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Transpalpebral measurement of intraocular pressure with the Tono-Pen XL, in a young, healthy, adult population

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Abstract

Identification of increased intraocular pressure has been conventionally limited by direct, corneal applanation, and indentation measurement procedures, conducted by highly trained eye-care specialists e.g. optometrists and ophthalmologists. This practice greatly limits the numbers of individuals which can and need to be screened, for increased intraocular pressures. Increased intraocular pressure is the second leading cause of preventable, irreversible blindness throughout the world and a major modifiable risk factor for the development and progression of glaucoma. Current screening practices are inadequate, leaving many undetected, resulting in high base-rates of unnecessary and preventable blindness worldwide. Three primary research questions are investigated: Can intraocular pressures be measured through the eyelid, using the Tono-Pen XL tonometer? If yes, can the transpalpebral values be transformed to approximate corneal values? If yes, are the transformed values sufficiently precise, accurate, and reliable to substitute for intraocular pressure values measured directly from the cornea, for screening purposes?. Ninety (n = 90), healthy, young, adults completed measurement of intraocular pressures, from each eye (n = 180 eyes), using the Tono-Pen XL tonometer. Intraocular pressures were measured directly from the cornea and then directly from the closed eyelid. Transpalpebral measurements were transformed by simple linear regression to estimate direct corneal measurements. Transformed values were assessed for accuracy, precision, reliability, and agreement with direct corneal measurements. Findings revealed high accuracy, precision, reliability, and agreement between direct corneal and transpalpebral measurements. Transformed transpalpebral measurements correctly classified 95% and 93% of subjects, within 4 mm Hg or less of direct corneal measurements, when intraocular pressures were measured from the right and left eyes, respectively. Intraocular pressures measured directly from the closed eyelid, using the Tono-Pen XL, can be linearly transformed, using simple linear regression, to estimate intraocular pressure values measured directly from the cornea with high agreement, precision, and reliability, in a healthy, young, adult population. Findings have implications for non-eye-care specialists e.g. primary care physicians, choosing to quickly, accurately, and reliably screen individuals for normal intraocular pressures, without the need to anesthetize the eyes or use expensive, office-bound. equipment.

Abbreviations: ANOVA = Analysis of Variance, ASTM = American Society for Testing and Materials, GAT = Goldmann applanation tonometry, ICC = intraclass correlation coefficient, IOP = intraocular pressure, LCD = liquid crystal display.

Keywords: corneal IOP measurement, Goldmann applanation tonometry, intraocular pressure, Tono-Pen, transpalpebral IOP measurement

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Informed written consent, in accordance with the latest version of the World Medical Association Declaration of Helsinki was obtained from each research subject, prior to participating in this study. The Informed Consent form and procedures were reviewed and approved by the Nova Southeastern University Institutional Review Board, May 19, 2023; IRB # 2023-236.

The authors have no conflicts of interest to disclose.

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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1. Introduction

1.1. Background/rationale

Identification of increased intraocular pressure (IOP) has been conventionally limited by direct, corneal applanation and indentation measurement procedures, conducted by highly trained eye-care specialists e.g. optometrists and ophthalmologists.[1] The procedures have changed very little over the past 70 years and continue to suffer from many limitations.[1–3] While primary care physicians routinely, competently assess, diagnosis, and treat many eye conditions, quantitative assessment of IOP is typically referred to the eye-care specialist.[4] Conventional measurement practices and procedures significantly and unnecessarily limit screening and assessment of IOP by primary care physicians and other non-eye-care specialists. Given current, modern digital technologies, coupled with new innovative measurement procedures, primary care physicians and other non-eye care specialists can now confidently contribute to the initial screening and routine reassessment of individuals at risk for increased IOP. The newer technologies and procedures offered in this study are not intended to replace conventional IOP screening by eye-care professionals but rather to complement conventional IOP screenings, especially when conventional screening is limited or unavailable.

High intraocular pressure is the second leading cause of preventable blindness throughout the world and a major modifiable risk factor for the development and progression of glaucoma.[5–13] Most patients suffering chronic high intraocular pressure fail to recognize the presence of high intraocular pressure, especially during the early stages, given the onset and progression is typically slow and painless.[12,14,15] Population-based studies estimate 50% to 94% of individuals with glaucoma go undiagnosed.[16–18] Undiagnosed high intraocular pressures produce permanent and irreversible blindness.[19–21] Current screening procedures and practices are inadequate.[22–25]

Identification of high intraocular pressure is especially problematic in underserved populations, residents of rural communities, and residents of developing countries worldwide. For example, within the United States, residents of low income and rural communities, individuals with limited financial resources or insurance coverage, lack of availability of eye-care specialists (optometrists and ophthalmologists) when referred by primary care physicians, and apprehension by many primary care physicians to measure IOP significantly contribute to failure to identify high intraocular pressures.[26–28] Special populations e.g. elderly, children, nursing home residents, movement disorder patients, individuals with specific physical limitations, and individuals unable to cooperate with conventional IOP procedures further contribute to the many who fail to be identified with high IOP. Residents of developing countries throughout the world are particularly challenged, where access to and availability of highly trained eye-care specialists e.g. ophthalmologists or optometrists is very limited or non-existent.[29–32] The absence of adequate intraocular pressure screening has resulted in a high prevalence of preventable blindness, especially in many underserved populations and developing countries throughout the world.[33–37]

Innovative, portable, quickly administered, reliable, accurate, relatively inexpensive, measurement of IOP is needed, which can be confidently performed by non-eye-care specialists e.g. primary care physicians, in the absence of expensive, non-portable, specialized equipment, and highly specialized training.

Transpalpebral measurement offers the potential to rapidly screen and identify individuals with high intraocular pressure, which may never have been identified through conventional assessment practices.

Conventional, quantitative IOP measurement made directly from the cornea has a relatively long history when compared to transpalpebral measurements. Introduction of the Goldmann applanation tonometry (GAT), approximately 70 years ago, continues to serve as the universally accepted gold standard against which all other tonometry is compared.[1,38] The GAT requires fixed, expensive, office-based equipment and the measurement and interpretation of measurements to be completed by a highly educated and highly trained eye-care professional e.g. optometrist or ophthalmologist.

The TonoPen XL, a lightweight, portable instrument, introduced into the eye-care community, approximately 38 years ago in 1987, offered an alternative, quantitative IOP measurement, made directly from the cornea.[39] The TonoPen XL eliminated several problematic issues associated with the GAT e.g. did not require fixed, expensive, office-based equipment, and eliminated subjectivity in GAT measurements.[40,41] However, the instrument failed to eliminate several issues shared in common with the GAT e.g. requires anesthetizing the eye prior to IOP measurement,[39] significant measurement error introduced due to variation in central corneal thickness (CCT)[42–44] or corneal shape,[45] and inability to make direct corneal IOP measurements in the presence of eye infections, unhealed corneal abrasions or ulcers, corneal scars, elevated astigmatisms, or recent corrective corneal surgery.[46]

A recent meta-analysis comparing GAT and TonoPen tonometry when IOP are conventionally measured directly from the cornea, revealed the 2 instruments generate similar IOP values, in healthy adults. TonoPen values were reported to be marginally higher than GAT values, but not clinically significantly higher. The point estimate for the summary effect size, using a random effects model, equaled −0.73 mm Hg.[3]

Transpalpebral measurements of IOP have a much shorter history and are much less extensively studied. Overall, there remains much debate, within the optometry and ophthalmology communities, about the clinical values of transpalpebral tonometers compared to corneal based tonometers. Two commercially available transpalpebral tonometers have been studied. The Diaton transpalpebral tonometer, first approved by the US Food and Drug Administration (FDA), approximately 19 years ago in 2006[47] and the more recently introduced Easyton transpalpebral tonometer, approved by the US Food and Drug Administration, approximately 5 years ago in 2019.[48]

Currently, there is a confused and incomplete professional literature as to whether transpalpebral measurement of IOP is sufficiently precise, accurate, and reliable to be routinely used for clinical screening or diagnostic purposes. Studies comparing the Diaton transpalpebral tonometer with the GAT have reported good agreement and reliability in healthy normal adults,[49–51] young healthy adults seeking transepithelial photorefractive keratectomy,[52] and glaucoma patietns,[49,50] while others have reported poor agreement and reliability in healthy normal adults,[53,54] unspecified patient populations presenting to a university hospital general ophthalmology clinic,[55] and glaucoma patients.[53,56,57] Studies comparing the Easton transpalpebral tonometer with the GAT have reported good agreeability and reliability,[58–61] while others have reported poor agreement.[62]

A recent systematic review and meta-analysis compared agreement and reliability of transpalpebral tonometers (TGDc-01 an older version of the Diaton tonometer, n = 14 studies; current version of the Diaton tonometer, n = 12 studies, and the new Easyton tonometer, n = 3 studies) with GAT.[63] In brief, the authors conclude GAT measurements are preferred over transpalpebral measurements; however, the authors remain optimistic regarding the potential use of the Easyton tonometer, during early detection and management of the glaucoma patient.[63]

The proposed transpalpebral procedure eliminates many of the limitations of direct corneal measurement e.g. requirement to anesthetize the eyes before measurements, measurement error introduced by variations in central corneal thicknesses, variation due to cornea shapes, contraindications of IOP measurement in the presence of eye infections, unhealed corneal abrasions or ulcers, corneal scars, elevated astigmatisms, or recent corrective corneal surgery, resistance by many elderly and children to

cooperate in conventional corneal measurements, and physical limitations imposed by movement disorder patients.

More than 150,000 TonoPen XL have been sold worldwide and routinely used by clinical eye-care professionals to measure IOP directly from the cornea. Demonstration of accurate and reliable transpalpebral measurements, using the same instrument, eliminates many of the problematic limitations of direct corneal measurements. Clinicians worldwide, currently in possession of the instrument and pending the findings of this and future studies, may soon be able to measure IOP directly from the cornea and the closed eyelid with confidence. The ability to measure IOP transpalpebrally without additional financial expenditures for additional equipment and instruments has clinical implications, especially in rural communities throughout the world, where access to specialized eye care professionals is limited or simply unavailable. Transpalpebral measurement of IOP by primary care physicians and other health care providers should contribute to identifying many more individuals worldwide with increased IOP, which go unnecessarily undetected and consequently reducing the numbers of individuals developing preventable blindness.

This study is unique. No other individual or group has ever reported or to our knowledge ever attempted to measure IOP through the eyelid, using the same clinical instrument, specifically designed to measure IOP directly from the cornea.

The purpose of this study is to evaluate the potential use of the TonoPen XL, originally designed to measure IOP directly from the cornea, to measure IOP indirectly through the closed eyelid, in an effort to mitigate the many limitations of direct corneal IOP measurements.

1.2. Objectives

This study investigates the use of transpalpebral measurement of IOP as an alternative to conventional, direct, corneal, applanation measurements, in a healthy, young adult population.

Three primary research questions are to be answered:

1. Can intraocular pressures be measured through the eyelid, using the Tono-Pen XL tonometer?
2. Can intraocular pressures measured through the eyelid be transformed, using simple linear regression analyses, to approximate intraocular pressure values, measured by conventional, direct, corneal applanation measurements?
3. Are intraocular pressures measured through the eyelid, using the Tono-Pen XL, when transformed using simple linear regression analyses, sufficiently precise, accurate, and reliable to substitute for IOP values measured directly from the cornea, when measured values are within normal limits, 10 to 21 mg Hg?

2. Materials and methods

2.1. Instrument

Reichert Tono-Pen XL tonometer[64] is a battery powered, portable, accurate, easy to use, lightweight device used to measure intraocular pressure (IOP) directly from the cornea. The instrument uses principles of indentation and applanation, utilizing a solid-state strain gauge to convert IOP into an electrical signal. Using microchip technology, each touch to the anesthetized cornea is stored and analyzed. When 4 valid readings are obtained, the instrument averages the 4 measurements and displays the results on a liquid crystal display (LCD) with the associated standard deviation for the 4 averaged measurements. The Tono-Pen XL is calibrated for clinical measurement of IOP, when measured directly from the anesthetized cornea, with the following ranges and variability in accuracy: 5 to 27 mm Hg ± 2 mm Hg; 28 to 80 mm Hg ± 5 mm Hg. Since its introduction into the eye-care market, in 1987 over 37 years ago,[65] Tono-Pen XL values have consistently correlated strongly with Goldmann applanation tonometry values.[3]

2.2. Study design

A balanced, two-factor, repeated measures, experimental research design was used. Factor one, EYE, was fixed and contained two-levels, right and left. Factor two, LOCATION of MEASUREMENT, was fixed and contained two-levels, corneal and transpalpebral.

2.3. Setting

Nova Southeastern University, Kiran C. Patel College of Allopathic Medicine and Nova Southeastern University, Eye Care Institute, College of Optometry, located in Fort Lauderdale, Florida, USA. All intraocular pressure measurements were made during the period September 20, 2023 through December 12, 2023, weekdays, between 12:00 PM and 3:00 PM. Intraocular pressure measurements were collected in conventionally equipped physical and optometry examination rooms.

2.4. Participants

Physically healthy students, 18 years of age or older, currently enrolled in Nova Southeastern University Health Professions Division programs, allopathic medicine, osteopathic medicine, optometry, and pharmacy were recruited by way of announcement flyers, classroom announcements by faculty, and personal contact by one of the 3 allopathic program medical student investigators. Participation was purely voluntary with no financial compensation or academic credit incentive provided for participation.

2.5. Variables

There was one dependent variable, intraocular pressure measured in mm Hg. There were 2 independent variables; EYE with 2 levels, right and left and LOCATION of MEASUREMENT with two-levels, corneal and transpalpebral. Nine subject variables were collected: age, sex, race, health professions program enrolled, history of eye surgery, vision correction with glasses or contact lenses, known allergies, overall assessments of eye health, and general physical health.

2.6. Procedures

Potential research subjects responding to recruitment flyer announcements contacted one of the 3 allopathic medical students or one of the 2 faculty investigators by university email. Potential subjects were contacted by return email, provided with exact copies of informed consent forms and authorization forms for release and sharing of medical information, a brief written blurb summarizing the purpose of the study, and opportunity to discuss the study and procedures with faculty and/or student investigators. Upon completion of preliminary evaluation and eligibility screening, appointments were set for measurement of IOP.

Upon arrival for IOP measurements, research subjects were again explained the purpose of the study, procedures to be used, reiterated participation in the study was strictly voluntary, with no compensation, and without any direct benefit to the subject from participating in the study, the subject could withdraw from the study without consequence at any time and without need to provide any reason to discontinue participation in the study. Informed consent and authorization for release of medical information forms were reviewed with the subject by the student or faculty investigator and signed by

the subject and investigator. Informed consent forms included contact information for student investigators, faculty Principal Investigator, and faculty Co-Investigator, in the event the subject had additional questions or concerns regarding their participation in the study or need to report any unanticipated outcomes resulting from the measurement session. Each subject was given an exact copy of the signed informed consent and authorization for release of medical information forms. All subjects' questions were answered prior to initiating IOP measurements. Total time to complete the informed consent process, collect relevant subject variable information, complete IOP measurements, and answer subject questions was approximately 30 minutes.

Prior to each IOP measurement from each individual subject, the Tono-Pen XL tonometer was calibrated in accordance with the instrument's manufacturer's instructions. The instrument was wiped clean with a sterilized, 70% isopropyl alcohol prep pad. A new, Reichert Ocu-Film Tip cover was securely fitted to the instrument's transducer assembly, ensuring the cover was properly seated and not too tight or too loose.

Investigator(s) making the IOP measurements wore ASTM Level 3 surgical masks and latex examination gloves.

The medical student investigator or faculty investigator reviewed relevant eye health history then physically examined both eyes for signs of any pathology, which might affect the measurement of IOP. Eye examinations and IOP measurements, conducted by allopathic medical student investigators, were supervised by faculty investigators (W.J.K. or P.H.) present during the eye examination and IOP measurements. All 4 student investigators completed approximately 4 hours of instruction and supervised training by a faculty investigator (W.J.K.), prior to conducting eye examinations and IOP measurements.

Intraocular pressure measurements were initiated by placing the subject in a sitting, upright position. One to 2 drops of topical anesthetic proparacaine hydrochloride 0.5% ophthalmic solution, was administered to the corneal surface of each eye. Approximately 15 seconds later the subject was instructed to look straight ahead at a fixed target, with both eyes fully opened, and IOP measurements were initiated.

First, IOP was measured directly from the cornea, in accordance with the usual and customary procedure recommended by the Tono-Pen XL tonometer User's Guide,[38] by gently and momentarily tapping the corneal surface with the tip of the transducer assembly. Measurements were taken from the central cornea with the Tono-Pen XL held at 90-degree angle, perpendicular to the central cornea surface. Only light monetary contact with the corneal surface was required to register a valid measurement. Indentation of the cornea was not required. A chirp sound from the instrument was heard, each time a valid measurement was detected by the tonometer. After four (4) valid measurements a final beep from the tonometer sounded and the average of the 4 valid measurements appeared on the LCD along with a signal bar denoting statistical reliability. Statistical reliability was set at < 10% criterion to accept the 4 measurements, as a valid measurement. The averaged valid measurement was then recorded. The process was repeated 4 more times, for a total of 5 trials, with each of the averaged 4 valid measurements constituting a single trial. The process was performed on the right eye and then the left eye.

Second, IOP was measured indirectly from the eyelid, by gently and momentarily tapping the eyelid with the tip of the transducer assembly. Subjects were instructed to close both eyes, look straight ahead, and imagine focusing on a fixed target. Measurements were taken from the center of the eyelid, at the approximate intersection of the central vertical and horizonal axis lines, approximately above the central cornea and again with the Tono-Pen XL held at 90-degree angle, perpendicular to the central cornea surface. Only light monetary contact with the eyelid surface was required to register a valid measurement. A chirp sound from the instrument was heard, each time a valid measurement was detected by the tonometer. After four (4) valid measurements a final beep from the tonometer sounded and the average of the 4 valid measurements appeared on the LCD along with a signal bar denoting statistical reliability. Statistical reliability was set at < 10% criterion to accept the 4 measurements, as a valid measurement. The averaged valid measurement was then recorded. The process was repeated 4 more times, for a total of 5 trials, with each of the averaged 4 valid measurements constituting a single trial. The process was performed on the right eye and then the left eye.

Intraocular pressures were measured from each subject, each eye, and under each of the 4 experimental conditions. The experimental conditions were right eye-corneal; right eye-transpalpebral, left eye-corneal, left eye-transpalpebral. Five measurements trials were made, under each of the 4 conditions. The 5 measurement trials, within each experimental condition were then averaged, resulting in a single, averaged IOP value for each of the 4 experimental conditions, for each subject. Separate, averaged IOP values were then entered into the study's master database, for each subject, for each of the 4 experimental conditions.

Upon completion of all IOP measurements, subjects were asked to report any eye pain or discomfort and provided an opportunity to ask questions regarding the study.

2.7. Bias

In efforts to minimize variability in IOP measurements, subjects were intentionally limited to young adults, in good to excellent physical health, with no reported history, or evidence of eye disease or injury at the time of IOP measurements, restricted time of day for IOP measurements, and all IOP measurements made with the subject in a standardized sitting position. All other sources of potential bias e.g. subject self-selection, volunteer participation, eye-lid thickness, central corneal thickness (CCT), variability in level of training of individuals making IOP measurements e.g. medical student, board certified licensed optometrist, were allowed to vary randomly.

2.8. Study size

The number of subjects recruited for this study was determined a priori by setting power = .80, alpha = .05, assuming a small to moderate effect size, applying Cohen's recommended criteria $r = 0.10$ small effect, $r = 0.30$ medium effect, $r = 0.50$ large effect, and considering preliminary pilot data collected elsewhere, suggesting a small to moderate effect size (W. J. Keller, Ph.D., unpublished data, 2021). The calculated number of subjects required to meet the a-prior power criteria was n = 85.

2.9. Statistical methods

Subject variables age, sex, race, health professions program currently enrolled, and overall health status are summarized by descriptive statistics, means, standard deviations, and counts.

The balanced, two-factor, repeated measures, experimental research design was evaluated by a 2-way Analysis of Variance (ANOVA) for repeated measures. Alpha was set at.05 (two-tail) for the overall model, with planned post hoc comparisons alpha levels adjusted using Bonferroni corrections. Paired *t* tests for dependent groups were used to assess mean differences between levels of each factor.

Simple linear regression was used to describe the zero-order correlation between IOP measurements collected directly from the cornea and from the eyelid, for each eye separately. Simple linear regression was used to calculate estimates of IOP measured directly from the cornea, from IOP measurements measured from the eyelid, for each eye separately.

Analysis of each regression model's residuals further assessed precision, reliability, and clinical relevance of estimated corneal IOP values, generated from the prediction models, when corneal IOP were predicted from transpalpebral measurements. The percentage of corneal IOP values correctly predicted within 0 to 1 mm Hg, 1 to 2 mm Hg, 2 to 3 mm Hg, 3 to 4 mm Hg, 4 to 5 mm Hg limits and cumulative percentages are reported for the right eye and left eye separately.

A Bland-Altman plot displays agreement between IOP measurements collected directly from the cornea and IOP measurements collected indirectly through the closed eyelid. A second Bland-Altman plot displays agreement between IOP measured directly from the cornea and estimated corneal measurement values generated from the regression models. Upper and lower levels of agreement were set at 1.96 × SD.

Reliability between direct corneal measurement and transpalpebral measurements was further assessed by calculating intraclass correlation coefficients for measurements collected from the right eye, left eye, and right and left eyes combined.

ANOVA evaluated variability in direct corneal and transpalpebral IOP measurements collected by the 4 student investigators and one board certified licensed optometrist. A-prior planned contrasts followed the assessment of the overall model, setting type-I error rates at 0.05 (two-tail) and adjusting for multiple comparisons using the Bonferroni correction method.

2.10. Statistical software

All statistical analyses were performed using Microsoft Excel for Microsoft 365 MSO (Version 2401 Build 16.0.17231.20236) 64-bit with Analysis ToolPak add-in; "Beagle Scouts," The R Foundation for Statistical Computing; and RStudio 2023.06.1 Build 524 "Mountain Hydrangea" Release (547dcf86, 2023-07-07) for Windows, Posit Software, PBC.

3. Results

3.1. Participants

Descriptive summary statistics for the sampled study population: Subjects, n = 90; Eyes, n = 180; Age (years), mean 25.38 (SD 3.46); Sex, males n = 44, females n = 46; Race, White n = 45, Asian n = 20, Multi-racial n = 13, Hispanic n = 10, Black n = 2; Health Professions Program, Allopathic medicine n = 69, Optometry n = 19, Pharmacy n = 1, Osteopathic medicine n = 1. Self- reported current health status, excellent n = 71, good n = 19.

3.2. Main results

Two-way ANOVA with repeated measures revealed no statistically significant interaction between IOP measured from the eyes (right, left) and location of the IOP measurements (cornea, eyelid) $F_{1,356} = 0.24$, $P = .62$. There was no statistically significant difference between the eyes from which the IOP were measured $F_{1,356} = 0.03$, $P = .84$. There was a statistically significant difference between the location from which the IOP were measured (cornea, eyelid) $F_{1,356} = 1\ 02{,}897$, $P < .001$. See Table 1 for means and standard deviations, measured in mm Hg, for IOP measured directly from the cornea and indirectly through the eyelid (transpalpebrally), from the right eye, left eye, and both eyes combined. See Figure 1 for Bland-Altman plot with 1.96 * SD upper and lower levels of agreement, for IOP measured directly from the cornea and indirectly through the closed eyelid.

Simple linear regression revealed a statistically significant positive association between IOP measured indirectly from the eyelid and IOP measured directly from the cornea. Specifically, for the right eye, $R = .33$, $F_{1,88} = 10.90$, $P = .001$ and for the left eye, $R = .30$, $F_{1,88} = 8.73$, $P = .004$. Corneal intraocular pressures, estimated by regression, computed from transpalpebral

Table 1

Means and standard deviations, in mm Hg for TonoPen XL intraocular pressure measured directly from the cornea, TonoPen XL intraocular pressure measured directly through the eyelid, and estimated corneal TonoPen XL intraocular pressure when estimated from TonoPen XL transpalpebral measurements, using the reported regression equations.

	Mean (SD)		
Location of measurement	**Right eye (n = 90)**	**Left eye (n = 90)**	**Right + left eyes (n = 90)**
Corneal measurement values	15.5 (2.5)	15.3 (2.3)	15.4 (2.4)
Transpalpebral measurement values	85.0 (1.5)	85.1 (1.8)	85.1 (1.6)
Estimated corneal measurement values from regression equations	15.4 (0.7)	15.4 (0.8)	15.4 (0.7)

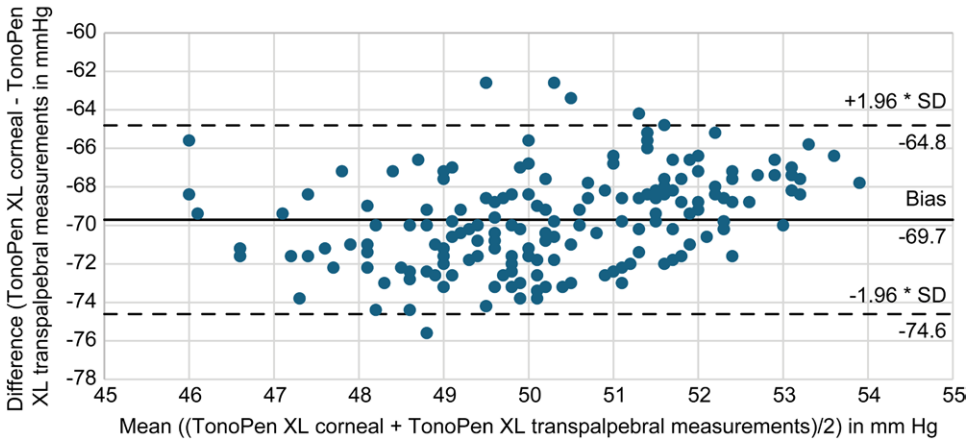

Figure 1. Bland-Altman plot comparing TonoPen XL direct corneal and transpalpebral intraocular pressures, measured in mm Hg.

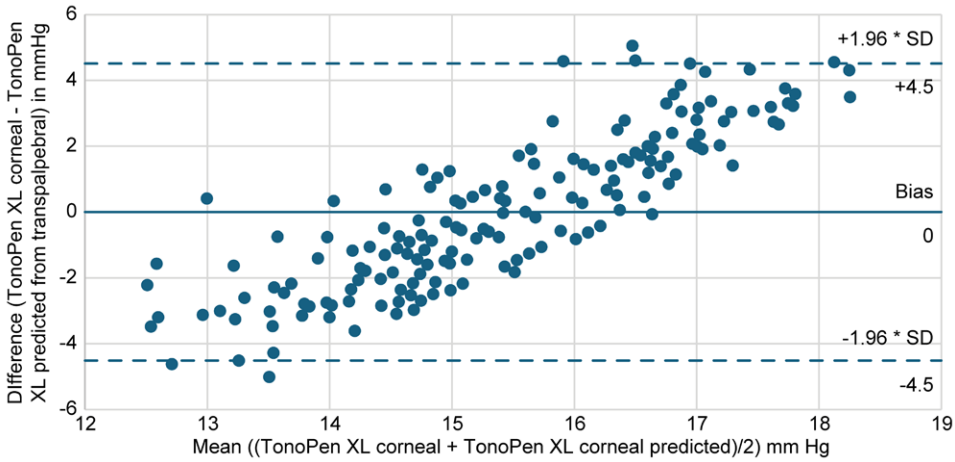

Figure 2. Bland-Altman plot comparing TonoPen XL direct corneal and predicted corneal intraocular pressures, when predicted corneal intraocular pressure values were estimated by way of simple linear regression from transpalpebral pressures.

Table 2

Precision of estimated corneal intraocular pressures, when measured from the eyelid and converted using the reported regression equations, for the Right and Left eyes.

Precision	n = 90	Percentage	Cumulative %
Right eye			
0–1 mm Hg	26	29	29
1–2 mm Hg	23	26	55
2–3 mm Hg	21	23	78
3–4 mm Hg	15	17	95
4–5 mm Hg	5	5	100
Left eye			
0–1 mm Hg	28	31	31
1–2 mm Hg	24	28	59
2–3 mm Hg	22	24	83
3–4 mm Hg	9	10	93
4–5 mm Hg	7	7	100

measurements, revealed high agreement, precision, and reliability with IOP measured directly from the cornea. See Table 1 for means and standard deviations, measured in mm Hg, for corneal IOP estimated from transpalpebral measurements, from the right eye, left eye, and both eyes. See Figure 2 for Bland-Altman plot with 1.96 * SD upper and lower levels of agreement, for corneal IOP estimated by regression, compared to IOP measured directly from the cornea.

Intraocular pressure measured indirectly through the closed eyelid, predicted IOP measured directly from the cornea, with high agreement, precision, and reliability. Specifically, for the right eye, $\hat{y} = -32.1082 + 0.5594x$ correctly classified 95% of IOP measurements made through the eyelid, within 4 mm Hg or less of the IOP measurements made directly from the cornea. See Table 2. Specifically, for the left eye, $\hat{y} = -17.8527 + 0.3898x$ correctly classified 93% of IOP measurements made through the eyelid, within 4 mm Hg or less of the IOP measurements made directly from the cornea. See Table 2.

Reliability, as measured by intraclass correlation coefficients (ICC), revealed high reliability between direct corneal and transpalpebral measurement of IOP, when measured by the TonoPen XL tonometer. Specifically, the intraclass correlation coefficients (ICC = (MSB – MSW)/MSB + (k – 1) * MSW), calculated for reliability between the 2 measurement procedures were 0.99 for the right eye, 0.99 for the left eye, and 0.99 for the left and right eyes combined.

Comparisons between student investigators and board-certified licensed optometrist revealed no statistically significant difference in the IOP measured directly from the cornea. Specifically, from the right eye $F_{4,85} = 1.35$, $P = .25$ or from the left eye $F_{4,85} = 1.53$, $P = .20$.

Comparisons between student investigators and board-certified licensed optometrist did reveal a statistically significant difference in the IOP measured from the closed eyelid. Specifically, from the right eye $F_{4,85} = 3.14$, $P = .02$. Inspection of planned contrasts revealed the difference was only between student investigators 2 and 4, $t_{32} = 3.51$, $P = .001$. There was no statistical difference between any of the 4 student investigators and the board-certified licensed optometrist. Comparisons from the left eye, also revealed a statistically significant difference between examiners, $F_{4,85} = 4.72$, $P = .001$. Inspection of planned contrasts revealed the only statistically significant difference observed was between student investigator 1 and the board-certified licensed optometrist, $t_{32} = 5.60$, $P = .001$. While the difference was statistically significant, the difference was not clinically significant, with a mean difference of 2.1 mm Hg.

See Table 3 for means and standard deviations for each student investigator and board-certified licensed optometrist, for direct corneal measurements, transpalpebral measurements, and estimated corneal measurements computed from transpalpebral measurements, using reported regression equations for the right eye, left eye, and both eyes combined.

4. Discussion

4.1. Key results

Findings indicate IOP measured directly from the eyelid can be linearly transformed, using simple linear regression models, to generate IOP values which approximate IOP values measured directly from the cornea, with high agreement, precision, and reliability.

Findings are consistent with studies reporting good agreement and reliability between direct corneal IOP measurements and transpalpebral measurements[49,52,58–62] and inconsistent with studies reporting poor agreement and reliability between direct corneal IOP measurements and transpalpebral measurements.[53,57,62] Inconsistencies between studies can be explained in part by variabilities in subject populations studied e.g. healthy subjects, eye pathologies, failure to adequately control or account for additional subject variables such as age, central corneal thickness, corneal shape, statistical methods used to analyze data, level of training and skill of individuals making IOP measurements, and the patients' ability to tolerate and cooperate with measurements of IOP.

Inspection of Figure 1 Bland-Altman plot, comparing TonoPen XL direct corneal IOP measurements with TonoPen

Table 3

Means and standard deviations in mm Hg, for each student investigator and licensed board-certified optometrist, when intraocular pressures were measured directly from the cornea, directly from the eyelid, and when transpalpebral measurements were converted into estimated corneal measurements using the reported regression equations.

	Mean (SD)		
Examiner	**Right eye (n = 90)**	**Left eye (n = 90)**	**Right + left eyes (n = 180)**
Corneal measurement values			
Student investigator 1	15.8 (3.0)	15.8 (2.4)	15.8 (2.7)
Student investigator 2	15.5 (1.8)	14.9 (2.7)	15.2 (2.0)
Student investigator 3	16.0 (2.4)	16.0 (2.4)	16.5 (2.4)
Student investigator 4	15.7 (2.9)	15.5 (2.4)	15.6 (2.6)
Licensed optometrist	14.4 (2.0)	14.4 (2.0)	14.4 (2.0)
Transpalpebral measurement values			
Student investigator 1	85.8 (1.6)	86.1 (1.0)	85.9 (1.3)
Student investigator 2	86.0 (1.2)	85.1 (1.8)	86.0 (1.5)
Student investigator 3	85.4 (1.3)	85.0 (2.2)	85.1 (1.8)
Student investigator 4	84.5 (1.3)	85.5 (1.7)	85.0 (1.6)
Licensed optometrist	86.0 (1.6)	84.0 (1.4)	84.8 (1.8)
Estimated corneal measurement values			
Student investigator 1	16.1 (0.6)	15.7 (0.4)	15.9 (0.6)
Student investigator 2	15.6 (0.6)	15.3 (0.7)	15.5 (0.2)
Student investigator 3	15.2 (0.8)	15.2 (0.9)	15.2 (0.9)
Student investigator 4	15.5 (0.8)	15.6 (0.6)	15.6 (0.7)
Licensed optometrist	14.9 (0.7)	14.8 (0.5)	14.9 (0.6)

XL transpalpebral IOP measurements revealed a significant mean difference bias, with the transpalpebral measurements being significantly larger than corneal measurements. This was anticipated, given the density of the additional tissues between the outside of the eyelid and the surface of the cornea. Notice the absence of systematic proportional bias.

Inspection of Figure 2 Bland Altman plot, comparing TonoPen XL direct corneal measurements with estimated corneal measurements generated from the regression of transpalpebral measurements onto direct corneal measurements reveals no statistically significant mean bias with presence of systematic proportional bias. This too was anticipated and is the result of how regression weights are generated. What is most important here is not that there is no mean difference bias between the 2 measurement procedures or that there is significant systematic proportional bias, but rather the procedure generates highly agreeable, reliable, precise, and accurate estimates of direct corneal measurements, without having to make direct corneal measurements. The capability to measure IOP directly from the cornea or indirectly through the eyelid with the same instrument (Tono-Pen XL) opens new opportunities, for non-eye-care specialists e.g. primary care physicians, to screen and monitor changes in IOP particularly in high-risk and underserved populations when access to eye-care specialists e.g. optometrists or ophthalmologists is limited or simply unavailable.

The capability of measuring IOP transpalpebrally eliminates the need to anesthetize the cornea, can be used when direct contact with the cornea is contraindicated e.g. communicable eye diseases, infections, cornea edema, cornea abrasions,[1,66,67] and can be completed quickly and without the need for expensive, office bound, fixed, specialized equipment e.g. slit lamp or Goldmann applanation tonometer. Given the Tono-Pen XL is light weight (2.1 oz), portable, and battery powered, measurements can be made almost anywhere e.g. primary care physician's office, patient's home, nursing homes and without the need for electricity e.g. rural medical clinics in developing countries.

Analysis of the agreement and reliability of IOP measurements collected by the medical student investigators and board-certified licensed optometrist revealed, with proper instruction and supervised practice, measurement of IOP by previously untrained support personnel can be made with high accuracy, agreement, and reliability, using the TonoPen XL to make direct corneal and transpalpebral measurements. These findings provide support for the potential use of properly trained support personnel, in measurement of IOP for widescale screening purposes, especially when conventional screening by highly educated and highly educated eye-care professionals is unavailable.

There is an immediate global need for greater access to IOP measurements and especially a need for large scale screening of at-risk glaucoma patients, particularly in rural, underserved areas of the world.[10,29,68–71] There is a need for accurate, reliable alternatives to direct corneal measurement, when direct corneal measurement of IOP is unavailable or contraindicated.[63,72] Transpalpebral measurements potentially provide a much needed, immediate solution and can potentially assist in reducing the current, unmet global burden, which if left unmet, results in unnecessary, preventable blindness.

Providing primary care physicians with an affordable, portable, accurate, reliable IOP measurement instrument, which can make corneal or transpalpebral measurements easily and quickly, should greatly increase the number of people screened for increased IOP. Early identification of individuals evidencing increased IOP can be referred to an appropriate eye-care specialist for further assessment and treatment. Intraocular pressure screening by primary care physicians and other health care professionals can potentially reduce the number of individuals never identified by current IOP screening practices and consequently reduce the number of individuals who suffer unnecessarily from preventable blindness.

This study is first to investigate the relationship between IOP measured directly from the cornea and through the eyelid, using the Tono-Pen XL tonometer.

In brief, the 3 specific research questions are answered:

1. Can IOP be measured through the eyelid, using the Tono-Pen XL? Yes.
2. Can IOP be measured through the eyelid be transformed, using simple linear regression analyses to approximate IOP values, measured by conventional, direct, corneal applanation measurements? Yes.
3. Are IOP measured through the eyelid, using the Tono-Pen XL, when transformed using simple linear regression analyses, sufficiently precise, accurate, and reliable to substitute for IOP values measured directly from the cornea, when measured values are within normal limits, 10 - 21 mg Hg? Yes.

4.2. Limitations

This study intentionally limited the research subject population to healthy, young adults, with expected IOP to be within the normal range (10–21 mm Hg). Given the Tono-Pen XL was originally designed and marketed to measure IOP directly from an anesthetized cornea, it was necessary to establish the instrument's capability to measure pressures transpalpebrally and evaluate the precision, accuracy, and reliability of estimated corneal IOP values, when measurements were made through the eyelid.

Given this study was designed, in part to assess the capability of making transpalpebral measurements with an instrument designed for corneal measurements, no patient populations e.g. glaucoma, ocular hypertension, specific medications and more were included. It is still unknown if the findings from this study are generalizable to patient populations, presenting with increased IOP. What is indicated by the present study is that the instrument can measure IOP through the eyelid, as well as directly from the cornea, with high accuracy, precision, and reliability in a healthy, young adult population when IOP are within the normal range of 10 to 21 mm Hg.

Inherent in any measurement instrument is variability in measurement explained by the physical limits of the measurement instrument itself. Measuring IOP transpalpebrally with the Tono-Pen XL presses the upper measurement limits of the instrument and contributes to the observed variability in transpalpebral measured values.

5. Conclusions

Intraocular pressures measured directly from the eyelid, using the Tono-Pen XL, can be linearly transformed, using simple linear regression, to estimate IOP values measured directly from the cornea with high agreement, precision, and reliability, in a young, healthy adult population. Findings have implications for non-eye-care specialists e.g. primary care physicians, choosing to quickly and reliably screen individuals for normal intraocular pressures.

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