

Outcomes of the Icare Rebound Tonometer versus the Gold Standard Tonometer in Measuring Intraocular Pressure among Mzuzu University Students, Malawi

François Régis Twiringirimana^{1*}, Clémentine Kanazayire², Okyere Bright Vandyke³, Andrew Kanzunguze³, Reverien Rutayisire¹, Grace Ogbona³

¹*School of Health Sciences, College of Medicine and Health Sciences, University of Rwanda, Kigali, Rwanda*

²*School of Nursing and Midwifery, College of Medicine and Health Sciences, University of Rwanda, Kigali, Rwanda*

³*Faculty of Health Sciences, Mzuzu University, Mzuzu, Malawi*

***Corresponding author:** François Régis Twiringirimana. School of Health Sciences, College of Medicine and Health Sciences, University of Rwanda, Kigali, Rwanda. Email: twifraregis@gmail.com

Abstract

Introduction

The Goldmann Applanation Tonometer (GAT) is accepted as the gold standard tool to measure Intraocular Pressure (IOP). Besides, there is an emerging Icare Rebound Tonometer (RBT) which can be an alternative in terms of measuring IOP.

Objective

This research aimed to analyze the agreement, and repeatability of intraocular pressure (IOP) measurements and compare the outcomes of RBT and GAT among Mzuzu University Students in Malawi.

Methods

For this cross-sectional study, 107 participants aged 18 to 29 years underwent ophthalmic examination with three IOP measurements taken by two examiners using the RBT and the GAT.

Results

The RBT and GAT were found to have a strong correlation ($r=0.809$, $p>0.001$), with an intra-class correlation of 0.787 ($p>0.001$). The mean difference of IOP measured by the two machines was 1.99 ± 1.05 mmHg, which was statistically significant. However, according to Bland-Altman analysis, there was no agreement between the results given by the two machines, with a bias of -1.979 (CI -2.28 , -1.68 , $p > 0.001$). In terms of repeatability, GAT was found to be better than RBT, with a CR of 7.512 and 10.418 respectively.

Conclusion

The RBT and GAT can offer comparable IOP measures. Therefore, RBT can be recommended for community outreach programs where GAT cannot be employed.

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Introduction

Glaucoma is the second leading cause of blindness worldwide as it affects 2 to 3% of people over the age of 40 years. In developing countries, 90% of glaucoma patients are not yet diagnosed.[1] Glaucoma is the second most common cause of blindness among the population of 50 years and above in Malawi, with the prevalence of 15.8% .[2] Intra-ocular Pressure (IOP) measurement is the key in early detection, monitoring and the management of glaucoma and this warrants the need for robust and easy-to-use measuring instruments.[3]

Goldmann Applanation Tonometry (GAT) is generally considered as the gold standard for the measurement of IOP.[4] The Goldmann Applanation Tonometer (GAT) utilizes a small probe to gently flatten a section of the cornea to measure intraocular pressure, coupled with a slit lamp microscope for inspection of the eye. Pressure within the eye is determined by the quantity of force needed to flatten the cornea.

Due to the necessity of anesthesia, instillation of fluorescein and the use of slit lamp, the application of the GAT procedure for children and bedridden patients is limited, thus making it undesirable to patients due to its invasive nature.[5] The newly developed iCare Rebound Tonometer (RBT) calculates intraocular pressure (IOP) by measuring the motion parabolic variation generated in response to the probe striking the cornea. Compared to that, the RBT is more user friendly, convenient, less invasive and free from any other external equipment requirements.[6] Other studies however, suggest the need to ensure sufficient levels of agreement and reliability of the RBT to GAT in order to encourage its utility in developing countries. Therefore, the current study compared the RBT with the standard GAT in measuring IOP among Mzuzu University Students in Malawi

Methods

The study was carried out using cross-sectional research design at the Academic Vision Centre (AVC) of the Optometry Department in Mzuzu University, Malawi. It adhered to the Declaration of Helsinki principles and was approved by the Mzuzu University Research Ethics Committee with approval number FHSRC/opt/19/033. Data was collected from a sample of Mzuzu University students, after obtaining written informed consent from all participants.

All study participants underwent a comprehensive ophthalmological examination, which included an analysis of medical history, visual acuity measurement, slit-lamp bio-microscopy, fundoscopy, and measurement of intraocular pressure (IOP) using Goldman Applanation Tonometry (GAT) and Rebound Tonometry (RBT).

In order to collect data, two optometrists initially administered the RBT and GAT tonometry procedures three times each to both eyes of each participant, recording results immediately. The procedure began with the RBT and was followed by the GAT with an interval of ten minutes in between. The results for each participant's right and left eye were recorded separately, as were age and gender. A corneal fluorescein test was also conducted on each patient before and after the tonometry to ensure corneal integrity.

To measure IOP using RBT, the participant was instructed to sit, during which the plastic probe loaded rebound tonometer was positioned 4 to 8mm away from the eye before taking three readings from each eye. During GAT measurement, each participant was instructed to sit comfortably in a slit lamp chair and then a drop of Xylocaine 4% was applied in the inferior fornix. Following this, a fluorescein strip was placed on the precorneal tear film, and the tonometer probe was brought into contact with the cornea, with a cobalt blue light focused perpendicularly onto the probe, in order to record the readings.

The GAT probe was sterilized before and after every procedure for each participant.

The current study made use of SPSS 17.0 (Chicago, IL, USA) to conduct statistical analysis. Descriptive statistics were run to characterize the population based on age and gender. Correlations were run to test the association in IOP measurements between instruments (Pearsons' r) as well as reliability (Intra Class Correlation), Bland Altman test was run to determine the level of agreement between RBT and GAT, and Independent T-test (and the equivalent non-parametric Mann-Whitney U Test) was run to determine the significance of mean IOP readings between RBT and GAT. Tables and scatterplots were used to visualize the data following analyses.

Results

A total of 107 participants aged between 18-29 years (mean age 22.5 ± 4.8) were recruited for this study and 214 eyes were included in the data analysis. 61.7% (66) of the participants were male and 38.3% (41) were female. Based on the IOP values obtained, IOP measured by RBT and GAT were grouped into 7-16mmHg category, >16 to <23mmHg category and overall category for further comparisons.

The overall average IOP measurements using the RBT (15.78) were significantly higher (p<0.001) than those of GAT (13.79), with a mean difference of 1.99±1.05mmHg. Further comparison at different categories of IOP (Table 1) revealed that the difference was not significant at lower IOP levels (p=0.115) unlike at higher IOP levels (p=0.012), with higher IOP measurements still recorded when using the RBT.

Table 1. Comparison between IOP means for RBT and GAT across IOP categories

IOP Category	GAT	RBT	P-value
7<16	12.68±1.72 (167)	12.99±1.69 (118)	0.115
16<23	17.76±1.66 (47)	18.54±1.76 (86)	0.012
Overall	13.79±2.71 (214)	15.78±3.76 (214)	<0.001

NOTE: Data are "means ± SD (n)".

Correlational analysis revealed a highly significant and strong positive correlation (r=0.809, p<0.001) between both instruments across all IOP categories (Table 2) as illustrated in Figure 1.

Table 2. Correlation analysis outputs for IOP measurements by RBT and GAT

Category	N	Pearson r	p-value
All data	214	0.809	<0.001
7 < 16	117	0.561	<0.001
16 < 23	36	0.516	0.001

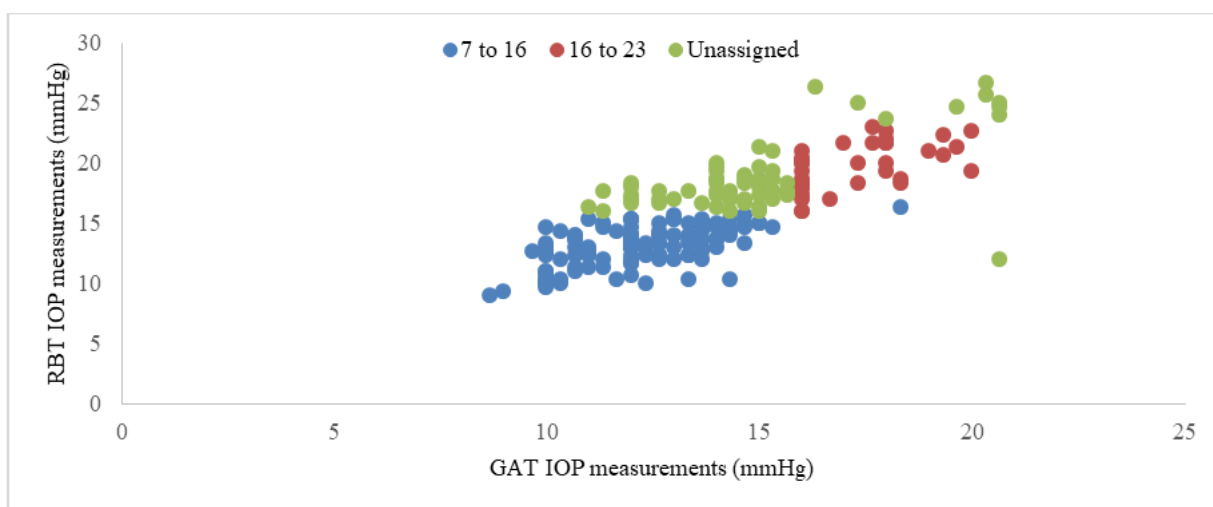


Figure 1. Association between RBT and GAT IOP measurements

Overall, the reliability of both RBT and GAT in measuring IOP was good (ICC=0.787), and less so for the segmented IOP categories as outlined in Table 3, even though the GAT produced better repeatability (CR=7.512) than the RBT (CR=10.418) for repeated measurements of IOP using both instruments.

Table 3. Intra-class correlation analysis results for RBT and GAT

Category	N	ICC	CI	Cronbach's Alpha	p-value
All data	214	0.787	[0.300, 0.905]	0.868	<0.001
7 < 16	117	0.654	[0.368, 0.795]	0.717	<0.001
16 < 23	36	0.414	[-0.219, 0.731]	0.652	0.001

Furthermore, it was also revealed that the RBT and GAT do not have a significant level of agreement as the mean difference between both instruments significantly deviated from 0 (p<0.001) in all categories of IOP measurement (Table 4). Figure 2 (Bland-altman plot) further illustrates the upper and lower limits for the level of agreement of the IOP measurements.

Table 4. Bland-Altman test results for level of agreement between RBT and GAT

Category	N	ICC	CI	Cronbach's Alpha	p-value
All data	214	0.787	[0.300, 0.905]	0.868	<0.001
7 < 16	117	0.654	[0.368, 0.795]	0.717	<0.001
16 < 23	36	0.414	[-0.219, 0.731]	0.652	0.001

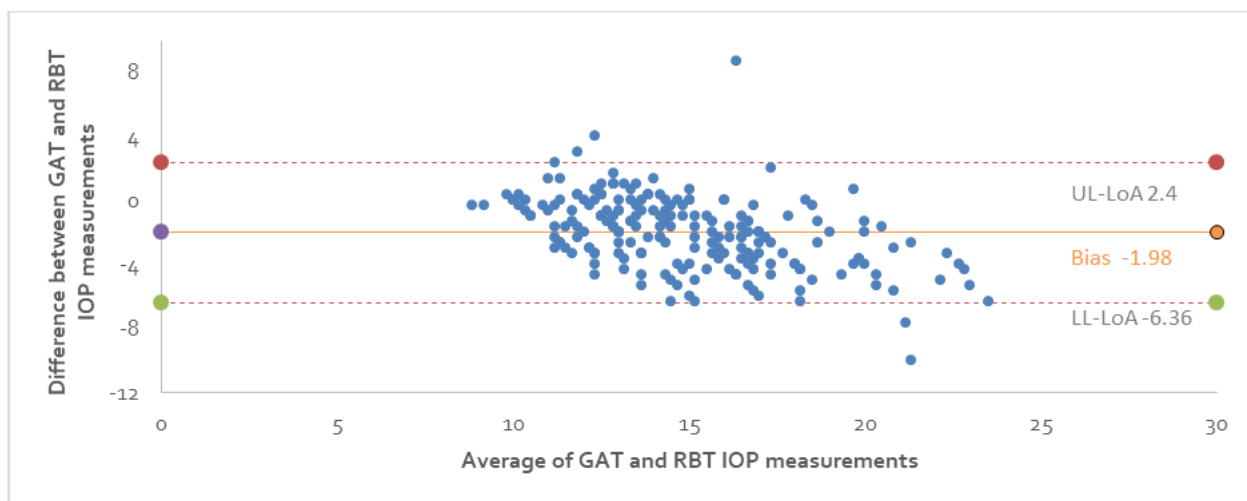


Figure 2. Bland-altman plot for RBT and GAT measurements of IOP

Discussion

Goldmann applanation tonometry is considered as the gold standard method employed by eye specialists to determine intraocular pressure in the clinical setting. It works by determining the force applied to flatten the cornea over a specified area. The greater the intraocular pressure, the more force required to flatten the cornea. [7] Despite the GAT being regarded as the benchmark in terms of IOP measurement, it has some drawbacks such as requiring a high amount of expertise to use, a slit lamp, topical anesthetic and electricity to function, thus making it difficult for rural areas without access to electricity to utilize it and during community outreaches.[8]

RBT offers a new, convenient alternative to traditional IOP measurement. This device is easy to use and more comfortable for patients, as it does not require topical anesthesia, or fluorescein. Furthermore, it can be used by non-eye trained personnel and in pediatric patients, thus overcoming the limitations of GAT. There is no need for a slit lamp and electricity hence makes it suitable for community screenings.[9-11] This research examined if the RBT approach would generate comparable results to the GAT approach among a youthful African population with regular cornea thickness.

The accuracy of RBT has been examined in numerous published studies, both in those with glaucoma and those who are healthy.

The results of this study showed that the mean IOP value determined by RBT was 1.99 ± 1.05 mmHg higher than the GAT mean IOP value, which was considerably significant ($P < 0.001$). This is in accord with findings from several other studies.[12,13] A comparison between RBT and GAT in a clinical setting revealed that RBT IOP measurement was higher than GAT reading in those with or without glaucoma, with an average difference of 1.92 ± 3.29 mmHg. [12] Fernandez et al,[13] research was comparable to the present study, which involved healthy eyes. The mean discrepancy of 1.34 ± 2.03 mmHg between the two tools demonstrates the overestimation of IOP by RBT in relation to GAT.[13] A different study on the contrary showed that the mean IOP readings were significantly lower when the RBT device was used compared to the GAT device when measuring normal eyes and eyes with primary open-angle glaucoma.[14]

In this study, Pearson correlation ($r=0.809$, $p>0.001$) revealed a strong positive correlation between RBT and GAT measurements, which was in agreement with a study done in Nigeria by Ashano et al.,[15] that reported a statistically significant r-value of 0.84 between RBT and GAT. Goa et al [16] also confirms a significant correlation between the two machines ($r=0.806$, $p>0.001$). Intra class correlation (ICC) was used to evaluate the reliability of RBT compared with GAT. This current research demonstrated a solid dependability (ICC=0.787) of RBT across all IOP readings compared to GAT; within the segment of IOP group ranging from 16 to 22 mmHg, it had a moderate reliability (ICC=0.414). This concurs with results of another study, except for the IOP group (17-22 mmHg), where they found a moderate reliability.[17]

Numerous investigations have employed Bland-Altman evaluation to investigate concurrence between RBT and GAT readings. Studies have revealed adequate agreement between the two. This study is in agreement with study [18] with respect to the mean and standard deviation of

the difference between the readings being 1.0 and 3.5 mm Hg respectively. Goa et al [16] reported strong agreement between RBT and GAT measurements, with their 95% CI of the difference being -5.80-6.24 mmHg and 78.3% of the differences having a value $\leq \pm 3$ mmHg, which is comparable to Iliev et al,[19] who also determined a 95% CI of -3.2-5.2 mm. In comparison, our research showed no significant agreement between RBT and GAT, with the mean difference being (bias = -1.979) and a 95% CI of -2.28 to -1.68. This agrees with the study of Dahlmann-Noor et al,[20] which reported similar results with a mean difference of bias = -3.34 at 95% CI -8.60 to 3.90.[20]

The comparison of the repeatability of both machines showed that GAT was superior in terms of repeatability. Our results were in agreement with the conclusions for which investigation of concordance and repeatability of RBT demonstrated that GAT had superior repeatability than RBT.[17] In addition, the study of Schweier et al,[21] also corroborated the notion that GAT had better repeatability and proposed that RBT should only be used in clinical settings when GAT is not an option.

Limitations

The sample size of our study was limited, featuring only subjects with close-to-normal Intraocular Pressure (IOP). To mitigate possible confounding effects on IOP measurements, individuals with high central corneal thickness, high astigmatism, glaucoma, or glaucoma suspects were excluded; yet further clinical agreement and repeatability can be examined in such patients in future studies.

Conclusion

The findings of the study illustrate that RBT can offer reliable and repeatable in low to moderate IOP readings in comparison to GAT and is therefore recommended for community outreach programs where GAT cannot be employed.

Authors' contribution

All contributed to the conception of the work, data analysis and interpretation of data, drafting the manuscript and revising final approval of the version to be published.

Conflict of interest

All authors affirm that there is no actual or potential conflict of interest including any financial, personal or other relationships.

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