

Comparison of the Intraocular Pressure Measurements with the Tono-Pen and the Goldmann Applanation Tonometer and the Effect of Central Corneal Thickness on Measurements

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ABSTRACT

Purpose: Incorrect values of applanation tonometers according to varying corneal thickness were investigated many times. In this study, we aimed to compare intraocular pressure (IOP) measurements of the Tono-Pen and Goldmann applanation tonometer (GAT) in eyes with normal corneas of various thicknesses.

Material and Methods: IOP was measured with Tono-Pen and GAT respectively in 255 patients' eyes with normal corneas. Only the right eyes were analyzed for statistical purposes. Central corneal thickness (CCT) was measured using an ultrasound pachymeter after all IOP determinations had been made.

Results: With both instruments, IOP varied with CCT. Readings with Tono-Pen showed a mean increase in IOP with increasing CCT of 0,18 mmHg/10µm and an increase of 0,16 mmHg/10 µm with the GAT. The Tono-Pen consistently recorded comparatively higher IOPs than the GAT (p<0,05).

Conclusion: In our study, the difference between the Tono-Pen and GAT measurements is statistically insignificant and 60% of this difference is within the 1 mmHg range. Although it is thought that Tono-Pen may be less affected by corneal thickness due to the measurement from a smaller area we did not obtain data that Tono-Pen is less affected by corneal thickness as a result of linear regression analysis. The Tono-Pen is more affected by CCT when used to measure IOP in eyes with normal corneas. This is contrary to expectations, based on the theory that Tono-Pen is least affected by the CCT because it needs smaller applanation area.

Keywords: Tono-Pen, Goldmann Applanation Tonometer, Intraocular Pressure, Central Corneal Thickness.

INTRODUCTION

Glaucoma is an ocular disease characterized by optic neuropathy which is caused by mechanisms connected to vascular and mechanical factors and is among the leading causes of preventable blindness in the world. Elevated intraocular pressure (IOP) is the most common risk factor. In the pathogenesis of glaucoma, blood flow in the eye, optic disc structure and ganglion cell degeneration are also important but the most important factor in diagnosis and treatment of the disease is IOP. Many instruments such as Schiottz indentation tonometry, Goldmann applanation tonometry (GAT), McKayMarg tonometry, noncontact

and contact pneumotonometers have come to the fore with the historical process in IOP measurements made from smooth corneal surfaces. Among them only McKay-Marg tonometry can measure irregular corneal surfaces due to scarring, edema or surgery¹ but it is not in production today. GAT developed by Goldmann in 1957 according to the Imbert-Fick law has been accepted as the gold standard today. According to the Imbert-Fick law the pressure to flatten the wall of an elastic full of water, for example a balloon, is equal to the applied force divided by the application area. In fact, this law recognizes that cornea is a structure that does not resist other forces than the internal pressure force against fine, applied gentleness

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in perfect elasticity. Goldmann and Schmidt stated that although the device is calibrated according to the standard corneal thickness (520 μm), it may theoretically be affected by corneal thickness changes.² There are many factors that can affect the IOP measurements made with this device. The accuracy of the measurement is expected to increase with the application of the appropriate measurement technique in large scale.³ As for the negative aspects of GAT, this device, which is developed with constant corneal thickness and higher values above the value may cause lower measurements at lower thicknesses, and corrections between 1 and 6.8 mmHg are also made for a 0.1 mm change in corneal thickness.⁴ Glaucoma prevalence, which is high in myopic patients, and the increase in refractive surgical procedures that change corneal thickness in recent years have made the relationship between IOP and corneal thickness more important.⁵ In addition to differences in race, age and gender, central corneal thickness (CCT) and corneal curvature and IOP and curvature associations are also discussed in corneal thickness.⁶ Medeiros et al. have shown that ocular hypertensive cases with early glaucomatous defects with perimeter have lower CCT values than those without a defect.⁷ In this context, the use of devices such as Tono-Pen, which is thought to be less affected by corneal surface irregularities and thickness in recent years, has come to the fore. Tono-Pen works according to the McKay-Marg principle, which expresses the conversion of mechanical energy into electrical energy. The measurement area measures from a smaller area (diameter of 1.02 mm) than the GAT (diameter of 3.06 mm) with a transducer movement as small as 10 μm , which may be considered to be less affected by corneal thickness. The positive aspects of the device are that it is easier to measure IOP in situations such as corneal irregularity, lid edema, narrow palpebral aperture, infant, small children, bedridden or wheelchair patients, head tremor or nystagmus patients. CCT can be measured by optic or ultrasonographic methods. Ultrasonic pachymetry is a more reliable, precise method than optic pachymetry, with repeated measurements of the observer and less variability between different observers.⁸ In this study, we aimed to investigate the effect of CCT on the IOP measurements of GAT and Tono-Pen devices. According to our hypothesis corneal thickness does not make a difference in IOP measurements between the Tono-Pen and the GAT.

MATERIALS AND METHODS

This study was performed in adherence with the tenets of the Declaration of Helsinki and was approved by the Kirikkale University Medical Faculty Ethics Committee (14.01.2004/2004106). Informed consent was obtained from all of the study participants. Participants with less than

2D spherical and 1D astigmatic refraction were enrolled. Two hundred and fifty-five patients who did not have any contact lens and volunteered to participate in the study were prospectively included in the study. Patients with a history of intraocular surgery history, unilateral anophthalmia, any corneal pathology or scarring and evidence of anterior segment inflammation were excluded. Visual acuity, refraction, biomicroscopy and funduscopy examinations were performed on both eyes of the participants. The age and sex of the participants were recorded. The participants' ages ranged from 10 to 80 (average 40.86). There were 109 males and 146 females. In all examinations the right eye was first evaluated. All examinations and measurements were made between 09:00 and 14:00 hours. In response to the possibility of the GAT dropping the IOP and causing the lower values that can be measured with the Tono-Pen, the GAT and IOP measurement examination was first applied to 128 participants. Measurements with GAT (Zeiss Co, Zurich, Switzerland) were performed on the patients looking at a target at a distance of 6 m, in the primary position, with a drop of 0.25% fluorescein in both eyes subconjunctivally as a mixture of 0.45% oxybuprocaine hydrochloride (Benoxinate, Alcon Couvreur, Puurs, Belgium) and fluorescein (Fluoroscite 10%, Alcon, Texas, USA). Participants were asked not to move their eyes and to breathe regularly. The blue light was turned on until the end and was brought to an angle of 45 degrees with the eye in the horizontal plane. The arithmetic averages were obtained by the experienced practitioner by performing 3 measurements within the limit of 1 mmHg (MSD). In the study, the same GAT was used regularly with annual calibration. The IOP measurements were then repeated with the Tono-Pen (Tono-Pen XL, Mentor Ophthalmics, CA, USA) instrument in a sitting position, looking at the target 6 m away in the primer position, Measurements with Tono-Pen were performed after the drop of 0.45% oxybuprocaine hydrochloride was applied to the lower conjunctival fornix of both eyes. For each patient, a new latex membrane (Mentor OcuFilm Type Covers) was placed on the transducer. After Tono-Pen was activated and the 'beep' sound was heard the transducer was contacted gently to the cornea, waiting for at least 1 second until the 'beep' sound indicating successful measurement. The procedure was repeated until two measurement results with reliability of 5% were obtained on the liquid display. All the IOP measurements with Tono-Pen were performed by the same practitioner (MSD). Tono-Pen was calibrated every morning in line with the manufacturer's recommendation. After the measurement with Tono-Pen or GAT, the measurement with the other instrument was made 15 minutes apart. After IOP measurements were completed by both methods, central corneal thickness (CCT) was measured with an ultrasonic pachymeter

(Optikon 2000 S.p.A., Rome, Italy). After dropping 0.45% oxybuprocaine hydrochloride to each lower conjunctival sac, the patient was held in the primary position, the probe was held perpendicular to the cornea and 3 measurements were taken from the undiluted pupil center and averaged. The participant was asked to blink between measurements. Pachymeter measurements were all made by the same person (MSD). Measurements were made in both eyes, and only right eyes were included in the study. Since the measurements are made with corneal contact, the possible complication is keratitis. Therefore antibiotic drops were applied to the eyes after the measurement.

When the alpha value (confidence interval) was 0.05 and the number of participants was 255, the power of the study was determined to be 80% to show a 2% difference between the two instruments' measurements. IOP measurements of both devices were evaluated by the Student t- test. Simple linear regression analysis (dependent on IOP measurement with Tono-Pen or GAT, corneal thickness as an independent variable) was used to determine the measurement averages of both devices in relation to the corneal thickness and regression equations were found. The increase in measured IOP by 10 μm in CCT is calculated from the graphs for each of the Tono Pen and GAT devices. For this statistical evaluation, SPSS Ver. 11.0 (SPSS Inc, Chicago, USA) program was used. The values of $p < 0.05$ were considered statistically significant.

RESULTS

There was no statistically significant difference in the measurements of Tono-Pen ($p=0.352$), GAT ($p=0.203$) and CCT ($p=0.734$) ($P < 0.05$) according to the gender. (Table 1) Using Tono-Pen and GAT, a total of 255 values were determined. In the measurements, the mean of the Tono-Pen measurements ($\pm\text{SD}$) was 16.71 (± 3.09) mmHg (8-30 mmHg) and the mean of the GAT measurements was ($\pm\text{SD}$) 16.10 (± 3.07) mmHg (7-26mmhg). The measurement difference between the two devices was statistically significant ($p < 0.05$) and Tono-Pen measurements were higher. Tono-Pen and GAT measurements differed from 0,6 to 1 mmHg (Figure 1). According to the point distribution graph and the regression curve for the comparison of the thickness of the cornea with Tono-Pen, the regression

equation is $y=6,812 + 0,018x$ ($r^2: 0.041$), where $y=\text{IOP}$ measured by Tono-Pen, $x=\text{CCT}$. An increase of 0, 18 mmHg was observed in the IOP measurement made with Tono-Pen in every 10 μm increase in CCT (Figure 2). According to the results of linear regression analysis, GAT is less affected by corneal thickness (An increase of 0, 16

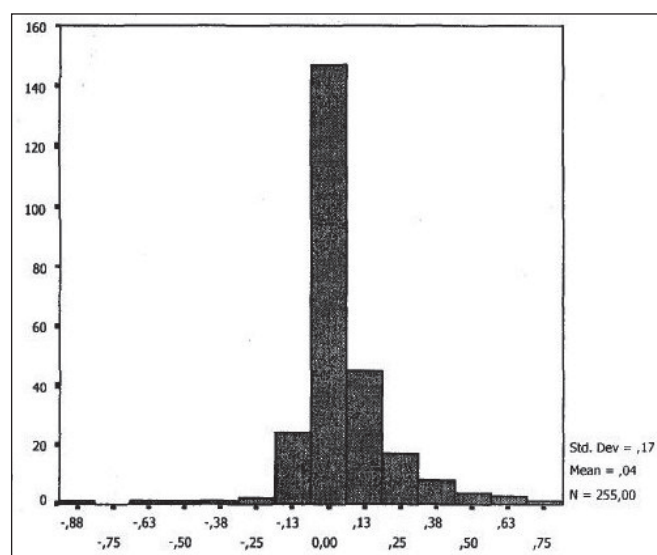


Figure 1. Measurement differences between Tonopen and Goldmann applanation tonometer (x-axis: mmHg, y-axis: n).

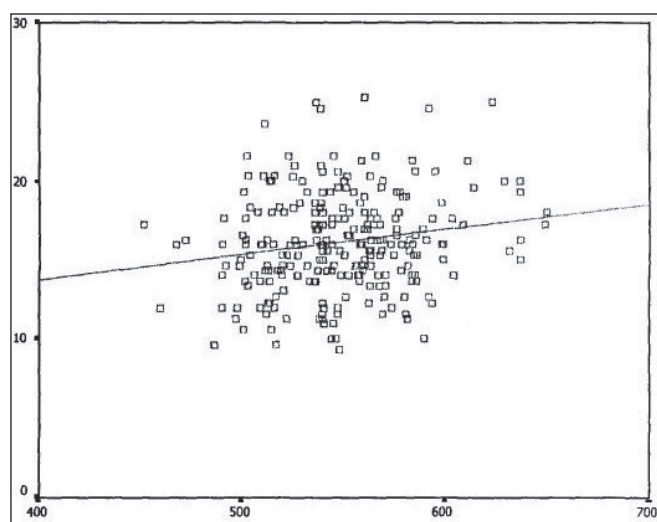


Figure 2. Regresyon analysis curve of the Goldmann applanation tonometer (y-axis, mmHg) and the central corneal thickness (x-axis, μm).

Table 1. Tono-Pen (mmHg), Goldmann applanation tonometry (mmHg) and Central corneal thickness (μm) values.

Gender	Tono-Pen	Goldmann Applanation Tonometer	Central Corneal Thickness	Age (years)
Male (n-108)	16,72 \pm 3,15	15,87 \pm 3,18	550,36 \pm 34,16	41,45 \pm 15,99
Female (n-147)	16,72 \pm 3,02	16,26 \pm 2,98	545,98 \pm 34,75	40,43 \pm 14,33

mmHg was observed in the IOP measurement made with GAT in every 10 μm increase in CCT).

In Table 2 and Figures 1, 2 and 3 we can see that the Tono-Pen measurements are higher than the GAT measurements. This difference in measurement was statistically significant ($p < 0.05$). The mean CCT (\pm SD) was 547 ($\pm 34.50 \mu\text{m}$) (range of 451.60-650 μm) (Figure 4). The regression equation is $y = 7,448 + 0,016x$ ($r^2 = 0,032$), where y = the IOP value measured with GAT and x = the CCT value. According to the point distribution graph for the CCT comparison of GAT and the regression curve, the IOP measurement value with GAT increased by 0.16 mmHg at a 10 μm increase in thickness (Figure 3). There was no statistically significant difference between measurements performed with Tono-Pen ($p = 0.411$) or with GAT ($p = 0.579$) (Table 2).

DISCUSSION

Glaucoma is one the most important cause of blindness in the world and the only currently accepted treatment is the reduction of IOP. For this reason correlations of IOP measuring devices with each other have always been the subject of research. Today GAT is accepted as the gold standard in IOP measurement but many factors are thought to affect its measurement results. Opinions have been

reported that changes in corneal thickness, which is the determinant of corneal rigidity, will affect measurements.⁹ In some studies in which invasive IOP measurement methods were used, the values obtained with the applanation method were normal with the corneal thickness increase.³ Recep et al. have shown that noncontact tonometers are also affected by corneal thickness.¹⁰ Feltgen and colleagues found that Tono-Pen and Perkins applanation tonometry measurements are correlated with manometric measurements and did not require any correction.¹¹ Comparison of GAT with the first sample of Tono-Pen (Tono-Pen-1) was made in 1987 by Minckler et al. and reported that Tono-Pen showed higher values at higher IOP and lower values at lower IOP.¹³ Hessemer et al. compared manometric measurements with Tono-Pen and reported that Tono-Pen showed lower values at 17 mmHg below and higher at 17 mmHg¹⁴ and Foster et al. observed a deviation of 2 mmHg (between -8 and +4) with Tono-Pen compared to the manometric measurements in their 23 eyes performed phacoemulsification but this deviation could not be correlated with corneal thickness.¹⁵ Similar results were reported in similar studies on rabbits and rats.¹⁶ Eisenberg et al. reported that they measured very well with the Tono-Pen in laboratory conditions but they found a decrease in the accuracy of the measured values compared with intraocular measurements.¹⁷ Feltgen et al. reported that Tono-Pen and

Table 2. There was no statistically significant difference between measurements performed first with Tono-Pen ($p = 0,411$) or first with GAT ($p = 0,579$).

	group measured first with Tono-Pen (mmHg)	Group measured with GAT (mmHg)
GAT (mmHg)	16,63 \pm 3,20	15,56 \pm 2,84
Tono-Pen (mmHg)	16,96 \pm 3,24	16,48 \pm 2,89

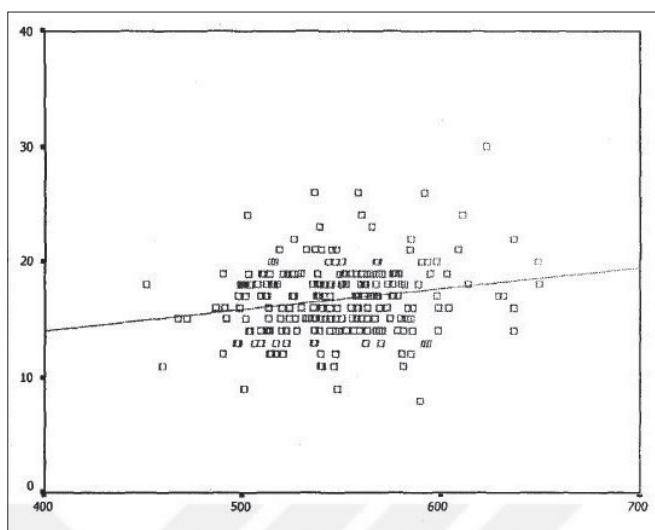


Figure 3. Regresyon analysis curve of the Tonopen (y-axis, mmHg) and the central corneal thickness (x-axis, μm).

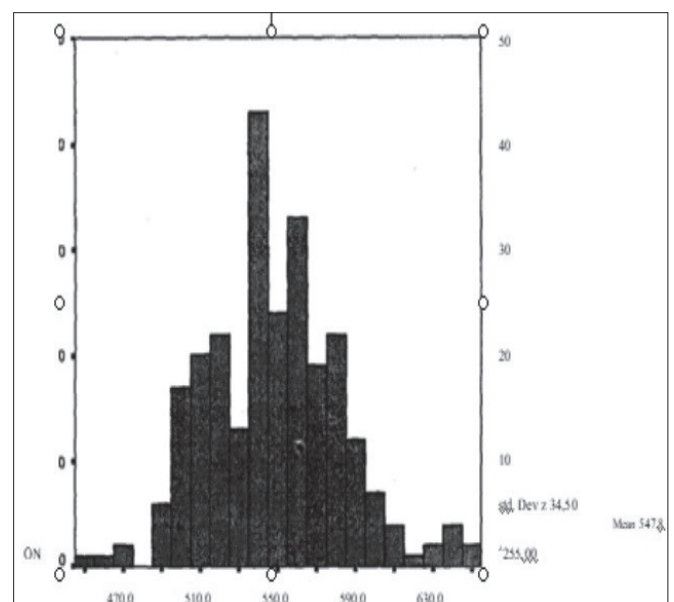


Figure 4. Central corneal thickness (μm).

Perkins applanation tonometers were correlated with each other and their measurement results were not affected by corneal thickness in their studies comparing applanation tonometry measurements with manometric measurements according to corneal thickness.¹¹

It has been shown that the cornea is thinner in pseudoexfoliation glaucoma cases.¹⁰ In order to avoid detection of false low IOP values in lower CCT, IOP measuring devices are required to minimize the effect of corneal thickness and make measurements close to true IOP values. It is known that changes in IOP measurements after surgery compared to the preoperative period are determined due to the decrease of corneal thickness after excimer laser photorefractive keratectomy in myopia cases. The incidence of increased glaucoma in myopic patients and the increase in refractive surgery applied to myopia today are considered to be significant. In some previous studies, Tono-Pen has been shown to make precise measurements in the eye bank eyes.¹⁸ However in vivo studies have identified some data suggesting that Tono-Pen and GAT measurements are incompatible with the clinic. For example Tono-Pen reported inconsistent results on measurements over 30 mmHg¹⁹ did not reflect IOP fluctuation and did not make precise measurements that could be used in glaucoma diagnosis and follow-up.²⁰ It is thought that the inaccuracies of in vitro studies are related to the absence of precorneal tear film, live corneal epithelium, normal corneal thickness and rigidity, extraocular muscle function, fluctuating blood pressure, respiration and even patient anxiety.²¹

In our study the difference between the Tono-Pen and GAT measurements is statistically insignificant and 60% of this difference is within the 1 mmHg range. Our sample size and standardized measurement procedures did not allow statistical uncertainty. Although it is thought that Tono-Pen may be less affected by corneal thickness due to the measurement from a smaller area we did not obtain data that Tono-Pen is less affected by corneal thickness as a result of linear regression analysis. We also observed slightly higher values with Tono-Pen as the thickness increased and found increases of 0.18 mmHg with TonoPen and 0.16 mmHg with GAT in 10 μ m CCT increase. Earlier studies in which Dohadwala et al. evaluated Tono-Pen's measurements of various corneal thicknesses reported increases in IOP of 0.29 mmHg in males and 0.12 mmHg in females with an increase in corneal thickness of 10 μ m.²² Bhan et al obtained 0,10 mmHg / 10 μ m and 0,23 mmHg / 10 μ m IOP increments in their studies investigating the relationship between Tono-Pen and GAT corneal thickness.²³ In our study we did not observe a statistically significant difference in Tono-Pen, GAT and CCT values according to sex.

It is known that astigmatism, refraction and visual acuity do not affect corneal thickness. The effect of corneal curvature on IOP measurements has been shown to be negligible.²⁴ For this reason, we did not evaluate the corneal curvature in our study. In our study we did not divide our values into subgroups, but we performed our measurements within the range of 11-20 mmHg in patients who applied to the eye polyclinic for the routine eye examination and observed that the Tono-Pen measurements were higher than the GAT measurements. We have not compared our measurements with manometric measurements but nowadays it is thought that even manometric measurements have some disadvantages because the applied paracentesis leads to changes in anterior chamber structure and volume, aqueous production, endothelial function and ocular temperature. The advantages of Tono-Pen compared to GAT are light, portable, easy to learn, able to measure from a smaller surface easier to measure IOP in corneal irregularities, uncooperative cases and pediatric patients. The measurement made with the Tono-Pen is reflected in the resultant liquid crystal screen and is not open to interpretation. In addition sterile latex tip covers maintain an advantage in postoperative cases and ocular or systemic infections (hepatitis, HIV, prion diseases). The use of the TonoPen in corneal pathology is important in several ways: It can be used in cases of corneal edema, scarring or band keratopathy. The latex allergy caused by Tono-Pen latex tip cover should be questioned before the measurement. Other portable tonometers are also available. Measurements with Schiøtz tonometry make the patient more uncomfortable and the values can be influenced by the elastic properties of the eye and the corneal curvature. With Draeger, Kowa and Perkins tonometric measurements to be more precise, you need to gain experience for quality measurements. The McKay-Marg tonometry can also provide more accurate measurements, but its transport is more difficult and is no longer produced. The appearance of the optic disc and the evaluation of the visual field are much more important than the assessment of the corneal thickness in order to make the decision to start treatment FOR glaucoma. Corneal thickness should be assessed in addition to IOP measurements in cases of ocular hypertension and normotensive glaucoma in our findings. Corneal thickness measurements are especially important when the clinically determined IOP value is inconsistent and target IOP evaluation needed after the treatment.

CONCLUSION

In summary, the slightly higher values were seen in the Tono-Pen measurements. This did not appear to cause problems clinically because Tono-Pen also has the above-

mentioned characteristics. Although GAT is still the gold standard for IOP measurement and is used as the most preferred tonometer, Tono-Pen is portable, it can be used in corneal pathologies and animal experiments and its sterility properties are superior.

Animal and Human Rights Statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards and was approved by the Kirikkale University Medical Faculty Ethics Committee (14.01.2004/2004106).

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Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Conflict of Interest: No conflict of interest

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