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Original Article

Reliability of the Non-contact TONO-i Tonometer Compared with the Goldmann Applanation Tonometer

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Purpose: The accuracy and agreement of intraocular pressure (IOP) measurements using a noncontact self-measuring tonometer, TONO-i, compared with the Goldmann applanation tonometer (GAT).
Methods: A total of 35 healthy participants and 42 primary open angle or normal tension glaucoma patients were enrolled in thisstudy. TONO-i and GAT measurements were obtained and the mean difference in IOPs was analyzed using a paired *t-test*. IOPagreement was calculated using the two-way random effects model. Bland-Altman analysis and simple linear regression were used to estimate the disagreement between IOP measurements.
Results: The mean IOPs measured using the TONO-i and GAT were 15.9 ± 3.3 mmHg and 16.4 ± 5.1 mmHg, respectively.In glaucoma patients, the mean values measured using the TONO-i (16.7 ± 4.1 mmHg) were lower than those measured using the GAT (17.9 ± 6.1 mmHg; $p < 0.001$). However, there was no significant difference among the healthy participants ($p = 0.273$).The intraclass coefficients (95% confidence interval) for all participants, normal participants, and glaucoma patients were 0.847 (0.702-0.920), 0.882 (0.804-0.941), and 0.828 (0.742-0.887), respectively, indicating good agreement between the IOP measurements. The mean difference and limits of agreement were not statistically significant. As IOP increased, the absolute difference between the GAT and TONO-i measurements also increased.
Conclusions: The TONO-i, a novel tonometer, may be used reliably for IOP self-measurement and detecting IOPelevations. However, caution must be exercised because of the possibility of underestimating high IOPs.
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Keywords: Intraocular pressure, TONOI tonometer, Tonometry

Intraocular pressure is known to be a major factor in the development and progression of glaucoma.[1,2] Accurate measurement of intraocular pressure is essential for evaluating patients with glaucoma and developing a treatment plan.

There are several ways to measure IOP, but the Goldmann applanation tonometer is currently considered the most accurate (gold standard) tonometer and is widely used clinically.[3,4] However, the Goldmann applanation tonometer can only be measured in the sitting position through a slit lamp microscope, so it is limited to ophthalmic laboratories equipped with a slit lamp microscope. Recently a newly developed TONO-i Ocular Tonometer (TONOI®, C&Vtech, Inc., Wonju, Korea) has been created, which

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is a portable, non contact tonometer that allows glaucoma patients to self- measure their own intraocular pressure at home. TONO-i is a non-contact tonometer that utilizes an applanation principle to measure intraocular pressure (IOP). It injects air onto the central part of the cornea to flatten it, and then measures changes in infrared signals before and after air injection to determine the IOP. Additionally, it has a feature that uses infrared to measure whether the tonometer and the eye are aligned in the correct position and distance, which can be represented by different colors according to the distance. By determining the alignment through colors, even the general public can position the tonometer correctly according to the distance without the assistance of experts, enabling accurate measurement of intraocular pressure (Fig 1).

Since there was no study on TONO-i tonometer compared to Goldman's pressure stabilizer,

Comparing the intraocular pressure of the TONO-i tonometer with the intraocular pressure of the Goldman pressure system for the normal eye and the inner eye of the Korean,

The clinical usefulness of TONO-i tonometer was confirmed by analyzing the tendency of difference between the two ocular pressure gauge measurements.

Test Subjects and Methods

We conducted a prospective study of glaucoma patients (normal-tension ocular hypertension, primary open-angle glaucoma) and a normal control group who attended our outpatient department from September 2021 to July 2022. The study complied with the Declaration of Helsinki and was reviewed and approved by our Institutional Review Board (IRB).

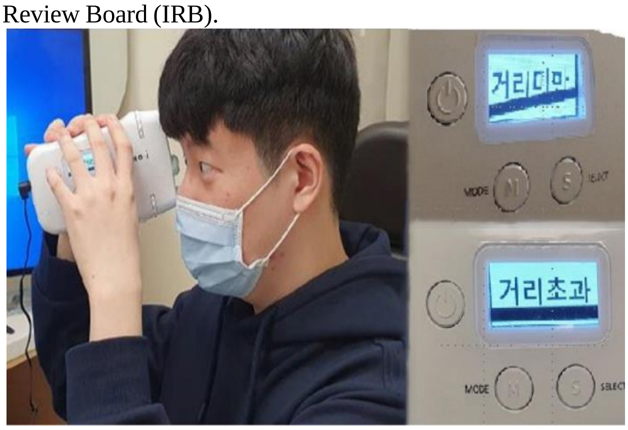

Figure 1. Self-intraocular pressure check using TONO-i tonometer. D ifferent colors are shown according to distancebetween central cornea and TONO-i tonometer (> 6.5 m m: blue, 5.5-6.5 m m: green, < 5.5 m m: red). A lso, the distance is displayed on m onitoring board of TONO-i tonometer

(Approval number: 2020-09-215) The diagnosis of primary open-angle glaucoma is defined as follows: initial intraocular pressure (IOP) before starting glaucoma medication is higher than 21 mmHg, the anterior chamber angle appears open during the gonioscopic examination, optic disc cupping and corresponding visual field loss indicative of glaucoma are observed, and there are no other identifiable causes of optic nerve damage apart from glaucoma. The diagnosis of normal-tensionglaucoma was defined as an initial IOP of 21 mm Hg or less before initiation of antiglaucoma medication, an open angle gonioscopy showing glaucomatous optic nerve papillary damage and corresponding visual field defects, and the absence of any disease causing optic nerve damage other than glaucoma. Normal controls were also definedas IOP of 21 mm Hg or less and no glaucomatous opticnerve papillary damage or visual field defects,

Those with corneal astigmatism of 3.5 diopters (D) or higher, those wearing contact lenses within two weeks, those with a history of trauma, and those with a history of corneal transplantation were excluded. Finally, 35 people in the normal control group and 42 people in the glaucoma patient group participated in the study. In the normal control group, intraocular pressure was measured in all right eyes, and in the glaucoma patient group, intraocular pressure was measured in those eyes that met the criteria defined in this study, and if both eyes met the criteria, they were targeted in the right eye.

The TONO-i tonometer was used for self-measruement by the participants after receiving instructions on how to use it from the examiner. On the other hand, the Goldmann applantation tonometer was used by a single experienced examiner. Intraocular pressure was first measured with the TONO-I tonometer and then with the Goldmann applanation tonometer. A time interval of at least 5 minutes was allowed between each measurement.

Afterwards, the length of the upper and lower supports of the TONO-I tonometer was adjusted to measure intraocular pressure (IOP) at a distance of 6 mm from the central cornea. This process was repeated three times to obtain three measurements of IOP. Any measurements where the patient closed their eyes and the examination were not performed properly, or where the machine indicated an error in measurement, were excluded. Subsequently, IOP was measured three times using the Goldmann applanation tonometer. A minimum of 1 minute was allowed between each measurement, and the average of the three measurements was used as the result for the evaluation of validity.

The average intraocular pressure (IOP) measured using the two types of tonometers was compared using a paired *t* -test. The intraclass correlation coefficient was evaluated using the two-way random effects model to assess the within-subject correlation. Bland-Altman analysis and multiple regression analysis were used to evaluate the agreement between the two tonometers. Statistical analysis was performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA), and a significance level of $p<0.05$ was considered statistically significant.

Results

The **77** test subjects ranged from 22 to 79 years, with a mean of 54.4 ± 16.2 years, and consituted of 34 males and 43 females. Central corneal thickness averaged 532.5 ± 42.0μm. Intraocular pressure in the subjects' eyes was 15.9 ± 3.3 mm Hg measured with a TONO-I tonometer and 16.4 ± 5.1 mm Hg measured with a Goldmann applanation tonometer.

A paired t-test was conducted to compare the mean differences in measurement values between the TONO-i tonometer and the Goldmann applanation tonometer in the glaucoma and normal control groups. In the normal control group, there was no significant difference in the mean difference between the two tonometers (p=0.273). However, in the glaucoma group, the measurement values from the TONO-i tonometer were significantly lower than those from the Goldmann applanation tonometer (p<0.001). Among the glaucoma group, in the subset where the Goldmann applanation tonometer measurements were equal to or below 21 mmHg, there was no significant mean difference between the two tonometers (p=0.126) (Table 1).

The acute intraclass correlation coefficient was 0.847 (95% CI 0.702-0.920), and 0.882 (0.804-0.941) in normal controls. The concordance was also high, at 0.828 (95% CI 0.742-0.887), based on the glaucoma patient population (Table 2, Fig .2).

A Bland-Altman plot was also performed to evaluate the relation between the TONO-I tonometer Measurements and the control measurements (Goldmann applanation tonometry IOP) (Fig. 3). The mean value of the difference between TONO-I tonometer and Goldmann applanation tonometry intraocular pressure was -0.5 mmHg.

The 95% limits of agreement (LoA) of the TONO-i tonometer is the upper LoA = 4.4, the lower LoA = -5.4 mmHg, the normal control LoA = 4.2 mmHg, the lower LoA = -3 mmHg, compared to the Goldmann application tonometer,Based on glaucoma patients, upper LoA = 4.1 mmHg and lower LoA = -6.5 mmHg were shown. (Table 3, Figure 3).

Table 2. ICC for each participant group

Participant group	ICC
Overall (n=77)	0.847 (0.702-0.920)
Normal (n=35)	0.882 (0.804-0.941)
Glaucoma (n=42)	0.828 (0.742-0.887)

We suggest that ICC values less than 0.5 are indicative of poor reliability, values between 0.5 and 0.75 indicate moderate reliability, values between 0.75 and 0.9 indicate good reliability, and values greater than 0.90 indicate excellent reliability.

ICC = interclass correlation coefficients.

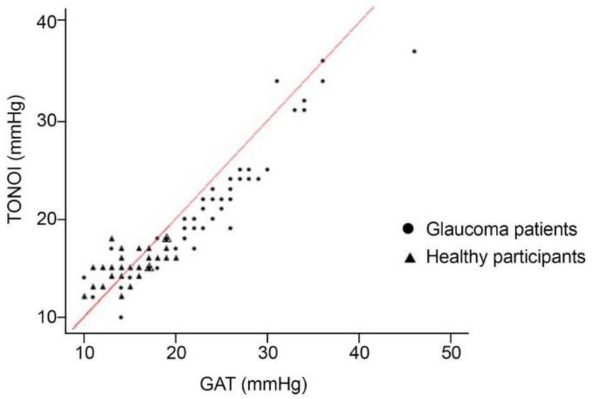

Figure 2. Scatter plot graph of TONO-i IOP and GAT IOP.

TONO-i = TONO-i tonomtery; GAT = Goldmann applanation tonometry; IOP = intraocular pressure.

Table 1. Mean measured IOP values of two different tonometers and p-values for each participant group

	Mean IOP value	*p*-value
Overall (n=77)		
GAT	16.4 ± 5.1 mmHg	0.097
TONO	15.9 ± 3.3 mmHg	
Normal (n=35)		
GAT	14.6 ± 2.7 mmHg	0.273
TONO	15.0 ± 1.7 mmHg	
Glaucoma (n=42)		
GAT	17.9 ± 6.1 mmHg	<0.001
TONO	16.7 ± 4.1 mmHg	
Glaucoma (IOP ≤21 mmHg, n=14)		
GAT	16.5 ± 3.1 mmHg	0.126
TONO	16.1 ± 2.1 mmHg	

IOP = intraocular pressure; GAT = Goldmann applanation tonometry; TONOI = Tono-i tonometry.

In the glaucoma group where the Goldmann applanation tonometer measure IOP in the range of 21-25 mm Hg, there was a 35% proportion of cases where the TONO-i tonomoeter measured IOP below 20%. This indicates a tendency for the TONO-i tonometer to yield slightly lower measurements in this specific IOP range (Table 4).

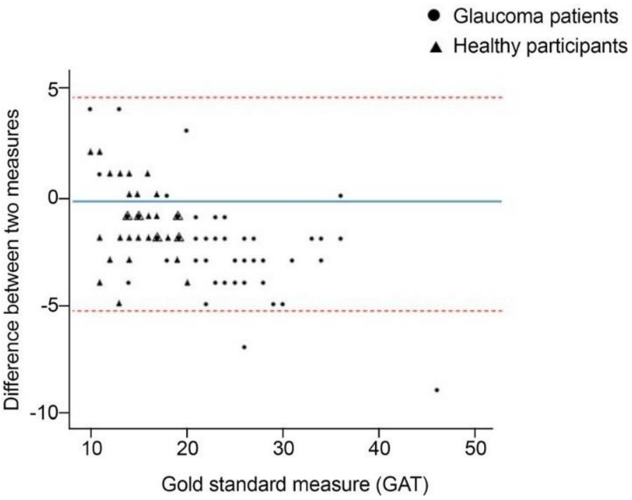

Figure 3. Bland-Altm an plots describing differences between TONOI IO P and GAT IOP. Blue line describes m ean differ- ence between TONOI IOP and GAT IOP, red dot lines de- scribeupper and lower limits of agreement. Difference = (TONOI IOP) - (GAT IO P); GAT = Goldm ann applanation tonometry; TONOI = TONO-i tonometry; IOP = intraocular pressure.

Discussion

This study aimed to evaluate the reliability and clinical utility of a new non-contact tonometer, the TONO-i, by comparing an IOP measured with the Goldmann applanation tonometer as a control. The TONO-i showed high agreement and correlation with the Goldmann applanation tonometer.

The Goldmann applantion tonometer is currently considered the most accurate and widely used tonometer in clinical practice[3,4] However, it has the disadvantages of being an invasive test that requires corneal anesthesia and contact with the cornea, which is performed using a slit-lamp biomicroscope.[5,6] In response to these limitations, the non-contact tonometer was first developed by Grolman in 1972[7] . Non-contact tonometry works on the principle of blowing air onto the cornea and optically measuring the pressure of the cornea to produce an IOP reading.[7] The non-contact tonometer operates on the principle of projecting air onto the cornea and optically measuring its applanation to determine intraocular pressure (IOP)..[8] The non-contact tonometer offers the advantages of being a non-invasive test that does not require corneal anesthesia or fluorescein staining, reducing the risk of infection. It also allows for relatively quick and convenient examination.[9-12] These studies have demonstrated statistically equivalent performance between the Goldmann applanation tonometer and these portable tonometers.[13-17]

Table 3. M ean difference between TON O I and G AT and LoA

	Overall (mmHg)	Normal (mmHg)	Glaucoma (mmHg)
Mean difference*	-0.5	0.4	-1.2
95% upper LoA	4.4	4.2	4.1
95% lower LoA	-5.4	-3.5	-6.5

TONOI = TONO-i tonometry; GAT = Goldmann applanation tonometry; LoA = limits of agreement; IOP = intraocular pressure.
*TONOI IOP – GAT IOP

Table 4. Proportion of underestimated IOP (< 20 mmHg) of glaucoma patients measured by TONOI tonometer

GAT IOP range (mmHg)	Proportion of underestimated IOP (<20 mmHg) of glaucoma patients measured by TONOI tonometer	Mean difference of (TONOI IOP)-(GAT IOP)*
Mean difference*	-0.5	-1.2
95% upper LoA	4.4	4.1
95% lower LoA	-5.4	-6.5

The denominator refers to total number of participants whose GAT IOPs fall within the range shown in the left column, and the numerator re-fers to the number of participants in the denominator group whose TONOI IOPs are measured to be lower than 20 mmHg. The averages of the measured difference between TONOI IOP and GAT IOP for each group classified according to GAT IOP are also described in the right column.
IOP = intraocular pressure; TONOI = TONO-i tonometry; GAT = Goldmann applanation tonometry.
* The average of the measured value of (TONOI IOP) - (GAT IOP) of each particiapant, for each group classified according to GAT IOP.

In this study, when comparing IOP measured by the TONO-i tonometer and Goldmann applanation tonometer, the acute intraocular correlation coefficient is of 0.847 (95% CI 0.717-0.896) in the overall population,0.882 (95% CI 0.804-0.941) in the normal controls, and 0.828 (95% CI 0.702-0.920) in the glaucoma patients. Furthermore, in this study, it was observed that as the intraocular pressure (IOP) measured by the Goldmann applanation tonometer increased, the absolute difference between the IOP measured by the TONO-i tonometer and the Goldmann applanation tonometer also increased (Table 4). In other words, when compared to the IOP measured by the Goldmann applanation tonometer as the reference, the TONO-i tonometer tended to yield relatively lower measurements at higher IOP levels. These findings are consistent with previous research on non-contact tonometers, indicating a similar trend.[17,18] The lower TONO-i intraocular pressure in the glaucoma group in this study compared to the Goldmann applanation tonometry may also be related to the higher mean IOP in the glaucoma group. The paired *t*-test in this study showed that the TONO-i tonometry measurements were significantly lower than the Goldmann applanation tonometry measurements in the glaucoma group, which may havebeen influenced by the lower TONO-i tonometry measurements in the higher IOP group; in fact, the paired t-test in the glaucoma group with a Goldmann applanation tonometry IOP of 21 mmHg or less did not show a significant difference between the two tonometry measurements (Table 1).

The TONO-i tonometer has several advantages. Unlike conventional non-contact tonometers, the color indicates whether the tonometer and eyeball are aligned at the correct position and distance, allowing the average person to properly align the tonometer for more accurate IOP measurements and eliminating the need for an examiner. Compared to existing self-measuring tonometers, such asthe Icare IC100®, it has similar accuracy, with a differenceof about 1 mmHg based on the average difference between[18] and Goldmann applanation tonometer pressure (Table 3). Indeed, traditional self-measurement tonometers typically use a rebound method, whereas the TONO-i tonometer employs a non-contact method. Unlike traditional self-measurement tonometers, the TONO-i tonometer does not require the additional replacement of tips and carries the advantage of reduced risk of infection.

However, the TONO-i tonometer uses a non- contact method to measure intraocular pressure at home, which can be difficult if the patient is not fully familiar withhow to use it. Therefore, it is difficult to use in cases wherecooperation is difficult, such as patients with poor cognitive function and pediatric patients. In addition, although the TONO-i tonometer showed high overall agreement compared to the Goldmann applanation tonometer, it should be noted that in this study, IOP in thelow 20 mmHg range was often measured as normal, andthe higher the IOP, the lower the IOP was measured compared to the Goldmann applanation tonometer.

The limitations of this study are as follows: firstly, the small sample size compared to previous studies. Secondly, the study was conducted on patients from a tertiary hospital outpatient department, so the sample group with a mean age of 54.4 years may not represent the entire population. Thirdly, variables related to corneal characteristics, such as central corneal thickness, corneal hysteresis, and corneal resistance were not included in the analysis,[19-24], and finally, it was not possible to conduct an analysis according to the presence or absence of intraocular pressure lowering agent eye treatment.[25,26]In the future, it is thought that research that supplements these points is needed.

In conclusion, when using the TONO-i tonometer, a portable self-measurement device for intraocular pressure (IOP), there was a high level of agreement with the Goldmann applanation tonometer. However, it is important to note that the TONO-i tonometer may yield slightly lower measurements at higher IOP levels. With this in mind, utilizing the TONO-i tonometer could be beneficial in diagnosing clinically significant IOP elevation in glaucoma patients, as it offers the convenience of portable self-measurement.

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= English abstract =

Reliability of the Non-contact TONO-i Tonometer Compared with the Goldmann Applanation tonometer

Objective: To evaluate the clinical utility of the TONO-i tonometer, a new non-contact, portable tonometer for self-measurement of intraocular pressure (IOP), by comparing IOP measured with the Goldmann applanation tonometer (GAT).

Patients and Methods: 35 normal eyes and 42 eyes with glaucoma (primary open-angle glaucoma, normal-tension glaucoma) were included. IOP was measured in all patients using a TONO-i tonometer and a Goldmann applanation tonometer. A paired t-test was performed to compare the mean difference between the IOP measurements of the two tonometers, a two-way random effects model was used to compare the agreement between the IOP measurements of the two tonometers, and a Bland-Altman analysis and asimple linear regression approach were used to specifically evaluate the mode of the difference between the two tonometer measurements.

Results: The mean IOP measured by tonometry was 15.9 ± 3.3 mmHg and the mean Goldmann applanation tonometry was 16.4 ± 5.1 mmHg. A paired t-test showed that in the glaucoma group, the mean TONO-i IOP (16.7 ± 4.1) was lower than the mean Goldmann applanation tonometry (17.9 ± 6.1) ($p<0.001$). There was no significant difference in the normal control group ($p=0.273$). When analyzed with a two-way random effects model, the interclass correlation coefficients (95% confidence interval) were 0.847 (0.702-0.920) in the overall group of patients, 0.882 (0.804-0.941) in normal controls, and 0.828 (0.742- 0.887) in glaucoma patients, showing high agreement. In a Bland-Altman analysis, the overall mean difference between the two tonometry measurements was not statistically significant, but the absolute value of the difference between the two tonometry measurements tended to increase as the Goldmann applanation tonometry IOP reading increased.

Conclusion: The TONO-i IOP tonometer shows good agreement with the Goldmann applanation tonometer. With the caveat that IOP maybe somewhat underestimated at high IOP, the TONO-i tonometer may be useful for self-measuring and screening for ocular hypertension.

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