

Agreement between Swept Source OCT Based and Scheimpflug / Placido Based Biometry Devices

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Purpose: To assess the agreement between a swept source OCT based IOL Master 700 biometer and a dual Scheimpflug ray tracing analyser, Galilei G6. to measure various parameters of biometry in cataractous eyes.

Study Design: Prospective Cross Sectional.

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Place and Duration of Study: Amanat Eye Hospital, Islamabad from April 2016 to June 2016.

Material and Methods: The 206 eyes of 110 patients scheduled for cataract extraction (consecutive sampling) were subjected to scanning by both devices by a single trained operator. Measurements recorded by each machine included keratometry (K), axial length (AL), astigmatism, anterior chamber depth (ACD), central corneal thickness (CCT), lens thickness (LT), white to white (WTW) and intraocular lens (IOL) power. The statistical package for social sciences software (SPSS version 22) and microsoft excel 2010 were applied to organize and tabulate the data collected. Paired T test was applied with 95% confidence interval to determine the association between parameters calculated with IOL Master 700 and Galilei 6.

Results: The mean age was 62.74 years (± 12.78) SD. In the sample of 206, frequency of IOL Master 700 failure was 3 (1.46%) and frequency of Galilei 6 failure was 59 (28.6%). High correlation was seen in CCT ($r = 0.976$), WTW ($r = 0.731$) and LT ($r = 0.958$) measurements. However, there was statistically

significant disagreement in keratometry (K_{avg} ; $p < 0.001$) measurements and ACD measurements and clinically significant difference in the mean AL measurements which eventually impacted the IOL power estimated by both devices.

Conclusion: Significant disagreement between these two devices was noted and hence they cannot be used interchangeably

Keywords: Biometry; Swept Source OCT based IOL Master 700; Galilei G6; Intraocular Lens; Target Refraction.

Cataract extraction in recent times has achieved unparalleled sophistication in surgical technique as well as IOL design. This advancement necessitates accurate measurement of biometric parameters of the eye in order to correctly determine the IOL power required for optimal visual results. Modern optical biometry devices use either partial coherence interferometry (PCI) or optical low coherence reflectometry (OLCR) to measure parameters such as axial length, lens thickness and anterior chamber depth¹. Additionally incorporated techniques can also enable keratometry².

The IOL Master 500 (Carl Zeiss Meditec) is considered the gold standard for modern biometry devices³⁻⁶. Recently, the manufactures of IOL Master 500 have introduced the first-of-its-kind swept source OCT based biometric device, the IOL Master 700⁷. Several studies conducted in different settings, compared different biometric devices to seek the agreement between them⁸⁻¹⁰. In this study, the IOL Master 700 was compared with the Galilei G6 (Zeimer Switzerland) to seek agreement between these two devices that work on very different principles to measure the same parameters i.e. K readings, axial length, lens thickness, ACD and CCT. Most importantly the IOL power estimate for achieving emmetropia provided by both devices was compared.

Measurement failure rates for these devices were also recorded.

MATERIALS AND METHODS

All the patients referred to the diagnostics department, Amanat eye hospital Islamabad (equipped with both technologies) for biometry from April 2016 to June 2016 were included in this study. This prospective cross sectional study followed the tenets of Declaration of Helsinki. Ethical review board of hospital approved the protocols of this study. All the participants were informed about the nature and purpose of the study.

Consecutive sampling technique was used to recruit the participants. A prior checkup was done, to ensure a good eye health, by an ophthalmologist. Patients with previous refractive or intraocular surgery, any ocular diseases that may hinder vision or have a bearing on post operative refraction such as keratoconus, glaucoma, posterior staphyloma, corneal pathologies, optic atrophy, retinopathy, and silicon oil filled eye were excluded. Parameters of 206 eyes of 110 patients were taken for sample. Measurements parameter were included Central corneal thickness (CCT), white-to-white (WTW), Flat keratometric value (K_1), Steep keratometric Value (K_2), mean keratometry

(K_{avg}), anterior chamber depth (ACD), lens thickness (LT), axial length (AL) and IOL power. To avoid any bias biometry were performed by single trained ophthalmic technologist. Both machines were calibrated prior according to the manufacturer's instructions. SRK-T formula was used to calculate the final IOL power with both IOL Master 700 and Galilei-6. The reason of choosing SRK-T was surgeon comfort level with this formula and also its benefits in shorter and longer eyes in predicting a target refraction $\pm 1.0D^{11}$. IOL Master 700 measures 2.5 mm central corneal zone while the Galilei G6 measures 3.0 mm central corneal zone. Failure rate with both devices was recorded and cataract type was graded into nuclear (N), cortical (C) and posterior subcapsular (PSC) cataract.

The statistical Package for social Sciences software (SPSS version 22) and Microsoft Excel 2010 were applied to organize and tabulate the data collected. Paired T test was applied with 95% confidence interval to determine the association between parameters calculated with IOL Master 700 and Galilei G6.

RESULTS

There were 206 eyes of 110 patients; the mean age was 62.74 years (± 12.78) SD; male participants were 49 (44.54%) and female participants were 61 (55.45%). In the sample of 206, frequency of IOL Master 700 failure was 3 (1.46%) and frequency of Galilei G6 failure was 59 (28.6%). The IOL Master 700 and Galilei 6 provided comparable mean CCT measurements and difference was found to be insignificant ($p = 0.854$). The mean difference of WTW was found to be significant ($p = 0.001$). Similarly, mean difference in keratometry measurements was found to be highly significant along different meridian ($p < 0.001$, $n = 206$). The mean difference between ACD measurements was significantly high ($p = 0.001$, $n = 198$) (Table 1) (Figure 1).

The mean difference between lens thickness was 0.033 mm which is insignificant ($p = 0.079$). Similarly, mean difference between axial lengths was 0.39 ± 2.941 mm, this difference was not statistically significant ($p = 0.11$). Moderate correlation existed between IOL Master 700 and Galilei 6 ($r = 0.39$) in measuring axial lengths. The IOL power measured with IOL Master 700 was $0.437 \pm 1.436D$ greater on average than measured with Galilei 6. This difference

is highly significant with $p < 0.001$, $n = 144$ (Table 1) (Figure 1).

The predictability of the IOL power calculation with the IOL Master 700, and Galilei 6 was similar (using the SRK/T formula and the A-constant recommended by the manufacturers) in 26 eyes only, which makes it 18.05% of total sample size. The difference of 0.50 D was found in 71 eyes (49.31%); 1.00D was present in 25 eyes (17.36%); 1.5 D difference was found in 21 eyes (14.58%); and 2.50 D difference was observed in 1 eye (0.69%) (Table 2).

Table 1: Mean Differences and SD of all parameters from both optical biometers, correlation and P value obtained from Paired T Test.

Parameter	N	IOL Master 700 Mean \pm SD	Galilei 6 Mean \pm SD	Correlation	Mean \pm SD difference (IOL Master 700 -Galilei 6)	Paired T test, P value ($\alpha = 0.05$, 95% CI)
Central corneal thickness (CCT) (μ m)	206	553.72 \pm 34.9	553.84 \pm 29.0	r = 0.976	-0.118 \pm 9.119	-0.185, p=0.854
White-to-white (WTW) (mm)	206	11.96 \pm 0.46	12.03 \pm 0.46	r = 0.731	-0.077 \pm 0.337	-3.23, p=0.001
Flat Keratometric value (K_1) (D)	206	43.23 \pm 1.847	43.49 \pm 1.82	r = 0.974	-0.253 \pm 0.422	-8.483, p<0.001
Steep keratometric value (K_2) (D)	206	44.12 \pm 1.91	44.38 \pm 1.92	r = 0.969	-0.263 \pm 0.48	-7.767, p<0.001
Average Keratometry ($K_{avg.}$) (D)	206	43.67 \pm 1.85	43.93 \pm 1.85	r = 0.978	-0.259 \pm 0.387	-9.518, p<0.001
Anterior chamber depth (ACD) (mm)	198	3.26 \pm 0.451	3.32 \pm 0.479	r = 0.876	-0.057 \pm .234	-3.412, p=0.001
Lens thickness (LT) (mm)	153	4.32 \pm 0.766	4.28 \pm 0.808	r = 0.958	0.033 \pm 0.232	1.77, p=0.079
Axial Length (AL) (mm)	147	24.33 \pm 3.16	23.94 \pm 1.621	r = 0.390	0.39 \pm 2.941	1.609, p=0.110
IOL Power (D)	144	20.31 \pm 2.758	19.87 \pm 3.207	r = 0.895	0.437 \pm 1.436	3.656, p<0.001

Table 2: Difference in IOL powers, frequencies and percentages.

Difference in IOL power (IOL Master 700 - Galilei-6)	n = 144	Percentage (%)
0 D (no difference)	26	18.05
+0.50 D	71	49.31
+1.0 D	25	17.36
+1.5 D	21	14.58
+2.5 D	1	0.69

Failure rate of IOL Master 700 was 1.46% and Galilei G6 was 28.6%. The highest failure rate was observed in grade 4 Posterior sub capsular cataract with both biometric devices and then failure was observed in nuclear cataract (Table 3).

Table 3: Failure rate and type of cataract: number and percentages.

Biometry Device	Cortical (C) n (%)	Nuclear (N) n (%)	Posterior Subcapsular (PSC) n (%)
IOL Master 700	0 (0.00)	1 (33.3)	2 (6.67)
Galilei G6	9 (15.25)	21 (35.59)	29 (49.15)

DISCUSSION

The advancement in cataract extraction techniques has been so tremendous in recent years that it is no longer considered a surgical procedure meant solely for removal of lens opacification but rather a method of acquiring near perfect visual result catering in

addition for any refractive abnormalities that existed preoperatively.

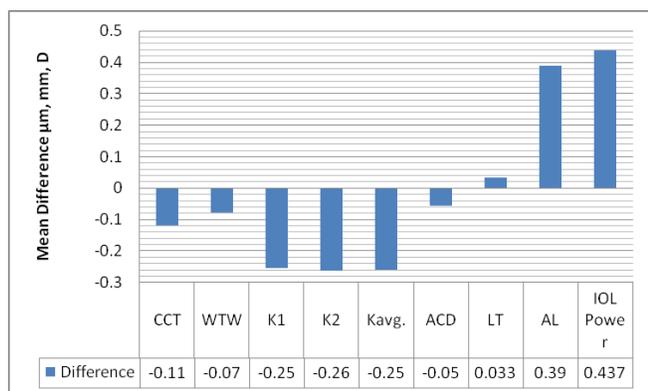


Fig. 1: Mean Difference across all eyes in CCT, WTW, K₁, K₂, K_{avg}, ACD, LT, AL, IOL Power between IOL Master 700 and Galilei-6. Units are in mm excepts for CCT, where units are in µm, and Keratometric reading, where units are in Diopters (D).

To obtain this desired near perfect result, different IOL designs have been introduced in the market catering for spherical and other aberrations, corneal astigmatism and accommodation. But such advancement in IOL design must parallel an equal precision in estimating the required IOL power to achieve emmetropia. Additionally, it is now necessary to fill in the possible ‘misses’ in pre-operative evaluation to lessen or extinguish the chance of any post-operative refractive surprise¹².

All biometric instruments are evaluated for repeatability before they become available for clinical practice. However, it is also necessary to compare one instrument with the others and establish agreement among them with the understanding that for any two devices to be used interchangeably, the degree of disagreement between them has to be clinically insignificant.

In this study the IOL Master 700 is compared with the Galilei G6 for agreement between their biometric estimates and the difference in the estimated IOL power proposed by each to achieve emmetropia in the same eye.

Foremost, it was noted that the Galilei 6 had considerably high failure rate (28.6%) in comparison to the IOL Master 700 (1.46%). This problem was encountered especially in the setting of dense cataract

and posterior sub capsular cataracts (PSC). Other studies have reported similar failure rates for the G6¹³⁻¹⁵. Since in PSC the opacities are located nearer to the nodal point of the lens, PCI or OCLR based devices have faced considerable problems in measurements. The IOL Master 700 bypasses this problem by taking a longitudinal scan of the entire visual axis instead resulting in much higher acquisition for AL even in the presence of dense cataracts and PSC. This failure of acquiring scans by the Galilei was independent of the K readings or the axial length of the eyes studied.

K readings and the AL measurements have the highest impact in IOL power calculations. Most IOL power calculation formulas use AL as well as keratometry measurements. Some also require other parameters such as ACD and white to white claiming more accurate calculations. The IOL Master employs a distance independent telecentric keratometer device and has, in this study, estimated a mean K reading (for both flattest and steepest K) which is 0.25 D (approximately) lower than the placido based G6. Similar statistically significant disagreement has been reported by other studies as well^{16,17}.

The AL estimates in our study were compared only for those eyes in which the G6 was able to give a result (i.e. 147 eyes out of 206). It was noted that the mean AL was underestimated by the G6 by approximately 0.39 mm. This difference though not statistically significant (p value > 0.05) has important clinical bearing as even 0.6 mm off set in AL can impact the IOL power calculation by 0.5D which is significant in term of post operative visual result.

The impact of this disagreement is reflected in the final IOL power estimates for emmetropia using the SRK formula where the same IOL power was estimated by both devices in only 18% of eyes. The majority of IOL estimates were offset by at least 0.5 Diopters.

The central corneal thickness (CCT), LT and WTW estimates by both machines correlated well with each other with mean difference that is neither statistically nor clinically significant. The ability to measure CCT is one main advantage of both these devices (not available on IOL Master 500).

The mean difference in ACD measurements acquired by the two devices showed statistically significant disagreement. This difference may be due to the different measuring technique and has also been reported by similar studies¹⁸⁻²¹. With the added fixation monitor of the IOL Master, measurement is

taken only after ensuring that the visual axis is properly aligned (a feature that is exclusive to the IOL Master 700). With other devices based on slit lamp illumination such as the IOL Master 500 and G6, the slit source is projected temporally²². This off center measurement of ACD may be a source of error²³.

It was observed during the course of this study that in addition to having minimum failure rate, the IOL Master 700 gave a unique advantage of directly visualizing the entire length of the visual axis making apparent such features as decentered, subluxated lenses and lens tilt that are possible causes of post-operative refractive surprises.

Also, by visualizing the foveal pit, it is possible to ensure correct alignment of the visual axis before measurements are taken that leads to unprecedented accuracy in results. In addition, gross abnormalities in the foveal image detected during biometry were noted and such patients were then subjected to a wider OCT scan of the macular area where "missed" macular abnormalities were recorded. Counseling the patient at this stage in pre-operative assessment proved easier and more fruitful as these patients had more realistic expectations of post-operative vision and were also more receptive to proposed retinal treatments.

It remains to be seen which of the IOL power predictions are more accurate in term of post operative refraction. This study is limited by the practical implementation of the results obtained by these biometric devices. Indeed, this is a direction for future studies in which post-operative refraction is observed for IOLs suggested by these machines.

CONCLUSION

This study establishes that there is a significant disagreement in biometric measurements obtained by the IOL Master 700 and the Galilei G6. It is suggested in light of these that results of these two devices not be used interchangeably.

CONFLICT OF INTERESTS: None.

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