Reichert
Ophthalmic Instruments

TONO-PEN® XL

Applanation Tonometer

Clinical Findings

TONO-PEN
Applanation Tonometer
I. Tono-Pen vs. Goldmann

A. Clinical Evaluation of the Oculab Tono-Pen

Don S. Minckler MD, George Baerveldt MD,
Dale K. Heuer MD, Beth Quillen-Thomas BSc, A. Frances Walonker DBO, John Weiner DrPH

American Journal of Ophthalmology 104:168-173, August 1987

"The Tono-Pen measurements in this clinical study were considered sufficiently consistent and accurate when compared to the Goldmann tonometer to be clinically accurate."

"... the difference was not clinically relevant and was within the difference often noted between serial Goldmann readings (that is, 1.7mm Hg)."

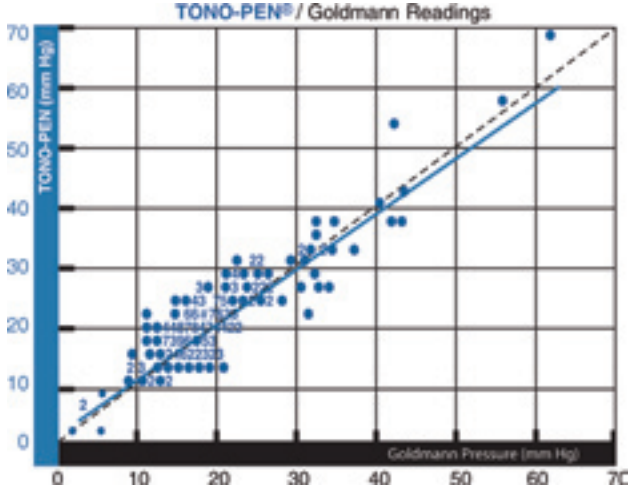

Fig.1 Scattergram and regression lines comparing Goldmann measurements (broken line) to Tono-Pen measurements (solid line). Points with overlapping data are denoted by single digit numbers.

"#" = Greater than 10 datapoints. **● = Single data point.**

I. Tono-Pen vs. Goldmann (Continued)

B. Comparison of the Tono-Pen to the Goldmann Applanation Tonometer

Ronald E. P. Frenkel MD, Young J. Hong MD, Dong H. Shin MD PhD

Arch Ophthalmol 1988;106:750-753

"We conclude that the Tono-Pen measures intraocular pressure in a manner that corresponds well to the Goldmann tonometer in the 11 to 20 mm Hg interval, and fairly well in the 4 to 10 mm Hg and 21 to 30 mm Hg intervals."

"It is especially useful for those with ocular or systemic infections, for hospital rounds, out of the office, in the operating room, and for patients whose physique is incompatible with the slit lamp."

C. Clinical comparison of the Oculab Tono-Pen to the Goldmann applanation tonometer

SF Kao, PR Lichter, TJ Bergstrom, S Rowe, DC Musch

Ophthalmology 1987 Dec;94(12):1541-4

"Each Tono-Pen showed high correlation with the Goldmann readings."

"…the Tono-Pen appears adequate for screening programs where an IOP of 21 mm Hg or above is considered abnormal; however at higher IOPs (greater than or equal to 30 mm Hg) the Tono-Pens tended to underestimate Goldmann IOPs."

D. Factors Affecting The Accuracy of IOP Measurement In Ocular Hypertension and Glaucoma

Weldon W. Haw MD

Ocular Surgery News, June 15, 2004

"A Tono-Pen is a lightweight portable device with a small diameter tip that is easy to use. This small diameter tip can negate confounding corneal parameters that adversely affect Goldmann applanation tonometry."

I. Tono-Pen vs. Goldmann (Continued)

E. Clinical comparison of the measurement of the IOP with the ocular blood flow tonometer, the Tono-Pen XL and the Goldmann applanation tonometer.

M Bafa, I Lambrinakis, M Dayan, M Birch

Acta Ophthalmol Scand 2001 Feb;79(1):15-8

"There was not any statistically significant difference between the measurements of all three tonometers."

F. The Tono-Pen - an accurate instrument for the measurement of the intraocular pressure

Joel M. Reisman MD, Olga C. Reisman COT

Second International Ophthalmologic conference in China, July 4-8, 1995 Beijing China

"The Tono-Pen in this study proved to be as accurate as the Haag Streit applanation for taking intraocular pressures."

"These correlation coefficients ($p<.001$) suggest a high degree of consistency between the pressures observed using the Tono-Pen applanation compared with the Goldmann applanation."

"We found no clinically significant difference between the Tono-Pen applanation and the Goldmann applanation."

"We find that the Tono-Pen is an accurate method of applanation and can be used in all clinical situations with results as consistent as the Goldmann applanation done by the slit lamp. In addition the Tono-Pen has particular advantages for screenings and bedridden patients where a slit lamp is not available or possible."

II. Tono-Pen vs. Manometry Standard

A. Comparative Tonometric Measurements of Eye Bank Eyes

Alan D. Mendelsohn MD, Richard K. Forster MD, Sara Mendelsohn MD, Jay J. Dennis MD, David G. Heidemann MD, Ira K. Levine MD, Jean-Marie Parel Ing ETS-G, J. Michael Di Maio MD

Cornea 6(3): 219-225, 1987

"A comparison was made of the accuracy of the Tono-Pen, Pneumatonometer, and Perkins hand-held tonometers by measuring the hydrostatically controlled intraocular pressure from 10 to 50 mm Hg in human eye bank eyes…The Tono-Pen displayed the least deviation from the controlled pressure over the entire range studied."

"At all five manometric levels, the Tono-Pen demonstrated the smallest variance from the ideal or set values."

"Over the entire range of IOP studied there were no statistically significant differences in the Tono-Pen measurements."

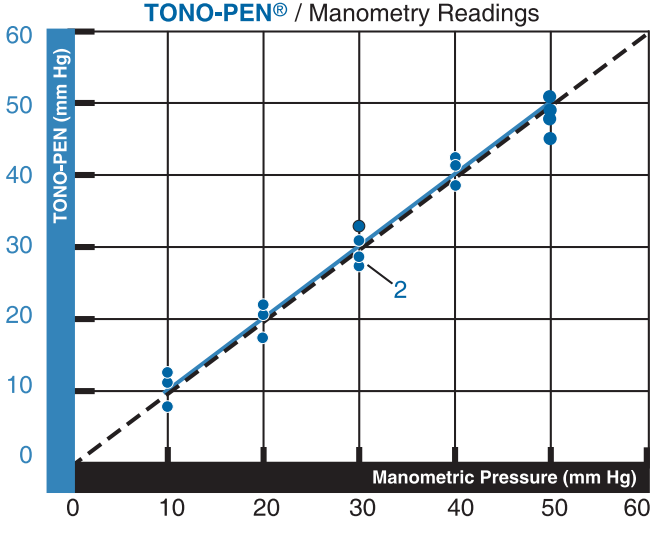

Fig.2 Scattergram and regression lines comparing manometric measurements (broken line) to Tono-Pen measurements (solid line). **● = Single data point.**

II. Tono-Pen vs. Manometry Standard

(Continued)

B. The Tono-Pen: A Manometric and Clinical Study

William A. Boothe MD, David A. Lee MD,
William C. Panek MD, Thomas H. Pettit MD

Arch Ophthalmol Vol 106, Sept 1988

"In the clinical study, no statistically significant difference was found between the Tono-Pen and the applanation tonometer at pressures of 10 to 35 mm Hg (the extent of the data spread)."

"The results obtained with Tono-Pen showed no significant difference ($p>.11$) from those obtained with applanation tonometry at pressures of 10 to 35 mm Hg in the clinical study."

"The accuracy of the Tono-Pen used was practically identical to the Goldmann applanation tonometer in the clinical study."

“The Tono-Pen has many features that make it attractive: compactness and portability, easy calibration and usability, capacity for use on abnormal corneas, a digital readout that minimizes user bias and disposable probe covers that prevent contamination from patient to patient.”

C. Comparison of intraocular pressure measurements with the Oculab Tono-Pen vs manometry in humans shortly after death

V Hessemer, R Rossler, KW Jacobi

Am J Ophthalmol 1988 Jun 15;105(6):678-82

"The correlation coefficient of the relation of Tono-Pen readings vs manometrically determined intraocular pressure was .99."

"In our experience the correspondence between Tono-Pen and manometer readings was superior to the correspondence between the readings obtained with the original Mackay Marg tonometer and manometry."

III. Tono-Pen and Corneal Thickness

A. Effects of Corneal Thickness on Intraocular Pressure Measurements with the Pneumatonometer, Goldmann Applanation Tonometer, and Tono-Pen

Archana Bhan, Andrew C. Browning, Sunil Shah, Robin Hamilton, Dinesh Dave, Harminder S. Dua

Investigative Ophthalmology and Visual Science 2002;43:1389-1392

"The Tono-Pen is least affected by CCT when used to measure IOP in eyes with normal corneas."

B. Factors affecting the accuracy of IOP measurement in ocular hypertension and glaucoma

Weldon W. Haw, MD

Ocular Surgery News Monograph, June 15, 2004

"A Tono-Pen is a lightweight portable device with a small diameter tip that is easy to use. This small diameter tip can negate confounding corneal parameters that adversely affect Goldmann applanation tonometry."

IV. Tono-Pen After Corneal/Refractive Surgery

A. Measuring IOP after LASIK

David Zadok MD

Review of Ophthalmology, June 2001

"...the mean IOP as measured by Goldmann tonometry was 1.8 ± 3.1 mm Hg lower than that measured by a Tono-Pen."

"...in eyes receiving steroids after surgery, the average pressures as measured by Goldmann tonometry were 2.2 ± 1.3 mm Hg lower than those measured with a Tono-Pen. Compared to their fellow eyes, the IOP of steroid-treated eyes was an average 4.3 ± 3 mm Hg higher when measured with the Tono-Pen, but only 2.3 ± 3.5 mm Hg higher when Goldmann tonometry was used. This raises the question as to whether measuring post-LASIK IOP with Goldmann actually masks steroid induced pressure increases."

"A device such as the Tono-Pen may be less affected by corneal changes after refractive surgery as a result of how it works."

"For the time being, to check IOP in a LASIK patient postop, the Tono-Pen may be the accurate way to do it."

B. Impact of LASIK on Goldmann Applanation Tonometry and Tono-Pen measurements

Anson T. Miedel MD, Barry N Wasserman, MD

2004 ASCRS Poster Presentation

"Peripheral Tono-Pen measurement and peripheral corneal thickness are not affected by LASIK."

"Peripheral Tono-Pen readings can be used to approximate pre-op central GAT."

IV. Tono-Pen After Corneal/Refractive Surgery (Continued)

C. Effects of Refractive Surgery on Early Glaucoma Detection

Marc R. Bloomenstein OD FAAO

Optometric Management, May 2002

"This tonometer only uses a 1.5-mm diameter head as compared to the 3.03 mm diameter of the GAT. This smaller applanation diameter allows the Tono-Pen to be less affected by corneal surface and curvature changes and therefore more accurate than the GAT."

"...you can use it outside the central cornea and away from the effects of keratorefractive surgery."

D. Tono-Pen versus Goldmann tonometry after excimer laser photorefractive keratectomy

Yair Levy MD, David Zadok MD, Yoseph Glovinsky MD, David Krakowski MD, Pinhas Nemet MD

J Cataract Refract Surg-Vol 25, April 1999

"In post-PRK eyes, mean GAT IOP was 1.8 ± 3.1 mm Hg lower than mean Tono-Pen IOP."

"In steroid-treated post-PRK eyes, mean GAT IOP was 2.2 ± 1.3 mm Hg lower than mean Tono-Pen IOP."

"…our findings indicate that the Tono-Pen is probably superior to GAT in measuring IOP after PRK. The Tono-Pen seems to be less affected by the indicated changes in the central cornea, and it appears to be a more reliable detector of steroid-induced IOP elevation in post-PRK patients."

"In conclusion, IOP measurement in post-PRK eyes appears to be more accurate with the Tono-Pen than with GAT. Moreover, the Tono-Pen may better disclose steroid-induced IOP elevations that can occur in post-PRK patients, preventing a delay in recognition and treatment of glaucoma in these patients."

IV. Tono-Pen After Corneal/Refractive Surgery (Continued)

E. Intraocular pressure and photorefractive keratectomy - a comparison of three different tonometers

Hanna J. Garzozi MD, Hak S. Chung MD PhD,
Yaron Lang MD, Larry Kagemann MS BME,
Alon Harris PhD

Cornea 2001 Jan;20(1):33-6

"Tono-Pen temporal periphery postoperative IOP measurements had the best correlation with preoperative GAT IOP…PRK reduced IOP reading as measured by GAT, noncontact tonometer, and Tono-Pen central; less so when measured by Tono-Pen temporal periphery."

"Early detection of glaucoma and IOP follow up in glaucoma patients may be done best by peripheral Tono-Pen measurements over the nonablated cornea."

"We found that peripheral measurements by Tono-Pen are the most accurate and correlate best to the preoperative measurements. We conclude that follow-up of IOP in PRK-operated patients is more accurate by Tono-Pen peripheral corneal measurements."

IV. Tono-Pen After Corneal/Refractive Surgery (Continued)

F. Effect of corneal thickness on the accuracy of intraocular pressure measurement in rabbits after excimer laser photoablation

Jason Stahl MD, Steven Vold MD

J Cataract Refract Surg-Vol 26, May 2000

"Photoablation of approximately 20% of the CCT in rabbits by excimer laser PTK did not significantly alter the accuracy of IOP measurements by the Tono-Pen or pneumatonometer."

"For measurements made with the Tono-Pen, there was no statistical difference in measurement error between the operated and control eyes."

"The findings for the measurements done with the pneumatonometer were similar to those with the Tono-Pen. There was no difference in measurement error between the two eyes."

"Our results using control and operated eyes reveal that removing approximately 20% of the CCT in rabbit eyes did not result in significantly less accurate measurements with the Tono-Pen or pneumatonometer."

V. Tono-Pen use with Scarred or Irregular Corneas

A. The Tono-Pen XL- a tonometer suitable for measurement of common and less common conditions associated with intraocular pressure

A. Filous, M. Burdova, J. Malec

Cesk Slov Oftalmol 1998 May;54(3):159-65

"The unique advantage of Tono-Pen as compared with all other methods of routine tonometry is the relatively accurate assessment of the IOP under irregular conditions of the cornea."

B. Accuracy and precision of the Tono-Pen in measuring intraocular pressure after keratoplasty and epikeratophakia and in scarred corneas

DS Rootman, MS Insler, HW Thompson,
J Parelman, D Poland, SR Unterman

Arch Ophthalmol 1988 Dec; 106(12):1697-700

"Intraocular pressure measurements with the Goldmann and Schiotz tonometers are unreliable when the cornea is irregular due to disease or surgery. The Tono-Pen is an electronic applanation tonometer based on the same principle as the MacKay-Marg tonometer."

"The data suggest that the Tono-Pen is as accurate as the MacKay-Marg tonometer in those situations where the Goldmann tonometer is inaccurate."

VI. Tono-Pen use with Contact Lenses

A. Intraocular Pressure Measurement With the Tono-Pen Through Soft Contact Lenses

William C. Panek MD, William A. Boothe MD, David A. Lee MD, Eve Zemplenyi MD, Thomas H. Pettit MD

Am J Ophthalmol 1990 Jan 109:62-65

"There was no significant difference in the Tono-Pen measurement of intraocular pressure over a plano-T contact lens compared with no lens."

"Measurement of intraocular pressure with the Tono-Pen was not significantly altered by the presence of a plano-T lens in either the manometric or clinical study."

"This study indicates that the Tono-Pen may also be reliable in this setting. In patients wearing bandage soft contact lenses, intraocular pressure can be accurately and reliably measured without disturbing the lens and underlying corneal epithelium."

B. The effects of therapeutic contact lenses on intraocular pressure measurement

GD Scibilia, WH Ehlers, PC Donshik

CLAO J 1996 Oct;22(4):262-5

"Both Tono-Pen and pneumatonometry proved to be equally reliable in recording accurate IOP measurements through therapeutic contact lenses."

C. Tono-Pen estimation of intraocular pressure through bandage contact lenses

JA Khan, BA LaGreca

Am J Ophthalmol 1989 Oct 15:108(4):422-5

"Our results suggest that the Tono-Pen is probably an effective way to estimate intraocular pressure through bandage contact lenses."

VII. Tono-Pen in Pediatrics

A. Tonometry in pediatric patients: a comparative study among Tono-Pen, Perkins, and Schiotz tonometers.

AF Bordon, O Katsumi, T Hirose

J Pediatr Ophthalmol Strabismus 1995 Nov-Dec;32(6):373-7

"We concluded that the Tono-Pen tonometer has a higher correlation coefficient, comparable to the Perkins tonometer, and can be used reliably to assess IOP in pediatric patients."

B. IOP in children during examination with the Tono-Pen

Fernando José Caride MD, Dante Manuel Dolzani MD

Ocular Surgery News, Vol. 16, No. 20, Oct. 1998

"The Tono-Pen has made it possible to obtain the IOPs of almost every child who comes for eye examination, including premature infants. Considering this, we can say that the Tono-Pen is as accurate as the hand-held applanation type."

"The Tono-Pen has definitely proved to be a safe, practical and useful method to survey and monitor IOP in children."

C. Comparison of Tono-Pen and Perkins Tonometry in Children without Glaucoma

Kim Cooper MD, Alex V. Levin MD, Mary Chipman

1995 AAPOS Poster Presentation

"This study indicates that the Tono-Pen may be a superior instrument in the accurate assessment of intraocular pressure in children as compared to the Perkins tonometer."

VIII. Tono-Pen in Oil and Gas Filled Eyes

A. A clinical comparison of the Tono-Pen with the Goldmann applanation tonometer in eyes filled with silicone oil

DV Alfaro, VT Tran

Retina 1991;11(2):219-20

"Intraocular pressure in 21 eyes filled with silicone oil was measured with two different instruments: the Tono-Pen and a Goldmann applanation tonometer…the mean difference between readings obtained from the two instruments was 0.64, which was not statistically significant. These results suggest that the Tono-Pen is an effective instrument with which to measure intraocular pressure in silicone-filled eye."

B. Oculab Tono-Pen, Goldmann Applanation Tonometry, and Pneumatic Tonometry for Intraocular Pressure Assessment in Gas-Filled Eyes

Michael W. Hines MD, Bradley F. Jost MD, Karen L. Fogleman RN

American Journal of Ophthalmology 106:174-179, August 1988

"Measurements made by using the Tono-Pen were accurate when compared to those made by Goldmann tonometry. In a subset of eyes with increased intraocular pressure (>25 mm Hg), the Tono-Pen provided measurements similar to those made by Goldmann applanation tonometry."

"We found the Tono-Pen to be satisfactory when compared to Goldmann tonometry in measuring intraocular pressure in gas-filled eyes."

"…we found that the Tono-Pen could be used in eyes in which it was not possible to use Goldmann applanation tonometry (eyes with marked eyelid swelling or nystagmus). We also believe the Tono-Pen may play a valuable role in measuring the intraocular pressure of eyes in which accurate Goldmann applanation tonometry is not possible because of corneal edema and bullous keratopathy."

IX. Model 30 Classic™ Pneumatonometer

A. The effect of Corneal Anatomical Indices on Measurements of Intraocular Pressure by Applanation Tonometry, Pneumatonometer, and Tono-Pen in Patients with Open-Angle Glaucoma

M.A. Latina MD, V. Gulati MD

2003 ARVO Poster Presentation

"Over the entire population, measurement of IOP by pneumatonometer was the least affected by CCT."

B. Pneumatonometry versus Goldmann tonometry after laser in situ keratomileusis for myopia

David Zadok MD, Dan B. Tran MD, Michael Twa OD, Miriam Carpenter MD, David J. Schanzlin MD

J Cataract Refract Surg-Vol 25, October 1999

"Postoperatively, there was a decrease in IOP measured by central GAT that was statistically significant. Differences in pneumatonometry were less substantial, with greater reliability of pneumatonometry than GAT after LASIK."

"In conclusion, our study suggests that in comparison to GAT, pneumatonometric measurements are probably less affected by the flattening and thinning of the central cornea that occurs after LASIK."

IX. Model 30 Classic Pneumatonometer

(continued)

C. A Manometric Evaluation of Pneumatonometry, Applanation, and Tono-Pen In Vitro and In Vivo

Dan L. Eisenberg MD, Brian G. Sherman MD, Craig A. McKeown MD, Joel S. Schuman MD

Ophthalmology Vol 105, Number 7 Jul 1998

"The pneumatonometer performed the best clinically and the best overall."

"Pneumatonometry estimates were not affected by patient age and came closest to manometric IOP."

"Based on our findings, we recommend the use of the pneumatonometer in individuals in any age group, especially for the diagnosis and management of pediatric glaucoma."

X. Tono-Pen and Intracranial Pressure

A. The Relationship of Intraocular Pressure to Intracranial Pressure

Matthew K. Lashutka MD, Abhinav Chandra MD, Holt N. Murray MD, Gary S Phillips MAS, Brian C. Hiestand MD

Annals of Emergency Medicine May 2004 43:5

"Abnormal intraocular pressure as measured with the handheld tonometer is an excellent indicator of abnormal intracranial pressure in patients with known intracranial pathology."

Reichert, Inc.
3362 Walden Ave.
Depew, NY 14043 USA
Internet: www.reichert.com
Toll free: (800) TONO-PEN
Tel: (716) 686-4500
Fax: (716) 686-4545

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