VALIDATION OF KERATOMETRIC MEASUREMENTS OBTAINED WITH AN INTRAOPERATIVE IMAGE-GUIDED SYSTEM: INTRA-SESSION REPEATABILITY AND INTERCHANGEABILITY WITH AN OPTICAL BIOMETER

Running head: Validation of intraoperative image-guided system

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1

All the authors have full control of all primary data and they agree to allow Clinical

Experimental Optometry to review the data of the current study if requested

ABSTRACT

Purpose: To evaluate the intra-session repeatability of the keratometric measurements obtained in healthy eyes with the Verion image-guided system (Alcon Laboratories Inc., Fort Worth, TX) as well as the interchangeability of such measurements with those obtained with an optical biometer (Aladdin, Topcon, Tokyo ,Japan).

Methods: A total of 53 eyes of 53 patients (age, 31-67 years) were enrolled in the study. All eyes received a comprehensive ophthalmologic examination including an analysis with the VERION image-guided and Aladdin systems. Three consecutive measurements of keratometry were obtained with the Verion system to assess the intra-session repeatability. Within-subject standard deviation (S_w) and intraobserver precision (± 1.96 x S_w) were calculated. Bland and Altman analysis was used for the interchangeability analysis.

Results: Mean S_w was 0.26, 0.24 and 0.10 D for the keratometric power in the flattest meridian (K1), keratometric power in the steepest meridian (K2), and astigmatism, respectively. Mean S_w was 4.29° for the axis of the flattest corneal meridian (AX1). Statistically significant but clinically acceptable differences were found in K1, K2, and keratometric astigmatism among systems ($p<0.01$). In contrast, differences among systems in AX1 were not statistically significant ($p=0.385$), but clinically relevant (mean difference: 15.74º; limits of agreement: -30.93 to 62.41º).

Conclusions: The Verion system provides consistent measurements of keratometric parameters, with measurements of AX1 that are not interchangeable with that provided by the optical biometer Aladdin, especially in low and oblique astigmatisms.

Key words: keratometry, optical biometry, Verion system, astigmatism, corneal curvature

INTRODUCTION

The prevalence of astigmatism increases with age, with most of studies reporting that approximately 30% of patients undergoing cataract surgery present more than 1.5 D of preexisting corneal astigmatism.[1-3] This astigmatism must be corrected to achieve a real spectacle independence after cataract surgery, with the presence of a minimal postoperative refractive error. It should be considered that currently patients undergoing cataract surgery are more demanding.[4] For this reason, sophisticated IOL designs are being developed in the last years to provide a correction of not only spherical but also astigmatic refractive errors, which are the toric IOLs. The selection of the cylindrical power of toric IOLs is based on the measurement of corneal astigmatism which should very accurate to avoid inadequate IOL power calculations.

Currently, there are many devices providing measurements of corneal curvature and astigmatism that can be used for toric IOL power calculation,[5] but the consistency of measurements provided by some devices is unknown as well as their interchangeability with those provided by other instruments. There is strong scientific evidence on the repeatability and consistency of keratometric astigmatism measurements provided by commercially available optical biometers, such as the IOL-Master system (Carl Zeiss, Jena, Germany)[6-9] or the Lenstar biometer (Haag-Streit, Koeniz, Switzerland),[6,10,11] with two of these studies confirming that keratometric measurements provided by both devices were not interchangeable.[10,11] To our knowledge, only one study has evaluated to this date the intra-session repeatability of keratometric astigmatism obtained with the Verion System (Alcon Laboratories Inc., Fort Worth, TX),[12] with an analysis of the interchangeability of such measurement with that provided by the IOL-Master optical biometer. The aim of our study was to evaluate

in healthy eyes the intra-session repeatability of ==point-based== keratometric readings and astigmatism value obtained with the Verion system as well as their interchangeability with those ==topographic simk keratometric values and astigmatism obtained== with an optical biometer based on non-contact optical low-coherence interferometry (Aladdin, Topcon, Tokyo ,Japan).

MATERIAL AND METHODS

Patients

A total of 53 healthy eyes of 53 patients ranging in age from 31 to 67 years (mean age 52.8 years) were included in this prospective and nonrandomized study. All participants were selected from the anterior segment consultation of the Department of Ophthalmology of the Marina Baixa Hospital (Villajoyosa, Alicante, Spain), where this investigation was developed. Only one eye from each patient was chosen for the study randomly according to a dichotomic sequence (0 and 1) in order to avoid the potential interference in the outcomes of the correlation that often exists between the two eyes of the same person. The inclusion criteria were healthy eyes, age of more than 30 years old and refraction error between +5.00 D and -10.00 D. The exclusion criteria were high refractive errors, previous ocular surgeries, corneal opacities or scars, ectatic corneal disease, and active ocular disease. Patients were informed about the aim of the study following the tenets of the Declaration of Helsinki of 1975 (As revised in Tokyo in 2004).

Measurement protocol

All eyes underwent a standardized comprehensive ophthalmologic examination comprising uncorrected and best-corrected visual acuity, manifest refraction, Goldmann tonometry, slit-lamp biomicroscopy examination, non-contact point-based keratometry with the Verion image-guided system (software version 2.5), and corneal topography and non-contact biometry with the Aladdin system (software version 1.3.2). Measurements with the Verion system were performed before the measurement with the optical biometer in all cases. All of them were performed by the same single experienced examiner (CRB). In all cases, three consecutive keratometric measurements were obtained with the Verion system in order to assess their intra-session repeatability. The recommendations of the manufacturer of the Verion system were followed and when measurements were performed, only those with green and yellow light indications in the simulated traffic light icon (positive recommendations) were accepted. The intra-session repeatability was only evaluated for the Verion system as this was the aim of the study and the intra-session repeatability of the optical biometric measurements of the Aladdin system has been widely evaluated in previous studies.[13,14]

The Verion system

The Verion image-guided system is composed of the Reference Unit and the Digital Marker and its aim is to facilitate the surgical procedure of cataract removal and IOL implantation (especially toric IOLs). The Reference Unit includes two modules: the Measurement Module that allows measuring different ocular parameters, such as keratometry, white-to-white horizontal distance, limbus position and diameter, pupil location, corneal reflex position or eccentricity of the visual axis, and the Vision Planner

that allows planning the cataract surgery, including selection of toric or multifocal IOLs, optimum corneal incisions, capsulorrhexis, and IOL centration and position.

In the current study, the manufacturer recommendations were followed for performing the measurements. With the Measurement Module, patients were asked to look all the time at a red fixating light to avoid misalignments. When a green circle appeared in the center of the cornea, the image was taken by pushing the button in the joystick. The measurement was completed when the four signs on the screen "centration", "corneal power", "focus" and "fixation" appeared in green. After this and before accepting the measurement, three important light indicators displayed on the monitor were reviewed: "corneal power", "astigmatism" and "vessel". These indicators provided information about the measurement quality. "Corneal power" was the first indicator revised. If it appeared in green, we continued checking the "astigmatism" indicator. If it appeared in yellow, the measurement was accepted but after performing additional measurements and confirming their consistency. In contrast, if "corneal power" indicator appeared in red, the measurement was cancelled and repeated. The indicator "astigmatism" was the second priority. If its light was green, we continued with the checking of the vessel indicator. If its light was yellow and the cylinder measured was 1.5 D or below, the measurement was accepted. In contrast, the measurement was cancelled and repeated if the examiner obtained yellow light for a measured cylinder of more than 1.5 D or red light. The "vessel" was checked at the end of the measurement procedure. Its light was green when the measurement was correct or yellow. In this last situation, the reference image was revised in detail confirming if the eye was focused before accepting the measurement.

Besides the measurement features of this system, it originates a high-resolution image of the anterior segment of the eye, capturing the scleral vessels as well as limbus

and iris details. These are used as references during cataract surgery to perform an automatic correction of the cyclotorsional rotation of the eye. All information from measurements and image analysis are transferred to the Digital Marker that can be used by the surgeon in the operating theater to see in real time the size and location of incisions, to control digitally the capsulorrhexis, and to guide IOL positioning (especially with toric IOLs).

The Aladdin biometer

The Aladdin system (Topcon) is a multi-function instrument that combines Placido-disk topography and low coherence interferometry technologies to provide a series of measurements including axial length, corneal topography, pupillometry, corneal diameter and anterior chamber depth. The topography system allows the measurement of more than 6,200 points, with a corneal coverage up to 9.8 mm, resolution of ±0.01 D, and accuracy of axial radius of ±0.02 mm. Additionally, the instrument includes the real corneal radii (RCR) technology, which gathers approximately 1,000 data points at the 3-mm diameter and measures the corneal radii as reliably and reproducibly as the auto-keratorefractometers. The optical low coherence reflectometry technology of the device can penetrate even high-density cataracts due to its use of an 850-nm superluminescent diode and signal processing, allowing the measurement of axial length in a range from 15 to 38 mm. The software of the device incorporates conventional intraocular lens (IOL) power calculation formulas such as SRK II, SRK/T, Holladay 1, and Haigis, and postrefractive surgery formulas including Camellin-Calossi and Shammas no-history.

Statistical analysis

The statistical analysis 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. Intra-session repeatability for the keratometric measurements obtained with the Verion system was assessed by means of the within-subject standard deviation (S_w) of the 3 consecutive measurements and the intrasubject precision.[15] The within-subject standard deviation (S_w) is a simple way of estimating the size of the measurement error. The intraobserver precision was defined as (± 1.96 x S_w) and this parameter indicates how large is the range of error of the repeated measurements for 95% of observations. Besides the intra-session repeatability analysis, an evaluation of the interchangeability of the keratometric measurements obtained with the Verion and Aladdin systems was performed using the Bland-Altman method. The limits of agreement were defined as the mean ± 1.96 standard deviation (SD) of the differences. Furthermore, Pearson correlation coefficients were used to assess the correlation between the magnitude of the parameters evaluated and their S_w. All statistical tests were 2-tailed, and p-values less than 0.05 were considered statistically significant.

Sample size calculation was performed in order to confirm if the sample of eyes included in the current study was of adequate size using the software PS version 3.1.2 (free availability online: http://biostat.mc.vanderbilt.edu/wiki/Main/PowerSampleSize). This software uses the Dupont and Plummer approach for sample size calculation.[16] We estimated the number of pairs needed to detect a true difference in population means (δ) with type I error probability α given a standard deviation (σ). Specifically, for a statistical power of 80%, considering δ and σ reported comparing the Verion system

and the optical biometer system IOL-Master,[12] and an α error of 0.05, the sample size required was 53 eyes.

RESULTS

The study involved 53 eyes of 53 subjects with a mean age of 52.8 years old (ranging from 31 to 67 years). Table 1 summarizes the outcomes of the intra-session repeatability analysis for the Verion keratometric measurements. The S_w was below 0.26 D for K1, K2 and keratometric astigmatism. For the axis of the flattest keratometric meridian, S_w was 4.29º. No statistically significant correlations of mean keratometric measurements with their associated S_w (K1: r=0.125, p=0.372; K2: r=0.035, p=0.804) and CV (K1: r=0.097, p=0.492; K2: r=0.000, p=0.995) were found. Likewise, no significant correlation among mean astigmatism and its S_w value associated was found (r=-0.031, p=0.824). Concerning the axis of the flattest keratometric meridian, poor but statistically significant correlations of the S_w of the axis of the flattest keratometric meridian with the magnitude of astigmatism (r=0.391, p=0.004) and the S_w corresponding to keratometric astigmatism were found (r=0.349, p=0.010).

Table 2 summarizes the results of the interchangeability analysis of the keratometric measurements obtained with the Verion and Aladdin systems. Statistically significant differences among systems were found in K1 (Figure 1), K2 (Figure 2) and keratometric astigmatism (Figure 3) (p<0.01), but these differences were within a clinically acceptable level. In contrast, no statistically significant differences among systems were found in the axis of the flattest keratometric meridian (p=0.385), but they were clinically relevant according to the Bland & Altman analysis (Figure 4). No

significant correlation was found between mean magnitude of astigmatism obtained with both instruments and the differences in astigmatic axis between them (r=0.090, p=0.539, Figure 5). Likewise, no significant correlation was found between mean axis of astigmatism obtained with both instruments and the differences in astigmatic axis between them (r=-0.052, p=0.722, Figure 6).

DISCUSSION

Biometric measurements have become indispensable in any anterior segment consultation, especially for planning different types of surgical procedures.[5] For this reason, studies evaluating the validity of biometric measurements provided with the different currently available devices are necessary to really know the clinical applicability of such devices. Intraoperative image-guided systems have been recently developed to assist during ophthalmic surgeries, especially during cataract surgery, but also to provide some biometric measurements to be used in IOL power calculations, such as corneal power or astigmatism. To this date, only one study[12] has previously assessed the repeatability of keratometric and corneal diameter measurements provided by the intraoperative image-guided system Verion. This study reported a high level of consistency of keratometric power, astigmatism and astigmatic axis measurements.[12] In the current study, we have tried to validate the use of the Verion system for the performance of keratometric measurements by assessing first the consistency of repeated consecutive measurements and afterwards the interchangeability of such measurements with those provided by a previously validated optical biometer.

In our sample of healthy eyes, intra-session repeatability was good for all keratometric measurements, with S_w below 0.26 D for K1, K2 and astigmatism and S_w

of 4.29º for the axis of the flattest meridian. These results are consistent with those obtained also by Nemeth et al[12] with the Verion system for keratometric power and corneal astigmatism. Likewise, our results are also consistent with those reported for other devices providing keratometric readings, such as corneal topographers or optical biometers.[17-19] Therefore, the measurement module of the Verion system is able to provide consistent measurements of keratometric parameters and might be used for IOL power calculations. However, it is still necessary to know if these measurements are interchangeable with those provided by another validated device. For this reason, an agreement study between the Verion system and a previously validated optical biometer was performed.

The agreement analysis of our study confirmed that there was a good clinical agreement among keratometric measurements obtained with the two systems compared, Verion and Aladdin systems. Although there were statistically significant differences among systems in K1, K2, and corneal astigmatism ($p < 0.01$), these differences were within a clinically acceptable level. It should be considered that mean differences in keratometry between devices were close to 0.25 D or below, and errors of 0.50 D in corneal power estimation can lead as much to 0.50 D of error in IOL power calculation,[20] which is the minimum IOL power step provided by most manufacturers. Nemeth et al[12] analyzed the agreement among the keratometric measurements obtained with the Verion system and another optical biometer based on partial coherence laser interferometry, the IOL Master system. These authors found that differences in the keratometric power vectors between the two devices were clinically acceptable.[12] However, they confirmed that differences in the axis of keratometric astigmatism were out of a clinically acceptable range, with all eyes with more than 15° of disagreement between devices having a cylinder value of less than 1.0 D.[12] This finding is consistent

with the outcomes of our agreement analysis between Verion and Aladdin systems for the axis of astigmatism. Although differences among systems in the flattest keratometric axis were not statistically significant, the Bland and Altman analysis showed clinically relevant ranges of agreement. A mean difference of 15.74º was obtained which is clinically unacceptable considering that 11.5º of toric IOL misalignment leads to residual astigmatism that is 40% of the initial astigmatic power.[21]

Differences in the flattest axis among Verion and Aladdin devices were especially relevant in our study for low astigmatisms, between 0 and 1 D. In contrast, good agreement in axis between systems was found for astigmatisms of more than 1.5 D (differences among devices of 5º or below). This is consistent with the results of the study of Nemeth et al,[12] in which larger disagreements between the Verion and Aladdin systems were observed in the axis of corneal astigmatism for those eyes with low magnitudes of corneal astigmatism. Several factors may have accounted for this fact, such as the less consistency of astigmatic axis measurements for low cylinders[22] or the different mathematical approach to determine the corneal astigmatism axis with each device. Visser and colleagues[23] confirmed by vector analysis that corneal astigmatism measurements were comparable using automated, manual, and simulated keratometry, but not comparable to those obtained with a Scheimpflug photography-based system (Pentacam). Kobashi and coauthors[24] compared a Placido disk-based corneal topographer and autokeratometer and found interchangeability of both systems for corneal power measurements but not for axis location, especially in those eyes with low astigmatism. Anayol and colleagues[25] concluded in another comparative study that three different Scheimpflug imaging-based systems (Pentacam, Galilei and Sirius) should not be accepted as interchangeable for keratometric and astigmatic in healthy subjects. In our sample, we also observed that the disagreement in axis between Verion

and Aladdin systems was higher in those eyes with oblique cylinder. As previously mentioned, the different algorithm used for each device for the calculation of astigmatism may have played a role on this. It should be considered that the Verion system provides a calculation of astigmatism based on point-based keratometric readings whereas the Aladdin system calculates the astigmatism based on topographic analysis. This suggests that measurements in oblique corneal cylinders should be performed with different devices and compared, especially in high oblique astigmatic values intended to be use for toric IOL power calculation, in order to select the most consistent value.

Although the Verion system may be considered as a useful tool for cataract surgery planning, it has two limitations that should be acknowledged. The first limitation is the inability of measuring the astigmatism of the posterior corneal surface that has been demonstrated to have a significant role on toric IOL power calculation.[26-28] As a second limitation, the Verion system does not provide axial length measurements to this date and therefore another device is useful for IOL power calculation.

In conclusion, the Verion image-guided system provides non-invasive and repeatable keratometric measurements, and the device can be used then for planning cataract surgeries. This system provides keratometric values comparable to those obtained with an optical biometry system, but differences may be clinically relevant for the axis of astigmatism, especially for low and oblique cylinders. Further studies are needed to compare the impact of the repeatability of measurements obtained with this device in other anterior segment surgeries, as well as to evaluate the agreement with other devices.

Declaration of interest

The authors have no financial or proprietary interest in a product, method, or materials described herein, and have no commercial relationships that could be viewed as presenting a potential conflict of interest

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Figure 1.- Bland-Altman plots for the comparison between the values of keratometric power in the steepest meridian (K1) obtained with the Verion and Aladdin systems. The dotted lines show the limits of agreement ($\pm1.96SD$).
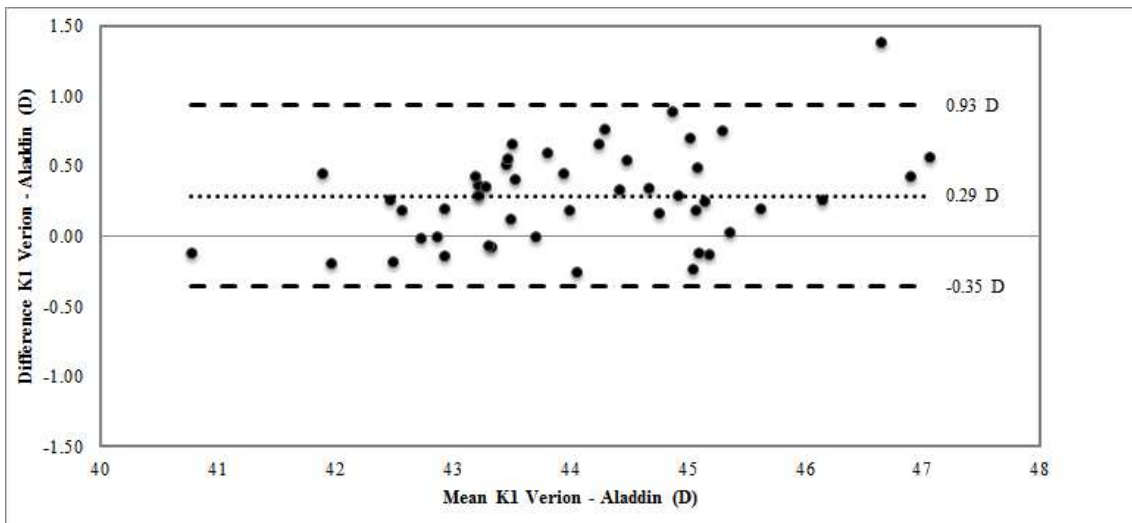

Figure 2.- Bland-Altman plots for the comparison between the values of keratometric power in the flattest meridian (K2) obtained with the Verion and Aladdin systems. The dotted lines show the limits of agreement ($\pm1.96SD$).
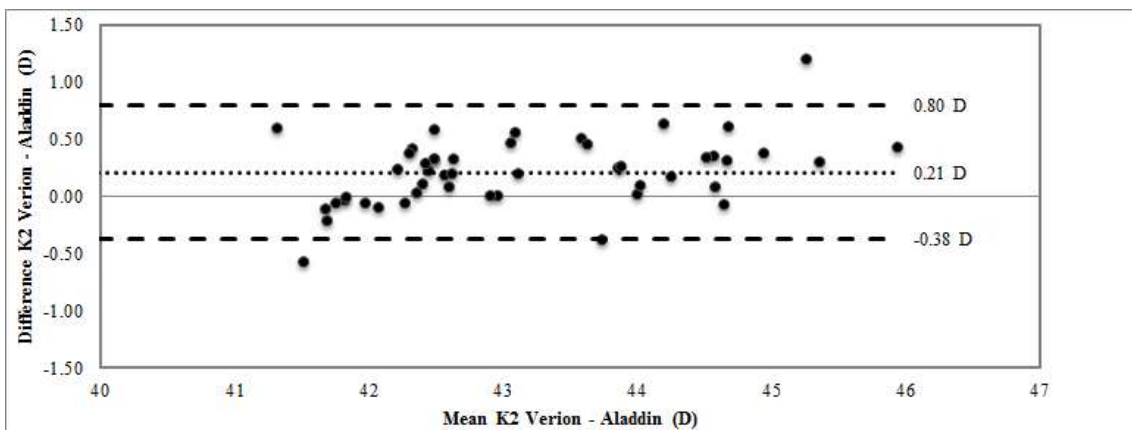
Figure 3.- Bland-Altman plots for the comparison between the values of keratometric power in the keratometric astigmatism obtained with the Verion and Aladdin systems. The dotted lines show the limits of agreement (±1.96SD).
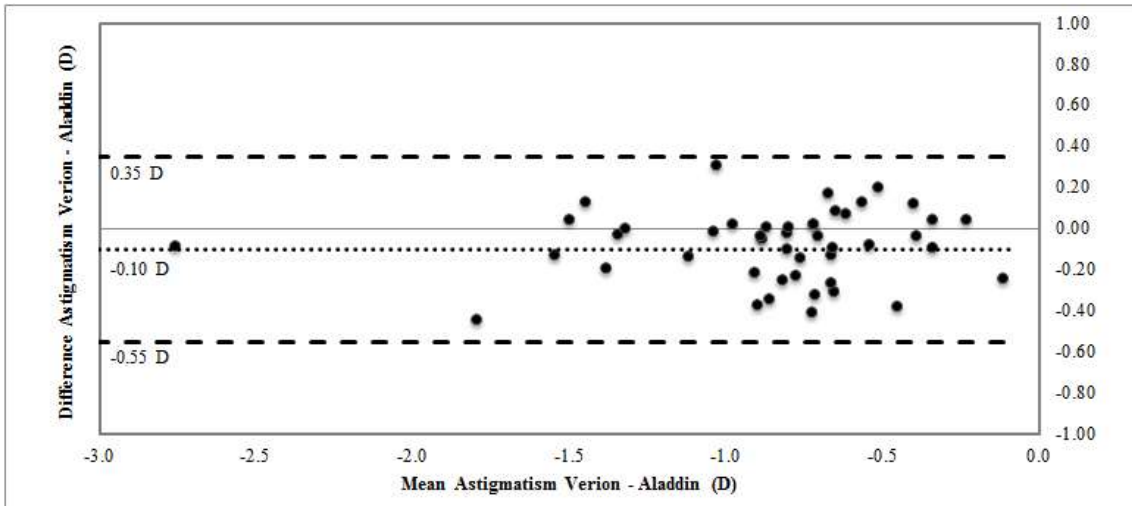

Figure 4.- Bland-Altman plots for the comparison between the values of keratometric power in the axis of the flattest of the keratometric meridian obtained with the Verion and Aladdin systems. The dotted lines show the limits of agreement (±1.96SD).
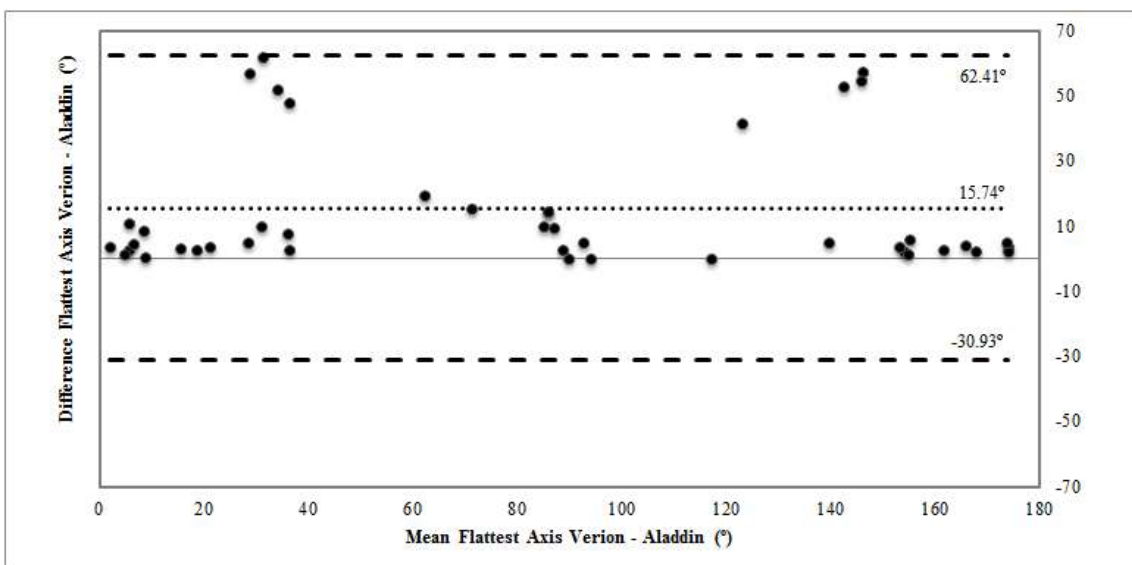
Figure 5.- Scatterplots showing the relationship between the mean magnitude of corneal astigmatism obtained with the Verion and Aladdin systems and the difference in the flattest axis obtained with both. The adjusting line to the data obtained by means of the least-squares fit is shown.
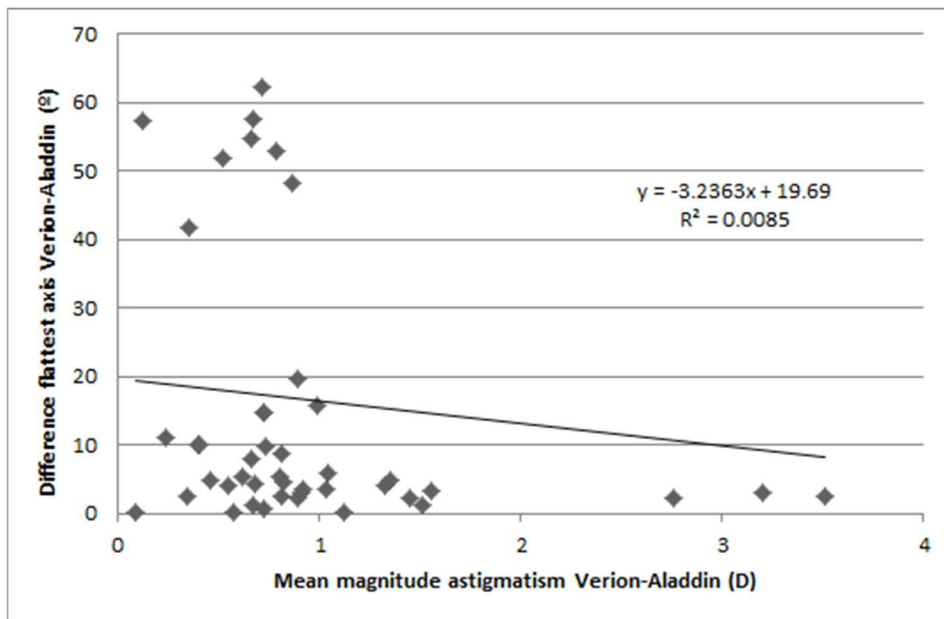

Figure 6.- Scatterplots showing the relationship between the mean axis of corneal astigmatism obtained with the Verion and Aladdin systems and the difference in the flattest axis obtained with both. The adjusting line to the data obtained by means of the least-squares fit is shown.
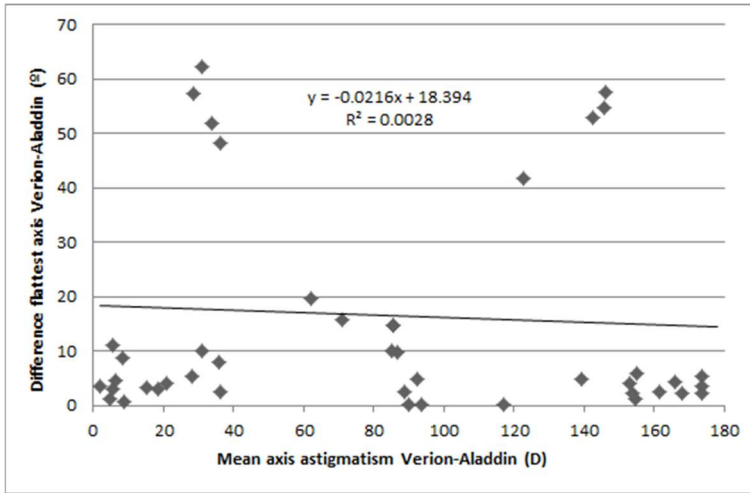
Table 1.- Summary of the intrasession repeatability outcomes for the keratometric measurements obtained with the Verion system.

	Overall mean (SD) Overall median (Range)	S_w	Pr (º)
K1 (D)	44.23 (1.38) 44.08 (40.71 to 47.34)	0.26	0.51
K2 (D)	43.20 (1.28) 42.90 (39.82 to 46.15	0.24	0.47
Corneal astigmatism (D)	-1.02 (0.71) -0.86 (-3.50 to -0.21)	0.10	0.20
Flattest keratometric axis (º)	86.45 (61.52) 80.00 (1.67 to 178)	4.29	8.41

Abbreviations: SD, standard deviation; K1, steepest keratometric reading; K2, flattest keratometric reading; S_w, within-subject standard deviation; Pr, intraobserver precision.

Table 2.- Bland & Altman analysis outcomes of the comparison between keratometric measurements obtained with the Verion and Aladdin systems.

	Mean difference ± SD	Limits of agreement	p-value
K1 (D)	0.29 ± 0.33	-0.35 to 0.93	<0.001
K2 (D)	0.21 ± 0.30	-0.38 to 0.80	<0.001
Corneal astigmatism (D)	-0.10 ± 0.23	-0.55 to 0.35	0.004
Flattest keratometric axis (º)	15.74 ± 23.81	-30.93 to 62.41	0.385

Abbreviations: SD, standard deviation; K1, steepest keratometric reading; K2, flattest keratometric reading.