

Introduction

Goldmann Applanation Tonometry (GAT) has been used as the international gold standard for measuring intraocular pressure (IOP) for many years now. Ophthalmologists measure IOP in routine exams to diagnose and manage several ocular diseases, such as glaucoma. GAT quantifies IOP using a standardized approach that measures the necessary force to flatten a corneal area of about 3.06 mm diameter. However, GAT has limited accuracy and cannot account for the variability in central corneal thickness, curvature, biomechanics. Recently, a newer device, the Falck Multifunctional Device (FMD, Falck Medical, CT, USA), has been approved by the FDA for tonometry. FMD's method of acquiring IOP through digital light and pressure contact sensor can account for moisture, capillary, and corneal elasticity forces.

Purpose

This study was designed to compare intraocular pressure measurements taken using Goldmann applanation tonometry with those obtained by the Falck Multifunctional Device to evaluate their respective accuracy and reliability.



Falck Medical Applanation Tonometer 1 for slit-lamp on the right, wireless display with the different available modalities and results output on the left

Evaluation of Impact of Blood Pressure on the Measurement of Intraocular Pressure: Falck Multifunctional Device vs Goldmann Applanation Tonometry

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Methodology

For the GAT measurement, IOP was assessed three times at intervals of 30 seconds (Average IOP GAT) in each eye. Subsequently, Central Corneal Thickness (CCT) was measured using a pachymeter (Pachmate 2, DGH Technology, Exton, PA, USA). Following this, IOP measurements were taken serially with the FMD in each eye. The device calculated an average IOP for each eye (IOP FMD), which was accepted for analysis only if the calculated variability was less than 10%. Additionally, Ocular Pulse Amplitude (OPA), which is the difference in IOP between systolic and diastolic phases, was recorded.

IOP RESULTS		
Save		
	OD	OS
IOP(mmHg)	17.3	16.0
+/-(%)	6.70	4.50
OPA(mmHg)	3.20	3.20
	70	64
OD		OS

FMD results screen. IOP shown will be the average IOP taken upon the measurement interval, considering both systolic and diastolic measurements. (+/-) will be the percent variation amongst all measured IOPs. OPA is difference of the cardiac phases. N value displays the multiple serial measurements taken.

GAT Corrected for Corneal Thickness

Corrected IOP = Measured IOP – $(CCT - 545)/50 \times 2.5 \text{ mm}$

FMD IOP Corrected for Systolic IOP

Diastolic $IOP = (FMAT IOP) - (.5 \times OPA)$

Notably, GAT measures IOP predominantly during diastole. Therefore, to correct for systolic contributions, half of the OPA value was subtracted from the IOP FMD (Corrected IOP FMD).



FMD IOP applanation from a single patient. IOP shows variation in time, showing IOP is dependent on the cardiac cycle. This variation is accounted for with OPA measurement.



FMD measuring OPA in a patient. Display shows OPA of both eyes (green/OD and blue/OS). Average OPA amongst study population was 3.0 mmHg with standard deviation of 0.21.

The mean average IOP GAT was 15.2 mm Hg, with a mean CCT of 561.4 μ m. In contrast, the mean corrected IOP FMD was found to be 16.3 mm Hg. This resulted in a significant difference of 1.1 mm Hg, with the Corrected IOP FMD being higher (p-value = 0.029). When corrected for CCT variations, the Mean Average IOP GAT adjusted to 14.4 mm Hg, leading to a discrepancy of 1.9 mm Hg (p = 0.01).



Conclusion

The study reveals that GAT, which operates on the premise of measuring IOP on a very thin and elastic membrane during diastole, inherently harbors sources of variability. It fails to take into account factors such as capillary forces affecting the moist corneal surface and the elasticity of corneal tissue. Consequently, GAT consistently underestimates IOP when compared to FMD measurements. This underestimation persists even after adjustments for corneal thickness and the systolic portion of the cardiac cycle are accounted for. The FMD, on the other hand, includes an algorithm that compensates for corneal wetness, tissue elasticity, and systolic variation during the cardiac cycle, thus potentially offering a more accurate and reliable method for IOP measurement.

Future Direction

Recognizing the more accurate and reliable method of measuring IOP through FMD, we can begin to consider this measurement of IOP into evaluating other vital parameters in the ophthalmology clinic. This same device the serial tonometry method into its takes ophthalmodynamometry and tonography functions. These functions should be studied next.

References

Cook, J. A., Botello, A. P., Elders, A., Ali, A. F., Azuara-Blanco, A., Fraser, C., ... & Surveillance of Ocular Hypertension Study Group. (2012). Systematic review of the agreement of tonometers with Goldmann applanation tonometry. *Ophthalmology*, 119(8), 1552-1557.

Ehlers, N., Bramsen, T., & Sperling, S. (1975). Applanation tonometry and central corneal thickness. Acta *ophthalmologica*, *53*(1), 34-43. Whitacre, M. M., Stein, R. A., & Hassanein, K. (1993). The effect of corneal thickness on applanation

tonometry. American journal of ophthalmology, 115(5), 592-596. Bhan, A., Browning, A. C., Shah, S., Hamilton, R., Dave, D., & Dua, H. S. (2002). Effect of corneal thickness on

intraocular pressure measurements with the pneumotonometer, Goldmann applanation tonometer, and Tono-Pen. Investigative ophthalmology & visual science, 43(5), 1389-1392. Kotecha, A., White, E. T., Shewry, J. M., & Garway-Heath, D. F. (2005). The relative effects of corneal thickness

and age on Goldmann applanation tonometry and dynamic contour tonometry. British Journal of Ophthalmology, 89(12), 1572-1575.

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