• Clinical Research •

Interchangeability of corneal curvature and asphericity measurements provided by three different devices

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Abstract

• AIM: To evaluate the interchangeability of keratometric and asphericity measurements provided by three measurement systems based on different optical principles.

• METHODS: A total of 40 eyes of 40 patients with a mean age of 34.1y were included. In all cases, a corneal curvature analysis was performed with IOL-Master (IOLM), iDesign 2 (ID2), and Sirius systems (SIR). Differences between instruments for flattest (K1) and steepest (K2) keratometric readings, as well as for magnitude and axis of corneal astigmatism were analyzed. Likewise, differences in asphericity (Q) between SIR and ID2 were also evaluated.

• RESULTS: Mean differences between devices for K1 were 0.20±0.21 (*P*<0.001), -0.12±0.36 (*P*=0.046) and -0.32±0.36 D (*P*<0.001) for the comparisons IOLM-SIR, IOLM-ID2 and SIR-ID2, respectively. The ranges of agreement for these comparisons between instruments were 0.41, 0.70, and 0.70 D. For K2, mean differences were 0.31±0.33 (*P*<0.001), -0.08±0.43 (*P*=0.265) and -0.39±0.38 D (*P*<0.001), with ranges of agreement of 0.65, 0.84, and 0.74 D. Concerning magnitude of astigmatism, ranges of agreement were in the limit of clinical relevance (0.49 D, *P*=0.011; 0.55 D, *P*=0.386; 0.43 D, *P*=0.05). In contrast, ranges of agreement were clinically relevant for astigmatic axis (26.68º, 33.83º and 18.37º, *P*≥0.121) and for Q between SIR and ID2 (0.16, *P*<0.001).

• CONCLUSION: The keratometric corneal power, astigmatic axis and asphericity measurements provide by the three systems evaluated cannot be considered as interchangeable, whereas measurements of corneal astigmatism obtained with SIR and ID2 can be considered as interchangeable for clinical purposes.

• KEYWORDS: astigmatism; corneal topography; keratometry; corneal asphericity

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INTRODUCTION

The analysis of corneal geometry has become an indispensable tool in clinical practice of cornea, refractive surgery and contact lens[1]. A great variety of devices has been developed for such purpose based on different optical principles and providing different applications[1]. Specular reflection topography systems, such as Placido disk-based devices or keratometry modules of some optical biometers, only allow a characterization of the anterior corneal surface in terms of corneal curvature whereas elevation data is derived according to a mathematical approximation[2]. In contrast, Scheimpflug imaging-based devices provide an accurate measurement of anterior and posterior corneal elevation data, with estimation of curvature based on specific mathematical algorithms[3]. In the last years, several devices combining both technologies, Placido disk and Scheimpflug imaging, have been developed in order to obtain accurate curvature and elevation corneal data[4-6]. As there are currently a significant number of devices commercially available to measure anterior corneal geometry, studies evaluating the interchangeability of measurements provided by each of them are necessary in order of confirm if they can be used clinically as systems providing comparable or equivalent data. The aim of our study was to evaluate the interchangeability of keratometric and corneal asphericity measurements obtained with three measurement systems based on different optical principles in healthy eyes.

SUBJECTS AND METHODS

Ethical Approval All patients were informed about the study

and gave their informed consent to perform the measurements following the tenets of the Declaration of Helsinki. The study was approved by the Ethics Committee of the University of Alicante.

Patients A total of 40 healthy eyes of 40 patients ranging in age from 23 to 48y were included in this prospective comparative study. All participants were selected from the refractive surgery consultation of the Department of Ophthalmology (OFTALMAR) of the Vithas Medimar International Hospital (Alicante, Spain), where this investigation was developed. To avoid the potential interference in the outcomes of the correlation that often exists between the two eyes of the same person, only one eye from each patient was chosen for the study randomly. Inclusion criteria for the study were healthy eyes, age of more than 18y and refraction error between +5.00 D and -10.00 D. Exclusion criteria were high refractive errors, previous ocular surgeries, corneal opacities or scars, ectatic corneal disease, and any active ocular or systemic disease.

Measurement Protocol A standardized comprehensive ophthalmologic examination was performed in all cases comprising uncorrected and best-corrected visual acuity, manifest refraction, Goldmann tonometry, slit-lamp biomicroscopy examination, optical biometry and keratometry with IOL-Master 500 system (IOLM; Carl Zeiss Meditec AG, Jena, Germany), and corneal topography with the Scheimpflug imaging-based system Sirius (SIR; CSO, Firenze, Italy) and with the full gradient specular reflection-based system iDesign 2 (ID2; Johnson and Johnson Vision, Irvine, CA, USA). The measurements were performed by the same single experienced examiner (Soto-Negro R) following a specific sequence, IOLM-S-ID2. Data analysis extraction and analysis were performed by another independent examiner (Piñero DP).

Measurement Devices The IOLMaster 500 is a non-contact optical device that measures the distance from the corneal vertex to the retinal pigment epithelium by partial coherence interferometry, being consistently accurate to within ±0.02 mm or better[7]. The Sirius system is a new topography device that uses the principles of Scheimpflug photography and enables the acquisition and processing of 25 radial sections of the cornea and anterior chamber in seconds. Specifically, the system can measure 35 632 points on the anterior corneal surface and 30 000 points on the posterior corneal surface in high-resolution mode in approximately 5 to 6s[6]. The iDesign 2 system is a topographer-aberrometer that estimates corneal topography using a propriety, full gradient method based on the Hartman principle. As in wavefront aberrometry, the lenslets and grids are used to capture x and y slopes for each spot projected on the cornea. A cone-and-shell design is used to produce uniformly illuminated spots on the cornea. The cone, which faces the cornea, is perforated with holes that allow spots of light to be projected onto the eye. These spots are projected onto the cornea and the reflection is analyzed using pattern-recognition software[8].

Statistical Analysis First, the Dupont-Plummer approach was used for sample size estimation[9]. For paired *t*-tests, we estimated the number of pairs of patients needed to detect a true difference in population means δ with Type I error probability α given a standard deviation (SD) σ. A sample size of 39 eyes was found to provide a statistical power of 90% and a consistent detection of a difference between devices of less than 0.15 D in keratometry, considering a SD of differences between devices of 0.28 D, and an α error of 0.05.

The statistical analysis of the outcomes obtained was performed using the software SPSS version 15.0 for Windows (SPSS, Chicago, Illinois, USA). Normality of all data distributions was confirmed by means of the Kolmogorov-Smirnov test. Then, parametric statistics was always applied. Differences between pair of devices were evaluated using the paired Student *t* test. Besides this, an evaluation of the interchangeability of corneal curvature and asphericity measurements obtained with the three measurement devices evaluated was performed using the Bland-Altman method. The limits of agreement (LoA) were defined as the mean±1.96 SD of the differences. Furthermore, Pearson correlation coefficients were used to assess the correlation between the different parameters evaluated. All statistical tests were 2-tailed, and *P* values less than 0.05 were considered statistically significant.

RESULTS

The study involved 40 eyes (23 right and 17 left eyes) of 40 subjects (18 males and 22 females) with a mean age of 34.1y (ranging from 23 to 48y). Mean axial length in the analyzed sample was 24.73 mm (SD: 1.42; median: 24.76; range: 24.76 to 27.82 mm) and mean anterior chamber depth was 3.69 mm (SD: 0.39; median: 3.72; range: 2.69 to 4.44 mm). Mean white-to-white corneal diameter was 12.09 mm (SD: 0.37; median: 12.10; range: 11.50 to 13.70 mm) and mean central corneal thickness was 539.29 μm (SD: 38.54; median: 533.00; range: 430.00 to 638.00 μm). Table 1 summarizes the mean keratometric and corneal asphericity data obtained with the three instruments evaluated. As shown, statistically significant differences were found in steepest keratometric readings (K1) between IOLM and SIR (P<0.001) as well as between SIR and ID2 (P<0.001). Regarding the comparison between IOLM and ID2, no statistically significant differences were found in flattest keratometric reading (K2; P=0.265) and the magnitude of keratometric astigmatism (P=0.386), whereas a difference in the limit of statistical significance was found in K1 (P=0.046). The difference in astigmatism was significant between IOLM and SIR (P=0.011), whereas was in the limit of

Table 1 Mean keratometric and corneal asphericity data obtained with the three instruments mean (SD); median (range)

Parameters	IOLM	SIR	ID2	IOLM-SIR	IOLM-ID2	SIR-ID2
K1 (D)	43.16 (1.52); 43.21 (40.08 to 46.87)	42.97 (1.53); 42.98 (39.87 to 46.89)	43.28 (1.59); 43.14 (39.93 to 46.94)	<0.001	0.046	<0.001
K2 (D)	44.46 (1.53); 44.23 (40.91 to 48.35)	44.15 (1.51); 43.96 (40.59 to 47.82)	44.54 (1.58); 44.52 (40.86 to 48.17)	<0.001	0.265	<0.001
Corneal astigmatism (D)	1.30 (0.90); 1.12 (0.13 to 4.08)	1.18 (0.77); 0.96 (0.09 to 3.25)	1.26 (0.82); 1.07 (0.08 to 4.15)	0.011	0.386	0.050
Flattest keratometric axis (º)	88.11 (75.83); 78.50 (0.00 to 179.00)	89.17 (76.63); 102.00 (0.00 to 179.00)	91.65 (75.45); 102.50 (0.00 to 178.88)	0.645	0.227	0.121
Q	Not available	-0.22 (0.10); -0.23 (-0.38 to 0.04)	-0.30 (0.08); -0.30 (-0.47 to -0.15)	-	-	<0.001

SD: Standard deviation; K1: Steepest keratometric reading; K2: Flattest keratometric reading; Q: Corneal asphericity.

Table 2 Bland-Altman analysis outcomes of the comparison of keratometric and corneal asphericity measurements obtained with the three devices

Parameters	IOLM-SIR		IOLM-ID2		SIR-ID2	
	Mean difference (SD); median (range)	LoA	Mean difference (SD); median (range)	LoA	Mean difference (SD); median (range)	LoA
K1 (D)	0.20 (0.21); 0.22 (-0.57 to 0.51)	-0.22, 0.61	-0.12 (0.36); -0.11 (-1.08 to 0.65)	-0.83, 0.58	-0.32 (0.36); -0.37 (-1.22 to 0.64)	-1.03, 0.39
K2 (D)	0.31 (0.33); 0.37 (-0.66 to 1.11)	-0.34, 0.97	-0.08 (0.43); -0.09 (-1.16 to 1.20)	-0.93, 0.76	-0.39 (0.38); -0.42 (-1.28 to 0.76)	-1.14, 0.35
Corneal astigmatism (D)	0.11 (0.25); 0.11 (-0.44 to 0.83)	-0.39, 0.61	0.04 (0.28); 0.03 (-0.58 to 0.87)	-0.51, 0.59	-0.07 (0.22); -0.07 (-0.90 to 0.40)	-0.50, 0.35
Flattest keratometric axis (º)	-1.06 (13.61); 0.00 (-70 to 30)	-27.74, 25.63	-3.54 (17.26); -0.04 (-81.78 to 29.52)	-37.37, 30.30	-2.48 (9.37); -0.58 (-48.09 to 10.14)	-20.84, 15.88
Q	-	-	-	-	0.08 (0.08); 0.08 (-0.06 to 0.25)	-0.07, 0.23

SD: Standard deviation; K1: Steepest keratometric reading; K2: Flattest keratometric reading; Q: Corneal asphericity.

statistical significance between SIR and ID2 (P=0.050). Strong and statistically significant correlations (P<0.001) were found between K1 (IOLM-SIR, r=0.990; IOLM-ID2, r=0.975; SIR-ID2, r=0.974), K2 (IOLM-SIR, r=0.976; IOLM-ID2, r=0.962; SIR-ID2, r=0.971) and astigmatism (IOLM-SIR, r=0.965; IOLM-ID2, r=0.951; SIR-ID2, r=0.965) measurements obtained with the three devices evaluated. The correlation between SIR and ID2 asphericity measurements was also statistically significant but weaker (r=0.693, P<0.001).

Table 2 summarizes the results of the interchangeability analysis of the keratometric and corneal asphericity measurements obtained with the three devices evaluated. As shown, lower LoA were observed for the comparison of all keratometric data between SIR and ID2 (Figures 1 and 2). Likewise, LoA of -0.07 and 0.23 were obtained for the comparison of asphericity measurements provided by SIR and ID2 devices. No significant correlations were found between the difference among pair of devices in keratometric and corneal asphericity measurements and the mean magnitude of such measurements ($-0.326 \leq r \leq 0.171$, $P \geq 0.052$). Only a poor but statistically significant correlation was found between the difference in keratometric astigmatism between SIR and ID2 and the magnitude of such astigmatism (r=0.441, P=0.007). The difference in axis of astigmatism between devices was higher than 10º in all cases for astigmatisms of 1 D or below (Figures 3 and 4).

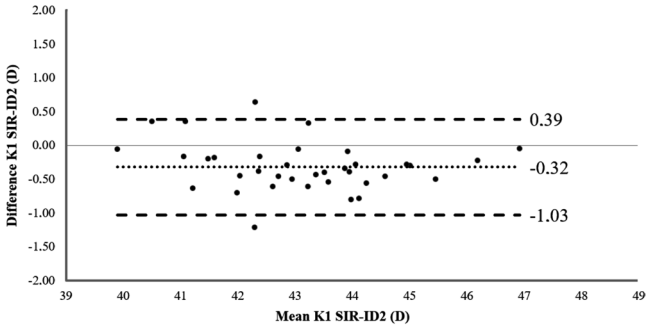

Figure 1 Bland-Altman plots for the comparison of the values of keratometric power in the flattest meridian (K1) obtained with SIR systems and iDesign 2 (ID2) systems The dotted lines show the limits of agreement (±1.96SD).

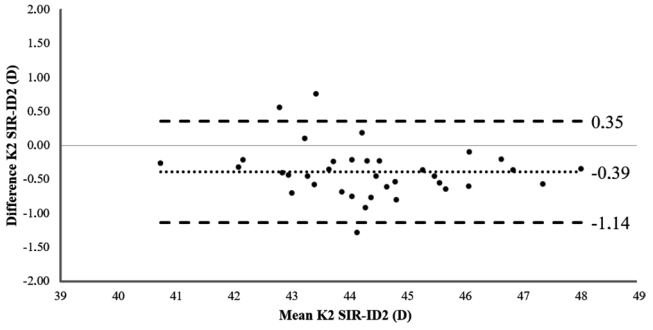

Figure 2 Bland-Altman plots for the comparison of the values of keratometric power in the steepest meridian (K2) obtained with Sirius (SIR) and iDesign 2 (ID2) systems The dotted lines show the limits of agreement (±1.96SD).

DISCUSSION

In our sample of healthy eyes, we have found that differences in keratometric readings between IOLM and the other two topographic systems were not statistically significant, whereas differences between topographers in terms of keratometry did reach statistical significance. When the clinical relevance of differences were analyzed by means of the Bland-Altman method, ranges of agreement between devices were found to

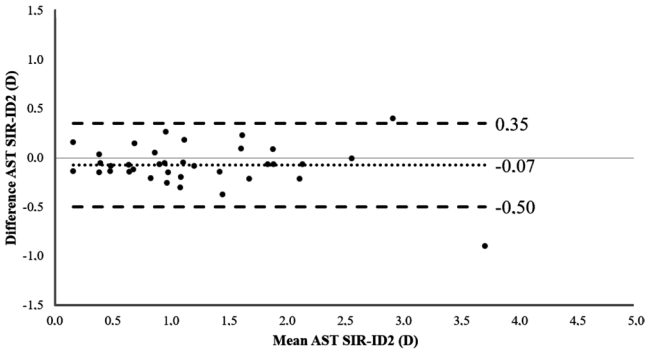

Figure 3 Bland-Altman plots for the comparison of the values of keratometric astigmatism (AST) obtained with Sirius (SIR) and iDesign 2 (ID2) systems The dotted lines show the limits of agreement (±1.96SD).

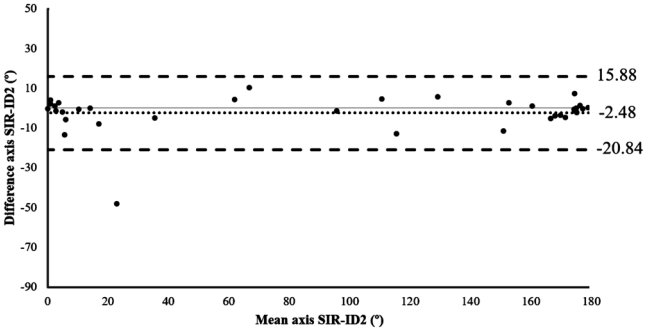

Figure 4 Bland-Altman plots for the comparison of the values of the orientation (axis) corresponding to the flattest meridian obtained with Sirius (SIR) and iDesign 2 (ID2) systems The dotted lines show the limits of agreement (±1.96SD).

be clinically inacceptable, except for the comparison of K1 between IOLM and SIR. Specifically, we found ranges of agreement (1.96 times the SD of differences between devices) for K1 of 0.41, 0.70 and 0.70 D for the comparisons IOLM-SIR, IOLM-ID2 and SIR-ID2, respectively, and of 0.65, 0.84 and 0.74 D for K2. This range of error is comparable to and consistent with that associated to the inherent level of consistency of the measurements provided by each device[6,8,10-14]. A test-retest repeatability for the K1 obtained with the SIR system of 0.74 D was reported by Kumar *et al*[10] in healthy eyes, and Montalban *et al*[6] reported within-subject SD of 0.04 mm for anterior corneal curvature measurements provided by this system for different corneal diameters. As keratometry is required for IOL power calculations, ranges of agreement between IOLM and SIR for K1 were within acceptable levels considering that intraocular lens (IOL) powers are currently manufactured in steps of 0.50 D and that an error of 0.50 D in corneal power estimation induces errors in IOL power estimation by only as much as 0.50 D at the corneal vertex according to optical simulations[15]. Similarly to our study, previous investigations have also shown acceptable levels of interchangeability between IOLM and SIR[11].

Concerning keratometric astigmatism, we obtained in our series ranges of agreement of 0.49, 0.55 and 0.43 D for the comparisons IOLM-SIR, IOLM-ID2 and SIR-ID2, respectively. In this case, the difference between IOLM and SIR was the only one that reached statistical significance. Differences among devices and the level of interchangeability can be considered as interchangeable for clinical purposes, as they are in the limit of clinical relevance. These differences are also consistent with the inherent variability of the devices, considering the outcomes of studies evaluating their intrasession repeatability[6,8,14]. Likewise, the impact of differences in astigmatism among devices is tolerable considering its potential impact on IOL power calculations[15-16]. However, differences of IOLM with SIR and ID2 in terms of axis of astigmatism cannot be considered as interchangeable as ranges of agreement were large (26.68º and 33.83º, respectively). These axis errors cannot be considered as acceptable when planning the alignment of a toric IOL considering the axis of corneal astigmatism. According to Viestenz *et al*[17], 11.5º of toric IOL rotation would lead to residual astigmatism that is 40% of the initial astigmatic power and 3º, 10% of the initial power. Likewise, Felipe *et al*[18] demonstrated that toric IOL rotations less than 10º are able to change the eye's refraction less than 0.50 D. When SIR and ID2 measurements were compared, a range of agreement of 18.37º was found, revealing the presence of a better level of agreement in astigmatic axis between these two devices, although associated to clinically relevant differences. It should be mentioned that only 4 eyes showed differences among devices over 10º, being associated in all cases to low levels of astigmatism (<1 D). This fact has been also reported for other topography systems, with all eyes with more than 15° of disagreement between devices having a cylinder value of less than 1.0 D[4,19]. This may attribute to the limitations in terms of intrasession repeatability of topography devices for the measurements of axis of low magnitude cylinders[20].

Finally, corneal asphericity measurements provided by SIR and ID2 systems were compared, as IOLM does not provide a measurement of this parameter. The range of agreement among devices for this parameter was 0.16, a value that cannot be considered as clinically acceptable. Likewise, the difference was statistically significant. This error is equivalent in terms of absolute magnitude to the mean value found in the healthy population with the SIR system[21-22]. The main factor that may have contributed to this discrepancy about devices may be the use of a different area of analysis for the adjustment (8 mm SIR, 6 mm ID2), although also the use of different mathematical approached may have contributed to this issue.

In conclusion, the corneal power measurements provided by IOLM, SIR and ID2 systems cannot be considered as interchangeable for clinical purposes, except for K1 between IOLM and SIR. However, differences between devices in terms

of the magnitude of astigmatism are in the limit of clinical relevance and devices can be considered as interchangeable for this parameter. Furthermore, a poor level of interchangeability in terms of astigmatic axis was found between SIR and ID2, with increasing clinically significant variability for low magnitude cylinders. Finally, corneal asphericity measures provided by SIR and ID2 cannot be used interchangeably as possibly they are estimated using different mathematical approaches.

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