Clinical Comparison of Rebound Tonometer with Goldmann Applanation Tonometer: Effects of Central Corneal Thickness*

Rebound Tonometresi ve Goldmann Applanasyon Tonometresinin Klinik Olarak Karşılaştırılması: Santral Kornea Kalınlığının Etkisi

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ABSTARCT

Purpose: This clinical study was conducted to compare the performance of a rebound tonometer with that of the Goldmann applanation tonometer (GAT) in the measurement of intraocular pressure (IOP) and to evaluate the effect of central corneal thickness (CCT) on IOP measurement with both devices.

Materials and Methods: One hundred and sixty-five healthy subjects were tested using rebound tonometer and GAT by two observers. The patients were divided into 3 groups according to CCT measurement and OHTS criteria as follows: group 1 with CCT<555 µm; group 2 with CCT 555-584 µm; and group 3 with CCT≥585 µm. Correlation analysis was performed to compare the 2 devices; paired sample t test, Bland and Altman analysis were used.

Results: The mean IOP levels measured by rebound tonometer and GAT were 13.9±2.3 and 13.5±2.5 mm Hg in Group1 (p=.587), 15.76±2.7 and 15.3±3.1 mmHg in Group 2 (p=.563), and 17.76±2.6 and 18.42±3.03 mm Hg in Group 3 (p=.878), respectively. Rebound tonometry and GAT readings were strongly correlated in terms of IOP measurement in all CCT groups (r=0.78, p<.0001).

Conclusions: The use of rebound tonometer is effective and safe in comparison to GAT readings. In eyes with a healthy cornea, the IOP measurements from the rebound tonometer and the GAT seemed to be similarly affected by CCT.

Key Words: Intraocular pressure, Icare, rebound tonometry, Goldmann applanation tonometry, central corneal thickness.

ÖZ

Amaç: Bu klinik çalışma rebound tonometresi ile Goldmann applanasyon tonometresi (GAT) göz içi basıncı (GİB) ölçümlerinin karşılaştırılması ve her iki cihazın GİB ölçümlerinin santral kornea kalınlığı (SKK) üzerine olan etkisini değerlendirmek amacıyla planlanmıştır.

Metod: Yüzaltmışbeş sağlıklı birey iki gözlemci tarafından rebound tonometresi ve GAT kullanılarak test edildi. Hastaların SKK ölçümleri OHTS kriterlerine göre 3 gruba ayrıldı: SKK<555 µm olanlar grup 1; SKK 555-584 µm olanlar grup 2; SKK≥585 µm olanlar grup 3. İki cihazın ölçümlerinin karşılaştırılması için korelasyon analizi; paired sample t testi ve Bland ve Altman analizi kullanıldı.

Sonuçlar: Rebound tonometre ve GAT ile ölçülen ortalama GİB değerleri sırasıyla Grup 1'de 13.9±2.3 ve 13.5±2.5 mmHg (p=.587), Grup 2'de 15.76±2.7 ve 15.3±3.1 mmHg (p=.563) ve Grup 3'de 17.76±2.6 ve 18.42±3.03 mmHg (p=.878) idi.

Tartışma: Rebound tonometre kullanımı GAT ölçümleri ile karşılaştırıldığında oldukça efektif ve güvenilirdir. Sağlıklı korneası olan gözlerde, rebound tonometre ve GAT göziçi basıncı ölçümleri SKK'dan eşit derecede etkileniyor gibi gözükmektedir.

Anahtar Kelimeler: Göz içi basıncı, Icare, rebound tonometresi, Goldmann applanasyon tonometresi, santral kornea kalınlığı.

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INTRODUCTION

Glaucoma is one of the major causes of blindness in Western countries,[1] and one of the main risk factors for glaucoma is elevated intraocular pressure (IOP).[2] Accurate determination of IOP is important in the diagnosis of glaucoma and in the assessment of treatment efficacy. Goldmann applanation tonometry (GAT) has become the gold standard against which other tonometers have been compared.[3] The accuracy of GAT measurements depends on many factors such as corneal thickness, corneal curvature, corneal structure, and axial length.[4] Determining central corneal thickness (CCT) has become an essential part of the evaluation of glaucoma, since CCT was proven to have a substantial effect on IOP measurements with GAT.[4]

The Icare® tonometer (Icare, TA01, Tiolat Oy, Helsinki, Finland) is the first commercially available tonometer with a design based on the principles of rebound tonometry (ie, impact tonometry), which were established 70 years ago.[5-8] This device was developed primarily for experimental use in rats or mice.[5-11] As a low-cost portable contact tonometer that does not require the administration of a corneal anesthetic, the Icare® can be a promising alternative to other handheld tonometers and to the more costly noncontact tonometers used in busy ophthalmology clinics and mass glaucoma-screening programs. In the recently published literature, a good correlation has been shown between the IOP measurements obtained with Icare tonometer and those from a GAT tonometer.[12-17] In this study, we aimed to verify the correlation of IOP measurements between Icare® and Goldmann tonometers in the IOP pressure range to the effect of CCT on IOP measurements between both devices for the CCT sub-groups.

MATERIALS AND METHODS

Institutional Review Board permission was obtained from Baskent University Hospital and informed consent according to the tenets of the Decleration of Helsinki was obtained from all patients before the initiation of the study. The study was designed to include 3 groups of patients, distributed according to their CCTs. We prospectively measured IOP using Icare and GAT in random order in 165 right eyes of 165 subjects. The subjects were separated into 3 groups (55 subjects per group) according to the ultrasonic pachymeter values of the OHTS criteria as follows:[18] group 1 patients had a CCT of less than 555 µm; group 2, a CCT ranging from 555 to 584 µm; and group 3, a CCT of higher than 584 µm. The CCT measurements with ultrasonic pachymeter (SP-3000, Tomey, Japan) and IOP measurements using two devices, Icare and GAT were taken from every patient who applied to the Ophthalmology Clinic at Baskent University Hospital for refractive purposes from 2008 to 2009. Each object also underwent a complete ophthalmologic examination.Exclusion criteria included a history of glaucoma or prior treatment with an antiglaucomatous medication, a corneal surface disorder, severe dry eye syndrome, previous ocular surgery, pregnancy, and IOP values in extreme of ≥25 mmHg, or ocular hypotony (IOP≤5 mmHg). The first 55 patients for each group who did not carry any of the exclusion criteria consisted of the study group according to the pre-defined CCT levels. The IOP measurements were made on a different day after the 165 patients were distributed into 3 groups according the defined criteria.

Measuring the IOPs

The Icare® software is pre-programmed for six measurements, and discards the highest and lowest IOP readings to calculate the average IOP value from the rest.[9] After the sixth measurement, the letter P appears in the display followed by the IOP reading. Two measurement series were obtained, and the average value was recorded by the first observer (SAB).

The probe of the rebound tonometer was held at a distance of 4 to 8 mm from the central cornea. A brand new sterile probe tip was used for each patient. No kind of topical anesthesia was used before Icare® readings. The measurements with GAT (Haag-Streit, Switzerland) were made by the second observer (AA) at least 5 minutes after the Icare measurements. Second observer was blinded to the rebound tonometry measurements. One drop of proparacaine hydrochloride (Alcaine, 0.5%, Alcon Lab., Canada) was instilled into each examined eye, and a dry fluorescein strip (Haag-Streit AG, Köniz, Switzerland) was used before the GAT measurement was obtained. The protocol for taking IOP readings with the GAT was similar to that described by Dielemans and colleagues.[3]

The same GAT device was used for all measurements in the study and the tuning of the device was checked each day. Three GAT measurements were obtained, and the mean of those measurements was recorded as final IOP. To minimize the effect of diurnal variations in IOP, all measurements were taken between 09:00 and 10:00 on consecutive days. Both eyes were tested with each tonometer, however for statistical purposes, only measurements from the right eye were used.

Measuring the CCTs

The CCT was measured with an ultrasonic pachymeter (SP-3000, Tomey, Japan) after a topical anesthetic drug (proparacaine hydrochloride) had been administered to the examined eye in each patient, and a mean of 10 measurements was recorded.

Icare® Tonometer

The construction of the rebound tonometer and the mathematical principles by which it functions have been described by various authors as follows:[5-8] The Icare® tonometer consists of a pair of coils coaxial with the probe shaft that are used to propel the lightweight magnetized probe toward the cornea and to sense the movement of the probe. The probe consists of a magnetized steel wire shaft, the end of which is covered with a round disposable plastic tip. That tip minimizes the risk of corneal injury from the probe impact, and the use of a disposable probe tip eliminates the risk of microbiologic contamination. Appropriate electronic components allow for the probe movement to be initiated by the solenoid coil and monitored by the sensing coil. An applied pulse of electrical current creates a magnetic field within the solenoid. The magnetic field causes the probe to be propelled onto the cornea, from which the probe rebounds. The tonometer measures the motion parameters of the probe indirectly by measuring the magnetic field caused by the moving probe. The probe is accelerated toward the cornea at a speed ranging from 0.25 to 0.35 m/s at the time of impact. A microprocessor gauges the motion parameters of the probe when it bounces back.[6-8]

Statistical Analysis

Data were expressed as the mean and standard deviation. Correlation analysis was used to compare the IOP levels or CCT levels for two devices, and the inter-group IOP measurements were compared with the paired sample t test. Correlations were calculated by Spearman's correlation. Inter-method agreement between tonometers was assessed using the method devised by Bland & Altman, which included calculation of the mean difference between measurements, the standard deviation and the 95% confidance interval (CI) of the differences.[19,20] Linear regression analysis was used to examine the role of CCT in IOP measurement by two tonometers. A p value of less than 0.05 was considered significant. Statistical analyses were performed using SPSS software (Statistical Package for the Social Sciences, version 15.0, SSPS Inc, Chicago, IL, USA).

RESULTS

The mean age of 165 healthy subjects (92 women and 73 men) was 57.03±1.2 years (range; 42 to 78). The mean IOP levels measured by Icare® and GAT were 13.9±2.3 and 13.5±2.5 mmHg, respectively, in group 1 (p=0.587); 15.76±2.7 and 15.3±3.1 mmHg, respectively, in group 2 (p=0.563); and 17.76±2.6 and 18.42±3.03 mmHg, respectively, in group 3 (p=0.878) (Table 1).

When Icare® measurements were compared with GAT measurements; Icare readings were slightly higher than GAT readings. But there was no any statistical significance (p>0.01 for all CCT groups). The mean difference between Icare and GAT readings were 0.38 mmHg in Group 1, 0.40 mmHg in Group2, and 0.65 mmHg in Group 3. Table 2 shows the mean difference and 95% CI (confidence interval) limits between two tonometers measurements in three groups.

Bland and Altman plots as shown in graphic 1 to 3 demonstrates 95% limit agreement between the two devices, represented by the plots remaining within the dashed lines. Graphic 1 shows a Bland and Altman scatter-plot comparing Icare and GAT readings. The mean of the differences between corresponding measurements (Icare value minus GAT value) was 0.38±0.95 mmHg (95% CI, -2.47 to +1.48 mmHg). There was a significant positive linear relationship between Icare and GAT (r2=0.18, p<0.01).

Graphic 2 shows a Bland and Altman scatter-plot for the agreement between Icare and GAT readings. The mean of the differences between corresponding measurements (Icare value minus GAT value) was 0.40±1.18 mmHg (95% CI, -2.712 to +1.98). There was a significant positive linear relationship between Icare and GAT (r2=0.21, p<0.01).

Graphic 3 shows a Bland and Altman scatter-plot for the agreement between Icare and GAT readings. The mean of the differences between corresponding measurements (Icare value minus GAT value) was 0.65±1.518 mmHg (95% CI, -3.69 to +2.329). There was a low positive linear relationship between Icare and GAT (r2=0.06, p=0.03).

Table 1: *The central corneal thickness measurements and intraocular pressure readings with Icare® and Goldmann applanation tonometer in the 3 study groups.*

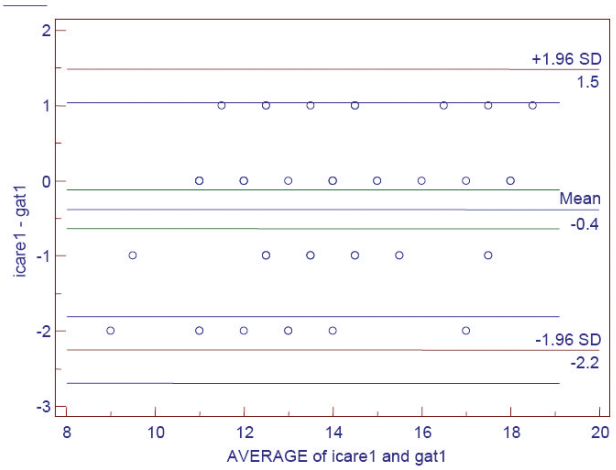
	CCT (µm) mean±SD	Icare (mmHg) mean±SD	GAT (mmHg) mean±SD	Spearman's Coefficient of rank correlation* rho values
Group 1 (n=55) CCT < 555µm	508.6±27.3 range, 451-552	13.9±2.3 range, 10-18	13.55±2.5 range, 8-19	.913
Group 2 (n=55) CCT: 555-584µm	565.2±8.4 range, 556-584	15.76±2.8 range, 8-21	15.33±3.1 range, 8-24	.925
Group 3 (n=55) CCT ≥ 585µm	610.7±21.8 range, 588-644	17.7±2.63 range, 11-23	18.42±3.03 range, 10-25	.884

**The rho value describes the comparison of IOP levels between the Icare® and Goldmann applanation tonometers.*
CCT: Central Corneal Thickness; GAT: Goldmann Applanation Tonometer.

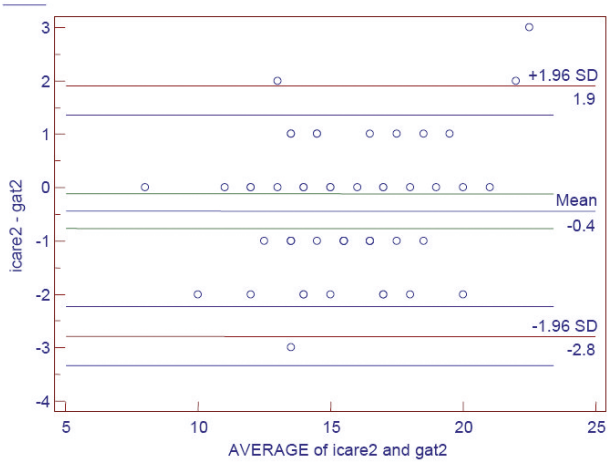
Table 2: *Mean difference and 95% CI limits for the difference of IOP readings between Icare® and Goldmann applanation tonometers.*

		Difference		Limits of agreement	
		Mean	**SD**	**Mean+1.96xSD**	**Mean-1.96xSD**
Icare-GAT	Group 1	0.38	0.95	1.482	-2.247
Icare-GAT	Group 2	0.40	1.18	1.98	-2.712
Icare-GAT	Group 3	0.65	1.52	2.329	-3.69

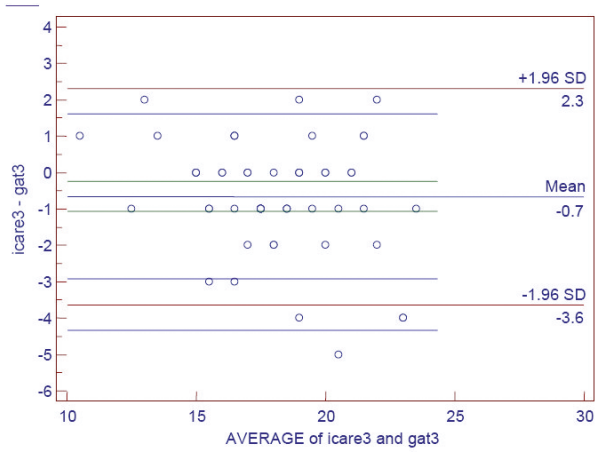
p<.0001, in all groups. The values are in mmHg.



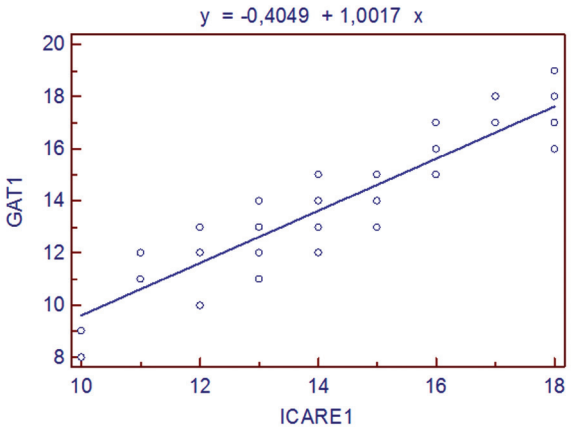
Graphic 1: *Bland-Altman plot for group 1 (n=55); central corneal thickness < 555 µm. The difference versus the mean of intraocular pressure values obtained with the Icare® and the Goldmann applanation tonometer.*



Graphic 2: *Bland-Altman plot for group 2 (n=55); central corneal thickness=555-584 µm. The difference versus the mean of intraocular pressure values obtained with the Icare® and the Goldmann applanation tonometer.*



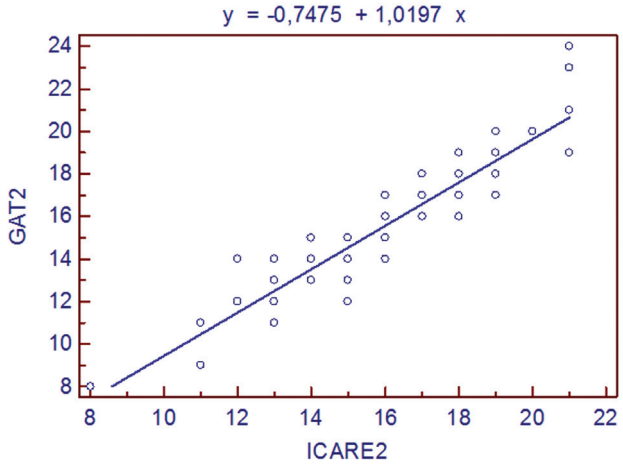
Graphic 3: *Bland-Altman plot for group 3 (n=55); central corneal thickness ≥585 µm. The difference versus the mean of intraocular pressure values obtained with the Icare® and the Goldmann applanation tonometer.*



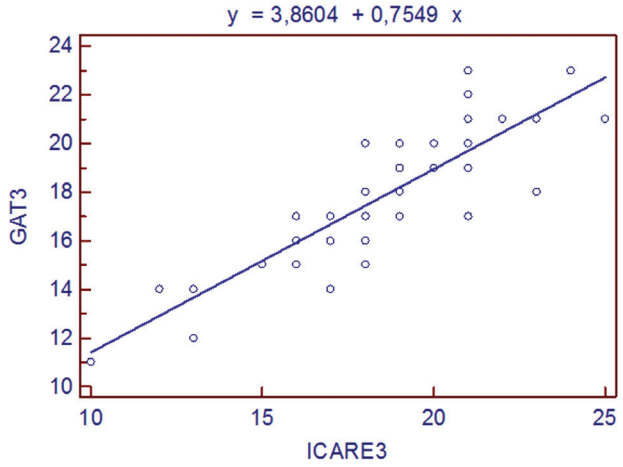
Graphic 4: *The correlation between Icare® and GAT values in group 1. Spearman's coefficient of rank correlation (rho) was 0.913 and p<0.001.*

The mean CCT levels for each group can be seen in Table 1: group 1, 508.6±27.3 µm (range; 451-552); group 2, 565.2±8.4 µm (range; 555-584); and group 3, 610.7±21.8 µm (range; 588-644). The mean differences between inter-group Icare and GAT IOP readings were; 0.7 and 0.7 mmHg for Group 1 versus 2, 1.8 and 1.8 mmHg Group 1 versus 3, 0.9 and 1.1 mmHg for Group 2 versus 3, respectively. And there was no statistical significance (p=0.302, p=0.562, p=0.243).

Linear regression analysis showed a mean change of 0.22 mmHg in IOP readings by Icare and 0.21 mmHg in IOP readings by GAT per 10 µm variation in CCT.



Graphic 5: *The correlation between Icare® and GAT values in group 2. Spearman's coefficient of rank correlation (rho) was 0.925 and p<0.001.*



Graphic 6: *The correlation between Icare® and GAT values in group 3. Spearman's coefficient of rank correlation (rho) was 0.884 and p<0.001.*

Spearman's correlation analysis demonstrated a significant correlation between the two tonometers in the measurement of IOP according CCT values (for group 1, rho=0. 913, p<0.001; for group 2, rho=0.925, p<0.001; and for group 3, rho=0.884, p<0.001) (Graphic 4,6).

DISCUSSION

For the last few decades, GAT has stayed as the gold-standard in measuring IOP, despite the commercial availability of new devices and technologies.[21-23] However, the OHTS results published in 2001 brought a new insight to the assessment of IOP levels. The importance of central corneal thickness mentioned in OHTS study led to a search for an alternative to GAT for a more precise IOP measurement.[18]

Attention was turned onto many new devices, including the Icare® tonometer. Although the principles of rebound tonometry has been described in 1930s, and significant modifications has been made in 60s and 70s; rebound tonometers were not widely available in the market.[5,8,24] Icare®, based on the rebound tonometry principles, and has become widely available recently.

Many studies in the past four years have compared the performance of the Icare® tonometer with that of the GAT and other available tonometers,[12-14] and several studies investigating the effects of CCT variations on Icare measurements have been published.[25-27] Our study is different from others in terms of the use of the OHTS criteria for CCT measurements in the comparison of Icare® and GAT measurements.

One of the main outcome measures of our study was to compare the IOP measurements taken by Icare® to that of the GAT.

The results of our study indicated a strong correlation between the values obtained from the Icare® and those from the GAT by the Pearson correlation analysis and Bland-Altman plots. The IOP values obtained with the rebound tonometer were not statistically different from those measured with the GAT. Most studies comparing these tonometers support our findings and confirm that IOP measurements with the Icare® tonometer and the GAT are well-correlated.[12,14,25-27]

There were many studies declaring an insignificant positive bias toward an IOP overestimation with the Icare® tonometer which was not supported by the findings in our study.[15,16,26,27] In our study, the IOP measured by Icare® was not significantly higher (p>0.001) than GAT (0.38 mmHg in Group 1, 0.40 mmHg in Group 2, and 0.65 mmHg in Group 3) in 3 CCT groups. The second part of our study pertained to investigate whether CCT affected the Icare® measurements. Theoretically, the measurements to study the effects of CCT on IOP measurements must be evaluated by comparing the results against the real-time manometric (true) IOP value, and even that approach is subject to bias because confounding factors cannot be eliminated.[28]

However, the effects of CCT on IOP measurements with a specific tonometer can be evaluated by comparing the results from the studied device with the results from another tonometer in which the effects have already been studied.[29-32] The GAT has been the gold-standard of IOP measurement and is the tonometer in which the effects of CCT on IOP measurement have been most frequently studied. Thus, we decided to compare the Icare® measurements to that of GAT. It is now well-known that the variation in CCT is the biggest factor in the overestimation or underestimation of IOP by the GAT.[18,33]

Although there is no consensus among investigators about the magnitude of IOP measurement bias for each micrometer of CCT change, numerous correction factors ranging from 0.19 to 0.7 mm Hg for each 10 µm difference in CCT have been proposed.[33-37] We found that in our study, mean change of IOP was 0.21 to 0.22 mmHg for per 10 µm CCT with Icare and GAT, respectively.

Krakau demonstrated that the rebound method was based on the same physical principle as that of the vibration tonometer; indicating that corneal properties such as thickness and hardness might affect tonometric measurements in a specific way.[38] Kontiola and Puska also stated that the rebound method might be subject to corneal thickness 9. A few studies on the effect of CCT on IOP measurement with Icare tonometer have been published.[12,15-17,26,27,39-41] More recent studies investigated this effect numerically. Iliev and colleagues declared that Icare and GAT measurements were similarly affected by CCT changes.[12] On the other hand, another research stressed that, the Icare results (when compared with those of the GAT and the Tonopen®) were significant overestimates of the IOP as the CCT became thicker in healthy subjects.[15-17,26]

Martinez-de-la-Casa and colleagues found that the two tonometers were similarly affected by the CCT but that rebound tonometry measurements were consistently higher than GAT results.[17,27] We found that, Icare readings slightly higher than GAT readings, but there was no statistically significance. But, we have noticed that a few extreme value in Icare in Group 3. This finding shows that, upper limits of IOP with Icare especially in thicker corneas should be kept higher levels than GAT readings. The upper values of Icare should be setting for CCT values, and the larger population should be analyzed for this.

To our knowledge, we firstly reported the effects of CCT on Icare® measurements according to the OHTS with a smaller group of patients at the World Glaucoma Congress in Vienna in July 2005. Our results of this pilot study and the larger population in our recent study showed that the effects of CCT on IOP measurements are comparable for the Icare® and the GAT tonometers.

Comparing the effects of CCT on IOP readings with different tonometers via linear regression analysis is one of the most frequently used methods of evaluation. In a study by Brusini and colleagues, linear regression analysis of the data from 178 consecutive patients showed that a CCT change of 10 µm resulted in an Icare reading deviation of 0.7 mm Hg.[14] Those authors pointed to the fact that the use of correction factors derived from linear regression analysis probably oversimplified a complex relationship between corneal parameters and IOP measurements.

Because there is no consensus on how to investigate, statistically analyze, or correct the IOP levels according to the patient's CCT value, we analyzed the results of 3 separate groups of patients (based on OHTS criteria) according to their degree of CCT (thin, normal, or thick).[18] We excluded the glaucomatous eyes from our study and measured only the eyes with normal IOP levels and healthy corneas so as to stay away from any possible confounding factor a diseased eye might provide. This approach showed no significant difference in the results obtained from the 2 tonometers studied in respect to CCT. In other words, both tonometers were affected similarly by the CCT in our patients composed of healthy corneas unaffected by a high IOP.

The use of a rebound tonometer has some superior properties to GAT: it is simple to use, the independant of the operator, and the measurement is virtually painless without anesthetic and contamination-free due to the use of disposable probes. Automatic measurement with a rebound tonometer does not lead to the subjective interpretation of semicircles, as it does with the GAT [4]. We believe that rebound tonometer is very helpful in the elderly with transportation problems, and the children with no cooperation to topical drops and the complexity of GAT techniques.[40,41]

According to our experience, there are few disadvantages of the rebound tonometer: dependence of the accuracy of the IOP values on the skill of the examiner since peripheral corneal measurements may be recorded by mistake when the measurements must be taken 3 mm into the central cornea, and the inability to use the device in supine or tilted positions.[39]

In summary, the IOP values obtained with the rebound tonometer in our study did not differ from those obtained with the GAT, and the IOP levels determined by the 2 instruments were strongly correlated. The measurements from the rebound tonometer and the GAT were equally affected by the CCT. In our experience Icare® tonometer measures IOP accurately, rapidly, and without the need for an anesthetic. However, further studies for the development of correction tables or correction factors specifically for the rebound tonometer need to be conducted.

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