Agreement between IOLMaster® 500 and Pentacam® HR for keratometry assessment in type 2 diabetic and non-diabetic patients

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Abstract

● **AIM:** To evaluate inter-device agreement of anterior keratometry obtained by the IOLMaster® 500 and Pentacam® HR in type 2 diabetic and non-diabetic patients.

● **METHODS:** Corneal measurements were sequentially performed in 60 diabetes mellitus (DM) and 48 age and sex-matched controls undergoing cataract surgery. Variables recorded included flat and steep keratometry, mean keratometry (K_m), astigmatism magnitude, axis location, J0 and J45 components. Bland-Altman plots and intraclass correlation coefficients were used for examination of agreement. Subgroup analyses were performed for astigmatism magnitude, diabetes duration, hemoglobin A1c (HbA1c) levels and diabetic retinopathy (DR) stage.

● **RESULTS:** Agreement for K_m and astigmatism magnitude were considered good and moderate, with 95% limits of agreement (LoA) of -1.09 to 1.23 diopters (D) and -0.83 to 0.86 D in DM group, respectively; and -0.59 to 0.72 D and -0.98 to 0.75 D in non-DM group, respectively. In contrast, the 95% LoA for corneal axis exceeded the clinically relevant margins in both groups. In the total sample, only 41 eyes (38%) had a smaller than 5-degree difference. Diabetes duration, HbA1c levels and DR stage were not found to significantly affect agreement. Logistic regression showed that higher corneal power (*P*=0.021) and astigmatism magnitude (*P*=0.011) were associated with a decreased risk of having a difference in axis location greater than 10-degrees.

● **CONCLUSION:** In both groups, IOLMaster and Pentacam agree well for corneal power and moderately for astigmatism. However, axis location disagreement is frequent in eyes with flatter corneas and small amounts of astigmatism.

● **KEYWORDS:** keratometry; diabetes mellitus; astigmatism; cataract; diabetic retinopathy

INTRODUCTION

Cataract surgery in patients with diabetes mellitus (DM) assumes particular importance, as cataract occurs earlier in life and at a higher rate[1], frequently in working-age individuals. The direct physical effect of hyperglycemia on the corneal hydration[2] can cause quantitative and qualitative visual refractive changes through corneal refractive index, thickness and topography variations. Thus, careful pre-operative evaluation is crucial to accurately plan and perform cataract surgery in these patients.

The cornea is the major refractive element of the eye, and correction of corneal astigmatism at the time of cataract surgery has become an interesting option for surgeons who seek the best possible refractive results[3]. Pre-operative assessment of corneal astigmatism plays a significant role in the refractive outcome, since preexisting astigmatism remains a common obstacle to achieving excellent postoperative uncorrected visual acuity. In fact, it has been estimated that about 21% of cataract surgery candidates have more than 1.50 diopters (D) and 11% have more than 2.00 D[4-5].

Currently, two of the most employed devices to measure keratometry are the IOLMaster® and Pentacam® HR. The validity of both instruments for this purpose has been established and there have been few studies assessing the agreement between these devices[6-9]; but, to the best of our knowledge, no studies addressed this topic in diabetic patients.

This study was designed to assess the agreement between anterior keratometric measurements made using the IOL Master 500 and Pentacam HR in a population of diabetic and non-diabetic patients undergoing phacoemulsification surgery. The present study also aimed to determine if the astigmatism magnitude, diabetes duration, hemoglobin A1c (HbA1c) levels, and diabetic retinopathy (DR) stage, affected the agreement of corneal measurements between these devices.

SUBJECTS AND METHODS

Ethical Approval A prospective cross-sectional observational study was performed including caucasian type 2 diabetic patients and controls, aged 50 or older, who were recruited from the Cataract Unit of the Ophthalmology Department of Centro Hospitalar São João (Porto, Portugal) between September 2015 and March 2016. Written informed consent was obtained from each participant before inclusion in the study. The study protocol adhered to the tenets of the Declaration of Helsinki and received local Institutional Review Board Approval.

Full inclusion criteria are described elsewhere[10], but in short, DM diagnosis was confirmed by medical history and HbA1c levels ≥6.5%. The exclusion criteria included the presence of any ocular disease, except cataract and DR (however, patients with eyes with uncontrolled complications of proliferative DR and/or white/brown cataracts were excluded), prior eye surgery (except for intravitreal treatment >120d or laser photocoagulation >90d before surgery of diabetics), wearing of contact lenses within the preceding 2wk and current treatment with glucocorticoids.

Study Protocol All subjects underwent a complete ophthalmological examination in a standardized fashion by the same ophthalmologist (Beato JN). The DR classification was based in 7 standard ETDRS fundus photographs.

The keratometry assessment was performed by an experienced operator (Esteves-Leandro J) with the IOLMaster® 500 (version 7.7) and the Pentacam® HR (software version 1.20r87). Only good-quality examinations were accepted, defined as scans that passed the software's quality check.

At the end of the visit, all patients carried out vital signs assessment and blood sampling for the evaluation of serum HbA1c.

Devices

IOLMaster® 500 The IOLMaster 500 (Carl Zeiss Meditec, Jena, Germany) is a partial coherence interferometer used for anterior segment and axial length (AL) measurements. It measures the anterior corneal keratometry (mean of three measurements), using the data from six light reflections (590 nm) oriented in a hexagonal pattern approximately 2.3 mm diameter, and the AL (mean of five measurements) through an infrared light (780 nm). Those parameters, which are

fundamental for IOL power calculation and implantation, have been show a high intra and interobserver reproducibility[11].

Pentacam® HR The Pentacam (Oculus, Wetzlar, Germany) uses a single rotating Scheimpflug camera and a monochromatic slit-light source (blue LED at 475 nm) combined with a static camera to generate a three-dimensional (3D) high-resolution (HR) image of the anterior segment. In fewer than 2s, the 180-degree rotating camera captures up to 25 slit images of the anterior segment, collecting 25 000 true elevation points. Any eye movement is detected by the static camera and corrected for in the process. The anterior corneal keratometry measurements have been shown to have excellent repeatability and reproducibility[12-13].

Sample Size Calculation Calculation of sample size was done with the following equation:

$$n = \frac{2 \times (\text{SD})^2 \times (Z_\alpha + Z_\beta)^2}{\Delta^2}$$

n= the number of subjects in each group.

SD=Standard deviation of keratometry measurement, which is accepted as 0.75 D[13].

Z_α =Value of Z table for α=0.05; which is 1.96.

Z_β =Value of Z table for β=0.10 (with 90% power); which is 1.28.

Δ= Clinically significant difference of median keratometry measurement; which is accepted as 0.5 D[6].

By applying this equation, the number of subjects in each group was calculated as 47. We included additional patients in the DM group in order to perform subgroup analysis.

Statistical Analysis Statistical analysis was performed using the SPSS® statistical software (version 21.0 for Mac OS; SPSS Inc., Chicago, IL., USA). Only the scheduled eye for cataract surgery of each individual was used for the statistical analysis to avoid cross-sectional correlation that exists between both eyes of the same patient[14-15].

The Kolmogorov-Smirnov test was used to confirm the normal distribution of the data. The corneal variables recorded were the flat and steep keratometry, mean keratometry (K_m), astigmatism magnitude, axis of the flattest meridian, J0 and J45 components. Due to the circular nature of the axis variable and the degree scale, the absolute difference was calculated for each pair of corneal axis location measurements, as described by Delrivo et al[16]. In addition, power vector analysis[17] was used to compare the corneal astigmatism measured by both devices. Corneal astigmatism was converted to rectangular vector coordinates as follows: J0=[-(C/2)×cos(2θ)] and J45= [-(C/2)×sin(2θ)], where C is the negative cylinder (flattest meridian–steepest meridian) and "teta" is the axis along the flattest meridian. The J0 vector describes a Jackson cross-cylinder with its axes at 180 and 90 degrees, while the J45 vector describes a Jackson cross-cylinder with its axes at 45 and 135 degrees.

Agreement was assessed using single measure intraclass correlation coefficients (ICCs) and the Bland-Altman method[18]. The one-sample t-test was performed to evaluate whether the measured differences were significantly different from zero. The 95% limits of agreement (LoA) were calculated as the mean difference ±1.96 SD. A linear regression was used to evaluate whether the difference between measurements was correlated to the mean value. For both K_m and astigmatism magnitude, we considered that having 95% of the differences within 1.0 D of the mean to be an acceptable LoA. Axis location difference greater than 5 degrees was considered clinically relevant[6]. Two-tailed parametric or non-parametric tests were used for continuous variables comparison between the DM and non-DM groups, according to the normality of data. Chi^2 or Fisher's exact tests were performed for categorical variables comparison. Statistical significance was set at a P value less than 0.05.

Subgroup analyses of agreement were performed based on the astigmatism magnitude, diabetes duration, HbA1c levels and DR stage. Average astigmatism magnitude [(astigmatism IOLMaster+astigmatism Pentacam)/2] of each patient was subdivided as follows: ≤1 D or >1 D. Diabetic subjects were classified into subgroups according to DM duration (≤5; 6-10 and >10y), HbA1c levels (≤7% and >7%) and presence of retinopathy.

A binary logistic regression model was constructed to identify the potential variables associated with clinically significant inter-device differences (corneal power >0.50 D, astigmatism magnitude >0.50 D, axis of astigmatism >10 degrees)[6]. The independent variables comprised both demographic (age, sex, diabetes, HbA1c levels) and clinical factors (AL, K_m, astigmatism magnitude) examined.

STROBE and GRRAS guidelines were followed for manuscript elaboration[19-20].

RESULTS

Sixty diabetic patients and 48 non-diabetic controls were enrolled in the study. Demographic characteristics of the study population did not show any significant differences between groups, except for the levels of HbA1c (Table 1). There was a significant association between the duration of diabetes and HbA1c levels in DM group (P=0.004). Severity of DR was associated with both duration of diabetes (P<0.001, Kruskal-Wallis test) and HbA1c levels (P=0.031, Kruskal-Wallis test). No significant differences were found between DM and non-DM groups for any corneal variable measured with the same device.

Corneal Power Agreement The mean differences for each keratometry value (mean, flat and steep) were not statistically significantly different from 0 in both groups. The agreement between instruments for K_m was within 0.5 D in 51 (85%,

Table 1 Demographic characteristics of the study population

n (%)

| Variables	DM group (n=60)	Non-DM group (n=48)	P
Age (y)	72.58±5.64	70.44±5.68	0.053[a]
Female	39 (65)	30 (62.5)	0.788[c]
Right eyes	31 (51.7)	30 (62.5)	0.259[c]
Axial length (mm)	23.00±0.79	23.02±0.77	0.925[a]
Astigmatism magnitude			0.481[c]
≤1 D	38 (64.4)	34 (70.2)	
>1 D	21 (35.6)	14 (29.8)	
HbA1c (%)	7.03±1.16	5.54±0.38	<0.001[b]
Duration of diabetes (y)	11.35±8.42	n/a	n/a
DR stage		n/a	n/a
NPDR absent	39 (65)		
NPDR mild-moderate	12 (20)		
NPDR severe-PDR	9 (15)		

DM: Diabetes mellitus; DR: Diabetic retinopathy; NPDR: Non-proliferative DR; PDR: Proliferative DR; n/a: Not applicable. [a]Independent samples t-test; [b]Mann-Whitney U test; [c]Chi-quare. Continuous variables are reported as mean±standard deviation.

DM) and 43 (89.6%, non-DM) eyes (Table 2). In each group, Bland-Altman analysis indicated very good agreement across the entire range of K_m measurements (Figure 1). The 95% LoA between instruments were within the clinically relevant margins of discrepancy in both groups (Tables 3 and 4). The ICC for K_m was 0.927 (95%CI 0.881-0.956) in DM group and 0.977 (95%CI 0.959-0.987) in non-DM group.

Astigmatism Magnitude Agreement The agreement between instruments was within 0.5 D in 46 (76.7%, DM) and 37 (77.1%, non-DM) eyes (Table 2). In DM group, the mean astigmatism difference was not statistically significantly different; however, a linear association existed between the average and the absolute difference of both instruments (r=0.318, P=0.013). In non-DM group, a statistical significant inter-device measurements difference was found [-0.02 (95%CI: -0.13, +0.09), P=0.048, one sample t-test], but there was no trend in bland-altman graphic (Figure 1). Despite these, the 95% LoA between instruments were within the clinically relevant margins of discrepancy in both groups (Tables 3 and 4). The ICC was 0.768 (95%CI 0.639-0.855) in DM group and 0.628 (95%CI 0.423-0.773) in non-DM group.

Axis Location Agreement The 95%LoA for corneal astigmatism axis (Figure 1) exceeded the clinically relevant margins in both groups[6]. In the total sample, only 41 eyes (38%) had an equal or smaller than 5-degree difference (Table 2). The ICC was 0.561 (95%CI 0.360-0.712) in DM group and 0.530 (95%CI 0.290-0.707) in non-DM group (Tables 3 and 4).

Astigmatism Vectors Agreement There was no statistically correlation between instruments for the J0 and J45 components
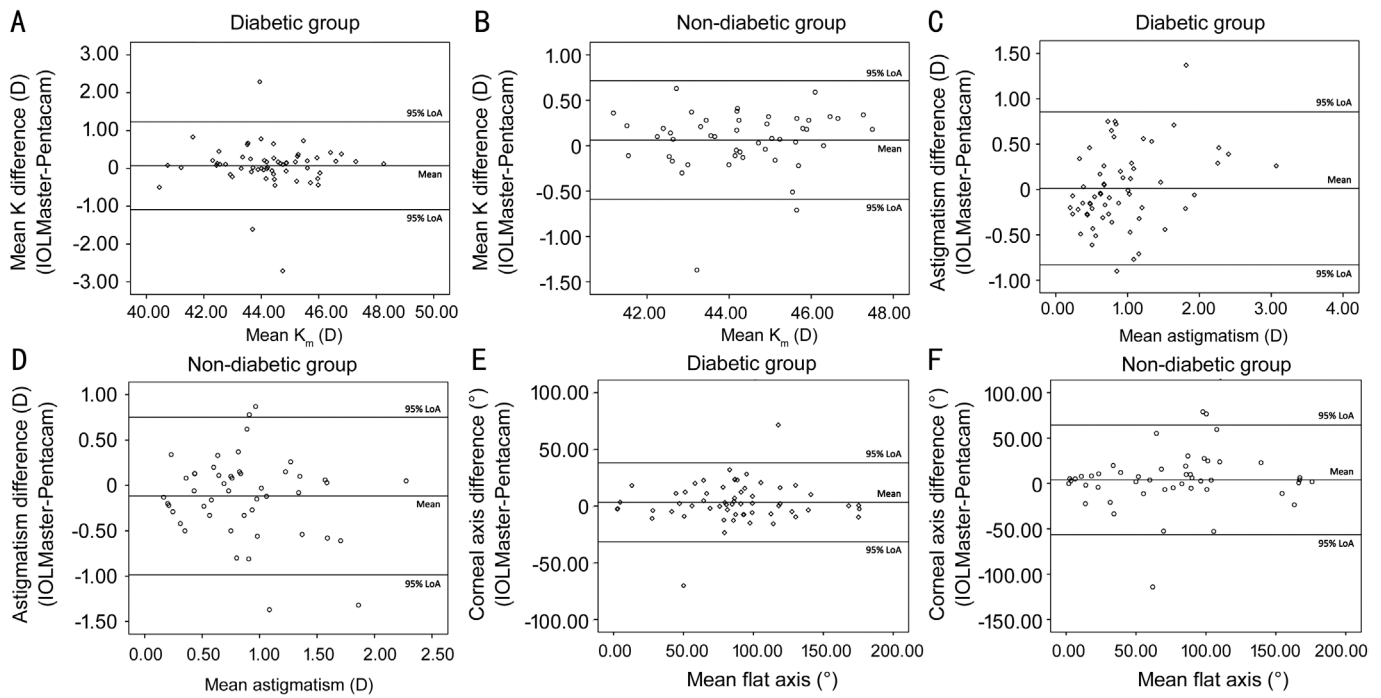
Figure 1 Bland-Altman analysis of agreement between IOLMaster and Pentacam tomography for diabetic and non-diabetic patients A, B: For K_m; C, D: Astigmatism magnitude; E, F: Corneal axis location.

Table 2 Clinically relevant margins and agreement between IOLMaster and Pentacam HR for corneal power and astigmatism measurements in both groups n (%)

Parameters	DM group (n=60)	Non-DM group (n=48)	Total (n=108)	P
K_m difference <0.5 D	51 (85)	43 (89.6)	94 (87.0)	0.451[a]
Astigmatism magnitude difference <0.5 D	46 (76.7)	37 (77.1)	83 (76.9)	0.959[a]
Axis difference				0.093[a]
<11 degree	36 (60)	26 (54.2)	62 (57.4)	
11-20 degree	15 (25)	7 (14.6)	22 (20.4)	
>20 degree	9 (15)	15 (31.3)	24 (22.2)	

DM: Diabetes mellitus; D: Diopters; K_m: Mean keratometry. [a]Chi-square test.

(Tables 3 and 4). Figure 2 corresponding to the differences in J0 and in J45 between the 2 devices, shows that many eyes are placed outside the ±0.5 D clinical relevant margin.

Subgroup Analysis of Agreement

Astigmatism magnitude in DM and non-DM groups There was no satistical significant difference between subgroups in the absolute difference for each of the corneal variables studied in both DM and non-DM groups. No inter-device measurements difference was found within each subgroup of DM or non-DM groups. However, eyes with ≤1 D astigmatism were found to present greater axis location disagreement (Figure 3) with wider LoA [4.99 (-36.78 to +46.83) for ≤1 D *vs* 0.41 (-15.90 to +16.71) for >1 D in DM group; 4.23 (-66.23 to +74.70) for ≤1 D *vs* 3.26 (-21.55 to +28.07) for >1 D in DM group] in both groups.

Subgroup analysis of DM group: duration of diabetes, HbA1c levels, DR stage There was no satistical significant

difference in the mean absolute difference for each of the corneal variables studied between subgroups of DM duration, HbA1c levels or DR stage. No inter-device differences were found within each subgroup.

Factors Influencing the Agreement Between Measurements Multivariate logistic regression, performed in a backward stepwise fashion, showed that higher corneal power [Exp(B)=0.69 (95%CI 0.50-0.95), P=0.021] and astigmatism magnitude [Exp(B)=0.24 (95%CI 0.08-0.72), P=0.011] were associated with a decreased risk of having a difference in axis greater than 10 degrees.

No factors evaluated were associated with having corneal power or astigmatism magnitude difference greater than 0.5 D.

DISCUSSION

This research evaluated the agreement of keratometric measurements between IOLMaster® 500 and Pentacam® HR in diabetic and non-diabetic subjects. We found that the
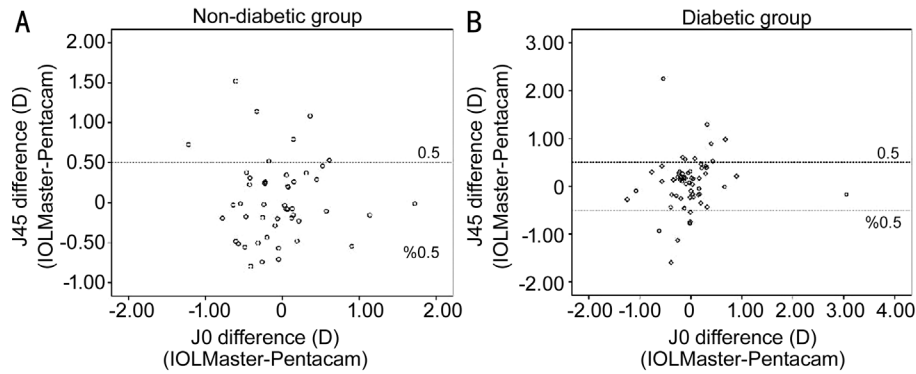
Figure 2 Vector analysis of keratometric data. J0 and J45 of the power vector differences between the 2 devices A: Non-diabetic; B: Diabetic group.

Table 3 Agreement between IOLMaster and Pentacam HR for corneal power and astigmatism measurements in diabetic patients

Parameters	Inter-device correlation, ICC[a] (P^1)	IOLMaster (mean±SD)	Pentacam (mean±SD)	Mean difference[b]±SD (P^2)	95% LoA
Flat K (D)	0.911 (<0.001)	43.85±1.54	43.77±1.53	0.07±0.65 (0.381)	-1.20 to +1.35
Steep K (D)	0.929 (<0.001)	44.77±1.59	44.71±1.64	0.06±0.61 (0.439)	-1.13 to +1.26
K_m (D)	0.927 (<0.001)	44.31±1.54	44.24±1.55	0.07±0.59 (0.371)	-1.09 to +1.23
Astigmatism magnitude (D)	0.768 (<0.001)	0.93±0.56	0.94±0.69	0.01±0.43 (0.820)	-0.83 to +0.86
Flat axis location (degree)	0.561 (<0.001)	88.72±45.42	84.39±45.19	3.31±17.73 (0.434)	-31.33 to +38.06
J0 (D)	0.040 (0.382)	-0.05±0.37	-0.03±0.42	-0.02±0.55 (0.787)	-1.10 to +1.06
J45 (D)	-0.005 (0.516)	0.07±0.39	-0.01±0.40	0.07±0.56 (0.969)	-1.03 to +1.17

D: Diopters; ICC: Intraclass correlation coefficient; K_m: Mean keratometry; LoA: Limits of agreement. Powers of the corneal axis are expressed in diopters. Data were derived from single measure intraclass correlation analysis[1] and one sample t-test[2]. [a]Inter-device correlation is presented as single measure ICC; [b]Difference expressed as IOLMaster® 500–Pentacam® HR.

Table 4 Agreement between IOLMaster and Pentacam HR for corneal power and astigmatism measurements in non-diabetic patients

| Parameters	Inter-device correlation, ICC[a] (P^1)	IOLMaster (mean±SD)	Pentacam (mean±SD)	Mean difference[b]±SD (P^2)	95% LoA
Flat K (D)	0.968 (<0.001)	43.88±1.52	43.88±1.49	-0.01±0.38 (0.910)	-0.76 to +0.74
Steep K (D)	0.965 (<0.001)	44.80±1.67	44.69±1.63	0.11±0.43 (0.080)	-0.72 to +0.94
K_m (D)	0.977 (<0.001)	44.34±1.57	44.28±1.54	0.06±0.33 (0.203)	-0.59 to +0.72
Astigmatism magnitude (D)	0.628 (<0.001)	0.92±0.56	0.81±0.48	0.12±0.44 (0.076)	-0.98 to +0.75
Flat axis location (degree)	0.530 (<0.001)	76.02±54.51	76.02±57.08	3.95±30.86 (1.000)	-56.54 to +64.41
J0 (D)	-0.032 (0.585)	-0.05±0.39	-0.004±0.32	-0.004±0.51 (0.550)	-1.05 to +0.96
J45 (D)	0.053 (0.361)	0.04±0.38	0.01±0.35	0.03±0.50 (0.708)	-0.95 to +1.01

D: Diopters; ICC: Intraclass correlation coefficient; K: Keratometry; K_m: Mean keratometry; LoA: Limits of agreement. Powers of the corneal axis are expressed in diopters. Data were derived from single measure intraclass correlation analysis[1] and one sample t-test[2]. [a]Inter-device correlation is presented as single measure ICC; [b]Difference expressed as IOLMaster® 500 – Pentacam® HR.

agreement for K_m and astigmatism magnitude was considered good and moderate, respectively, in both groups. However, the two devices showed clinically relevant discrepancies regarding axis estimates. Axis disagreement was greater in eyes with lower corneal power and astigmatism magnitude.

Agreement studies are extremely frequent in the literature, since they provide information about the amount of error inherent in any diagnosis, score or measurement[20]. Despite this, many of them lack appropriate statistical methods or differ in the definition of acceptable agreement[14]. For instance, the use of the Pearson correlation coefficient may be misleading because it reflects the agreement between two different variables, rather than the same variable measured at least twice[15,18].

When comparing to previous studies comparing the IOLMaster and the Pentacam, we found that agreement in DM and non-DM groups for K_m (ICC 0.94 and 0.98, respectively) and
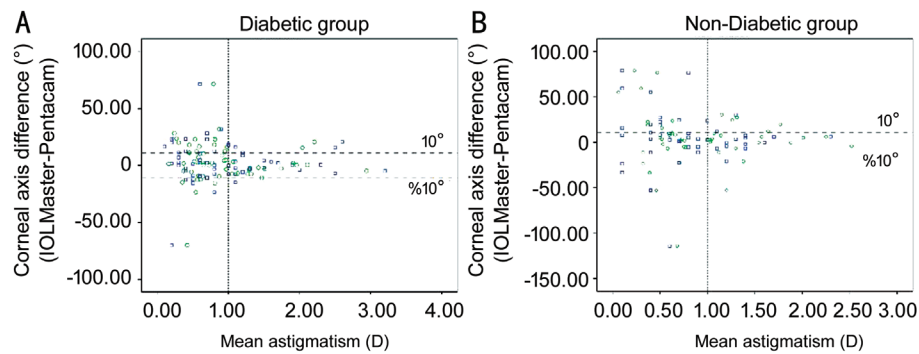
Figure 3 Amount of corneal astigmatism and the disagreement in axis location between IOLMaster and Pentacam in the diabetic (A) and non-diabetic (B) groups The vertical line (X axis) represents 1.00 D of corneal astigmatism and the two horizontal lines (Y axis), ±10 degrees of axis location. Measurements of IOLMaster are represented as green circles and Pentacam with blue squares.

astigmatism magnitude (ICC 0.77 and 0.63, respectively) were similar to those obtained by Lee *et al*[6] (ICC 0.94 and 0.69, respectively) in a sample of patients undergoing cataract surgery with a mean age of 73y. Interestingly, keratometry readings have consistently been found to be higher in IOLMaster than in Pentacam measurements (≤4 mm diameter)[8-9,21-22], as occurred in our study in both groups (+0.07 and +0.06). The exact reason for this difference is unclear although it may be attributable to the different optical principles or light sources used by each device.

Despite the comparable values obtained for corneal power and astigmatism magnitude between devices, axis location was considered to significantly differ between technologies. Mean axis difference was <4 degrees in both groups, however, the wide LoA found arguably exceeds the clinically acceptable range of agreement. In our study, 42.6% of eyes had greater than 10-degree and 22.2% greater than 20-degree difference. These findings were slightly higher to those of Lee *et al*[6] (30% and 13%, respectively). Curiously, axis disagreement is not a totally unexpected finding in these studies, since MacAlinden and colleagues[13] previously reported that Pentacam HR shows poor repeatability limits for axis estimates in all scan models.

In binary logistic models, evaluating the factors associated with clinically significant discrepancies in corneal power, astigmatism, and axis, we found that higher corneal power and astigmatism magnitude were associated with a reduced likelihood of a significant difference in axis between technologies. This has clinical implications for preoperative surgical planning, since astigmatism correction significantly depends on precise axis determination. Thus, higher degrees of astigmatism may confer more accurate axis estimates. Our data is in line with other studies comparing corneal topography and autokeratometry[23], or corneal topography and tomography[16]. Diabetes has been considered to be a relative contraindication for keratorefractive surgery due to the possible influence of hyperglycemia on corneal hydration and, subsequently, topographic changes[24]. So, statistical subgroup analyses

of agreement were performed in this group. Despite some minor differences found in the ICCs and LoA, binary logistic regressions showed no statistically significant impact on clinical discrepancies between the two devices.

This study has several strengths but also some limitations. Considering that true keratometry values are unknown, the study only compares two different methods and it is not possible to conclude which device obtains the most accurate measurements. Also, we cannot conclude which device provides the most reliable measurements to achieve astigmatism reduction after surgery since we did not perform postoperative evaluations. Another drawback is the fact that we were able to include a low number of patients in the more advanced stages of DR. These patients frequently have other ocular and systemic co-morbidities and for that reason many did not meet the selection criteria. Nevertheless, the sample of diabetic patients seems to be representative of the different degrees of diabetes duration and HbA1c levels and so, the obtained results regarding those analyses are valid and might be generalized to similar populations of Caucasian patients.

In conclusion, the IOLMaster and Pentacam HR were found to be precise for corneal power measurements in both DM and non-DM groups. Nevertheless, inter-device variations in axis estimates, especially in those eyes with flatter corneas and lower degrees of astigmatism, may result in different clinical outcomes.

Authors' contributions: Study concept and design: Beato JN, Falcão M, Rosas V, Carneiro Â, Falcão-Reis F; Data collection: Esteves-Leando J, Reis D, Matos R; Analysis and interpretation of data: Beato JN, Esteves-Leandro J, Falcão M, Carneiro Â, Rosas V, Falcão-Reis F; Drafting of the manuscript: Beato JN, Esteves-Leandro J, Reis D, Matos

R; Critical revision of the manuscript: Falcão M, Rosas V, Carneiro Â, Falcão-Reis F; Statistical expertise: Beato JN, Falcão M.

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