICare ic100 and ICare Home devices. Another study assessed the intersession and experienced operator effect with ICare devices,[24] finding statistically significant differences both with one operator, which suggests a practitioner effect, and between operators in the second session. Dabasia et al.[7] assessed the agreement between the Goldmann tonometer and the ICare Home tonometer and found that self-tonometry with the ICare Home tonometer underestimated values by 0.3 mmHg, with a similar bias for the experienced operator versus a volunteer. Asrani et al.[9] found greater differences between the measurements made by the experienced operator and patients with a previous version of the ICare device, with a difference range of ±3 mmHg.

The most accepted technique for measuring IOP is applanation tonometry with a Goldmann or Perkins tonometer,[7] which could be affected by different factors, such as capillary attraction between the tonometer tip and the cornea, assumptions of the Imbert–Fick Law, and the concentration of fluorescein.[25] Additionally, the IOP value is not static and fluctuates constantly, as it is affected by contact lens use, scleral rigidity, corneal variations, such as oedema, venous pressure, respiration, extraocular muscle contraction and nyctohemeral rhythms, as well as factors independent of tonometer type.[25] Moreover, the most important factor that influences IOP is corneal thickness because it is well known that IOP is overestimated in thick corneas and underestimated in thin corneas.[26] However, one of the advantages of repeated non-invasive IOP measurement throughout the day with a rebound tonometer could be that the impact of corneal thickness on the IOP outcome could be minimised, making it easy to detect IOP variations. Nevertheless, other tonometers have been developed, such as transpalpebral tonometers[27] and rebound tonometers,[9] with the advantage that the use of topical anaesthesia is not necessary. Other applanation tonometers, such as the Pascal tonometer, can provide corneal thickness-independent IOP measurements.[28]

Self-tonometry could facilitate monitoring of the circadian IOP rhythm to provide complementary data in glaucoma patient care, consisting of IOP values measured outside of office hours. It is difficult to know whether an increase in IOP is produced based on clinical measurements achieved in the consulting room because the peak IOP occurs outside of office hours.[10,11] Moreover, while daily IOP fluctuations of up to 5 mmHg have been reported in healthy subjects, which may not be related to eye damage, glaucoma patients show greater IOP variations, which could be of interest in some patients to understand their pattern of IOP fluctuations and improve treatment.[13,29] Although the ICare Home device does not show the best repeatability, it is currently the only device designed for this purpose; thus, the values obtained must be interpreted with caution.

To improve self-tonometry by patients, new versions of the ICare (ICare ic100 and ICare Home) device incorporate a positioning assistant to guarantee the perpendicular alignment of the tonometer relative to the cornea because significant differences between centred versus off-centre IOP measures (nasal and temporal) with ICare devices have been reported.[24]

This study has some limitations, such as the inclusion of a small sample size of young volunteers; however, this sample size is similar to that described in previous reports,[16] so this limitation could have a limited impact on study conclusions. Moreover, this study included only young and healthy people and excluded patients who were affected by glaucoma, eye surgery (intraocular lens implantation, vitrectomy or trabeculectomy) and older patients[26] because the first research approach to assess the repeatability and agreement with the Perkins tonometer of different rebound tonometers may be conducted in healthy eyes. Although IOP values derived from the Perkins tonometer are interchangeable with those derived from the Goldmann tonometer, further research is necessary to assess the agreement of the ICare tonometers with the Goldmann tonometer. Moreover, contact tonometry is recommended in cases of an abnormal IOP or when other eye findings (optic disc alterations) are detected; thus, the results of this study will be of interest to primary eye-care practitioners. It is possible that the repeatability of the ICare rebound tonometers could be influenced by the processes of ageing and ocular diseases,[30,31] but our results are similar to those of studies

comparing IOP determined using the ICare rebound tonometer versus the Goldmann applanation tonometer in subjects aged 75 years or older with or without glaucoma and evaluating the influence of the central corneal thickness on IOP readings. These studies concluded that there was excellent agreement between the ICare rebound and Goldmann applanation tonometers within the allowable range in elderly subjects with or without glaucoma.[30,31] However, in future studies, it would be necessary to assess the repeatability and reproducibility of the ICare ic100 and ICare Home devices in unhealthy patients, such as glaucoma patients, to prove the clinical utility in glaucoma follow-up care.

Another limitation is the heterogeneous statistical analysis conducted in different studies to report repeatability, considering that the CV is the only repeatability value that is expressed as a percentage, making it easier to compare among studies. Moreover, absolute values cannot always be compared (depending on the assessed patients' characteristics). However, a small CV is too sensitive when the mean value is close to zero, which limits its usefulness; nevertheless, because the minimum unit of measurement is 1 mmHg for ICare devices and 2 mmHg for the Perkins tonometer according to the manufacturers' specifications, the CV seems to be an easier value to use to assess and compare the repeatability of different tonometers.

Conclusion

The ICare ic100 tonometer provides repeatable IOP measurements, close to the measurements of the Perkins tonometer (good agreement) in healthy subjects. However, the ICare Home device provides less repeatable values, showing poorer agreement with the Perkins tonometer in healthy subjects. Future studies of patients of different ages and with different ocular diseases, such as glaucoma patients, are necessary to assess the clinical utility of the self-monitoring of IOP using these rebound tonometers in follow-up patient care.

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