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Analysis of biometric data generated by interferometry compared with Scheimpflug

Analise dos dados biométricos gerados por interferometria comparada com Scheimpflug

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ABSTRACT

Objective: *Observe the agreement between IOL Master 500 and Pentacam AXL and describe the averages.* ***Methods:*** *We analyzed 35 medical records, totaling 61 eyes. All patients underwent biometric evaluation on both devices from August 2018 to August 2019. The data collected were: age, gender, anterior chamber depth, axial length, K1, K2, biometrics and IOL target.* ***Results:*** *The averages of the variables analyzed between the optical biometric devices in question had a statistically significant difference (p <0.05). Linear regression showed no influence of any anterior chamber variables on the difference in biometrics and target values between the devices.* ***Conclusion:*** *There was no statistical agreement between the devices for the analyzed variables. Therefore, the interchange of Pentacam AXL with IOL Master 500 should be avoided.*

Keywords: *Dioptric power of IOL; Biometry; IOL master; Pentacam AXL; Agreement; Axial length*

RESUMO

Objetivo: Observar o grau de concordância das variáveis analisadas entre os dispositivos IOL Master 500 e Pentacam AXL e descrever as medias **Métodos:** Foram analisados 35 prontuários, totalizando 61 olhos. Todos os pacientes se submeteram à avaliação biométrica nos dois dispositivos, no período de agosto de 2018 a agosto de 2019. Os dados coletados foram: idade, sexo, profundidade da câmara anterior, comprimento axial, K1, K2, poder dióptrico da LIO e alvo refracional. **Resultados:** As médias das variáveis analisadas entre os dispositivos de biométricos óptica em questão tiveram diferença estatisticamente significante (p<0,05). A regressão linear não apontou influência de nenhuma das variáveis da câmara anterior na diferença de valores do poder dióptrico da LIO e do alvo refracional entre os dispositivos. **Conclusão:** Não houve concordância estatística entre os dispositivos para as variáveis analisadas. Portanto, deve se evitar intercambiar o uso do Pentacam AXL com o IOL Master 500.

Descritores: Poder dióptrico da LIO; IOL Master; Pentacam AXL; Concordância; Comprimento axial; Biometria

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Introduction

According to the latest data made available by the World Health Organization (WHO) in the Global Data on Visual Impairments survey (WHO, 2012) [1], estimates have indicated that 285 million individuals worldwide have some visual impairment and 39 million of them are blind. Cataract is the opacification of the lens of the eye [2], which is highly prevalent in elderly individuals and/or in individuals presenting isolated risk factors such as photooxidative (UV radiation) and oxidative stress (e.g., medications, diabetes, smoking, among others). [2-5]

According to CBO data, Brazil has 1.15 million reversible blindness cases - cataract accounts for approximately 350,000 new cases per year. [6] Surgical therapy based on phacoemulsification, which was introduced in Brazil in 1975 [8], is the most effective way to treat cataract. [6-7]

The accuracy assured by new techniques has enabled physicians to indicate surgical therapies at early disease stages. However, intraocular lens (IOL) calculation remains an important factor to be taken into consideration, [9] since cataract surgery not only focuses on visual improvement, but it can also improve refractive errors. [10]

The desired final refraction can be achieved through IOL dioptric power. Nowadays, optical biometrics [10] is a fundamental tool used in the cataract surgery-preoperative period. [6] Optical biometer uses different variables to calculate IOL power, the main ones are axial length of the eyeball (AL), keratometry values (K), lens thickness (LT) and anterior chamber depth (ACD). [11] It is worth emphasizing that the instrument must be properly calibrated and handled by an experienced operator who must repeat the measurements and use state-of-the-art formulas to calculate IOL power by adapting its constants. [12] Formulas used to calculate IOL power have been achieving great progress, since they enable getting better and more predictable refractive results. [13]

The essential role played by optical biometrics in the final outcome of IOL implantation processes and the small number of articles about this topic available in the medical literature justify the implementation of a study focused on comparing two different devices to help setting a likely gold standard in the near future. The aims of the current study were to investigate the degree of agreement between variables analyzed by two different biometric devices, and to describe their means, to help improving the knowledge about and to assure the best outcome for cataract patients.

Methods

Cross-sectional study focused on analyzing data about the preoperative period of cataract surgery patients treated in a private hospital in Goiânia City, Goiás State, Brazil. The study was approved by the Ethics and Research Committee of the Pontifical Catholic University of Goiás.

Thirty-five (35) records of cataract patients subjected to optical biometrics in the IOL Master 500 and Pentacam AXL devices were analyzed by the same ophthalmologist, from August 2018 to August 2019 - 61 eyes, in total.

The study population comprised 15 female (53.6%) and 13 male (46.4%) patients. The sample comprised the total number of 23 right (52.3%) and 21 left (47.7%) eyes. Table 1 shows the distribution of sociodemographic variables associated with the investigated population.

Inclusion criteria comprised 18-year-old (or older) individuals who had not been previously subjected to eye surgery and/or experienced eye diseases or trauma. Exclusion criteria encompassed patients younger than 18 years, who had been previously subjected to eye surgery and/or who have experienced eye diseases or trauma, contact lens wearers, or individuals who did not present crystalline opacification and whose data in the medical record were incomplete.

Seventeen (17) eyes were excluded from the study because they lacked essential information, as well as because they did not meet the inclusion criteria and/or because the formula selected to calculate IOL was not applied to them. This process resulted in the final number of 28 medical records and in final sample comprising 44 eyes.

IOL Master 500 optical biometer (Carl Zeiss Medtec, AG - Germany) was usedbased on the physical principle of partial coherence interferometry (PCI). Variables analyzed in this biometer were AL, K, ACD and white-to-white corneal diameter, which was considered optional. [14] AL value was obtained through double-beam PCI, which was used to measure the infrared laser reflection reaching internal eye interfaces. Keratometry (K) reading was carried out by calculating the anterior corneal curvature [10] based on 6 points of light in a 2.4-mm zone, whereas ACD was measured through slit lamp examination. [11]

Data collected through optical biometer, which uses the physical principle of partial coherence interferometry (PCI) (IOL Master 500, Carl Zeiss Medtec, AG-Germany), were compared to data collected by the Scheimpflug device (pentacamAXL (Oculus-Germany).

Variables such as age, sex, ACD, AL, K1 and K2, IOL dioptric power and refractive target zero, obtained in both biometers, were selected for the study. Holladay 1 formula (3rd generation) was used to calculate IOL in all IOL dioptric power calculations. The implanted IOLs were of the SN60WF model, Alcon.

Data were entered and manipulated in Excel spreadsheet for further analysis in the Statistical Package for Social Science (SPSS) software (version 21.0) for Windows. Kolmogorov-Smirnov test was used to determine whether there was normal distribution of continuous variables. Wilcoxon test was used to check whether, or not, there was significant difference between means recorded for the study variables in both biometric devices. Linear regression analysis was used to investigate whether there was correlation among ACD, AL, K1, K2, IOL dioptric power and refractive target values. All tests adopted significance level of 5% ($p < 0.05$) and confidence interval of 95% (CI).

Results

The mean age of the investigated population was 66.28 years (standard deviation was 12.87 years, both upwards and downwards). Mean values recorded for variables analyzed in both devices were calculated, namely: K1 (43.01mm), K2 (44.21mm), ACD (3.20mm), AL (23.34mm), IOL dioptric power (21.93D) and refractive target (-0.06D). Mean value recorded for pachymetry performed in the Pentacam AXL device (529.40 mm) was also calculated. Table 1 shows the distribution of eyes (based on side) and individuals (based on sex).

The mean of differences in values recorded for variables between the two devices was also calculated, namely: K1 (0.41mm), K2 (0.46mm), ACD (0.12mm), AL (0.02mm), IOL dioptric power (0.71D) and refractive target (0.22D). Table 2 shows the means of differences in variables between devices, as well as their SD,

Table 1
Distribution of socio-demographic variables associated with the investigated population.

Variables	n	(%)
Eye		
Righ	23	52.3
Left	21	47.7
TOTAL	44	100.0
Sex		
Female	15	53.6
Male	13	46.4
TOTAL	**28**	**100.0**

(f): absolute value / (%): percentage

Table 2
Overall parameters of differences recorded for the investigated variables based on measurements carried out in IOL Master 500 and Pentacam AXL devices

Variables	Mean ± SD	95% CI
K1	0.41 ± 0.44	0.28 – 0.55
K2	0.46 ± 0.24	0.39 – 0.53
ACD	0.12 ± 0.25	0.04 – 0.20
AL	0.02 ± 0.03	0.01 – 0.02
IOL dioptric power	0.71 ± 0.52	0.56 – 0.87
Refractive target	0.22 ± 0.31	0.12 – 0.31

Table 3
Parameters and comparison of the investigated variables based on IOL Master 500 and Pentacam AXL devices

Variables	IOL device		AXL device		P value
	Mean ± SD	Med (95% CI)	Mean ± SD	Med (IC 95%)	
K1	43.1±1.7	43.1(42.6-43.7)	42.9±1.8	43.2(42.4-43.5)	0.003*
K2	44.4±1.7	44.4(43.9-44.9)	44.0±1.7	44.3(43.5-44.5)	< 0.001*
ACD	3.2±0.3	3.2(3.1-3.3)	3.3±0.4	3.2(3.1-3.4)	< 0.001*
AL	23.3±1.1	23.5(23.0-23.7)	23.3±1.1	23.3(23.0-23.7)	0.045*
IOL dioptric power	21.7±3.2	22.0(20.7-22.7)	22.1±3.1	22.25(21.2-23.1)	< 0.001*
Refractive target	-0.01±0.10	0.01(-0.04-0.02)	-0.10±0.34	-0.2(-0.21-(-0.0))	< 0.001*

Med: median
* Significant according to Wilcoxon test

medians and CIs.

Means recorded for variables analyzed in each device were compared to each other. Means recorded through optical coherence interferometry were K1 (43.1mm), K2 (44.4mm), ACD (3.2mm), AL (23.3mm), IOL dioptric power (21.7D) and refractional target (-0.01D). Means recorded by Scheimpflug device were K1 (42.9mm), K2 (44.0mm), ACD (3.3mm), AL (23.3mm), IOL dioptric power (22.1D) and refractive target (-0.10D). P values have shown statistically significant difference among all variables ($p < 0.05$). Table 3 shows the comparison of means recorded for variables between devices, as well as their SD, medians, CIs and p values.

Linear regression was used to investigate whether variables K1, K2, ACD and AL would influence the difference between IOL diopter power and refractive target values recorded by both devices. No variable recorded $p < 0.05$; thus, they did not influence IOL diopter power and refractive target values.

Discussion

Cataract is significantly associated with aging, a fact that turns it into a relevant public health issue given the growth of elderly populations. Cataract surgery has been improved over the years and it is nowadays seen as a form of refractive surgery. IOL dioptric power plays a fundamental role in surgical success, since it is used to calculate IOL power, and its ideal refractive target, in the preoperative period. Biometric data such as AL, K and ACD are necessary to determine IOL power. [10] Inaccurate AL and ACD measurements can lead to 36% and 42% IOL refractive error, respectively. [20]

Few articles focused on comparing optical coherence interferometry to the Scheimpflug system were found in the medical literature, so far. Optical coherence interferometry has shown high precision and good resolution; it is considered the gold standard in AL calculation, which is the primary measurement to help determining IOL power. [15] Patients' expectations towards cataract surgery have significantly increased due to technological advancements achieved in this procedure. [13] Therefore, it is important assessing not only the success of facectomy procedures, but also patients' satisfaction with their post-surgery visual acuity.

The current study presented the prevalence of women (53.6%) and mean age of 66.28 years in the investigated population. Similar results were reported in studies carried out in Goiânia (6) and Recife (21) cites in 2017 (one study in each city), which recorded prevalence of women in the investigated population 7% and 18.7% higher than that of the current study, respectively. Mean age of the investigated population in the aforementioned studies was 3 years younger and 0.53 years older than that of the current study, respectively. However, when it comes to international studies, although a Polish study[22] carried out in 2019 presented prevalence of women, the mean age of the population investigated in it was 58 years - 8.6 years younger than the mean age of the population investigated in the present study. The younger mean age recorded for the population investigated in the Polish study may be associated with earlier access to cataract surgery, in comparison to the Brazilian population. The overall prevalence of women in the investigated populations may be associated with the fact that women are more careful about their health and have longer life expectancy than men.[23]

A recent study conducted with a Brazilian population[6] that presented similar physical and genetic features to that of the current study, recorded overall mean values for variables K1, K2, ACD and AL, similar to those of the current study, although it used the IOL Master 700 and Lenstar LS900 biometers.

Based on the comparison between mean values recorded for variables analyzed in the two optical biometers used in the current study, there was no agreement between them. All parameters presented statistically significant difference ($p < 0.05$). Recently, Muzyka-Woźniak et al. [23] performed the same comparison and found statistically significant difference in AL and K values; however, it differed from the present study in ACD, which presented high agreement between devices ($p = 0.36$). Another study conducted by Shajari et al. [17] performed this very same comparison and found 100% concordant variables ($p > 0.05$), which differed from the current results; however, they also included the IOL Master 700 device in their study. Finally, a third recent study, conducted by Sel et al. [24], compared Pentacam AXL to IOL Master 700 and recorded statistically significant difference ($p <0.05$) for variables AL, ACD and K, thus corroborating the present study.

Pentacam originally uses the Scheimpflug technology; thus, it is not possible performing IOL power calculations only based on variables measured by it. Pentacam AXL has an additional module that allows calculating the AL value through PCI, similar to optical coherence interferometry. [17] Despite the statistically significant difference in AL recorded in the current study, the mean difference recorded for this variable between devices was 0.02mm ± 0.03mm. Studies conducted by Muzyka-Woźniak et al. [22] and Sel et al. [24] have also recorded differences of 0.01mm, 0.026mm and 0.05mm, respectively, which are clinically insignificant to calculate IOL [17,22,24]. According to Eibschitz-Tsimhoni et al. [25], an error of 0.1 mm in AL measurement can produce from 0.2 to 0.35D refraction error – this value is significantly different from those observed in the aforementioned studies.

ACD was the divergent variable between the present study and the ones conducted by Muzyka-Woźniak et al. [22] and Shajari et al. [17], who compared the Scheimpflug System to optical coherence interferometry and found high agreement in ACD. Mean difference recorded for ACD between the two devices used in the current study was 0.12mm ± 0.25mm. Based on this clinical context, Sel et al. advocated that ACD values lower than 0.09 mm would not influence the final IOL results [24]. However, the ACD value found in the present study exceeded it by 33%, which is considered clinically significant.

With respect to K value, optical coherence interferometry takes into consideration the anterior corneal curvature, whereas the Scheimpflug system also takes into account the posterior corneal curvature and reports its total refractive power. [17] Measurement error of 1.0D in K reading can lead to error between 0.9 and 1.4D in IOL power. [20] Variables K1 and K2 presented statistically significant differences between the two devices used in the current study. The difference recorded for mean K1 and K2 was 0.41D ± 0.44D and 0.46D ± 0.24D, respectively. K2 recorded higher mean difference between devices than K1. According to Muzyka-Woźniak et al. [22] and Shajari et al. [17], K2 also recorded mean difference higher than K1 and Kmean, when the Scheimpflug System was compared to optical coherence interferometry; the recorded values were 0.33D and 0.19D, respectively. According to Özyol and Özyol, Kmean difference > 0.14D between Pentacam HR and IOL Master 700 devices does not allow using them interchangeably, since it can provide different constant to calculate IOL power. [26] Although variable 'keratometry' presented good agreement in the study by Shajari et al., [17] both the aforementioned study and the study conducted with the Polish population reinforced the need of conducting further studies with the investigated devices before using them interchangeably to calculate K.

The current study used Holladay 1 formula to calculate IOL power (SN60WF, Alcon), whereas the other aforementioned studies used other formulas. Despite this divergence, the study by Muzyka-Woźniak et al. [22] has shown statistically significant difference in IOL power calculation, which was compatible to that in the current results.

Linear regression carried out in the present study aimed at checking whether anterior chamber variables have influenced the difference in IOL diopter power and refractive target values between biometric devices. Finally, anterior chamber variables did not influence the difference in IOL dioptric power and refractive target values calculated in both devices.

So far, the literature does not present any other study focused on comparing the Scheimpflug system to optical coherence interferometry that has performed this very same regression. Rodrigues et al. [6] have used Lenstar LS900 and IOL Master 700 biometers. Variables AL and K1 analyzed in their study had positive and negative influence, respectively, on the difference in IOP diopter power between devices. Similar to the current study, the aforementioned authors did not find influence of any of the analyzed variables on refractive target.

According to the current study, greater safety is achieved by avoiding interchangeability between Optical Coherence Interferometry and Scheimpflug System devices at the time to calculate the analyzed variables, since there was no statistical agreement between them and only AL presented clinically insignificant difference between devices.

The current study presented points that agreed and disagreed with the medical literature. It may have happened due to small sample size, to the use of the Holladay 1 formula and to different statistical methodologies adopted in these studies. Therefore, it is necessary conducting further research about these biometers, based on a larger sample size. It would also be interesting conducting double-blind, randomized and multicenter studies capable of corroborating data from other studies available in the medical literature. The comparison between results enables improving the use of biometrics as diagnostic tool and helps optimizing postoperative outcomes.

Further studies on the topic are necessary to enable comparing their results to the ones reported in the medical literature, as well as to help improving and optimizing IOL dioptric power in the postoperative period.

Conclusion

The analyzed variables did not present statistical agreement between biometers. Therefore, interchangeability between Scheimpflug system and optical coherence interferometry biometer should be avoided. Anterior chamber variables did not influence the difference in IOL diopter power and refractive target values between devices.

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