Comparison of the iCare, Tono-Pen, non-contact airpuff, and Goldmann applanation tonometers in eyes with corneal edema after penetrating keratoplasty

Shih-Jung Yeh[a], Ko-Hua Chen[a,b], Tung-Mei Kuang[a,b], Catherine Jui-Ling Liu[a,b], Mei-Ju Chen[a,b,*]

[a]Department of Ophthalmology, Taipei Veterans General Hospital, Taipei, Taiwan, ROC; [b]School of Meidicine, National Yang Ming Chiao Tung University, Taipei, Taiwan, ROC

Abstract

Background: To compare the utility of the iCare, Tono-Pen, and non-contact airpuff (NCT) tonometers with the Goldmann applanation tonometer (GAT) for measuring intraocular pressure (IOP) in patients with corneal edema after penetrating keratoplasty (PKP) and to assess the effects of central corneal thickness (CCT) and corneal curvature (CC) on IOP measurements.

Methods: Thirty-two eyes of 27 patients with corneal edema after PKP due to corneal abnormalities and 43 control eyes of 30 patients with normal corneas were recruited. Before IOP measurements, all patients underwent a baseline examination, including auto-refraction, keratometry, slit lamp biomicroscopy, and CCT measurement. IOP was measured using the devices in the same order: first the NCT, followed by the iCare, Tono-Pen, and GAT. The differences between the iCare, Tono-Pen, NCT, and GAT were calculated with repeated-measures analysis of variance. The Bland-Altman method was used to assess the agreement between the iCare, Tono-Pen, and NCT versus the GAT. The influences of CCT and CC on IOP measurement were evaluated by correlation analysis using Pearson's correlation coefficient.

Results: Mean IOP measurements were significantly higher with the NCT and Tono-Pen than with the GAT in the PKP and control groups. When compared with GAT, iCare showed significantly higher IOP readings in the control group, but the IOP readings did not differ between the iCare and GAT in the PKP group. Poor agreement was noted between the NCT and GAT in both groups. The Tono-Pen showed clinically acceptable agreement with GAT in control eyes and poor agreement in PKP eyes. The agreement between the iCare and GAT appeared to be clinically acceptable in both groups. Correlation analysis of the results from control eyes showed that the IOP measurements with the GAT and NCT were weakly related to CCT and moderately correlated with CC. The iCare IOP readings were weakly correlated with CCT and CC.

Conclusion: In the PKP group, the NCT and Tono-Pen significantly overestimated IOP, whereas the iCare IOP readings were similar to those obtained using the GAT. Poor agreement was noted between the NCT and GAT as well as between the Tono-Pen and GAT, but the iCare showed clinically acceptable agreement with GAT. In normal corneas, the GAT, NCT, and iCare were affected by CCT and CC. The iCare tonometer was less affected by corneal edema than were the NCT and the Tono-Pen. The iCare appears to be a useful device for IOP measurement in eyes with corneal edema after PKP.

Keywords: Intraocular pressure; Penetrating keratoplasty; Tonometer

1. INTRODUCTION

Reliable and accurate intraocular pressure (IOP) measurement is very important in the management of glaucoma and in all intraocular surgeries. The Goldman applanation tonometer (GAT)[1] is considered the gold standard for IOP measurements in clinical settings. The GAT measures the force necessary to flatten an area of the cornea of 3.06-mm diameter, with an estimated average corneal thickness of 520 μm. However, some operator bias such as insufficient or excessive fluorescein in the tear film, pressure from the finger on the eyelid, or the patient's holding their breath may affect the readings. Several sources of measurement error have been noted, including high astigmatism, an irregular or scarred cornea, and biomechanical properties,[2–6] especially in eyes after penetrating keratoplasty (PKP).

The iCare (iCare TA01i, iCare, Helsinki, Finland) is a handheld tonometer based on the principle of the rebound tonometer[7] that analyzes the motion of a bounce probe (1.8-mm ball) after it impacts the cornea, using an induction coil system. The deceleration and contact time of the probe vary with IOP. The main advantages of rebound tonometry are that it is fast and easy to use and needs no local anesthesia, slit lamp, or maintenance calibration. The iCare tonometer has shown good correlation

*Address correspondence. Dr. Mei-Ju Chen, Department of Ophthalmology, Taipei Veterans General Hospital, 201, Section 2, Shih-Pai Road, Taipei 112, Taiwan, ROC. E-mail address: mj_chen@vghtpe.gov.tw (M.-J. Chen).

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with the GAT and other tonometers and good repeatability in healthy eyes.[8,9] Rebound tonometry is therefore considered an acceptable alternative method for measuring IOP in pathologic corneas. For postkeratoplasty eyes, studies have compared postoperative IOP readings acquired using an iCare tonometer with readings from the GAT, but without consistent results. Earlier studies showed that rebound tonometer significantly underestimated IOP in relation to GAT in eyes with PKP[10] and in eyes after Descemet's stripping automated endothelial keratoplasty.[11] However, Salvetat et al[12] demonstrated iCare tonometer significantly overestimated IOP compared with GAT in the edematous grafts. In addition, accurate IOP measurements are crucial for assessing postoperative inflammation, steroid response, and graft survival in eyes with corneal edema after PKP. Also, previous studies focused on GAT with NCT, GAT with Tono-Pen, or GAT with iCare. Evidence regarding the comparative reliability of all four different methods is lacking. Therefore, the purposes of our study were to recruit and to compare IOP readings obtained with the iCare tonometer, the Tono-Pen, the noncontact tonometer, and the GAT in normal eyes and in eyes with corneal edema after PKP. In addition, the influences of central corneal thickness (CCT) and corneal curvature (CC) on IOP measurement were investigated.

2. METHODS

2.1. Study design

This was a prospective, cross-sectional study that recruited patients with PKP who visited the outpatient clinic of Taipei Veterans General Hospital from September 2017 to October 2018. Also, age-matched control subjects with normal corneas were enrolled by recruiting healthy volunteers from the same hospital. The study protocol was approved by the Institutional Review Board of our hospital and was designed in accordance with the Declaration of Helsinki. Written informed consent was obtained from all subjects.

All participants underwent a comprehensive ophthalmic examination, including best-corrected visual acuity, automated refraction and keratometry, slit-lamp examination (performed by a corneal specialist [CKH] to identify signs of clinical corneal edema), fundus biomicroscopy examination, and CCT determined by anterior segment optical coherence tomography at the center of the cornea (Anterior Segment Analyzer; Optical Coherence Tomography, Optovue, USA). CC measurements were made using an automatic keratometer (KR-800 Auto Kerato-Refractometer, Topcon, Japan). K1 and K2 are averaged to obtain a single CC value.[6,12]

IOP measurements were performed with the subject in the sitting position and always in the same order: first the NCT (CT-800A, Non-contact airpuff tonometer, Topcon, Japan), followed by the iCare, the Tono-Pen (Tono-Pen XL, Reichert Inc., Depew, NY, USA), and the GAT. Previous studies showed that a small but statistically reduction in IOP measurement was found following GAT but not with NCT.[13] Therefore, the NCT was the first and the GAT was the last to measure IOP. Topical anesthetic (proparacaine hydrochloride) was used before Tono-Pen and GAT measurements. Each method was repeated three times to obtain the average value. A minimum 3-minute time interval was interposed between readings to avoid the tonographic effect of applanation. An experienced ophthalmologist (YSJ) took NCT, iCare, and Tono-Pen readings to the center of the corneas. To minimalize the error, Tono-Pen was performed by touching the center of the corneas as precisely as possible. A senior glaucoma specialist (CMJ) performed GAT measurements. Both examiners were blinded to the information from the subjects' clinical evaluations. The iCare was used according to the manufacturer's guidelines. This tonometer is a small handheld device consisting of a probe and a solenoid. The tip of the probe is positioned in front of the central cornea at a distance of 4 to 8 mm. An electrical pulse creates a magnetic field in the solenoid when the button is pressed. IOP calculation is based on the movement of the probe toward the cornea and its bounce off the cornea. The average IOP value is the result of six automatically calculated measurements. The average of three consecutive IOP readings was recorded. The letter "P" on the display indicates the quality of the measurements performed. Any IOP values with an error bar was excluded.

2.2. Patients

Inclusion criteria for all participants were age ≥20 years and reliable IOP measurements. Control subjects had a normal anterior segment on the slit-lamp examination without signs of corneal edema or any corneal pathologies. The PKP group were eyes with corneal edema caused by rejection or graft failure. Corneal diseases requiring corneal transplantation include pseudophakic bullous keratopathy, trauma, endothelial dystrophy, herpes simplex keratitis, and cytomegalovirus endotheliitis. All PKP surgeries were performed by a single surgeon (CKH). Eyes were excluded if GAT or NCT could not be performed in eyes with corneal opacities or scarring, and in cases of acute conjunctivitis, ocular inflammation, history of intraocular surgery other than PKP, ocular surgery within 3 months prior to the examination date, or concurrent diseases that may have interfered with IOP measurements.

2.3. Statistical analysis

The differences between IOP measurements acquired using the NCT, Tono-Pen, iCare, and GAT were assessed by repeated-measures analysis of variance. The Bland-Altman method was used to evaluate the agreement between tonometers. The correlations of CCT and CC with the IOP measurement were calculated using Pearson's correlation coefficient for normal corneas only. The correlation coefficient r indicates a high correlation if $r = 0.7$ to 0.99, a moderate correlation if $r = 0.4$ to 0.69, and a weak correlation if $r < 0.4$.[10] The statistical analysis was performed using SPSS 11.0 (SPSS, Chicago, IL, USA). A p value < 0.05 was considered to indicate statistical significance.

3. RESULTS

3.1. Baseline patient characteristics and IOP measurement

This study included 43 eyes with normal corneas (control group: 30 healthy subjects) and 32 eyes that underwent PKP (PKP group: 27 subjects). The demographics and corneal characteristics of the subjects are shown in Table 1. The mean time between PKP and date of recruitment was 29.9 ± 36.5 months. Table 2 shows the IOP measurement results. Mean IOP measurements were significantly higher with the Tono-Pen and NCT

Table 1

Demographics and corneal characteristics

	PKP	Controls
No. of subjects	27	30
Sex (female/male)	4/23	6/24
Eyes	32	43
Age, y	62.4 ± 16.0	59.5 ± 16.5
VA (LogMAR)	0.67± 0.33	0.07 ± 0.10
CCT, μm	698 ± 268	545 ± 47
CC (diopters)	52.1 ± 1.9	43.7 ± 1.8

CC = corneal curvature; CCT = central corneal thickness; PKP = penetrating keratoplasty; VA = visual acuity.

Table 2

Intraocular pressure measurements results

	GAT	iCare	TonoPen	NCT	*p**	*p***	*p****
PKP	14.30 ± 7.40	13.16 ± 8.45	18.69 ± 9.01	16.69 ± 9.45	0.154	0.002	0.008
Control	14.37 ± 4.38	15.26 ± 4.9	15.84 ± 3.84	17.29 ± 5.23	0.007	<0.001	<0.001
All	14.34 ± 5.82	14.36 ± 6.68	17.05 ± 6.66	17.04 ± 7.29	0.714	<0.001	<0.001

GAT = Goldman applanation tonometry; NCT = noncontact tonometry; PKP = penetrating keratoplasty.

**p*, comparison between GAT and iCare.

***p*, comparison between GAT and TonoPen.

****p*, comparison between GAT and NCT.

than with the GAT in the PKP and control groups. Compared with the GAT, the iCare gave significantly higher IOP readings in the control group. However, the IOP measurements did not differ between the iCare and GAT in the PKP group.

3.2. Agreements between tonometers

In eyes with PKP, Bland-Altman analysis revealed a bias between the iCare and GAT, between the Tono-Pen and GAT, and between the NCT and GAT of –1.15, 4.39, and 2.39 mmHg, respectively, with 95% limits of agreement of –8.59 to 6.30 mmHg, –8.12 to 16.89 mmHg, and –9.89 to 14.67 mmHg, respectively (Fig. 1A–C). In the control group, Bland-Altman analysis revealed a bias between the iCare and GAT, between the Tono-Pen and GAT, and between the NCT and GAT of 0.89, 1.47, and 2.93 mmHg respectively, with 95% limits of agreement of –3.05 to 4.83 mmHg, –2.76 to 5.70 mmHg, and –1.81 to 7.67 mmHg, respectively (Fig. 2A–C). Considering an IOP difference between tonometers of greater than ±2 mmHg to be clinically relevant, the agreement between the iCare and GAT appeared to be clinically acceptable in both the control and PKP groups (Figs. 1A and 2A). However, the agreement between the NCT and GAT was poor in both groups. Measurements acquired using the Tono-Pen and GAT were in clinically acceptable agreement in control eyes, while poor agreement was noted in PKP eyes.

3.3. Correlation analysis

Correlation analysis for control eyes showed that the IOP measurements with the GAT and NCT were weakly related to CCT and moderately correlated with CC. The difference between the Tono-Pen and GAT readings revealed a weak correlation with CCT and CC. The iCare IOP readings were weakly correlated with CCT and CC (Table 3).

4. DISCUSSION

GAT has been considered the gold standard for IOP measurements, although the trans-corneal method is influenced by corneal biomechanics. Our study showed that IOP values acquired using the NCT, Tono-Pen, and iCare were significantly higher than those acquired using the GAT in the control group. The NCT uses air to flatten the cornea instead of touching it.[14] In agreement with previous studies,[15,16] in our study the NCT overestimated IOP readings compared with the GAT in normal corneas. Although some authors have reported good agreement,[15,17] our results showed poor agreement between the NCT and the GAT in normal corneas. Because NCT applanates a wider area as compared to GAT, NCT was more affected by corneal thickness (0.4-0.63 mmHg/10 µm of CCT) compared with GAT (0.18-0.37 mmHg/10 µm of CCT).[18] The Tono-Pen is a handheld tonometer used to measure IOP with a 1.0-mm transducer tip.[19] In accordance with previous reports,[15,20] the Tono-Pen tended to overestimate IOP when compared with the GAT. Both the NCT and the Tono-Pen work by trans-corneal applanation. Eyes with higher CCT may yield higher IOP readings than those with lower CCT.[21] The GAT measures the force necessary to flatten an area of the cornea with estimated average CCT of 520 µm, which is lower than the CCT reported in Chinese (552 µm), Black (529 µm), Hispanic (545 µm), and Caucasian (550 µm) subjects in previous studies.[22,23]

Previous reports have shown that iCare and GAT IOP readings are highly correlated in normal corneas.[12,24] However, the relationship between iCare and GAT readings remains controversial. When compared with GAT readings, our iCare results are in line with most studies reporting that it overestimates IOP,[23,25,26] yet in disagreement with others reporting underestimated IOP measurements in normal corneas.[10,12] This discrepancy might be due to the different characteristics of our cohort of subjects. When considering a mean IOP difference between tonometers greater than ±2 mmHg to be clinically relevant, the agreement between the iCare and GAT tonometers appeared to be clinically acceptable in our study, in agreement with previous reports.[10,12,20]

In eyes having corneal pathology and after PKP, an accurate and reliable estimation of IOP is often difficult due to conditions such as corneal surface irregularities, corneal scars, high or irregular astigmatism, and corneal edema. No perfect method exists yet, but many tonometers have been designed to determine IOP correctly. To our knowledge, we are the first to compare three other devices (iCare, Tono-Pen, and NCT) with the GAT in IOP measurements in eyes with corneal edema after PKP. Our study showed that the NCT and Tono-Pen significantly overestimated IOP, whereas iCare measurements did not differ significantly from those acquired using the GAT. Our results are in accordance with previous reports about the NCT,[27] yet in disagreement with earlier reports regarding the iCare.[10–12] Rosentreter et al[10] reported rebound tonometer significantly underestimated IOP in relation to GAT. Salvetat et al[12] demonstrated iCare tonometer significantly underestimated IOP compared with GAT, but overestimated IOP in the edematous grafts. Achiron et al[11] showed IOP underestimation in eyes after DSAEK, but not eyes with PKP. The discrepancy might be an effect of altered corneal biomechanics induced by corneal edema. Previous studies showed that the GAT tends to overestimate IOP in edematous corneas,[25,26] while other studies demonstrated IOP underestimation in edematous corneas.[28,29] Theoretically, GAT needs more force to flatten a fixed corneal area in edematous cornea with increased thickness and rigidity. Previous studies have shown that a small increase in corneal hydration, thickness, and rigidity may cause a clinically significant overestimation of IOP measured by GAT.[25,26] A corneal hydration-induced change in corneal thickness of 10 µm was responsible for a 0.35 to 0.46 mmHg error in IOP measurement.[26] Relative to the GAT, the iCare is reported to be less influenced by corneal hydration,[10] and this is supported by an in vitro model revealing the iCare as yielding the most accurate IOP values across all the adjusted IOP values.[29] This is due to its relatively small contact area with the cornea and consequently lesser dependence on corneal biomechanical properties.[29]

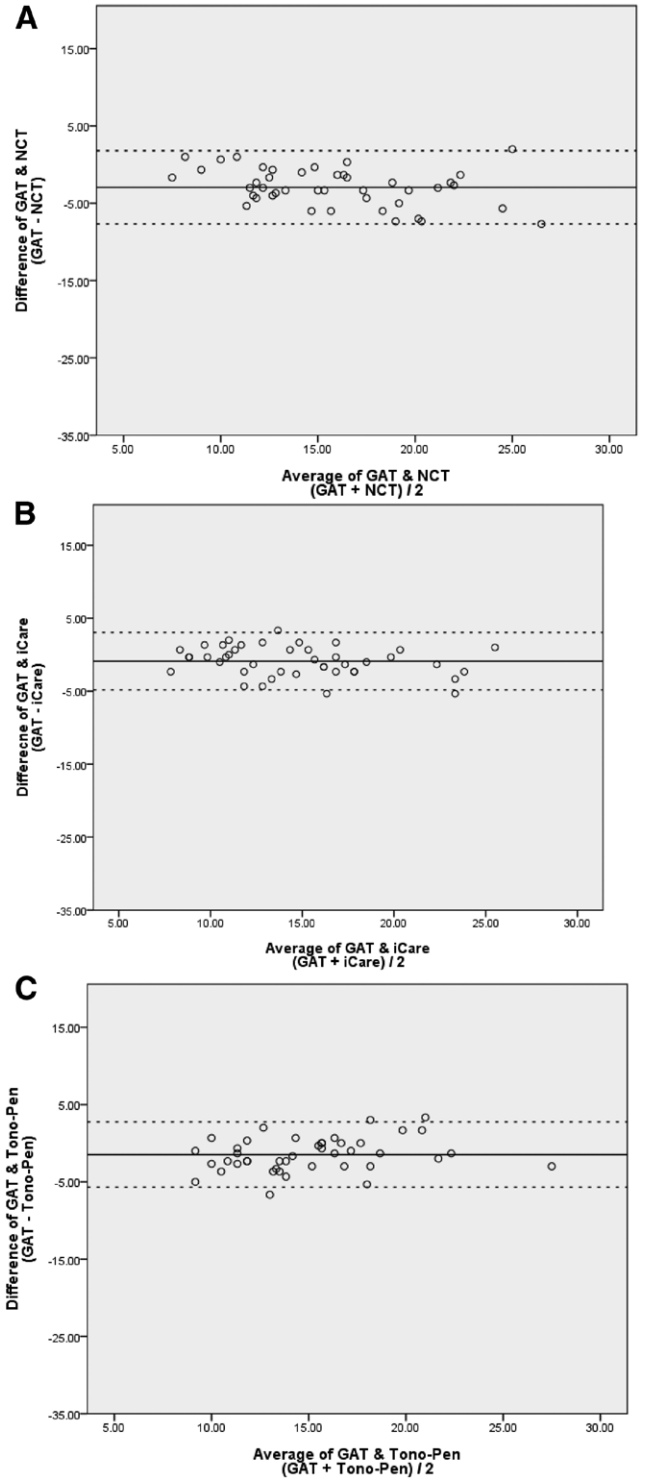

Fig. 1 Bland-Altman analysis for PKP eyes. X axis: mean of intraocular pressure (IOP) measurements of Goldmann applanation tonometer (GAT) and iCare (A), Tono-Pen (B), and NCT (C). Y axis: difference between IOP measurements of GAT and iCare (A), Tono-Pen (B), and NCT (C), respectively. Dotted line: bias (A, –1.15 mmHg, B, 4.39 mmHg, C, 2.39 mmHg). Dashed lines: 95% limits of agreement (A, –8.59 to 6.30 mmHg; B, –8.12 to 16.89 mmHg; C, –9.89 to 14.67 mmHg).

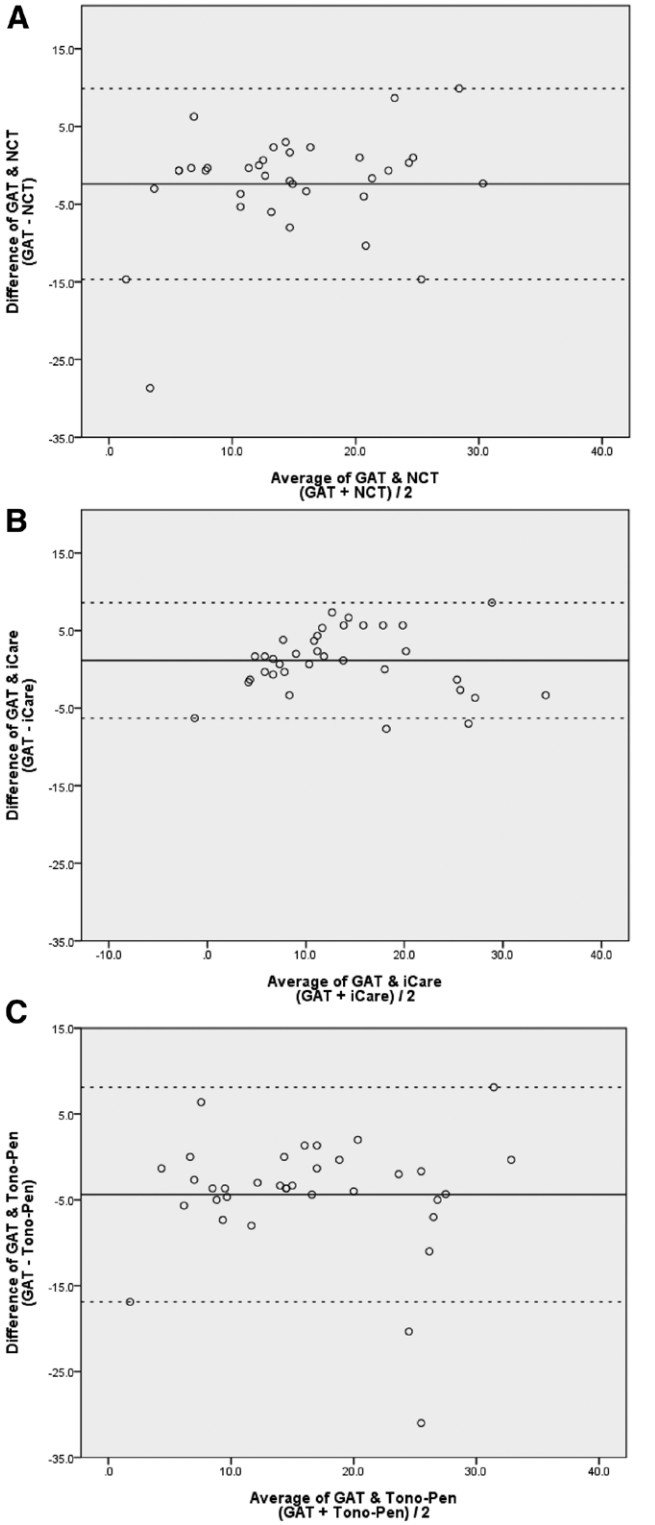

Fig. 2 Bland-Altman analysis for control eyes. X axis: mean of intraocular pressure (IOP) measurements of Goldmann applanation tonometer (GAT) and iCare (A), Tono-Pen (B), and NCT (C). Y axis: difference between IOP measurements of GAT and iCare (A), Tono-Pen (B), and NCT (C). Dotted line: bias (A, 0.89 mmHg; B, 1.47 mmHg; C, 2.93 mmHg). Dashed lines: 95% limits of agreement (A, –3.05 to 4.83 mmHg; B, –2.76 to 5.70 mmHg; C, –1.81 to 7.67 mmHg).

Table 3

Correlation analysis

	CCT		CC	
	r	*p*	*r*	*p*
GAT	0.380	0.012	0.451	0.005
iCare	0.311	0.043	0.336	0.026
iCare - GAT	0.071	0.649	0.061	0.719
TonoPen	0.216	0.163	0.289	0.083
TonoPen - GAT	0.382	0.011	0.362	0.028
NCT	0.342	0.034	0.475	0.003
NCT - GAT	–0.013	0.936	-0.242	0.149

CC = corneal curvature; CCT = central corneal thickness; GAT= Goldman applanation tonometry; NCT= non-contact tonometry.

Our results showed that IOP was related to CCT in subjects with normal corneas, in line with previous studies on GAT,[12,24,30] NCT,[31] and iCare IOP measurements.[12,24,30] CC also affected GAT, NCT, and iCare IOP measurements in normal corneas. Previous studies on the influence of CC on GAT IOP have been inconclusive. Some authors have reported no effect of CC on GAT IOP,[12,32] while others have shown correlations between CC and GAT IOP.[33] It is likely that all the devices employ transcorneal methods of tonometry, which are dependent on corneal properties to various degrees. With regard to the effect of CC on iCare IOP measurement, earlier studies[12] showed underestimation of IOP in normal steep corneas and overestimation of IOP in normal flat corneas. Steeper corneas may decrease the iCare probe velocity, causing it to underestimate IOP.[12]

The study has the following limitations. First, our cohort of subjects was relatively small and the results may not be applied to all patient with corneal transplant. Second, some ocular parameters (axial length and corneal biomechanical properties) were not evaluated. Third, the nonmasked IOP measurements are a weakness. Fourth, GAT readings were defined as the reference standard in this study. We excluded the PKP eyes if they were unable to yield reliable GAT IOP readings. Therefore, our results cannot be generalized to all eyes with corneal edema after PKP. Moreover, all four devices are transcorneal tonometers. Future research about intraocular manometric measurements is warranted to determine the most accurate method of measuring IOP in the eye after PKP.

In conclusion, mean IOP measurements were significantly higher when taken with the NCT, Tono-Pen, and iCare than with the GAT in the control group. In the PKP group, the NCT and Tono-Pen also gave significantly higher IOP readings compared with the GAT, but the iCare and GAT IOP readings were similar. The poor agreement was noted between the NCT and GAT as well as between the Tono-Pen and GAT, while clinically acceptable agreement was noted between the iCare and GAT. In normal corneas, the GAT, NCT, and iCare were affected by CCT and CC. When compared with the NCT and Tono-Pen, the iCare tonometer was less affected by corneal edema. The iCare appears to be a useful device for IOP measurement in eyes with corneal edema after PKP.

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