Original Article

Reliability of Handheld Rebound Tonometer When Reusing Handheld Rebound Tonometer Probes

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Background: The iCare® Pro handheld rebound tonometer (HRET) is a reliable and portable tonometer. Although the probes have been indicated for single use, many healthcare practitioners reuse the probes after disinfection with alcohol. Only one result has been reported the validity of reusing HRET probes on artificial corneas.

Objective: To determine the reliability of HRET when reusing HRET probes in glaucoma and glaucoma suspected patients.

Materials and Methods: The present study was prospective and observational. HRET was performed on 58 sitting-position participants by a single experienced examiner. Individual measurements were shown digitally in mmHg. Each participant's intraocular pressure (IOP) was measured using a new probe, and the test was repeated 3 additional times with the same probe after being wiped with a 70% isopropyl alcohol swab between each test. A total of four IOP values were recorded for each participant, and subsequent data trends were analyzed.

Results: Fifty-eight eyes of 58 participants were enrolled in the present study. The mean IOP values of the new, the first reuse, the second reuse, and the third reuse of the HRET probes were 13.8±2.6, 13.9±2.9, 13.8±2.7 and 13.6±2.5 mmHg, respectively. The IOP values were analyzed using the Bland-Altman method which showed agreement between the new, first reuse, second reuse, and third reuse measurement values of the same HRET probe. There was a statistically significant difference between the IOP measurements obtained using the new HRET probe testing and those obtained from reusing the HRET probe for the third time by paired t-test (p=0.005).

Conclusion: There was good agreement of IOP measurements between the new, first reuse, and second reuse measurement values of the same HRET probe.

Keywords: Handheld rebound tonometer; New iCare® probe; Reusing iCare® probe; Tonometry; Intraocular pressure; Glaucoma

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Glaucoma is the most common cause of irreversible blindness in the world[1]. One of the most important factors for the diagnosis and management of glaucoma is the accurate measurement of intraocular pressure (IOP). Many devices for IOP measurement have been developed and each has its own advantages and disadvantages when considered in terms of accuracy, convenience, cost, and patient comfort. At the present time, there are many commercial tonometries such as the Goldmann applanation tonometer (GAT), Perkins tonometer, Tonopen, non-contact tonometer, and handheld rebound tonometer (HRET). GAT is still the gold standard in IOP measurement for glaucoma diagnosis due to its relatively low intraobserver and interobserver variability[2,3]. However, GAT has two major disadvantages. The first disadvantage is its requirement of topical anaesthetic and fluorescein dye application to obtain measurement, which can cause patient discomfort. The second drawback is the need to use slit-lamp biomicroscopy, which makes IOP measurement difficult in the disabled, the elderly, and in children.

HRET is a reliable and portable tonometer that does not need topical anaesthesia or fluorescein dye to obtain a measurement[4]. HRET is based on a rebound measuring principle, in which a very lightweight probe is used to make momentary contact with the cornea[5,6]. In rebound technology, the motion parameters of the probe are recorded during the measurement. An induction-based coil system is used for measuring the motion of the probe. The software analyzes the probe deceleration, contact time and other parameters of the probe while it touches the cornea. The deceleration and other rebound parameters of the probe change as a function of IOP. Many previous studies show a degree of agreement with GAT which is the gold standard of IOP measurement[7,8]. Although, HRET probes have been indicated for single use only, many healthcare practitioners in the community reuse HRET probes after disinfection with alcohol, since reusing probes could greatly reduce the cost of HRET utilization.

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Even though research indicates that HRET probes can be reused without compromising patient safety[9], only one report has been published regarding the validity of HRET by reusing the probe in artificial corneas[10]. Thus, the aim of this study was to determine the reliability of HRET when reusing HRET probes in patients.

Materials and Methods

The present study was prospective and observational. It was approved by the Institutional Review Board of Srinakharinwirot University (SWUEC-453/2561F and TCTR20210302001). The inclusion criteria were subjects aged 18 years and over who were diagnosed with primary open-angle glaucoma (POAG), normal-tension glaucoma (NTG), primary angle-closure glaucoma (PACG), and glaucoma suspected. All participants were consecutively enrolled in this study according to the inclusion criteria. The enrolled eyes were classified into 4 groups. The first POAG group had open anterior chamber angles on gonioscopy, base-line IOPs exceeding 21 mmHg, cup-to-disc ratios more than 0.5, and visual field defects. The second NTG group characteristics were identical to POAG except that the baseline IOPs never exceeded 21 mmHg. The third PACG group characteristics were similar to POAG except that the anterior chamber angles were closed. The last glaucoma suspected diagnosis group was reserved for individuals who definitely did not have glaucoma at the present time, but had characteristics suggesting that they were at high risk of developing the disease in the future based on a variety of factors such as ocular hypertension, optic nerve features suggestive of glaucoma, and visual field abnormalities. All participants were registered at the Ophthalmic Outpatient Department (OPD), Department of Ophthalmology, HRH Princess Maha Chakri Sirindhorn Medical Center, Faculty of Medicine, Srinakharinwirot University, Thailand. Written informed consent was obtained from each individual prior to his or her participation. The exclusion criteria were any patients with corneal pathology (e.g. corneal epithelial defect, scarring, edema), previous corneal surgery or intraocular surgery within 3 months, corneal astigmatism more than 3 diopters, eye infection, one-eye patients, and pregnancy. Sample size was calculated and assessed via the Bland-Altman method. The given values were shown as the following:

Alpha error (Type I error) = 0.05
Power = 0.80
Expected mean of difference = 0.25 mmHg
Expected Standard deviation of difference = 0.08
Maximum allowed difference methods = 0.46
n = 58 patients

Central corneal thicknesses were measured by a noncontact tonometry/pachymeter (Nidex Model NT-530P, Japan). The IOP was measured using the iCare® Pro HRET (Tiolat Oy, Helsinki, Finland) measurement system included a solenoid, lightweight, magnetized probe, and processing electronics. The HRET probe, with a 1.7-mm diameter plastic end tip, travels towards the cornea at a speed of approximately 0.2 m/s. After the initial propulsion pulse is completed, the HRET probe impact decelerates and rebounds from the anterior corneal surface[4]. The HRET software is preprogrammed for 6 measurements. According to the product's recommendation of HRET, the measurement range is 5 to 50 mmHg. The software excluded the highest and lowest IOP measurements, and calculated the average IOP value from the remaining measurements[11]. Moreover, the software was able to detect any incorrect measurement such as an absence of probe movement, no probe-eye contact, low probe speed, or incorrect positioning of the HRET probe. HRET was performed on 58 sitting-position participants by a single examiner (NW), who was a trained physician in HRET utilization. The tonometer was adjusted via a forehead support that ensured a 3- to 7-millimetre probe-to-eye distance. Of note, the probe must be aligned perpendicularly to the central cornea for accuracy of IOP measurement. The mean IOP in mmHg was displayed on the tonometer screen. Each participant's IOP was measured using a new probe in his or her right eye, and the test was repeated 3 additional times with that same probe after being wiped with a 70% isopropyl alcohol swab. One minute interval breaks were obtained between each swab to make sure that the alcohol solution was completely vaporized from the probe surface. This prevented the solution from damaging corneal surfaces. Antibiotic and artificial tear eye drops to prevent infection and reduce ocular discomfort were instilled in all probed eyes after completion of the four HRET measurements. Subsequent slit lamp biomicroscopy was also performed to assess for corneal abrasions.

The IOP readings produced each time were recorded and subsequent data trends were analyzed. The IOP values measured by new HRET probes were compared with those obtained with reused probes. Agreement among them was evaluated by the Bland and Altman method[12,13]. The Bland-Altman method (95% limits of agreement) was capable of assessing agreement between IOP measurements of the new and reuse values of the HRET probe which provided the mean plus or minus 1.96 SD of the differences between the 2 methods.

Results

Fifty-eight eyes of 58 participants were enrolled between May 2019 and January 2020. There were no reports of non-consenting participants or adverse events in this study. The demographic data were summarized in Table 1. There were 26 female (44.8%) and 32 male (55.2%) participants. The mean age was 67$\pm$8.5 years (range 46 to 85 years). There were 24 eyes with POAG (41.4%), 15 eyes with NTG (25.9%), 11 eyes with suspected glaucoma (19%), and 8 eyes with PACG (13.8%). The mean central corneal thickness was 526.45$\pm$26.82 microns. The mean IOP values of the new, the first reuse, the second reuse, and the third reuse of the HRET probes were displayed in Table 2 (13.8$\pm$2.6, 13.9$\pm$2.9, 13.8$\pm$2.7 and 13.6$\pm$2.5 mmHg, respectively). Table 3 demonstrated the mean IOP value differences of the new, the first reuse, the second reuse, and the third reuse of the HRET probes were 0.026, 0.009 and -

Table 1. Patient demographic data (n=58)

Variable	Mean±SD or n (%)
Gender	
Female	26 (44.8)
Male	32 (55.2)
Mean age (years)	66.98±8.45 (46 to 85)
Mean central corneal thickness (microns)	526.45±26.82 (460 to 584)
Diagnosis	
Primary open-angle glaucoma	24 (41.4)
Normal tension glaucoma	15 (25.9)
Primary angle-closure glaucoma	8 (13.8)
Glaucoma suspect	11 (19)

Table 2. Results of IOP values of new, first reuse, second reuse, and third reuse of HRET probes

HRET probe	Mean±SD (mmHg)	Range (mmHg)
New	13.8±2.6	8.2 to 20.1
First reuse	13.9±2.9	8.8 to 21.4
Second reuse	13.8±2.7	8.5 to 20.1
Third reuse	13.6±2.5	9.0 to 21.1

IOP = Intraocular pressure; HRET = handheld rebound tonometer

0.252 mmHg, respectively, and the p-value was 0.839, 0.947 and 0.005, respectively.

The IOP values were analyzed using the Bland-Altman method which showed agreement between the two measurements. A good correlation was shown between the new and first reuse HRET probe measurement values of the same HRET probe ($r=0.943$, $p<0.001$) in Figure 1. Figure 2 demonstrated the great correlation between the new and second HRET probe reuse measurement values of the same HRET probe ($r=0.930$, $p<0.001$). Finally, a desirable correlation was reported in the new and third HRET probe reuse measurement values of the same HRET probe ($r = 0.969$, $p<0.001$) in Figure 3.

Discussion

Although the Goldmann applanation tonometer (GAT) is the gold standard for measurement of IOP, it requires a high degree of skill to use correctly. Safe, quick, and precise measurement methods of IOP are key in efficiently determining whether patients have risks of developing glaucoma or not. HRET has proven itself to be a valid, fast, and mobile device. Furthermore, HRET shows good correlation with GAT. However, the manufacturer of HRET recommends single use of these HRET probes after each measurement to reduce the risk of cross-infections. The tips of HRET probes are made of polymethylmethacrylate, the same material as GAT heads, which are approved for multiple usage after being disinfected. This raises the issue whether HRET probes can be reused after adequate sanitization. Presently, a single published study reported that transmission of possibly infective material through reused HRET probes was significantly lower than from reusable GAT probes. This indicates that reused HRET probes are safe after being disinfected with 70% isopropyl alcohol wipes. Thus, reusing HRET probes could reflect on total healthcare cost reduction in developing countries. To our acknowledgement, there is only one report that has been published in regards to the validity of HRET by reusing probes in artificial corneas[10]. The study reported that statistically different readings were noticed between the no-wipe and wipe groups for most of the settings evaluated. Additionally, statistically significant readings were observed for a few of the settings as the number of readings increased for either group. Nevertheless, the difference in readings did not exceed 2 mmHg, except for the highest setting which would not be considered clinically significant.

Hence, the aim of our study was to determine the reliability of HRET when reusing HRET probes. According to our study, IOP analyzed using the Bland-Altman method showed good agreement between the new, first reuse, second reuse, and third reuse measurement values of the same HRET probe. However, there was a statistically significant difference between the IOP measurements obtained using the new probe and those obtained from reusing the probe for the third time by paired t-test ($p=0.005$). The previous study showed an interesting issue when compared with the no-wipe group, IOP measurements were significantly higher in the wipe group[11]. Moreover, the wipe group presented larger standard deviations for almost all pressure readings compared with the no-wipe group. Thus, one might infer that wiping the probe with alcohol pads may damage the probe. Although rebound tonometer was affected by central corneal thickness (CCT)[14], the CCT was not affected in this study since we measured IOP by new and reused HRET probes in the same

Table 3. Differences in IOP values between new HRET probe versus first, second, and third probe reuses (paired t-test analysis)

	Mean difference	95% CI	p-value
HRET 1st vs. HRET (new)	0.026	-0.227, 0.279	0.839
HRET 2nd vs. HRET (new)	0.009	-0.252, 0.270	0.947
HRET 3rd vs. HRET (new)	-0.252	-0.423, -0.080	0.005

HRET = handheld rebound tonometer; CI = confidence interval

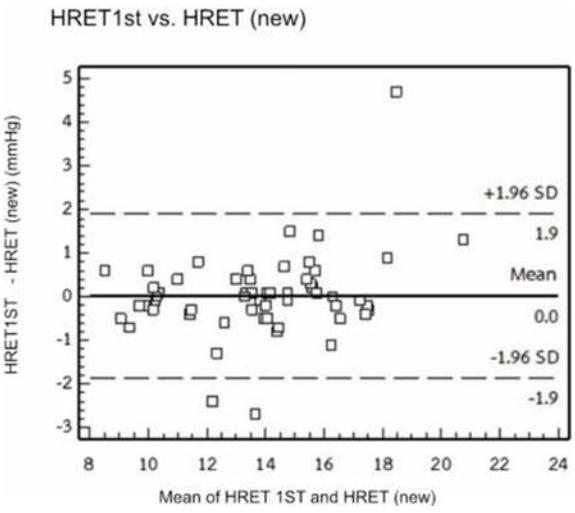

Figure 1. Bland-Altman analysis results showing distribution of IOP differences (the first HRET reuse probe value minus the new HRET probe value, mmHg; y-axis) and mean IOP values for the new and the first HRET probe reuse (x-axis) for right eye (n=58).

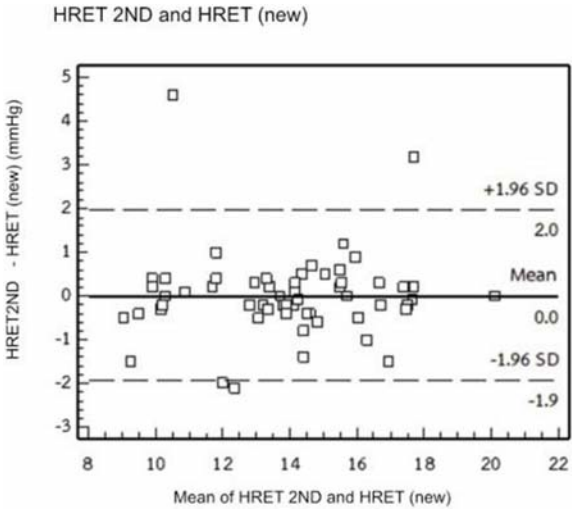

Figure 2. Bland-Altman analysis results showing distribution of IOP differences (the second HRET probe reuse value minus the new HRET probe value, mmHg; y-axis) and mean IOP values for the new and the second HRET probe reuse (x-axis) for right eye (n=58).

participants who had the same CCT.

There are some limitations in our study. For the first limitation, the participants who enrolled in this study all had IOP measurements within the normal range (8 to 22 mmHg), which would not be the case in actual practice. The second limitation reflects on our decision to only include POAG, NTG, PACG and glaucoma suspects in this study. Any conclusions drawn from this study might not be applicable to patients with other types of glaucoma not included in this study. As for the third limitation, we performed only 3 HRET probe reuse IOP measurements in each patient. The results could have been affected if more than 3 IOP measurements had been taken. Finally, we used 70% isopropyl alcohol pads to sanitize reused HRET probes. If reused HRET probes were sterilized by different methods, the IOP measurement validity might have possibly varied from our findings. Moreover, HRET probes could be destroyed and performance reduced if the probes are removed from the HRET apparatus for sanitization.

In the future, we will expand our study on the reliability of HRET when reusing HRET probes in the supine position in glaucoma and glaucoma suspected patients with higher and lower IOP ranges.

Conclusion

In the present study, there was good agreement of IOP measurements between the new, first reuse, and second reuse measurement values of the same HRET probe.

What is already known on this topic?

To our knowledge, only one report has been published in terms of validity of HRET by reusing the probe with artificial corneas. Thus, the aim of this study was to determine the reliability of HRET when reusing HRET probes in patients.

What this study adds?

This study shows good agreement of IOP

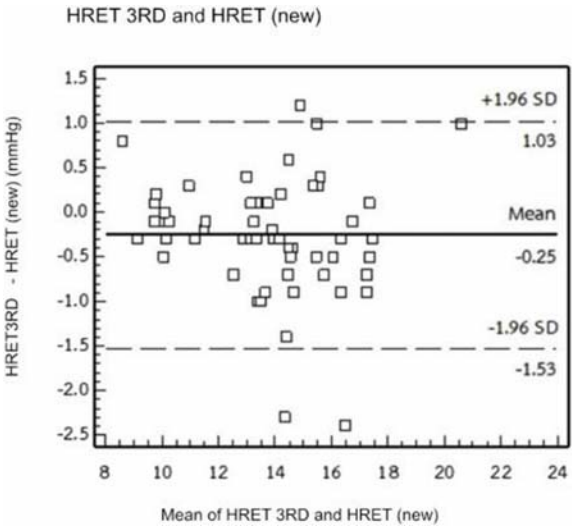

Figure 3. Bland-Altman analysis results showing distribution of IOP differences (the third HRET reuse probe value minus the new HRET probe value, mmHg; y-axis) and mean IOP values for the new and the third HRET reuse probe (x-axis) for right eye (n=58).

measurement between the new, first reuse, and second reuse measurement values of the same HRET probe after disinfection with 70% isopropyl wipes.

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Potential conflicts of interest

The authors declare no conflict of interest.

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