COMPARISON OF BIOMETRIC PARAMETERS AND THE LEVEL OF AGREEMENT BETWEEN OB820 AND IOL MASTER

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ABSTRACT

Objective: Compare the axial length and other biometric parameters by two biometric devices. Compare their level of agreement for these parameters.
Study Design: Cross-sectional study.
Place and Duration of Study: Armed Forces Institute of Ophthalmology, from Jul 2016 to Apr 2018.
Methodology: Study was carried out in Armed forced institute of ophthalmology on 70 eyes of 53 patients with Nucleus sclerosis grade II, III cataract. Patients under went ophthalmic and biometric examination using optical biometery devices IOL-Master (Carl Zeiss) and OB-820 (Wave Light, Germany). Parameters included axial length, keratometric indices and anterior chamber depth. Results were evaluated using Bland Altman analyses for level of agreement, while differences were assessed using the paired samples t test, and correlation was evaluated by interclass correlation coefficient.
Results: Mean axial length assessed by OB820 and IOL Master differed significantly in two groups (23.16 ± 1.25 vs 23.53 ± 1.34), with a *p*-value of 0.018. Bland-Altman analysis confirmed significant difference among ranges and 95% limits of agreement for Axial Length with interclass correlation of 0.659. While for other parameters including Keratometery[1,2] and anterior chamber depth excellent correlation was found between IOL-master and OB-820 with interclass correlation of 0.960, 0.968 and 0.976 respectively.
Conclusion: IOL-master and OB-820 shouldn't be used interchangeably due to lack of agreement in axial length measurement which is infact the most important biometry parameter.

Keywords: Axial Length, IOL Master, Level of Agreement, OB 820.

INTRODUCTION

The advent of new technology in intraocular premium (IOL) design and sophisticated surgical techniques has increased the expectations of patients for optimal postoperative vision without residual refractive errors or refractive surprises. However, the accuracy in biometric measurements axial length (AL) and corneal powers-are crucial for the calculation of IOL power; consequently achievement of the desired postoperative refraction[1]. The accurate axial length measurement is of paramount importance in all modern formulas, as any discrepancy in its measurement of as low as 0.5mm can alter the desired IOL power by 1.5 dioptre. In conventional A-scan biometry, the reflection of a thin parallel sound beam is translated by the biometer into spikes as it strikes each interface in the eye. The height of the spikes is relevant to the strength of the reflecting echo and distance between the spikes is equivalent to the time needed by echo to travel between each interface[2,3]. However, it has high variability of measurements, partly owing to the fact that the probe has to be in contact with the corneal epithelium. Modern optical biometers employ principles of partial coherence interferometry (PCI) and optical low coherence reflectometry (OLCR) to measure biometric parameters addressing the limitations of A-scan biometry. Its function is based on Mickelson's interferometer, which produces interference fringes by splitting a beam of monochromatic light. The reflected beams from fixed mirror and other movable mirror are brought back together to forman

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interference pattern that is recieved by an appropriate detector[2-5].

ZEISS IOL-Master (Carl Zeiss Meditec, Jena, Germany) is a non-contact device that can determine the AXL of the eye with high precision and accuracy (± 0.01 mm in a measurement scale of 14-39 mm). It also measures anterior chamber depth (ACD) utilizing visual pachymetry and Keratometric data[6-9]. Wave Light OB-820 (Wave Light, Germany), is another non-contact PCI biometry device that used low coherence reflectometry for the very first time. It provides comprehensive measurements for AXL, central corneal thickness, ACD and crystalloid lens thickness analyzing 16 different measurements alongside the optic axis in a single scan[6,10]. Moreover, the built-in software in these devices besides providing more accurate IOL power calculation in routine and complicated cases, also offer multiple choices of IOL formulas. However, measurement scan is difficult or unreliable in the presence of ocular conditions with poor fixation (for PCI or OLCR based devices) e.g. corneal opacities, macular diseases and sub-capsular or advanced cataracts[4,5]. It is evident that both previously mentioned devices utilize trailblazing technology to calculate certain indexes that are integral in modern cataract surgery. However, level of agreement between these two devices in terms of axial length and keratometric data is less searched aspect. Minimal literature had published in this regard with controversial results, which demands other trials to validate their results[8-10]. Hence, the study analyzed the level of agreement of fundamental biometric parameters (AXL, ACD, keratometry) between IOL-Master and Wave Light OB-820 in nuclear seclrosis grade II and grade III cataract patients. The rationale of this study was to sort out the parameter that is effecting the biometric values and find the level of agreement in measurement of axial length by both biometric devices.

METHODOLOGY

This cross sectional study was carried out in Armed Forces Institute of Ophthalmology from July 2016 to April 2018 after approval from institute's ethical review committee (IERB no 198) written informed agreement was taken from all the participants.

Sample size for this study was calculated by using WHO online calculator for a two-tailed hypothesis, considering prevalence of nuclear sclerosis grade III cataract of 4.0% 10, 95% level of confidence and study power of 80%. 70 eyes of 53 patients between 46 to 80 years of age, with senile grade II and grade III cataracts were recruited on a consecutive if eligible basis from out-patient department. Non-probability convenience sampling technique was employed to enroll the patients. All consecutive patients of nuclear sclerosis grade III cataract undergoing comprehensive ophthalmic and biometric examination using the IOL-Master (Carl Zeiss Meditec, Jena, Germany) and OB-820 (Wave Light, Germany) were enrolled in the study. Exclusion criteria were prior or active corneal pathology, surgery, corneal edema/scarring, refractive procedure, transplant, diabetic macular edema, age-related macular degeneration, neurologic disorders that affect the neuroretina and the optic nerve.

The study parameters included: 1) AXL, 2) ACD, 3) K1 flat Keratometry, 4) K2 steep Keratometery. All eyes were evaluated for these parameters on both IOL master and OB 820. Data acquisition was performed in a consistent manner by the same operator. Preoperative data was obtained with the "phakic" setting on the software of the IOL-Master. Five measurements were taken for AXL calculation only if signal to noise ratio (SNR) was not less than 100. For OB-820, the AXL was measured by means of the patient's visual optical line. Sixteen point measurements in each eye were arranged in two rings for corneal thickness. The diameter of outer ring is 2.30 mm and the diameter of inner ring is 1.65 mm. The white-to-white distance is ascertained by photographing iris and combining with the keratometric values that represent an ideal circle's diameter. IOL calculation formulas that were originally derived from ultrasound

biometry uses an integrated conversion factor to measure Intraocular IOL power. Five valid measurements were considered mandatory to obtain pupil diameter.

All the data obtained from patients were entered into IBM SPSS (version 23.0). The continuous data was analyzed and reported as mean and standard deviation, whereas categorical data was analyzed and reported as frequencies and percentages. Normality of data was tested by constructing histograms with normal distribution curves and by applying Shapiro-Wilk statistical test. Comparison of various biometric parameters between OB820 and IOL Master technique was done by using paired samples t-test after checking the normality of data. The level of agreement between these two devices was calculated with Bland–Altman analysis. A *p*-value of ≤0.05 was reported and considered to be statistically significant. Reliability analysis for interclass consistency and reliability was done using interclass correlation coefficient (ICC) and Cronbach's alpha. An interclass correlation coefficient ICC of 0.8 and 0.9 was considered good and excellent in terms of reliability and interclass consistency respectively between the two devices.

RESULTS

A total of 53 patients were enrolled in the study with mean age of 62.97 ± 7.97 years (range 47-81). There were 28 males (52.8%) while 25 (47.2%) female study participants. Total number of eyes examined for biometric parameters were 70 for 53 patients, out of which 32 (45.7%) were right while 38 (54.3%) were left eyes.

Table-I: Shapiro-Wilk test for assessing normality of data.

Parameters	Mean ± SD	Shapiro-Wilk	
		Statistic	*p*-value
Master IOL Axial Length (AXL)	23.16 ± 1.25	0.939	0.002*
Master IOL K1	42.66 ± 1.40	0.959	0.023*
Master IOL K2	43.24 ± 1.71	0.981	0.353
Master IOL ACD	2.70 ± 0.36	0.987	0.660
OB820 Axial Length (AXL)	23.53 ± 1.34	0.976	0.192
OB820 K1	42.73 ± 1.46	0.979	0.300
OB820 K2	43.36 ± 1.72	0.979	0.304
OB820 ACD	2.73 ± 0.37	0.991	0.915

Shapiro-Wilk test; *significant *p*-values

Table-II: Comparison of biometric parameters between two groups.

Parameters	Biometric Device		Mean Difference	*p*-value
	IOL Master (n=70)	OB820 (n=70)		
Axial Length (AXL) (Mean ± SD)	23.16 ± 1.25	23.53 ± 1.34	-0.37	0.018*
K1 (Mean ± SD)	42.66 ± 1.40	42.73 ± 1.46	-0.071	0.29
K2 (Mean ± SD)	43.24 ± 1.71	43.36 ± 1.72	-0.11	0.11
ACD (Mean ± SD)	2.70 ± 0.36	2.73 ± 0.37	-0.02	0.09

Wilcoxon Singed-rank Test; *significant *p*-values

Table-III: Reliability analysis via Interclass Correlation Coefficient (ICC) for biometric parameters by IOL-Master and OB820.

Parameters	Cronbach's alpha	Inter-class Correlation	Confidence Interval	
			Lower Limit	Upper Limit
Axial Length (AL)	0.674	0.659	0.452	0.788
Keratometery1	0.960	0.960	0.936	0.975
Keratometery2	0.969	0.968	0.949	0.980
Anterior Chamber Depth	0.976	0.976	0.961	0.985

Majority of the data from biometric measurement variables (including Master IOL Keratometery 1 and 2, Master IOL anterior chamber, Master IOL axial length, OB820 keratometery 2, OB820 anterior chamber depth) was normally distributed, as the *p*-values were not significant (0.300, 0.304, 0.915, 0.192, 0.353 and 0.660 respectively) as shown in table-I. Therefore, paired samples t-test was applied to find any significant differences between two groups. It was observed that, mean axial length assessed by OB820 and IOL Master differed significantly in two groups (23.16 ± 1.25 vs 23.53 ± 1.34), with a *p*-value of 0.018. These results showed a probable inconsistency in limits of agreement for this parameter for which Bland-Altman analysis was run to further confirm the finding. In figure, bland altman plots show significant difference range and 95% limits of agreement for axial length measurement. While all other parameters including K1, K2 and ACD were same for both groups (42.66 ± 1.4 vs 42.73 ± 1.46, 43.24 ± 1.7 vs 43.36 ± 1.7, and 2.70 ± 0.36 vs 2.73 ± 0.37 respectively) and their means were not found to be significantly different in two groups (*p*=0.29, *p*= 0.11, and *p*=0.09 respectively) as shown in table-II. Bland Altman analysis was also performed for K1, K2 and ACD presented level of agreement range within 95% confidence interval, which sho wed excellent agreement between two techniques (table-II & III).

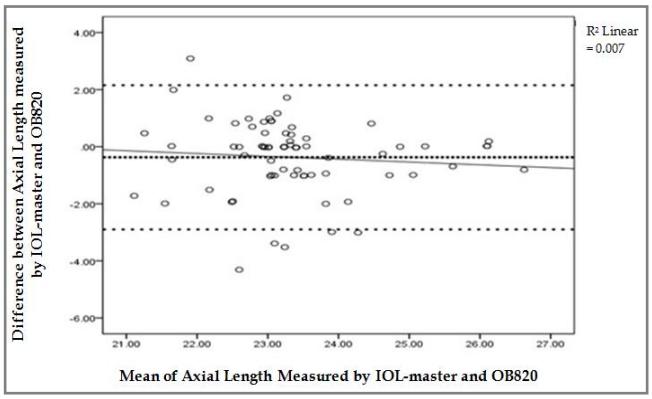

Figure: Bland-Altman plot for Axial Length measured by two techniques (where mean difference is -0.3727, -2.899 – 2.1539 95% CI).

Same results were obtained after performing reliability analysis using interclass correlation coefficient (ICC) and Cronbach's alpha. Correlation coefficient value of at least 0.7 was considered satisfactory, while value of 0.8 and 0.9 showed good and excellent correlation and terms of reliability and internal consistency. For axial length, the ICC was calculated to be 0.659 which shows that the correlation and internal consistency was not satisfactory between two groups, while for remaining parameters the inter-class correlation values showed excellent.

DISCUSSION

This prospective comparative study evaluated two optical biometers-IOL Master and OB 820 in terms of level of agreement for biometric parameters-axial length, Keratometry and anterior chamber depth. The parameter of paramount importance in biometry is axial length that did not show satisfactory level of agreement between two groups. Reliability analysis using interclass correlation coefficient further provides this evidence of low internal consistency and correlation between these two devices. The remaining parameters displayed excellent level of agreement. These two quintessential devices may not be interchangeably used for AXL.

The first study to evaluate the level of agreement between IOL-Master and OB-820 was conducted by Labiris *et al*, University Hospital of Alexandroupolis, Eye Institute of Thrace, Greece[10]. Before that, majority of published literature consisted of comparative trials of IOL-Master, A scan ultrasonic biometry and LENSTAR LS 900 (Haag Streit AG). Labiris *et al* pointed out regarding potential discrepancies in prevalent IOL-Master and OB-820 biometric devices suggesting that Range and 95% limits of agreement (LoA) were clinically significantly different for AXL parameter pre and post-3w and for radius and spherical equivalent postoperatively (*p*, 0.001). The rest of the parameters presented satisfactory 95% LoA. They concluded: IOL-master and OB-820 should not be used interchangeably due to discrepancy in the important

AXL parameter. Both biometers may provide reliable and consistent results regarding cylinder ACD and radius R110. Our study outcomes mainly substantiated these results regarding preoperative measurements in our population cohort. However,owing to scarce literature, regarding the cogency or repeatability of OB-820 and the comparison of two devices generally, and no such study so far on thorough literature review in our population, gives credit and validation to this study as to be first one of its kind.

In previous studies, ACD, AL and keratometric measurements acquired with IOL Master have been reported and compared with several optically and US-based biometric devices with variable results[11-15]. Majority of studies revealed that Optical biometres, IOL master and Lenstar, displayed high AL measurements in contrast to A scan ultrasound. The reason for this difference may be A scan biometry employing emmersion technique. The AL is measured by indentation of corneal epithelium and measure axial length to level of vitreoretinal surface that is shorter in normal and small eyes in contrast to optical biometres that utilizes non contact methodology and in addition measurements are taken upto retinal pigment epithelium. These studies depicted minor differences in AL and other measured parameters such as ACD, keratometry for small, normal and long eyes and gives adequate level of agreement between them and satisfactory post op refraction[16]. The new large coherence length swept source optical coherence tomographer compared with the IOL Master 500 (partial coherence interferometry [PCI]) and the Lenstar LS 900 (optical low-coherence reflectometry [OLCR]) biometers measured high AL[17]. However, The schiemflug based optical biometers Pentacam AXL provided similar measurements of AL and flat K, though there were statistically significant differences in ACD, steep K, and mean K measurements in contrary to previous methods[18,19], study showed excellent agreement between thetwo new biometers IOL Master 700 and OA-2000 on ocular biometric measurements (AL, ACD and mean keratometry) and astigmatism power vectors. However, lens thickness and predicted IOL powers showed significant difference by SRK/T formula. These results differ from our study on OB820 VS IOL Master 500 probably because the study was performed on healthy eyes of young people and with a different device OA 2000[20]. Nevertheless, it is still recommended to further validate these results in a large sample size and further stratified in different grades of cataract compared against additional biometers employing different principles of transmission, reflection and absorption of light and sound.

In conclusion, OB820 and IOL master ought not to be interchangeably used for measurement of axial length, owing to lack of agreement between the two devices.

CONCLUSION

IOL-master and OB-820 shouldn't be used interchangeably due to lack of agreement in axial length measurement which is infact the most important biometry parameter.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

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