Test retest variability of TonoPen AVIA

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The study was conducted to evaluate the intra-session repeatability of Tonopen AVIA (TPA). 180 eyes of 180 patients (50 eyes with glaucoma, 130 eyes of controls) were recruited for this observational study. The mean age of patients enrolled in the study was 43.9 ± 16.7 yrs (84 males, 96 females). Mean IOP recorded with Tonopen AVIA was 19.5 ± 9.5 mmHg, 19.4 ± 9.6 mmHg and 19.3 ± 9.2 mmHg, respectively in the first, second and third instances (P = 0.656). The intraclass correlation coefficient (ICC) ranged from 0.996 (95% CI: 0.956 - 0.998) for glaucoma subjects to 0.958 (95% CI: 0.934 - 0.975) for controls. The coefficient of variation in the study population ranged from 3.47% (glaucoma patients) to 8.10% (healthy controls), being 6.07% overall. The coefficient of repeatability varied between 2.96 (glaucoma patients), 3.35 (healthy controls) to 3.24 (overall). Thus, the Tonopen Avia shows good intrasessional repeatability of IOP in both glaucomatous patients and healthy subjects.

Key words: Glaucoma, intraocular pressure, tonopen

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Tonopen AVIA (TPA, Reichert Inc. NY, USA) utilizes an electronic micro strain gauge transducer and a digital microprocessor, which generates objective digital measurements from changes in voltage utilizing McKay-Marg principle to measure IOP.[1] It displays the average of 10 independent readings unlike its predecessor the TonoPen –XL, which takes 4 readings. This study was conducted to determine the intra-session test retest variability of TPA in glaucoma patients and normal subjects.

Material and Methods

This prospective observational study included 50 glaucoma patients and 130 controls attending the outpatient services of a tertiary eye care center. The study conformed to the ethical standards stated in the 2008 Declaration of Helsinki. An informed consent was obtained from all the participants before inclusion into the study.

All subjects underwent detailed ocular evaluation. Inclusion criteria were a best corrected visual acuity of ≥20/40, open anterior chamber angle, and absence of ocular pathology other than glaucoma. Exclusion criteria included ametropia ≥ ± 5 D, corneal astigmatism >2 D, corneal diseases, history of any intra-ocular surgery, and contact-lens wear.

The study participants were subjected to measurement of IOP by 2 instruments; Goldmann applanation tonometer (GAT) and TPA. The measurements were obtained by 2 examiners (GAT by SJB, TPA by SB), masked to the IOP readings obtained with the other instrument. The order of measurement was randomized. The repeated TPA measurements were performed

at an interval of 5 minutes.

Measurements from 1 eye were randomly selected for analysis. The data analysis was done using SPSS 16.00 (Chicago, Il.) and Stata version 9.1 (StataCorp., College Station, TX). 2-way ANOVA was used for comparison of the 3 readings obtained with TPA.

Results

The mean age of patients enrolled in the study was 43.9 ± 16.7 yrs (84 males, 96 females). The overall mean IOP recorded with TonoPen AVIA was 19.5 ± 9.5 mm Hg, 19.4 ± 9.6 mm Hg and 19.3 ± 9.2 mm Hg, respectively in the first, second and third instances (P = 0.656, Table 1).

The intraclass correlation coefficient (ICC) between the 3 readings of TPA ranged from 0.996 (95% CI: 0.956 - 0.998) in glaucoma group, to 0.956 (95% CI: 0.934 - 0.975) in healthy subjects. Table 2 shows the coefficient of variation and coefficient of repeatability values in the study population.

Fig. 1 shows the Bland Altman plot for the agreement between the GAT and mean TonoPen Avia readings. The 95% limits of agreement between the 2 tonometers were + 6.3 to - 6.9 mm Hg. The difference between the overall IOP readings (GAT-TPA) was ± 1 mm Hg in 18.74% subjects; ± 2 mm Hg in 51.12% subjects and ± 3 mm Hg in 85.2% subjects.

Discussion

TonoPen is a minimally invasive, portable, handheld device, which makes the IOP measurements on the Mackay Marg principle. While TonoPen XL gives an average of 4 applanation readings; a newer version, TonoPen Avia, takes an average of 10 IOP readings in a short time to give the measured IOP. The measurements are made with a sterile Ocu-film coated tonometer, and the instrument has a shorter learning curve. The limitations of the TPA include its high cost and requirement for a large quantity of sterile covers for the tonometric tip in busy clinical settings.

To our knowledge, no studies have been published regarding an accuracy of IOP measurement with TPA. Various authors have commented on the inter-instrument agreement and validity of the TonoPen and Tonopen XL and have found that the instruments are reliable and correlate well with Goldmann tonometry.[2-5] TonopenXL has been reported to overestimate low values and underestimate high values.[6] However, the intrasession test retest variability of the TonoPen remains an underreported issue.

In the present study, the repeated measurements of IOP with TPA during the same session showed excellent correlation in both glaucoma subjects and healthy controls (ICC >0.9). The analysis showed 95% of the second and third readings of TPA would be expected to fall within 3 - 3.4 mm Hg (coefficient of repeatability).

The test retest repeatability of various other tonometers has been reported. Ogbuehi *et al.* in 60 healthy eyes reported the 95% limits of agreement (LoA) for the Goldmann applanation tonometer (GAT) to be −2.54 to +2.94 mm Hg.[7] For Topcon CT80 non-contact tonometer (NCT), the LoA were reported to be −2.45 to +2.65 mm Hg.[7] Another study by the same authors included 72 healthy eyes for the measurement of IOP and showed the 95% LoA to be ± 3 mm Hg for both GAT and NCT (Keeler Pulsair EasyEye).[8]

Table 1: The mean IOP recordings in the three instances in glaucoma patients and healthy subjects

	Mean IOP (mm of Hg) Glaucoma subjects (N = 50)	Mean IOP (mm of Hg) Controls (N = 130)	Mean IOP (mm of Hg) Overall (N = 180)
TA 1	30.94 ± 10.50	15.05 ± 3.44	19.47 ± 9.47
TA 2	31.04 ± 10.59	14.92 ± 3.58	19.39 ± 9.61
TA 3	30.56 ± 10.11	15.05 ± 3.44	19.35 ± 9.23

TA 1: 1st reading with TonoPen Avia, TA 2: 2nd reading with TonoPen Avia, TA 3: 3rd reading with TonoPen Avia, IOP: Intraocular pressure

Table 2: Comparison of coefficient of repeatability, coefficient of variation and intrasession within subject standard deviation

	Overall mean (mm Hg)	Sw* (mm Hg)	Coefficient of Variation %	Coefficient of Repeatability
All subjects (N = 180)	19.40	1.17	6.07	3.24
Healthy subjects (N = 50)	15.0	1.21	8.10	3.35
Glaucoma patients (N = 130)	30.84	1.07	3.47	2.96

*Sw: Intrasession within subject standard deviation

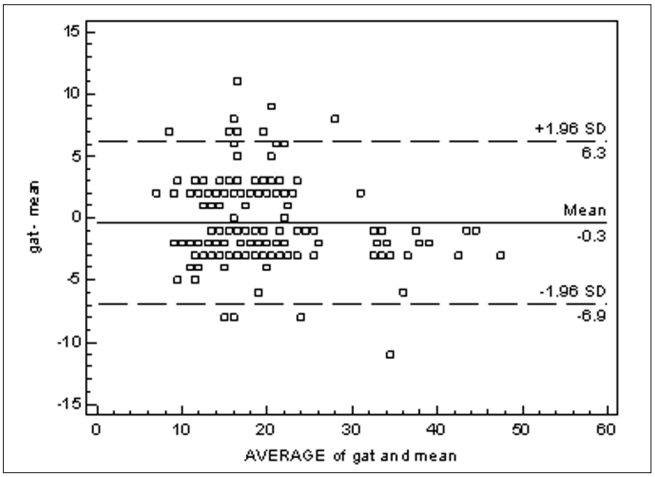

Figure 1: Bland Altman plot showing agreement between Goldmann applanation tonometer and TonoPen Avia

The strengths of our study are that we attempted to measure the intrasession variability of TonoPen Avia which, to our knowledge, has not been reported previously in literature. In order to eliminate an observer error, all measurements were performed by a single trained operator who was using the instrument over 3 months for IOP measurements in our outpatient services. To minimize the effect of a possible transient lowering of IOP following applanation of the cornea,

and to minimize any temporal variation in IOP, we repeated the measurement after an interval of 5 minutes.[8] However, there are a few limitations of our study. The first limitation was that inter-session and inter-observer variability of the instrument were not evaluated. Secondly, a similar test retest evaluation was not done for the GAT in our subjects, which could have been directly compared to the results within the same subset of patients. Also, we did not attempt to evaluate the effect of central corneal thickness on the IOP measurement by TonoPen Avia. As refractive error could have a possible influence on the accuracy of TonoPen Avia,[3] we tried to minimize the same by including patients with refractive error within ± 5 D. Thus, our results may not be applicable to subjects with higher degree of ametropias.

To conclude, the intrasession IOP measurements obtained with Tonopen AVIA show excellent correlation and reasonable test retest repeatability in both glaucoma subjects and in normal subjects. However, it may not be used interchangeably with Goldmann applanation tonometer due to the wide limits of agreement.

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