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Intrasession and Intersession Repeatability of a new PCT-200 Corneal Topographer on Calibrated Steel Surfaces and Healthy Eyes

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PURPOSE: To assess intrasession and intersession repeatability of a new tilted-cone, Placido-disc based corneal topographer (PCT-200, Optopol Tech., Poland) on calibrated steel surfaces and healthy human eyes.

METHODS: Five repeated measures of surface topography were obtained on a set of four different calibrated steel spherical surfaces and on a sample 30 healthy human eyes in each of two sessions. Variance of apical radius, eccentricity and Fourier Indices was assessed both within and between sessions using analysis of variance (ANOVA), paired samples t-test and intraclass correlation coefficients (ICC).

RESULTS: Repeated measurements on calibrated steel surfaces and human eye sample of all parameters were not significantly different within session (ANOVA) nor between sessions (paired samples t-test), p-values exceeded greatly 0.05 in all cases. ICCs were greater than 0.98 and 0.77 for steel surfaces and human eyes, respectively, for all parameters analysed.

CONCLUSIONS: The new tilted-cone corneal topographer performs well in both spherical surfaces and healthy human eyes, providing with repeatable measures of corneal topography, comparable to other Placido-based devices currently in the market.

KEYWORDS: Corneal topographer, Repeatability, Calibrated steel spherical surfaces, Healthy eyes.

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INTRODUCTION

The cornea is the eye's most important lens, contributing nearly two-thirds of the total refractive power of the eye. Is the anterior optical element of the eye and therefore plays an important role in focusing images on the retina.

Good vision depends on good retinal image quality, and this in turn depends on good optical quality of the cornea and lens. Accurate measurement of this surface is therefore important for diagnostic and therapeutic applications, including intraocular lens power calculation and for planing procedures to correct corneal astigmatism.

The use of the videokeratoscope (VK) to determine many aspects of human corneal topography has increased greatly in recent years, providing powerful tools for detecting subtle, but clinically significant, alterations of corneal contour¹⁻⁶. The clinical applications of the VK include: planning and assessing orthokeratology therapy, monitoring of corneal changes over time; contact lens-induced changes and fitting contact lenses in patients with irregular astigmatism; evaluation of the cornea after refractive and cataract surgery and to understand patients visual complaints; evaluation of unexplained visual loss and to determine visual complications from corneal dystrophies, scars, pterygia, recu-

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urrent erosions, and chalazia⁷⁻¹³. In addition, the rapid development of excimer laser refractive surgery in the 1990s was paralleled by equally rapid developments in computerized corneal topography.

Placido-based videokeratoscopes are the most popular systems in clinical practice. In 1882, Placido used reflections of circles shone onto the cornea to determine astigmatism qualitatively. This technique is the origin of the Placido disc-based systems that are the basis of many of the commonly used VKs. The system is based on the principle that the cornea acts as a convex mirror. Keratotomy permits the inspection of the central and peripheral cornea without assuming it is spherocylindrical. The color-coded image facilitates qualitative detection of variations in corneal curvature and quantitative descriptors of corneal topography such as the surface asymmetry index, the surface regularity index, and simulated keratometry value augment the information provided by color-coded topographic maps. Recently, the addition of new cone designs, more sensitive video cameras, and correcting algorithms have increased the benefits of these instruments. Shape descriptors, including p-value, eccentricity, asphericity and shape factor, can be derived from the measurement of central and peripheral corneal curvature.

The data provided by topography must be accurate, repeatable, and reproducible if clinical decision-making is to be directed by VK data and moreover to avoid errors in complex lens designs required for modern corneal treatments. Repeatability assess whether repeated measures of the same surface with the same instrument will give the same values. A number of reports have been published on the reliability or accuracy of different corneal topographers¹⁴⁻⁴⁴.

The aim of this study was to evaluate the performance of a new tilted-cone Placido disc based corneal topographer (PCT-200, Optopol Tech., Poland) on calibrated steel surfaces and 30 healthy eyes, with regards to apical radius (Ro), eccentricity and Fourier Indices, and therefore to determine the number of repeated readings required for the topographer studied to minimize the error.

METHODS

In this study, initially five repeated measures of surface topography were obtained on a set of four different calibrated steel spherical surfaces, and posteriorly three repeated measures of healthy eyes in each of two sessions. All measurements were taken on the same day.

Calibrated model eye sample

The calibrated steel surfaces used in this study were spherical with radius of curvature of 6.13 mm, 7.10 mm, 7.94 mm and 9.00 to represent the broad

range of corneal curvatures encountered. The calibrated steel surfaces were mounted on a specially designed apparatus and secured perpendicular to the instrument axis. The surface was cleaned with a fluid alcohol and with a high-quality lint-free lens cloth. The measurements were taken in random order under identical illumination conditions, and the instrument was realigned before each acquisition. Five repeated captures of corneal topography were done with the PCT-200 Corneal Topographer and registered in the database for subsequent analysis. To avoid the possible effect of diurnal variation, all measurements were taken in late morning⁷.

Human eye sample

Second, this study evaluated 30 eyes of 15 subjects (6 male and 9 female), aged between 26 and 37 years. A full explanation of the procedure was given prior to entering the study in order to obtain informed consent from each patient. Inclusion criteria were no known ocular irritation, no history of contact lens use, no tear problems, no anterior segment abnormality, and a manifest refractive error of less than -5.00 dioptres of myopia, less than $+4.00$ dioptres of hyperopia and less than 2.00 dioptres of astigmatism with a best corrected visual acuity of 20/20 or better. Three repeated captures of corneal topography were done in the evaluated subjects. The subject's chin was placed on the chin rest and the forehead rested against the forehead strap. The subject was instructed to look at a blinking green fixation light. The examiner adjusted the optical head using a joystick to align and focus the eye so that the cornea was centred on the video monitor. The video image was then captured.

Corneal topographer

The new tilted-cone Placido disc based corneal topographer (PCT-200, Optopol Tech., Poland) utilize autofocus followed by auto capturing of the image. There are 26 rings for each image, each ring consisting of 16000 points. To analyze the data, each ring was decomposed into its corresponding Fourier series. These coefficients can be calculated from corneal topographic data using numerical integration. In some cases, the ring data had missing values. Fourier series analysis of incomplete data can lead to large sampling errors if the gap is large compared to the frequency of the harmonic. Linear interpolation was therefore used to fill in gaps in the ring data.

Statistical analysis

To evaluate intrasession and intersession repeatability, variance of Ro, eccentricity (Simulated keratometry values) and Fourier Indices was assessed both

within and between sessions using analysis of variance (ANOVA) (P value less than 0.05 was considered statistically significant), paired samples t-test and intra-class correlation coefficients (ICC) (The maximum ICC value is 1.00, and the closer the ICC value is to 1.00, the stronger the reliability. In general, Portney and Watkins suggested that ICC values above 0.75 indicate good reliability, but for most clinical measurements ICC should be ≥ 0.9 to ensure reasonable validity)⁴⁵, using the statistical package SPSS v.11.0 (SPSS Inc, Chicago, IL, USA). And also represented graphically using Bland-Altman analysis and regression plots⁴⁶⁻⁴⁸.

RESULTS

Calibrated steel spherical surfaces

Repeated measures ANOVA showed no significant difference in the data obtained nor between sessions (paired samples t-test), p -values exceeded greatly 0.05 for all parameters assessed. ICCs were greater than 0.98 for all parameters analysed (see table 1). The 95% limits of agreement (LoA) values for all parameters were very

small, indicating small discrepancies between measurements. In regression plots (figure 1) can be seen that the trend lines are very close to the line of slope 1.

In analyzing the accuracy of the new PCT-200 (see table 2) we detect differences in the order of 0.12 mm in all calibrated steel spherical surfaces evaluated. If we consider that the difference is the same for the 4 surfaces, a systematic instrument error may be considered, and therefore corrected, with little clinical relevance.

Human eye sample

After removing two outliers in the human eye sample, and analyzing the remaining 28 healthy eyes, repeated measures ANOVA showed no significant difference in the data obtained within session nor between sessions, p -values exceeded greatly 0.05 for all parameters assessed. ICCs were greater than 0.77 for all parameters analysed (see table 3). Figure 2 presents a summary of the results obtained for Bland-Altman analysis and figure 3 presents regression plots.

The values obtained in session 1 were slightly different from the values of session 2.

Table 1: Results of intrasession and intersession repeatability of PCT-200 obtained in calibrated steel spherical surfaces

	Ro	Ecc	Fourier Indice Ro	Fourier Indice Ecc
ANOVA Intrasession	0.156	0.405	0.419	0.224
ICC Intrasession	1	0.996	0.999	0.975
ICC Intersession	1	0.998	1	0.999
Mean difference	0.013±0.039	-0.005±0.020	0.006±0.058	0.002±0.014

Ro= apical radius (mm); Ecc= eccentricity; ICC= intraclass correlation coefficient.

Table 2: Accuracy of PCT-200

Real Value Ro	Mean Ro S1	Mean Ro S2	Difference S1-Real Value	Difference S2-Real Value
6,13	5,98	5,99	0,15	0,14
7,1	7,01	7,02	0,09	0,08
7,94	7,84	7,83	0,1	0,11
9	8,88	8,84	0,12	0,16

Ro= apical radius (mm); S1= session 1; S2= session 2.

Table 3: Results of intrasession and intersession repeatability of PCT-200 obtained in human eye sample

	Ro	Ecc	Fourier Indice Ro	Fourier Indice Ecc
ANOVA Intrasession	0.460	0.365	0.475	0.287
ICC Intrasession	0.966	0.772	0.964	0.800
ICC Intersession	0.987	0.914	0.987	0.893
Mean difference	0.024±0.030	0.022±0.019	-0.102±0.161	0.018±0.022

Ro= apical radius (mm); Ecc= eccentricity; ICC= intraclass correlation coefficient.

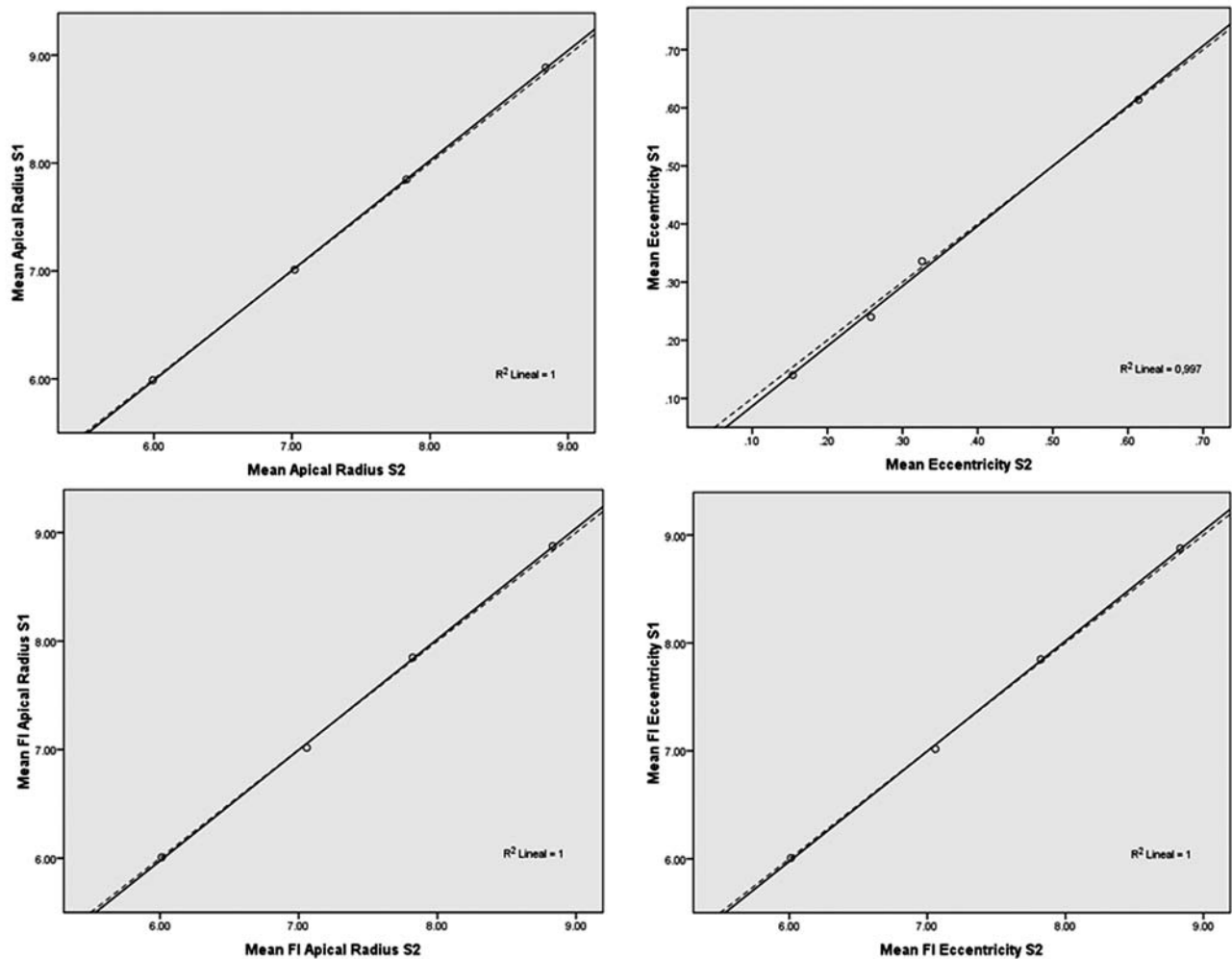


Figure 1. Regression plots showing the correlation between session 1 (S1) and session 2 (S2) for all parameters assessed in calibrated steel spherical surfaces. Trend lines are represented by the solid lines and lines of slope 1 are represented by the dashed lines.

DISCUSSION

In this study good intrasession and intersession repeatability of PCT-200 corneal topographer in both calibrated steel surfaces and 30 healthy eyes was obtained, with regards to Ro, eccentricity and Fourier Indices. P-values exceeded greatly 0.05 and ICCs were greater than 0.98 for all parameters analysed for calibrated steel surfaces. Considering healthy eyes, P-values exceeded greatly 0.05 for all parameters assessed and ICCs were greater than 0.77 for all parameters analysed. The mean difference values were less than 0.01 and 0.1, for all parameters analysed, for calibrated steel surfaces and healthy eyes, respectively.

To our knowledge, no study has analysed the repeatability of a PCT-200 VK. However, the results obtained with this topographer are comparable to those previously obtained with other corneal topographers. González-Pérez et al.¹⁴ compared the accuracy and precision on the measurements of the central curvature on calibrated steel balls using the EyeSys VK and the Orbscan corneal

topography system, and obtained that both instruments are accurate and precise enough for research and clinical purposes. They obtained that the mean difference from real value was less than 0.05 for both instruments. However, our results showed differences in the order of 0.12 mm. Tang et al.¹⁹ assessed the accuracy and precision of three placido-disk videokeratoscopes (Keratron, Medmont and TMS) and one rasterphotogrammetry topographer (PAR-CTS) in elevation topography using six test surfaces. The results showed high accuracy for the Keratron and Medmont instruments in measuring sphere, asphere, and multicurve surfaces, but not the bicurve surfaces. The precision of the Keratron and Medmont instruments were high.

Considering human corneas, previous reports also assessed the performance of different corneal topographers and obtained good results. Koch et al.²¹ compared the accuracy and reproducibility of the Marco keratometer Model 1 and EyeSys Corneal Analysis System (CAS) Model I using four poly (methyl methacrylate) spheres, three steel spheres, and 20 normal human eyes

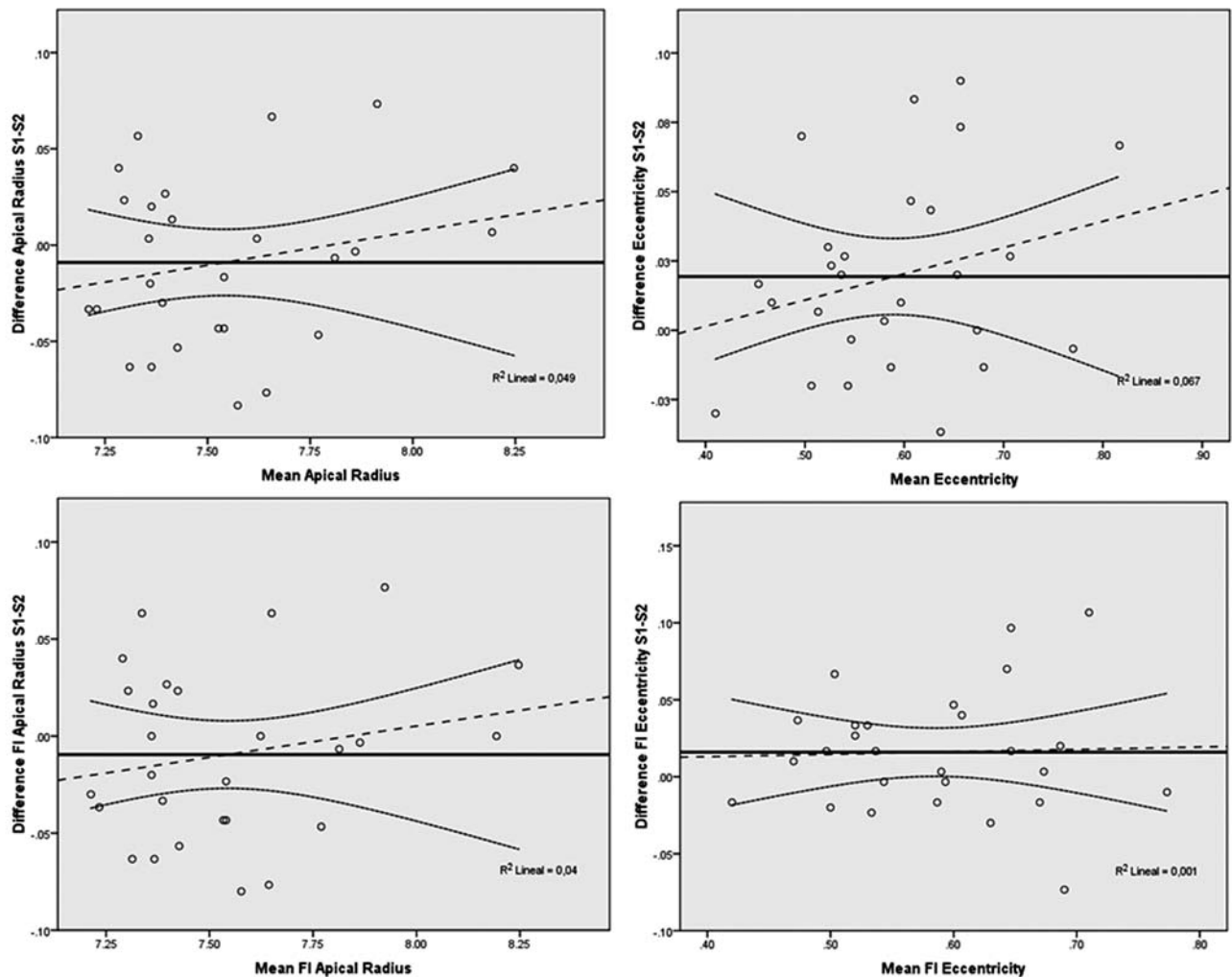


Figure 2. Bland-Altman plots showing the difference in apical radius (mm), eccentricity and Fourier indices (FI) between session 1 (S1) and session 2 (S2) in human eye sample. Central solid lines represents the mean difference, more extreme dotted lines represents 95% limits of agreement and central dashed lines represents lineal adjustment line.

and found that for the spheres, the standard deviations of intra-observer and overall reproducibility for both devices were less than 0.12 D, in agreement with the values reported in the present study. For the normal corneas, the standard deviations of intra-observer and overall reproducibility for dioptric measurements were 0.07 D and 0.14 D for the keratometer and 0.13 D and 0.19 D for the EyeSys. The EyeSys CAS Model I exceeded keratometer accuracy in reading calibrated spheres and approaches keratometer reproducibility in measuring the 3-mm zone of normal human corneas.

Pardhan et al.²² investigated the agreement between the Topcon KR-3500 autokeratometer and the EyeSys videokeratoscope on human corneas and calibrated convex surfaces and reported that the two instruments showed excellent agreement on convex buttons but not for human corneas. Repeatability was also calculated and was shown to be better with the Topcon autokeratometer than with the EyeSys videokeratoscope.

Similarly, Dave et al.²³ reported measurements using a Bausch & Lomb keratometer in 19 eyes (19 subjects) and compared with the simulated keratometry values using the EyeSys CAS. EyeSys simulated keratometry values were not interchangeable with the keratometer. Repeatability of both the Bausch & Lomb keratometer and the EyeSys CAS was found to be similar. In a second study, Dave et al.²⁴ evaluated the precision and repeatability of EyeSys computerized videokeratoscope, using convex surfaces. Repeatability for the aspheric surfaces showed to be high (SD +/- 0.01 mm in all quadrants) and the accuracy of the EyeSys CAS in measuring central and peripheral radius of curvature showed to be dependent on the shape of the surface to be measured. Cho et al.³⁰ evaluated the performances of four different corneal topographers: Humphrey Atlas 991, Orbscan II, Dicon CT200 and Medmont E300 on 22 young Chinese adults. There were no significant differences for any of the parameters tested for each topo-

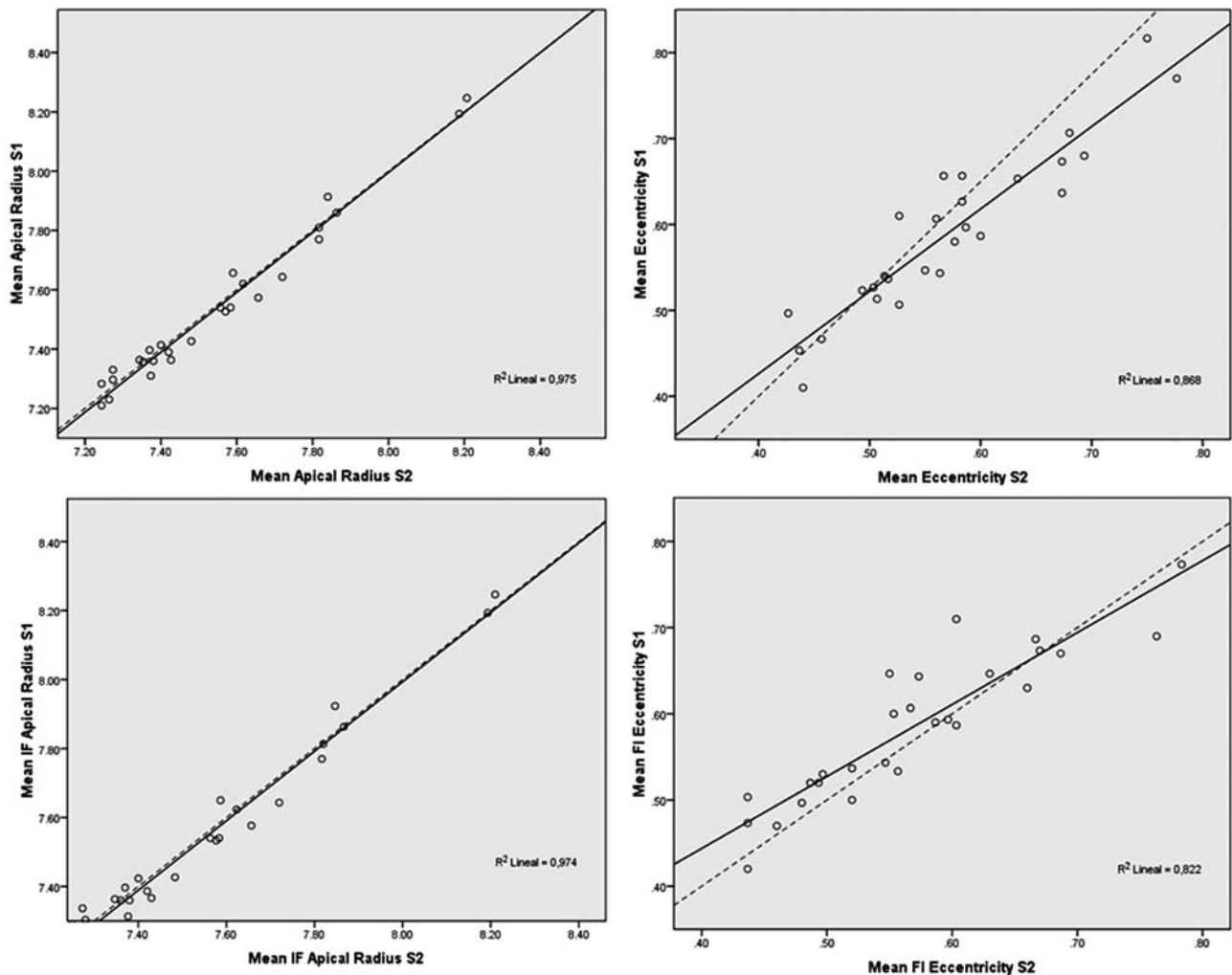


Figure 3. Regression plots showing the correlation between session 1 (S1) and session 2 (S2) for all parameters assessed in human eye sample. Trend lines are represented by the solid lines and lines of slope 1 are represented by the dashed lines.

grapher. ICC values were higher than 0.94 for repeatability of Humphrey and Medmont. Values of different topographers are not interchangeable. In the current study, ICCs values were greater than 0.77 in human corneas. Salmon et al.⁴³ analyzed differences between the EyeSys and ORBSCAN surface elevation measurements and obtained that the EyeSys was about three times more precise than the Orbscan for repeated measurements of a normal human cornea. In a different study, Kawamorita et al.³⁹ evaluated the repeatability and reproducibility Pentacam eye scanner and Keratron corneal topographer for the measurement of corneal parameters and obtained that both devices provided good repeatability and reproducibility, but Pentacam readings for central curvature were statistically significantly different than those from the Keratron and are not interchangeable. Recently, Shirayama et al.⁴¹ assessed the repeatability and comparability of corneal powers obtained from four different devices (Humphrey Atlas corneal topographer,

IOLMaster, manual keratometer and Galilei Dual Scheimpflug Analyzer) and found that all devices were highly reproducible (ICCs were higher than 0.99 in all devices) and well correlated.

In conclusion, the results obtained in the present study are comparable to those of previous reports about the performance of the VKs. Through our study, we were able to demonstrate that new tilted-cone Placido disc based corneal topographer PCT-200 provides as good repeatability in both calibrated steel surfaces and healthy eyes as other corneal topographers currently in the market being also better on calibrated surfaces (in agreement with previous studies). Results for accuracy on human corneas and comparison of results against gold standard would be desirable for future reports.

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