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# Correlation of Tono-Pen and Pneumatonometer Measurements from Four Scleral Quadrants with Intraocular Pressure Measurements from the Cornea

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## Abstract

**Objective:** To assess whether Tono-Pen and pneumatonometer measurements obtained from the sclera correlate to intraocular pressure measurements obtained from the cornea.

**Methods:** This is a prospective, cross-sectional study, conducted at the New York Eye and Ear Infirmary of Mount Sinai. Patients were randomized to have their left or right eye included in the study. Exclusion criteria included prior intraocular surgery (except uncomplicated cataract extraction), uveitis, corneal or scleral thinning, central corneal thickness <500 μm or >575 μm, and hyperopia greater than +2 diopters or myopia greater than -4 diopters. Goldmann applanation tonometry, Tono-Pen and pneumatonometer measurements were obtained from the cornea. Tono-Pen and pneumatonometer measurements were obtained from the sclera in the superonasal, superotemporal, inferonasal, and inferotemporal quadrants. Product moment correlation and linear regression were used to examine correlations between the measurements.

**Results:** 50 eyes of 50 patients were enrolled. The scleral intraocular pressure measurements (S-IOP) differed significantly from the corneal intraocular pressure (C-IOP) readings. Moderate correlation was found between the pneumatonometer readings from the superotemporal ($r=0.64$, $P<0.01$) and inferotemporal ($r=0.64$, $P<0.01$) quadrants with the Goldmann C-IOP, with the following linear relationships, respectively: C-IOP=(0.52 × superotemporal S-IOP)+1.35, and C-IOP=(0.41 × inferotemporal S-IOP)+0.88. A combined superotemporal pneumatonometer S-IOP of >30 mmHg and an inferotemporal pneumatonometer S-IOP of >39 mmHg was 92.3% (95% Confidence Interval [CI] 63.9%, 98.7%) sensitive and 94.6% (CI 81.8%, 99.2%) specific for a C-IOP ≥ 20 mmHg with positive likelihood ratio of 17.1 (CI 4.4-66.3).

**Conclusion:** S-IOP measurements, especially from the superotemporal and inferotemporal quadrants, can provide useful information about intraocular pressure in eyes in which accurate C-IOP measurements cannot be obtained.

**Keywords:** Intraocular pressure; Tonometry; Pneumatonometer; Goldmann applanation; Glaucoma; Sclera; Cornea; Tono-Pen

## Introduction

Despite the numerous modalities of applanation currently available, intraocular pressure (IOP) estimation remains a challenge when corneal thickness and surface irregularities are present [1]. Goldmann applanation tonometry (GAT) remains the gold standard for IOP assessment; however, its accuracy is greatly affected by corneal irregularities [1]. Tono-Pen and pneumatonometer, which have a smaller contact area, may be more useful in such patients; however, even these tools have limited use when extensive corneal pathology is present.

Unfortunately, patients with significant corneal pathology often have concomitant glaucoma [2]. In addition, keratoprosthesis is becoming an increasingly accepted alternative in patients deemed at high risk for failure after standard keratoplasty. Glaucoma is prevalent after keratoprosthesis surgery [3]; however, the keratoprosthesis implant precludes assessment of IOP by corneal measurement. Digital palpation is often used to estimate IOP in these patients [4], which has questionable reliability [5].

There is increasing interest in using scleral measurements as an alternative method for IOP measurement in patients for whom corneal measurements are not possible [6-8]. Although Tono-Pen and pneumatonometer measurements on the sclera may not provide an accurate assessment of IOP, a correlation may exist between these measurements. If such a correlation does exist, then scleral measurements may provide useful information for physicians caring for patients in whom IOP assessment through direct corneal measurement is not possible.

Only two prior studies have evaluated the relationship between pneumatonometer measurements on the sclera as compared to the cornea in live patients [6]. These studies are limited in that only pneumotonometry was used for scleral measurements, and only one scleral location was studied (inferotemporal for Kapamajian et al., and temporal for Kuo et al.). No prior studies have been done to evaluate

which scleral quadrant yields measurements that correlate most highly with IOP as measured on the cornea, or whether the Tono-Pen or the pneumatonometer is better for this purpose. Our study aims to evaluate whether there is a relationship between pneumatonometer and Tono-Pen measurements of IOP obtained from each of the four scleral quadrants, as compared to pneumatonometer, Tono-Pen, and GAT measurements obtained from the cornea.

## Methods

The researchers followed the tenets of the Declaration of Helsinki in the treatment of patients reported herein. Study approval was obtained from the Institutional Review Board at the New York Eye and Ear Infirmary of Mount Sinai.

This is a prospective study enrolling patients at the New York Eye and Ear Infirmary of Mount Sinai between 2009 and 2012 who met the following inclusion criteria.

All patients were 18 years of age or older with no prior history of ocular surgery other than uncomplicated cataract extraction. Patients with a history of corneal or scleral thinning or uveitis were excluded. Patients were also excluded if they had central corneal thickness (CCT) <500 μm or >575 μm, hyperopia greater than +2.00 spherical equivalent, or myopia greater than -4.00 spherical equivalent.

Consecutive patients meeting the above criteria who gave informed consent to participate in this study provided a complete ocular history and underwent a thorough eye examination, including Snellen visual acuity, slit lamp examination, and measurement of CCT. Patients were then randomized to have either their right or their left eye evaluated in the study. IOP measurements were then obtained from the study eye as follows: GAT, followed by Tono-Pen (Reichert Tono-Pen XL Applanation Tonometer) and pneumatonometer (Reichert Model 30 Pneumatonometer) on the cornea; pneumatonometer on the sclera (in each of the superonasal, superotemporal, inferonasal and inferotemporal quadrants); Tono-Pen on the sclera (in each of the superonasal, superotemporal, inferonasal and inferotemporal quadrants). At least 2 acceptable measurements were obtained from each location, using each of the applanation modalities. Tono-Pen measurements were deemed acceptable if they were within 5% confidence levels. Pneumatonometer readings were deemed acceptable if their standard deviation was less than or equal to 2.0. Scleral measurements using the pneumatonometer and the Tono-Pen were taken with the instruments centered 3.5 mm posterior to the limbus. For scleral measurements, patients were seated in an upright position with their heads tilted slightly back (for superior scleral measurements) and tilted slightly forward (for inferior scleral measurements) with the eyes directed as close to primary gaze as possible. The pneumatonometer tip was held at a horizontal position at all times while obtaining measurements. Topical proparacaine was used for anesthesia. Each patient had all study measurements performed by 1 of 2 glaucoma specialists (TYTT or NH).

### Statistics

Using a Type 1 error probability of 0.05, and seeking a power (1-Beta) of 0.8, a minimum sample size of 48 was estimated to be needed to detect a significant correlation of 0.38. Intraobserver reliability was assessed using Cronbach's alpha. Product moment correlation and linear regression were used to examine correlations between the measurements.

## Results

50 eyes (25 right eyes, 25 left eyes) of 50 patients (23 males, 27 females) were enrolled in this study. The average age of the patients was 65.8 (standard deviation 13.1) years. The average CCT of study eyes was 542.4 μm (standard deviation 22.0 μm).

There was excellent intraobserver reliability of the corneal IOP (C-IOP) measurements using GAT, Tono-Pen and pneumatonometer, with Cronbach's alpha of 0.99, 0.98 and 0.98, respectively. The intraobserver reliabilities of the IOP readings from the sclera (S-IOP) were also excellent, with readings from the superotemporal and inferotemporal sclera using the pneumatonometer having the highest reliability of the scleral measures (Table 1).

| | **Reliability by Cronbach's alpha** |
|---|---|
| **Cornea** | |
| Goldmann applanation | 0.99 |
| Tono-Pen | 0.98 |
| Pneumotonometer | 0.98 |
| **Superotemporal** | |
| Tono-Pen | 0.93 |
| Pneumotonometer | 0.95 |
| **Superonasal** | |
| Tono-Pen | 0.94 |
| Pneumotonometer | 0.84 |
| **Inferotemporal** | |
| Tono-Pen | 0.90 |
| Pneumotonometer | 0.95 |
| **Inferonasal** | |
| Tono-Pen | 0.91 |
| Pneumotonometer | 0.86 |

**Table 1:** Intraobserver reiliability.

The average C-IOP by GAT was 16.4 mmHg (standard deviation 5.1; range 7.5-30.0). C-IOP measurements using the Tono-Pen and pneumatonometer showed high correlation (r=0.71 and 0.92, respectively) with the GAT measurements. The S-IOP measurements differed significantly from the C-IOP readings; however, moderate correlation was found between the pneumatonometer readings from the superotemporal (r=0.64, P<0.01) and inferotemporal (r=0.64, P<0.01) quadrants with the GAT C-IOP (Table 2). The only measurements that did not show a statistically significant correlation with GAT C-IOP were those from the inferonasal sclera by Tono-Pen (P>0.05). The relationships between S-IOP measurements and the GAT C-IOP were found to be best described by linear models, as opposed to curved models.

Linear regression models were used to further evaluate the relationships between the S-IOP measurements with the GAT C-IOP (Figure 1). The relationship between each measurement modality with

the GAT C-IOP, described by the following: GAT C-IOP=(Measured IOP × Relationship Coefficient)+Constant, was found to be statistically significant at the 95% level for all measurement modalities, except for inferonasal sclera Tono-Pen (Table 3). The two S-IOP readings, superotemporal sclera pneumatonometer and inferotemporal sclera pneumatonometer, that showed moderate correlation with the Goldmann C-IOP, had adjusted r-squared values of 0.40. For the superotemporal sclera pneumatonometer, the Relationship Coefficient (defined in this study as change in GAT C-IOP/change in measured IOP by specified modality) was 0.52 (P<0.005), the Constant was 1.35 mmHg, and the Standard Error was 0.70. For the inferotemporal sclera pneumatonometer, the Relationship Coefficient was 0.41 (P<0.005), the Constant was 0.88 mmHg, and the Standard Error was 0.58 (Table 3).

| | Mean IOP | Standard Deviation | Min | Max | *Correlation Coefficient, r |
|---|---|---|---|---|---|
| **Cornea** | | | | | |
| Goldmann | 16.4 | 5.1 | 7.5 | 30.0 | 1.0 |
| Tono-Pen | 14.5 | 3.6 | 7.0 | 23.5 | 0.71 |
| Pneumatonometer | 19.7 | 3.9 | 11.5 | 29.8 | 0.92 |
| **Superotemporal Sclera** | | | | | |
| Tono-Pen | 30.0 | 7.7 | 16.0 | 47.5 | 0.35 |
| Pneumatonometer | 29.2 | 6.4 | 16.5 | 51 | 0.64 |
| **Superonasal Sclera** | | | | | |
| Tono-Pen | 29.0 | 7.7 | 15.0 | 46.0 | 0.43 |
| Pneumatonometer | 28.4 | 5.8 | 18.5 | 41.0 | 0.54 |
| **Inferotemporal Sclera** | | | | | |
| Tono-Pen | 41.8 | 14.7 | 23.5 | 87.5 | 0.42 |
| Pneumatonometer | 37.8 | 7.9 | 21.5 | 64.5 | 0.64 |
| **Inferonasal Sclera** | | | | | |
| Tono-Pen | 41.0 | 12.7 | 22.5 | 82.7 | 0.22 |
| Pneumatonometer | 37.2 | 7.5 | 21.0 | 56.5 | 0.61 |

*Pearson product moment correlation when the intraocular pressure obtained is compared to the corneal Goldmann applanation value. All correlations are significant at P<0.0, except for the inferonasal Tono-Pen measurement, which has P>0.05.

**Table 2:** Intraocular pressure readings (mmHg) obtained from the cornea versus four scleral quadrants.

| Mean IOP | Relationship Coefficient (change in GAT C-IOP / change in measured IOP by specified modality) | Constant (mmHg) | Adjusted R Squared | Standard Error* (mmHg) |
|---|---|---|---|---|
| **Cornea**<br>Tono-Pen | 0.99 (P<0.005) | 1.95 | 0.49 | 0.53 |
| Pneumotonometer | 1.21 (P<0.005) | -7.47 | 0.85 | 0.29 |
| **Superotemporal sclera** | | | | |
| Tono-Pen | 0.23 (P=0.01) | 9.56 | 0.10 | 0.70 |
| Pneumotonometer | 0.52 (P<0.005) | 1.35 | 0.40 | 0.70 |
| **Superonasal sclera** | | | | |
| Tono-Pen | 0.28 (P<0.005) | 8.18 | 0.17 | 0.68 |
| Pneumotonometer | 0.48 (P<0.005) | 2.79 | 0.28 | 0.63 |
| **Inferotemporal sclera** | | | | |

| | | | | |
|---|---|---|---|---|
| Tono-Pen | 0.15 (P<0.005)) | 10.29 | 0.16 | 0.68 |
| Pneumotonometer | 0.41 (P<0.005) | 0.88 | 0.40 | 0.58 |
| **Inferonasal sclera** | | | | |
| Tono-Pen | 0.09 (P=0.13) | 12.83 | 0.03 | 0.73 |
| Pneumotonometer | 0.41 (P<0.005) | 1.14 | 0.36 | 0.60 |

**Table 3:** Linear regression model with corneal goldmann applanation intraocular pressure as outcome variable.

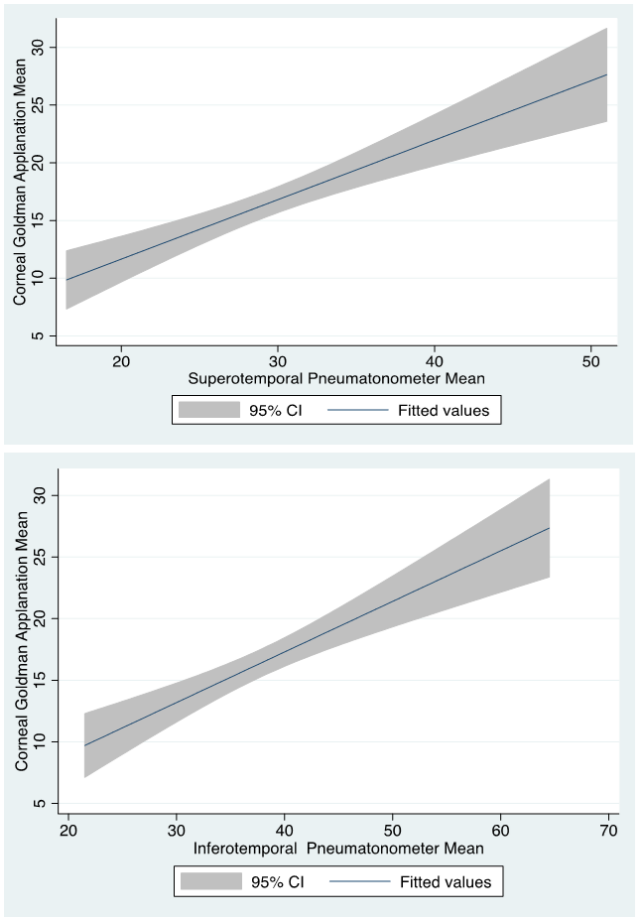


**Figure 1:** Upper graph: Linear regression graph of pneumatonometer readings (mmHg) from the superotemporal scleral quadrant versus corneal Goldmann applanation readings (mmHg). Lower graph: Linear regression graph of pneumatonometer readings (mmHg) from the inferotemporal scleral quadrant versus corneal Goldmann applanation readings (mmHg).

13 out of 50 patients had GAT C-IOP ≥ 20 mmHg. Obtaining superotemporal pneumatonometer S-IOP of >30 mmHg was 92.3% (95% confidence interval [CI] 63.9%, 98.7%) sensitive and 70.3% (95% CI 53.0%, 84.1%) specific for having a GAT C-IOP of ≥ 20 mmHg. An inferotemporal pneumatonometer S-IOP of >39 mmHg was 100% (95% CI 75.1%, 100%) sensitive and 81.1% (95% CI 64.8%, 92%) specific for a GAT C-IOP of ≥ 20 mmHg. A combined superotemporal pneumotonometer S-IOP of >30 mmHg and an inferotemporal pneumatonometer S-IOP of >39 mmHg was 92.3% (95% CI 63.9%, 98.7%) sensitive and 94.6% (CI 81.8%, 99.2%) specific for a GAT C-IOP ≥ 20 mmHg with positive likelihood ratio of 17.1 (95% CI 4.4-66.3).

## Discussion

Glaucoma is a common comorbidity in patients with corneal disease. In eyes that have undergone penetrating keratoplasty, the incidence of glaucoma has been reported to vary between 9-31% in the early postoperative period and 18-35% in the late postoperative period [2]. Glaucoma can be found in approximately two-thirds of patients who undergo keratoprosthesis, and its management in these patients can be challenging [2,3]. In addition to the difficulty in obtaining a reliable IOP due to the corneal pathology, media opacities may obscure the view of the optic nerve head, as well as compromise the patient's ability to perform visual field testing.

Digital palpation is often used to estimate IOP in patients with severe corneal disease or patients with keratoprostheses; however, a study by Baum et al. showed that there was little correlation between tactile assessment of IOP and IOP by tonometry [5]. One study by Birnbach and Leen showed that digital palpation estimation of IOP on cadaveric eyes may be improved by training using an eye model [9].

With the increased use of keratoprostheses, there has been increasing interest in using scleral measurements as an alternative method for assessing IOP. Two prior studies evaluated Tono-pen measurements on the sclera compared to the cornea in cadaver eyes. Khan et al., found that scleral measurements were 8-17 mmHg higher than corneal measurements over the range of IOP from 10-40 mmHg. However, this study did not specify the location of sclera used for Tono-pen measurements, and did not assess whether the scleral measurements showed any correlation with the corneal measurements [10]. Lin et al., showed that serial measurements of scleral pneumotonometry correlated strongly and linearly to IOP over the range from 20-50 mmHg, as set by infusion cannula, with the equation: assigned IOP=(1.01 × S-IOP) – 14.14.9 This relationship was unchanged after the cadaver eyes underwent keratoprosthesis implantation. These studies have limitations inherent to the use of preserved cadaver eyes (including lack of precorneal tear film, corneal epithelium, normal corneal thickness and rigidity, and eyelid and extraocular muscle function).

Two studies have evaluated the relationship between corneal and scleral measurements of IOP in live patients. Both these studies used only the pneumatonometer to obtain measurements from the cornea and one designated position on the sclera. Kapamajian et al. found the

following linear relationship using measurements from the inferotemporal sclera: C-IOP=(0.32 × S-IOP) – (0.05 × Age)+11.9.6 Kuo et al., found the following linear relationship using measurements from the temporal sclera: C-IOP=(1.04 × S-IOP)–10.37.8.

Our study assessed pneumatonometer and Tono-Pen readings, and studied measurements from all four scleral quadrants. The Tono-Pen sclera measurements correlated poorly with corneal IOP measurements. There was moderate correlation between pneumatonometry measurements on the superotemporal and inferotemporal sclera as compared to Goldmann applanation tonometry on the cornea, with the following linear relationships, respectively: C-IOP=(0.52 × superotemporal S-IOP)+1.35, and C-IOP=(0.41 × inferotemporal S-IOP)+0.88. Similar to the results of Kuo et al., we found that the relationship between scleral and corneal measurements was not impacted by age. The differences in the relationship found in our study as compared to the two prior studies can be attributed to the difference in location from which scleral measurements were made. In addition, we compared scleral measurements to corneal measurements as obtained using Goldmann applanation, whereas the prior studies compared scleral measurements to corneal measurements obtained by pneumatonometry.

Our findings suggest that IOP measurements by pneumotonometer at scleral locations superotemporal and inferotemporal, may be an alternate method, other than digital palpation, to provide useful information about IOP in eyes in which cornea measurements cannot be obtained. The patients in our study purposely had no corneal pathology or prior ocular surgeries, but it is possible that the relationship between S-IOP and C-IOP measurements is different for those patients who do have corneal pathology. Future research into novel IOP measurement devices that do not rely on a clear native cornea will be helpful in managing glaucoma in patients with severe corneal disease or keratoprosthetic implants.

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