ARTICLE

# Pachymetric measurements with a new Scheimpflug photography–based system

## Intraobserver repeatability and agreement with optical coherence tomography pachymetry

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**PURPOSE:** To evaluate the intraobserver repeatability of pachymetric measurements obtained with a new Scheimpflug photography–based system and the agreement of the measurements with those obtained by optical coherence tomography (OCT).

**SETTING:** Vissum Corporation, Alicante, Spain.

**DESIGN:** Evaluation of diagnostic technology.

**METHODS:** Corneal thickness was measured at different locations (center; 2.5 mm and 4.0 mm nasal, temporal, superior, and inferior) in 18 eyes of 18 patients with no ocular pathology or previous surgery with a Scheimpflug photography–based system (Sirius). Three consecutive measurements at each location were obtained with the system to evaluate intraobserver repeatability. Afterward, pachymetric measurements were obtained at the same locations with an OCT system (Visante) to evaluate the agreement between techniques using the Bland-Altman method.

**RESULTS:** The intraclass correlation coefficient of repeated measures ranged from 0.990 to 0.997. The coefficient of variation was lower than 1% and the standard deviations of the repeated measurements ($S_w$) were below 6 μm at all corneal locations. Statistically significant differences were found between the coefficient of variation and $S_w$ values of the repeated measurements corresponding to the 2.5 mm and 4.0 mm locations ($P \leq .037$). The agreement with OCT pachymetric measurements was poor, with ranges of agreement larger than 20 μm at all corneal locations. Statistically significant differences were found between standard deviations of the differences between the 2 devices at the 2.5 mm and 4.0 mm locations ($P \leq .017$).

**CONCLUSION:** Scheimpflug photography–based technology provided repeatable pachymetric measurements that were not equivalent to those obtained with OCT.

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Several devices with different physical bases have been developed for the clinical measurement of corneal thickness; they can be classified into 4 categories: Scheimpflug-based, ultrasound (US) based, slit-scanning and optical coherence tomography (OCT) based.[1–3] Scheimpflug photography–based, slit-scanning topography, and OCT systems allow the clinician to obtain corneal pachymetric information by means of a noninvasive procedure. These devices provide pachymetric maps without the use of anesthesia or contact with the cornea, as is required when using US-based systems.[4,5] This contact required with US pachymetry is considered a main disadvantage of the technique, as is the method's dependence on reliable probe alignment by the operator.[6]

There are numerous studies of the reliability of the different pachymetric devices used in clinical practice. Excellent intraobserver or intrasession repeatability of pachymetric measurements obtained by means of all the different technologies has been reported.[7,8] These studies show the relevance and usefulness of noninvasive optical technologies in clinical practice, which



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allow consistent corneal pachymetric mapping without corneal contact and in a very few seconds. Specifically, pachymetry by OCT and Scheimpflug photography has been shown to be reliable and noninvasive.[6–10]

The aim of the current study was to evaluate the intraobserver repeatability of central and peripheral pachymetric measurements obtained with a new topography system that combines Scheimpflug photography and Placido disk technologies and to evaluate the agreement of these measurements with those obtained by an OCT system.

## SUBJECTS AND METHODS

The subjects in this study were selected from the personnel of Vissum Corporation, Alicante, Spain, where the study was developed. One eye of each subject was randomly chosen for the study according to a random number sequence (dichotomic sequence, 0 and 1) that was created with specific software. This was done to avoid the correlation that often exists between the 2 eyes of the same person. All subjects in the study were free of ocular pathology to eliminate this variable as a cause of measurement error. In addition, all were informed previously about the study and signed an informed consent document in accordance with the Declaration of Helsinki.

### Measurement Protocol

The same single experienced examiner (F.A.) performed all tests. First, 3 consecutive measurements were taken with the Sirius Scheimpflug-based system (Costruzione Strumenti Oftalmici). Then, 1 pachymetric record was obtained with the Visante OCT system (Carl Zeiss Meditec AG). Once the measurements were obtained and recorded, another experienced examiner (M.M.) comprehensively analyzed all images and pachymetric maps. The same eye of each subject was used for measurements with both instruments.

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Corneal thickness was recorded in all pachymetric maps obtained with both systems at the same locations following this order:

1. Corneal thickness at the geometric center of the cornea; that is, the central corneal thickness (CCT).
2. Corneal thickness 2.5 mm nasally, 2.5 temporally, 2.5 superiorly, and 2.5 inferiorly.
3. Corneal thickness 4.0 mm nasally, 4.0 mm temporally, 4.0 mm superiorly, and 4.0 mm inferiorly.

The corneal thickness at the geometric center was the first measurement performed in all cases. This point was used as the reference for defining the rest of the locations through the *x*–*y* Cartesian coordinate grid provided by the software of each instrument.

### Measurement Systems

**Scheimpflug Photography–Based** The Sirius system is a new topography device that uses the principles of Scheimpflug photography and enables rapid acquisition and processing of 25 radial sections (Figure 1, *top*) of the cornea and anterior chamber. The combination of 2 monochromatic, 360-degree rotating Scheimpflug cameras and a Placido disk fully analyzes the cornea and anterior segment, giving tangential and axial curvature data of the anterior and posterior corneal surfaces, the global refractive power of the cornea, a biometric estimation of various structures, a corneal wavefront map with an analysis of visual quality, and corneal pachymetry maps (Figure 1, *bottom*). Specifically, this system can measure 35 632 points for the anterior corneal surface and 30 000 for the posterior corneal

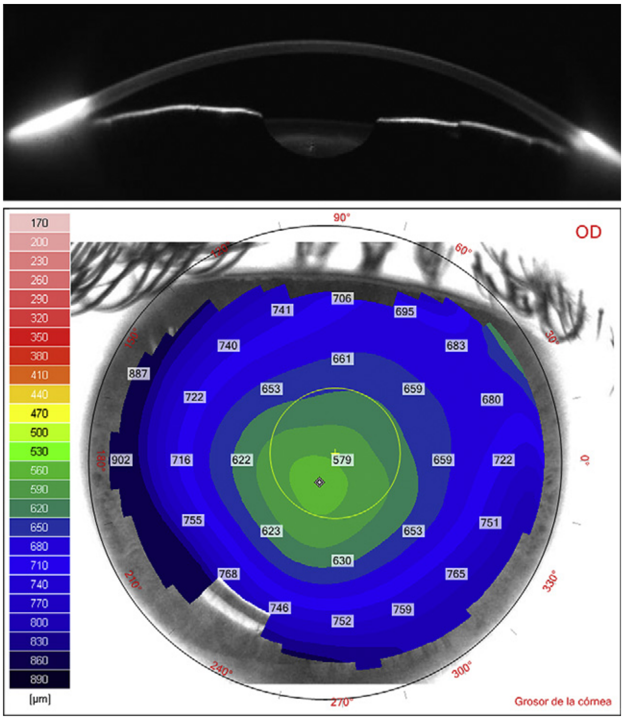


**Figure 1.** *Top*: Scheimpflug photography of the anterior segment of the eye. *Bottom*: Pachymetric map obtained with the Scheimpflug photography–based topography system.

surface on high-resolution mode in approximately 5 to 6 seconds. A pachymetric map is then reconstructed using the point-by-point anterior and posterior corneal surface data. The current study used software version 1.0.5.72 (Phoenix, Costruzione Strumenti Oftalmici).

**Optical Coherence Tomography** The time-domain Visante OCT system uses a beam of infrared light of 1310 nm wavelength to scan different structures of the anterior segment.[2] The system is connected to a computer with specific software providing different image-capturing and measurement options. The optical basis of the instrument is the analysis of the interference generated between a reference beam and the beam reflected by the different anterior segment structures. Images are then reconstructed from the interferometric data recorded and transformed into a grayscale or color image (Figure 2, *top*). The software eliminates distortion in the measurements induced by optical factors of transmission and provides different anatomic information, such as pachymetric maps (Figure 2, *bottom*). In the current study, 1 scan was obtained in each case.

### Statistical Analysis

Statistical analysis was performed using the software SPSS for Windows software (version 11.0, SPSS, Inc.). Normality of all pachymetric data distributions was confirmed by the Kolmogorov-Smirnov test. Then, parametric statistics were applied in all cases. The unpaired Student *t* test was used to compare of the pachymetric measurements between the 2 techniques. All tests were 2 tailed, and a *P* value less than 0.05 was considered statistically significant.

Intraobserver repeatability for each corneal parameter was assessed using the following statistical parameters: the within-subject standard deviation ($S_w$) of the 3 consecutive measurements, the intraobserver precision, the intraobserver repeatability, the coefficient of variation (expressed as percentage), and the intraclass correlation coefficient (ICC). The $S_w$ method is a simple way of estimating the size of the measurement error. The intraobserver precision was defined as ($\pm 1.96 \times S_w$),[11] and this parameter indicates the size of the range of error of the repeated measurements for 95% of observations. The repeatability was computed as ($2.77 \times S_w$) and it is another useful way of presenting the range of measurement error.[12] Finally, the ICC is an analysis of the variance-based type of correlation that measures the relative homogeneity within groups (between the repeated measurements) in ratio to the total variation.[13] The ICC will approach 1.0 when there is no variance within repeated measurements, indicating the total variation in measurements is solely the result of the variability in the parameter being measured.

The agreement of pachymetric measurements of the Scheimpflug photography–based system and the OCT system was evaluated by Bland-Altman analysis.[11] This graphical method assesses whether there is an agreement between 2 clinical procedures.[11] Graphs of the differences between measurements obtained with each instrument were plotted against the means (Bland-Altman plots). The limits of agreement (LoA) were calculated as the mean difference in measurements obtained with each device $\pm 1.96$ standard deviation (SD) of the differences[11]; 1.96 times this SD is, by definition, the range of agreement between techniques, with lower values indicating higher agreement. The agreement between pachymetric techniques is not acceptable if the range of agreement is clinically relevant (error with significant implication in the clinical practice), indicating that the evaluated clinical methodologies do not provide equivalent measurements.

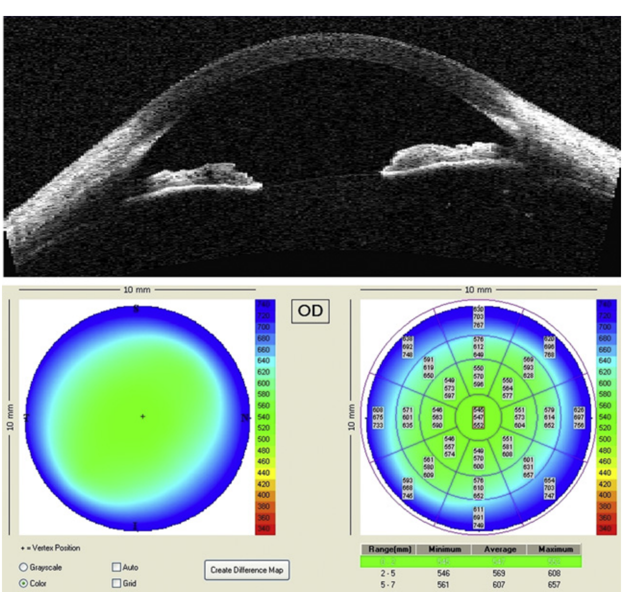


**Figure 2.** *Top*: Grayscale image of the anterior segment of the eye. *Bottom*: Pachymetric map obtained with the time-domain OCT system.

## RESULTS

The study enrolled 18 eyes of 18 subjects. The mean age of the subjects was 36 years (range 22 to 53 years).

### Intraobserver Repeatability

Table 1 shows the ICC values for the repeated pachymetric measurements at different corneal locations obtained with the Scheimpflug photography–based system. The ICC values ranged between 0.990 and 0.997. The coefficient of variation was lower than 1% at all corneal locations. Specifically, the coefficient of variation was closer to 1% at the 4.0 mm temporal and 4.0 mm nasal locations. Furthermore, the SD of the repeated measurements was always less than 6 μm.

No statistically significant differences were found between $S_w$ and coefficient of variation values corresponding to the central locations and those corresponding to the 2.5 mm corneal locations ($P \geq .1$) except for the $S_w$ value corresponding to the 2.5 mm nasal location ($P = .045$). In contrast, statistically significant differences were found between the coefficient of variation and $S_w$ values corresponding to the 2.5 mm and 4.0 mm locations as follows: temporal $S_w$ ($P = .037$), nasal $S_w$ ($P = .001$), nasal coefficient of variation ($P = .009$), and inferior $S_w$ ($P = .004$).

**Table 1.** Intraobserver repeatability outcomes for pachymetric measurements obtained at different corneal locations by the Scheimpflug photography–based topography system.

| Parameter | Overall Mean (μm) ± SD | CV (%) | $S_w$ (μm) | Pr(μm) | Rep (μm) | Value | ICC Range |
|---|---|---|---|---|---|---|---|
| CCT | 552.7 ± 35.2 | 0.6 | 3.1 | 6.1 | 8.6 | 0.997 | 0.994–0.999 |
| CT at 2.5 mm | | | | | | | |
| Temporally | 578.0 ± 37.2 | 0.6 | 3.3 | 6.5 | 9.1 | 0.997 | 0.993–0.999 |
| Nasally | 619.7 ± 39.7 | 0.6 | 3.9 | 7.7 | 10.9 | 0.996 | 0.991–0.998 |
| Superiorly | 637.5 ± 43.5 | 0.6 | 3.8 | 7.4 | 10.4 | 0.997 | 0.993–0.999 |
| Inferiorly | 603.4 ± 38.1 | 0.5 | 3.1 | 6.2 | 8.7 | 0.997 | 0.994–0.999 |
| CT at 4.0 mm | | | | | | | |
| Temporally | 651.8 ± 47.3 | 0.8 | 4.9 | 9.6 | 13.6 | 0.995 | 0.989–0.998 |
| Nasally | 709.1 ± 39.3 | 0.8 | 5.8 | 11.4 | 16.0 | 0.990 | 0.978–0.996 |
| Superiorly | 721.0 ± 42.3 | 0.6 | 4.5 | 8.9 | 12.5 | 0.993 | 0.979–0.998 |
| Inferiorly | 700.9 ± 41.7 | 0.6 | 4.5 | 8.7 | 12.4 | 0.995 | 0.989–0.998 |

CCT = corneal thickness at the geometric center of cornea; CT = corneal thickness CV = coefficient of variation; ICC = intraclass correlation coefficient; Pr = intraobserver precision; Rep = intraobserver repeatability; $S_w$ = within-subject standard deviation

## Agreement Between Pachymetric Techniques

Table 2 shows agreement between the 2 pachymetric techniques. Statistically significant differences between techniques were found in the different pachymetric measurements evaluated ($P \le .016$) except for the 2.5 mm temporal location ($P = .2$). The range of difference in the pachymetric measurement between instruments was not constant throughout the cornea. There was a larger range of difference between devices in the most peripheral pachymetric measurements. The minimum difference between devices was at 2.5 mm temporally, whereas the maximum difference was at 4.0 mm inferiorly. Furthermore, as expected, the lowest thickness recorded in all cases was at the central location with both devices.

Figures 3 to 5 show the Bland-Altman plots for analysis of the agreement between pachymetric measurements provided by the 2 pachymetric systems at the central, 2.5 mm inferior, and 4.0 mm temporal corneal locations. Figures 4 and 5 show the agreement analysis in the most favorable conditions at 2.5 mm and 4.0 mm. The ranges of agreement were large and clinically relevant and were larger than 20 μm at all locations. In addition, the ranges of agreement were progressively larger moving from the center to the periphery of the corneal, with statistically significant differences between the SD of the differences at the 2.5 mm locations and the 4.0 mm locations ($P \le .017$).

## DISCUSSION

Currently available corneal topography systems have been implemented widely because of advances in diagnostic technologies and the increasing interest in corneal refractive surgery techniques. These types of systems provide very detailed information about the corneal anatomy, and they are the best tools for characterizing the configuration of this ocular structure. Most new developments in corneal topography include an additional feature, especially helpful in refractive surgery practice[14]; that is, analysis of the thickness throughout the cornea. Until recently, US-based methods were the only way to obtain an accurate measurement of corneal thickness. This technique requires direct contact with the cornea or immersion of the eye in saline solution as well as the use of topical anesthesia. Therefore, US-based pachymetry is a contact technique. This clinical procedure for obtaining the corneal thickness is highly dependent on the operator. When corneal contact is required, small errors of applanation can occur.[15] Furthermore, the instillation of topical anesthesia could cause overestimation of pachymetric measurements.[16] The patient's collaboration is also essential for accurate US pachymetry because perfect alignment with the corneal surface should be maintained during the measurement procedure. Therefore, there are several advantages in using a noninvasive procedure for corneal pachymetry,[7,17–19] such as methods using advanced corneal topography systems. The aim of the current study was to evaluate the pachymetry mode of a new corneal topography system that combines Scheimpflug photography and Placido disk technologies. Specifically, we evaluated the intraobserver repeatability of the central and peripheral pachymetric measurements obtained with this topographic system as well as the agreement of the measurements with those obtained by a time-domain OCT system.

First, we evaluated the intraobserver repeatability of the pachymetric measurements obtained centrally and at different corneal locations. This analysis confirmed that the instrument provided consistent and

**Table 2.** Comparative analysis of the pachymetric measurements at different corneal locations by the Scheimpflug photography–based topography system the OCT system.

| | | Corneal Thickness (μm) at 2.5 mm | | | |
|---|---|---|---|---|---|
| Parameter | CCT | Temporally | Nasally | Superiorly | Inferiorly |
| Mean ± SD | | | | | |
| Scheimpflug | 545.1 ± 36.8 | 570.3 ± 38.0 | 612.9 ± 37.3 | 628.7 ± 43.3 | 597.8 ± 37.9 |
| OCT | 518.2 ± 37.6 | 557.1 ± 35.8 | 580.1 ± 46.5 | 591.0 ± 40.4 | 570.3 ± 37.9 |
| Difference | 22.4 ± 10.4 | 9.4 ± 17.0 | 25.7 ± 17.0 | 34.1 ± 22.1 | 25.6 ± 13.3 |
| RoA | 20.4 | 33.4 | 33.4 | 43.3 | 26.0 |
| LoA | 2.0, 42.7 | −24.0, 42.8 | −7.6, 59.1 | −9.2, 77.5 | −0.4, 51.6 |
| *P* value | .016 | .2 | .010 | .003 | .015 |

CCT = corneal thickness at the geometric center of cornea; LoA = limits of agreement; OCT = optical coherence tomography; RoA = range of agreement

repeatable pachymetric measures centrally and peripherally. The coefficient of variation did not exceed 1%, and the ICC was close to 1 for all type of measurements. The range of values for the ICC is between 0 and 1 (grading system: ICC $<0.75$ = low intraobserver repeatability; ICC $\geq 0.75$ to $<0.90$ = moderate intraobserver repeatability; ICC $\geq 0.90$ = high intraobserver repeatability).[1] In any case, measurements 4.0 mm nasally, inferiorly, and temporally were somewhat less consistent than central and peripheral measurements at 2.5 mm. This less consistency in peripheral pachymetry was also reported by Miranda et al.[20] in a study using another topography system also based on the Scheimpflug rotating camera. Two factors could have accounted for the lower consistency of peripheral pachymetric measurements: (1) the greater difficulty in processing Scheimpflug images at the edges due to the greater degree of distortion and blur usually present at this level and (2) the reduction in data sampling per area in the periphery versus the central region for the case of rotated section images. It has also been pointed out that the error of repeatability of peripheral pachymetry with a system based on Scheimpflug photography could be due to the use of an unstable reference point as the center of the pupil instead of the vertex cornea.[21]

In addition to intraobserver repeatability analysis, agreement of the pachymetric measurements provided with the Scheimpflug photography–based system with those provided by another noninvasive pachymetry system, OCT, was evaluated by means of the Bland-Altman method. Optical coherence

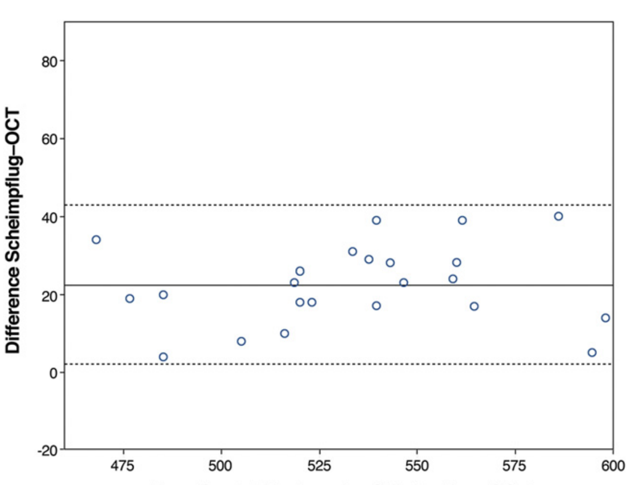


**Figure 3.** Bland-Altman plot of the differences in CCT between the Scheimpflug photography-based system and the OCT system plotted against the mean value of both. The upper and the lower lines represent the LoA, calculated as mean ± 1.96 SD.

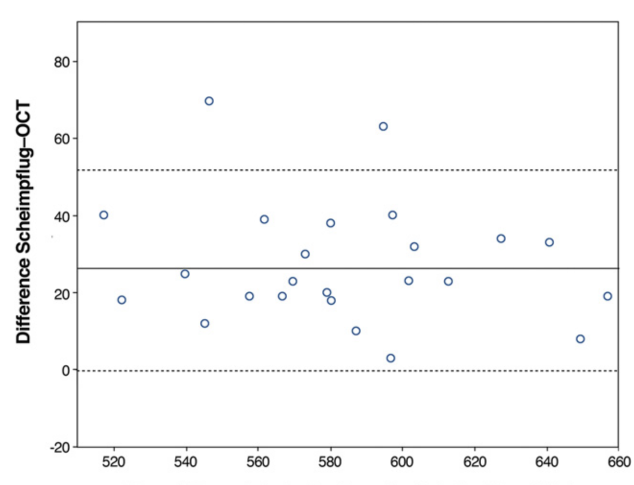


**Figure 4.** Bland-Altman plot of the differences in the corneal thickness 2.5 mm inferiorly between the Scheimpflug photography-based system and the OCT system plotted against the mean value of both. The upper and the lower lines represent the LoA, calculated as mean ± 1.96 SD.

**Table 2.** (Cont.)

| Corneal Thickness (μm) at 4.0 mm | | | |
|---|---|---|---|
| Temporally | Nasally | Superiorly | Inferiorly |
| Mean ± SD | | | |
| 647.8 ± 44.4 | 704.5 ± 38.3 | 713.6 ± 41.5 | 699.2 ± 43.6 |
| 616.3 ± 39.5 | 653.9 ± 48.5 | 665.4 ± 39.0 | 638.3 ± 46.6 |
| 26.6 ± 30.4 | 44.7 ± 34.4 | 36.8 ± 26.5 | 61.4 ± 34.5 |
| 59.5 | 67.5 | 51.9 | 67.5 |
| −32.9, 86.1 | −22.8, 112.2 | −15.2. 88.7 | −6.2, 128.9 |
| .013 | <.001 | .002 | <.001 |

tomography is based on the principles of low-coherence interferometry.[2–4,6,7,14,15,17] Several studies have confirmed the ability of this technology to provide repeatable measurements of various anatomic parameters of the anterior segment,[3,4,6,14,17] with a high rate of reproducibility of corneal pachymetry maps in healthy eyes and in keratoconic eyes.[6] Furthermore, several studies[15,18,22] have compared this technology with US, slit-scanning, or Scheimpflug photography–based devices, with results showing a trend toward underestimation of pachymetry.

The Bland-Altman analysis showed poor agreement between the pachymetric maps provided by the Scheimpflug-based and time-domain OCT devices. The LoA were always larger than 20.4 μm, which is clinically relevant, especially when screening candidates for excimer laser refractive surgery. Specifically, the measurements obtained with the Scheimpflug-based system were always larger than those obtained by OCT. Ho et al.[18] report similar central pachymetry measurements with another Scheimpflug photography–based system and the same OCT device used in our study, although they detected a slight trend toward lower thickness values with the OCT technique. In our study, we not only evaluated central pachymetry but also corneal thickness in some peripheral locations. The potential role of the tear film in the discrepancy between Scheimpflug and OCT techniques should be addressed in future studies. Another relevant finding is the increase in the ranges of agreement for the pachymetric measurement obtained at peripheral corneas locations. This is consistent with our finding of poorer intraobserver repeatability of pachymetry at the most peripheral locations. Again, distortion of the Scheimpflug images at the periphery or the use of unstable reference points could be the source of this limitation.

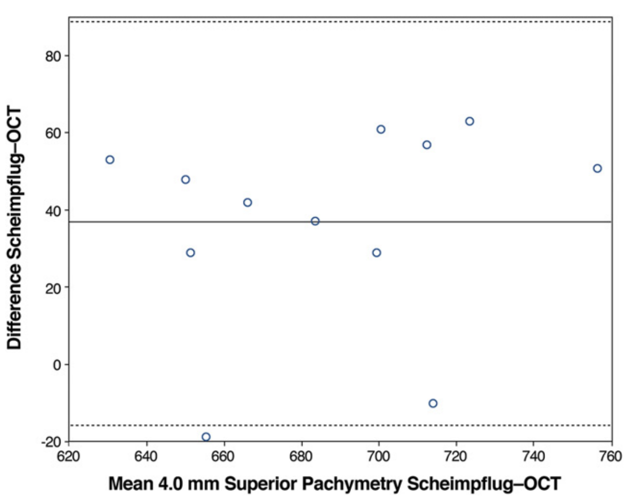


**Figure 5.** Bland-Altman plot of the differences in the corneal thickness 2.5 mm temporally between the Scheimpflug photography-based system and the OCT system plotted against the mean value of both. The upper and the lower lines represent the LoA, calculated as mean ± 1.96 SD.

In summary, the new topography system, based on the combination of a rotating Scheimpflug camera and a Placido disk, provided repeatable pachymetric measurements fast and noninvasively. As with other topography systems containing a rotating Scheimpflug camera, 3 consecutive measurements should be performed for peripheral pachymetry to confirm the consistency of the measurements. On the other hand, pachymetric data obtained with this system cannot be used interchangeably with those obtained with another noncontact technique—time-domain OCT—because pachymetric information obtained using the 2 technologies is not equivalent. Therefore, pachymetry monitoring should rely on the same technology in the clinical practice to draw valid conclusions.

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