Int Ophthalmol (2020) 40:439–445
https://doi.org/10.1007/s10792-019-01204-7

ORIGINAL PAPER

Error in measurement of intraocular pressure with the Icare and IcarePRO

Mitsuya Otsuka · Naoki Tojo · Atsushi Hayashi

Received: 10 June 2019 / Accepted: 22 October 2019 / Published online: 6 November 2019

Abstract
Purpose We sought to determine whether changes in the measurement angle of the Icare TA01i and IcarePRO tonometers led to errors in the measurement of intraocular pressure (IOP).
Methods In this prospective, single-facility study, we analyzed 77 patients from November 2017 to September 2019. We measured IOP with the Icare TA01i and IcarePRO while changing the angle of the device with the cornea center and analyzed the associated changes in the measurement.
Results IOP measured with the Icare tilted − 30°, − 15° vertically was significantly higher than that measured with the Icare tilted horizontally ($p < 0.0001$, $p < 0.0001$). The IOP measured with a + 10° vertical tilt was significantly lower than that measured horizontally ($p < 0.0001$). When the IcarePRO was tilted + 90° vertically, the IOP was significantly lower with the patient in the supine position than in the lateral position ($p = 0.00058$).
Conclusions IOP measured with the Icare and IcarePRO is affected by the measurement angle. The study results will direct the clinicians to exercise extra precautions in determining the measurement angle while measuring IOP.

M. Otsuka (✉) · N. Tojo · A. Hayashi
Department of Ophthalmology and Graduate School of Medicine and Pharmaceutical Sciences, University of Toyama, 2630 Sugitani, Toyama 930-0194, Japan
e-mail: ootsuka-tym@umin.co.jp

Keywords Icare TA01i · IcarePRO · Intraocular pressure · Measurement error · Measurement angle

Introduction

Measurement of intraocular pressure (IOP) is an essential examination in glaucoma, since lowering the intraocular pressure is the fundamental basis of glaucoma treatment [1–3]. By reducing IOP, it is possible to improve visual function in the long run, and therefore, accurate IOP assessment is of paramount importance.

Until recently, intraocular pressure measurement has been possible only with the Goldmann applanation tonometers (GAT) or Schiotz tonometers. However, newer tonometers are emerging, one of which is the Icare TA01i (Icare Finland, Oy, Finland), which can measure IOP in geriatric patients and children, who cannot be easily positioned in front of a slit lamp. The Icare TA01i is a contact tonometer that can measure the IOP without the need for local anesthesia.

Several studies have compared the accuracy of IOP measurement by Icare TA01i and GAT [4–7]. Gao et al. [4] reported that the Icare rebound tonometer readings correlated with those of the GAT. Therefore, the Icare TA01i was deemed to be as accurate as the GAT in measuring IOP. Although Icare TA01i is user-friendly, if the instrument body is tilted without a

positioning sensor [8], the correct IOP value will not be obtained. Moreover, IOP cannot be measured in the supine position as the probe has a tendency to fall even on slight tilting of the instrument body.

Newer tonometers such as IcarePRO and Icare ic100 have been developed to address this issue. The IcarePRO (Icare Finland, Oy, Finland) is an updated version of the Icare TA01i that has been available since 2011. It measures IOP with a short probe, different from the one used in Icare TA01i, and IOP measurement is possible without dropping the probe even in the supine position. The positioning sensor allows IOP measurements in the vertical and horizontal positions, and prevents the probe from being launched when the inclination is not correct [8].

However, the Icare TA01i is currently used worldwide, and it is necessary to determine the effect of measurement angle on IOP measurement by the Icare TA01i. Therefore, the aim of this study was to determine whether the measurement angle influences the IOP measurements obtained with the Icare TA01i. In case of IcarePRO, we investigated whether an error in IOP measurement error is introduced in the lateral or supine position.

Materials and methods

This was a prospective observational study. Ethical approval was obtained from the institutional review board of the Toyama University Hospital. The study was conducted adhering to the tenets of the World Medical Association Declaration and the Committee On Publication Ethics (COPE). Informed consent was obtained from all individual participants included in the study. We measured IOP in 154 eyes of 77 patients who were admitted to the Toyama University Hospital for cataract or glaucoma surgery from November 2017 to September 2019. We excluded patients with corneal opacities or angle closures of Shaffer grade 2 or less and those with diseases affecting corneal thickness, such as Fuchs corneal endothelial dystrophy.

We measured IOP with the Icare TA01i and the IcarePRO. The measurements were recorded by glaucoma specialists, and the probe was set in position such that it would hit the center of cornea from a distance of about 6 mm. In case of an error, we reconfirmed the distance between the probe and the eye and measurements were recorded again. For both the Icare and IcarePRO, a mean of 6 independent measurements was considered as the IOP value.

For IOP measurements with Icare, the patient was made to sit straight, looking ahead. Vertical measurements were recorded at four different angulations: − 30°, − 15°, 0° (i.e., level) and + 10° (see Fig. 1a–d), where an upward tilt of 30° was defined as − 30°. For horizontal measurements, the Icare was tilted at angles of 0° (i.e., horizontal) 45° and 90° (Fig. 1e–g). The angulations were measured by attaching an angle measuring device (slant level 5.5 m, Tajima, Japan) to the bottom of Icare (Fig. 1). It was not possible to measure the IOP with the Icare tilted in a downward direction more than + 10°, because at that angle the probe would fall down.

The IcarePRO can be used to measure IOP even in the supine position. In the present study, IcarePRO was used to measure IOP with patients in the sitting, supine and lateral positions. For the supine and lateral measurements, the device was tilted at 90° (Fig. 2a) or 0° (i.e., level; Fig. 2b), respectively. For the measurements in the sitting position, the device was tilted 90° or held horizontally (Fig. 2c, d).

In a previous analysis of Icare measurements in 42 healthy human eyes, the average IOP value was 16.7 ± 4.1 mmHg [mean ± standard deviation (SD)] [6]. From this, we estimated the SD and set the β error to 0.2 and α error to 0.05. It was impossible to predict how much the average difference would be, but we reasoned that a 1 mmHg difference would be clinically significant. A sample size calculation was then performed using Easy R [9] (Saitama Medical Center, Jichi Medical University, Saitama, Japan). To detect a difference of 1 mmHg, 134 cases per group were required. Possible confounders were related to postural variation, and only 126 cases were measured in supine and lateral positions with the IcarePRO.

Statistical analyses were performed using unpaired and paired t tests in Microsoft Excel (Microsoft Corporation, Mountain View, CA). p values < 0.05 were considered to indicate statistical significance. When p value < 0.05, the power $(1 - \beta)$ was obtained by power analysis.

Results

The mean age of the enrolled patients was 75.4 ± 8.8 years. The mean IOP values measured

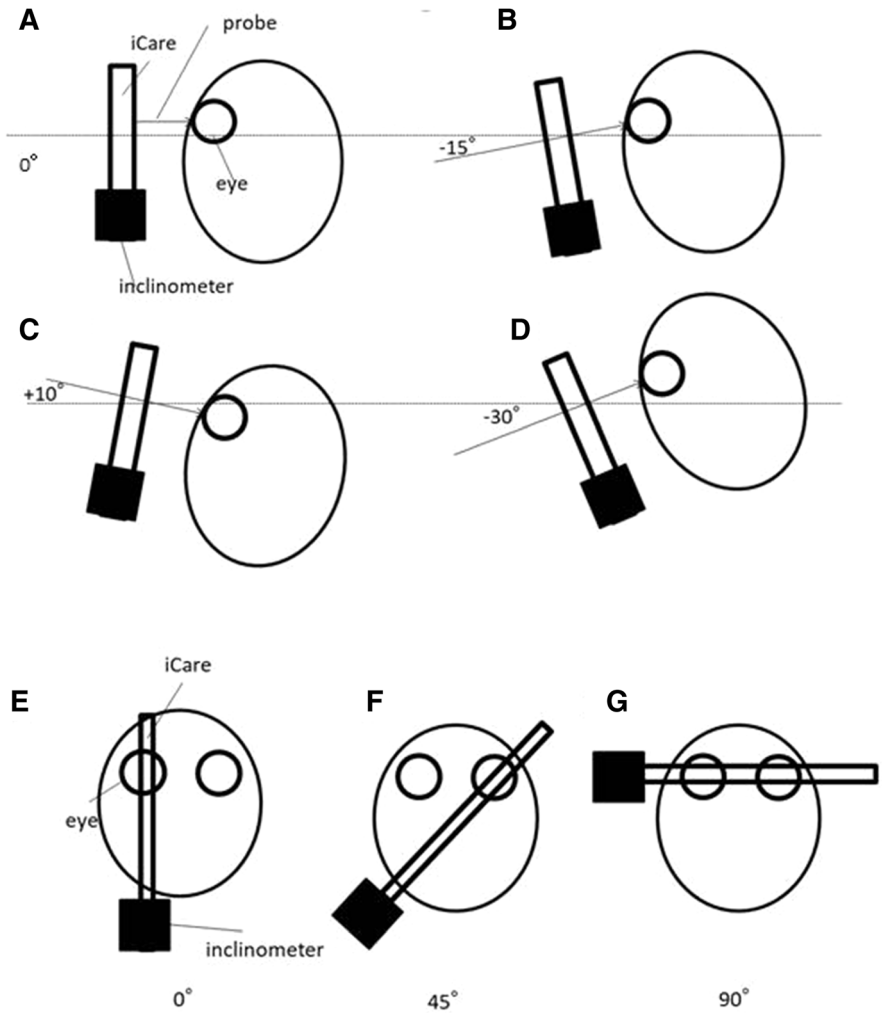

Fig. 1 Tilting the Icare device at angles of − 30°, − 15°, 0° and + 10° vertically, and 45° and 90° horizontally, with the patient in the sitting position. **a–d** Vertical tilting of Icare at 0°, − 15°, + 10° and − 30°, respectively. **e–g** Horizontal tilting of Icare at 0°, 45° and 90°, respectively

with Icare and IcarePRO, in the seated position with the device held at level (0°), were 12.2 ± 4.7 mmHg (n = 154) and 15.0 ± 5.1 mmHg (n = 126), respectively (Table 1). The mean IOP values when the Icare was angulated at − 30°, − 15° and + 10° were 13.9 ± 5.3, 13.4 ± 5.5 and 11.3 ± 4.4 mmHg, respectively, and the mean differences between the measurements at 0° and those at − 30°, −15° and 10° were 1.7 ± 2.0, 1.2 ± 2.0 and − 0.9 ± 1.4 mmHg, respectively (Fig. 3a). The IOP measured at an angle of − 30°, − 15° was significantly higher (Fig. 3b) ($p < 0.0001$, $p < 0.0001$, the power $(1 - \beta) = 0.99$, 0.84, respectively), and that measured at + 10° was significantly lower (Fig. 3c) than that measured at a 0° vertical tilt ($p < 0.0001$, the power $(1 - \beta) = 0.64$).

In the lateral position, the mean IOP measured with the IcarePRO at 0° was 17.4 ± 5.5 mmHg. In the supine position, the mean IOP measured with the IcarePRO tilted at 90° was 16.5 ± 5.2 mmHg. This value was significantly lower than the IOP measured with the same device held at 0° (i.e., level) in the lateral position ($p = 0.00058$, the power $(1 - \beta) = 0.98$). The mean difference between the IOP measured with the IcarePRO at 0° and the patient in the lateral position and the IcarePRO tilted 90° vertically with the patient in the supine position was − 1.9 ± 2.6 mmHg (Fig. 4a, b).

The mean IOP values measured with the Icare device tilted horizontally at angles of 45° and 90° with the patient in the sitting position were 12.2 ± 4.8 mmHg and 11.9 ± 4.8 mmHg, and these were not significantly different from the measurements at an angle of 0° ($p = 0.89$, $p = 0.13$, respectively). The mean IOP measured with the IcarePRO

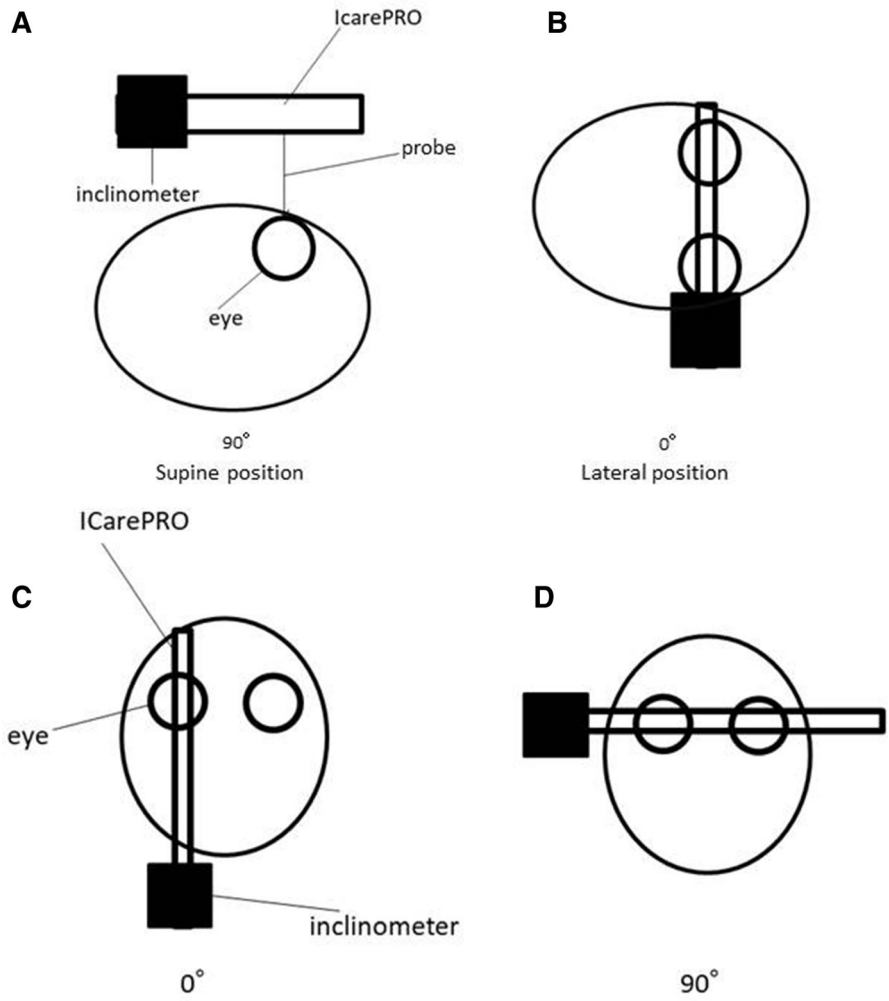

Fig. 2 Vertical tilting of the IcarePRO device at an angle of 90° with the patient in the supine position (**a**), 0° with the patient in the lateral position (**b**) and 0° with the patient in the sitting position (**c**); and horizontal tilting of the IcarePRO device at 90° with the patient in the sitting position (**d**)

Table 1 Patient characteristics and intraocular pressure obtained by Icare and IcarePRO

	Mean ± SD
Age	76.4 ± 8.0
Sex (male to female)	50:104
Icare	12.2 ± 4.7 mmHg
IcarePRO (n = 126)	15.0 ± 5.1 mmHg

tilted 90° horizontally (Fig. 2d) with the patient in the sitting position was 15.5 ± 5.5 mmHg and was significantly different from the measurement at 0° (Fig. 2c, $p = 0.0005$). However, the power ($1 - \beta$) was 0.28.

Discussion

We found that the measurement angle significantly affected the IOP values measured with the Icare. As the use of Icare devices is increasing all over the world, the assessment of IOP measurement errors is an important consideration in glaucoma management. It was previously proved that in the absence of a positioning sensor, the accuracy of measurements obtained with Icare TA01i was affected by the tilt angle, but the extent of such deviations was unclear. This study examined the difference in IOP values depending on the Icare TA01i inclination angle, and the results can guide the use of this instrument for the correct measurement of IOP.

Moreover, in IcarePRO, which features a positioning sensor, the values may differ depending on

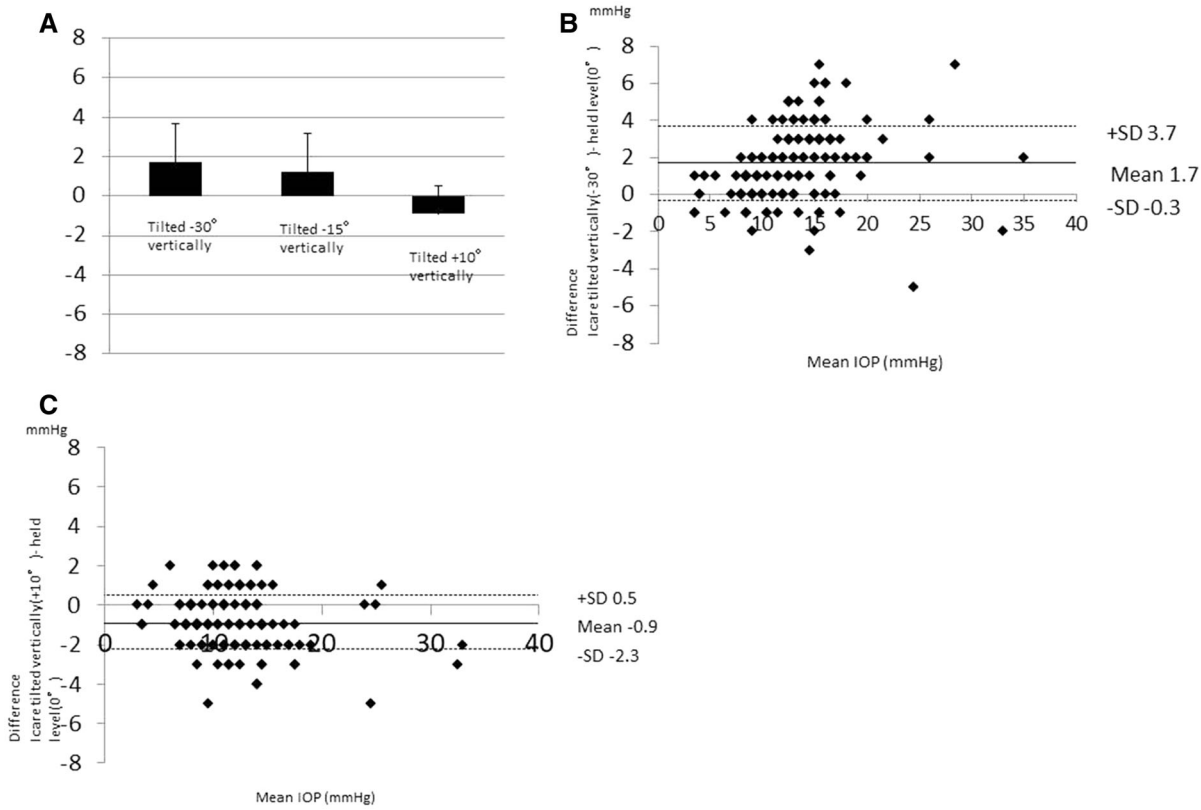

Fig. 3 Mean difference in IOP measured using the Icare device held level (0°) or tilted vertically at − 30°, − 15° and + 10°. **a** Mean difference in IOP measured using the Icare device held level (0°) or tilted at − 30°, − 15° and + 10°. **b** Comparison of mean IOP measurements with the Icare tilted vertically − 30° or held level (0°). The mean IOP was calculated as IOP (Icare tilted vertically at − 30°)/2 + IOP (held at level 0°)/2. Irrespective of the initial IOP value, the IOP became higher when the Icare was tilted vertically − 30°. **c** Comparison of mean IOP measurements with the Icare tilted vertically + 10° or held level (0°). Irrespective of the initial IOP value, the mean IOP became lower when the Icare was tilted vertically at + 10°

whether the instrument is held vertically in the lateral position or vertically inclined at 90° in the supine position.

We should therefore weigh the situations where it would be recommendable to use an inclined Icare for the measurement of IOP. For example, in geriatric patients who cannot keep their head straight when their hips are bent forward, it may be necessary to use the Icare in the position depicted in Fig. 1b, d. It may also be possible to use the Icare (Fig. 1c) in children who cannot stay still. Furthermore, when performing tonometry on bedridden or unconscious people, the IcarePRO can measure IOP in a supine position. In the case of a bedridden patient who cannot attain a supine position, the measurements can be recorded by tilting the Icare and IcarePRO 90° horizontally in the lateral position. When holding the Icare and IcarePRO vertically while measuring in the lateral position, the lower end of Icare may hit the bed, so we suggest to perform the measurements by tilting the device 90° horizontally. In this study, we concluded that the IOP measured by tilting the Icare horizontally did not change compared with the IOP measured by holding them vertically.

Since the Icare performs simple tonometry, it can also be used for 24-h tonometry. The IcareHome is an Icare device that enables measurement of IOP at home and, unlike the Icare TA01i, features a positioning sensor [8]. Analysis in the supine position is difficult, and changes in IOP are evident in different positions of the patient. However, it is possible to obtain more information on IOP fluctuations by adding a tonometric IOP evaluation using the Icare TA01i or the

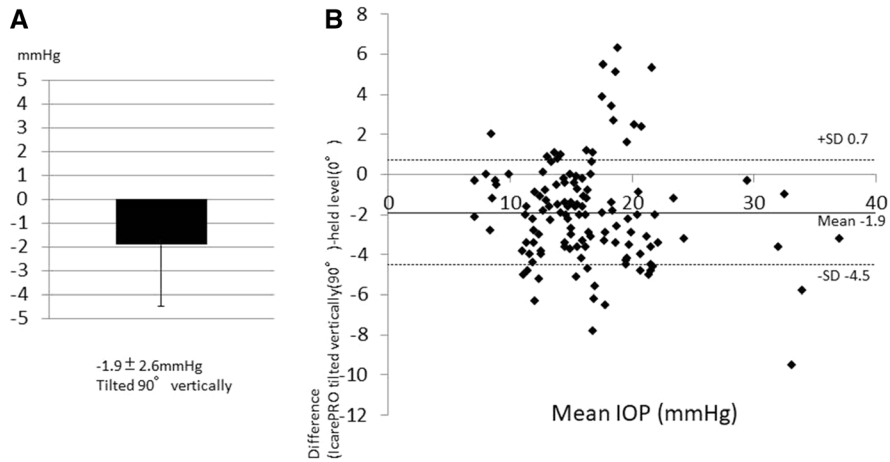

Fig. 4 Mean difference between IOP measured with the IcarePRO held level (0°) in the lateral position and with the device tilted vertically 90°, with the patient in the supine position. **a** Mean difference between IOP measured with the IcarePRO held level (0°) in the lateral position and with the device tilted vertically 90° with the patient in the supine position. **b** Comparison of mean IOP measurements with the IcarePRO tilted vertically 90° with the patient in the supine position or held level (0°) with the patient in the lateral position. Mean IOP was calculated as IOP (IcarePRO tilted vertically 90°)/2 + IOP (held level 0°)/2. Irrespective of the initial IOP value, the IOP became lower when the IcarePRO was tilted 90° vertically with the patient in the supine position

IcarePRO. Further studies are needed to determine the feasibility of this possibility.

A limitation of this study is that the influence of central corneal thickness (CCT) was not considered. Previous studies have reported that Icare IOP measurements are affected by CCT [5, 7]. In this study, the correlation between CCT and the deviation of the IOP upon tilting the device was not studied. The second limitation is that IcarePRO measurements were taken with the device tilted vertically at 90° when the patients were in the supine position and with the device held level when the patients were in the lateral position. Although it is known that IOP values in supine position tend to be higher than those in the sitting position [10–13], it remains unclear whether there is a difference in IOP between the lateral decubitus position and the supine position. In the lateral decubitus position, it has been reported that the dependent eyes of patients (i.e., the lower eye in the lateral decubitus position) show higher IOP than the nondependent eyes [14]. In the current study, IOP was measured with patients in the right lateral decubitus position, but the difference between the left and right eyes was not considered. It is known that the repeatability of IOP measurements by both Icare and IcarePRO is good when patients are in the sitting position [15]. However, it has also been reported that the repeatability of IOP measured with the IcarePRO declines when patients are in the supine position [16]. In our present analysis, it is possible that the IOP values measured by the IcarePRO with patients in the supine position were less reliable than those measured in the sitting or lateral decubitus position.

In conclusion, we found that the measurement angle significantly affects IOP values measured with an Icare tonometer. While the Icare and IcarePRO devices are very useful tools because they do not require local anesthesia, we should be aware of the effects of the measurement angle when using the Icare tonometer.

Funding None.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

References

1. Collaborative Normal-tension Glaucoma Study Group (1998) The effectiveness of intraocular pressure reduction in the treatment of normal-tension glaucoma. Am J Ophthalmol 126:498–505
2. Collaborative Normal-Tension Glaucoma Study Group (1998) Comparison of glaucomatous progression between

untreated patients with normal-tension glaucoma and patients with therapeutically reduced intraocular pressures. Am J Ophthalmol 126:487–497
3. The AGIS investigators (2000) The relationship between control of intraocular pressure and visual field deterioration. Am J Ophthalmol 130:429–440
4. Gao F, Lix X, Zhao Q et al (2017) Comparison of the Icare rebound tonometer and the Goldmann applanation tonometer. Exp Ther Med 13:1912–1916
5. Nakamura M, Darhad U, Tatsumi Y et al (2006) Agreement of rebound tonometer in measuring intraocular pressure with three types of applanation tonometer. Am J Ophthalmol 142:332–334
6. Davies LN, Bartlett H, Mallen EA et al (2006) Clinical evaluation of rebound tonometer. Acta Ophthalmol Scand 84:206–209
7. Pakrou N, Gray T, Mills R et al (2008) Clinical comparison of the Icare tonometer and goldmann applanation tonometry. J Glaucoma 17:43–47
8. Nakamura S (2018) Icare® rebound tonometers: review of their characteristics and ease of use. Clin Ophthalmol 12:1245–1253
9. Kanda Y (2013) Investigation of the freely available easy-to-use software EZR for medical statistics. Bone Marrow Transplant 48:452–458
10. Jablonski KS, Rosentreter A, Gaki S et al (2013) Clinical use of a new position-independent rebound tonometer. J Glaucoma 22:763–767
11. Schweier C, Hanson JV, Funk J et al (2013) Repeatability of intraocular pressure measurements with Icare PRO rebound, Tono-Pen AVIA, and Goldmann tonometers in sitting and reclining positions. BMC Ophthalmol 13:44
12. Barkana Y, Gutfreund S (2014) Measurement of the difference in intraocular pressure between the sitting and lying body positions in healthy subjects: direct comparison of the IcarePro with the Goldmann applanation tonometer, pneumatonometer and Tonopen XL. Clin Exp Ophthalmol 42:608–614
13. Ozkok A, Tamcelik N, Capar O et al (2014) Posture-induced changes in intraocular pressure: comparison of pseudoexfoliaton glaucoma and primary open-angle glaucoma. Jpn J Ophthalmol 58:261–266
14. Seo H, Yoo C, Lee TE et al (2015) Head position and intraocular pressure in the lateral decubitus position. Optom Vis Sci 92:95–101
15. Kato Y, Nakamura S, Matsuo N et al (2018) Agreement among Goldmann applanation tonometer, Icare, and Icare PRO rebound tonometers; non-contact tonometer; and Tonopen XL in healthy elderly subjects. Int Ophthalmol 38:687–696
16. Nakamura S, Mori E, Yamamoto M et al (2015) Intradevice and interdevice agreement between a rebound tonometer, Icare PRO, and the Tonopen XL and Kowa hand-held applanation tonometer when used in the sitting and supine position. J Glaucoma 24:515–521