Repeatability of automatic measurements by a new Scheimpflug camera combined with Placido topography

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PURPOSE: To assess the repeatability of anterior segment measurements performed by a Scheimpflug camera combined with Placido corneal topography (Sirius) in unoperated, post-refractive surgery, and keratoconus eyes.

SETTING: Private clinical ophthalmology practice.

DESIGN: Evaluation of diagnostic test or technology.

METHODS: Three consecutive scans were acquired for each eye. The following parameters were evaluated: simulated keratometry, posterior corneal power, mean pupil power (ie, corneal power assessed by ray tracing through the anterior and posterior corneal surfaces), corneal asphericity, thinnest and apex corneal thickness, aqueous depth, anterior chamber volume, and corneal spherical aberration. Repeatability was assessed using test—retest variability, the coefficient of variation, and the intraclass correlation coefficient (ICC).

RESULTS: Sixty-four unoperated eyes, 17 eyes that had myopic excimer laser surgery, and 13 eyes with keratoconus were analyzed. High repeatability was achieved for most parameters in the 3 groups, with an ICC higher than 0.99 for all measurements except posterior corneal power and mean pupil power in keratoconus (ICC, 0.868 and 0.976, respectively), anterior and posterior asphericity in normal eyes (ICC, 0.904 and 0.977, respectively), and spherical aberration in normal eyes (ICC, 0.806), post-refractive surgery eyes (ICC, 0.980), and keratoconus eyes (ICC, 0.981).

CONCLUSION: The anterior segment measurements provided by the new Scheimpflug camera—Placido corneal topography system were highly repeatable and can be relied on in clinical routine and for research purposes.

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The introduction of Scheimpflug cameras into clinical practice has significantly improved capabilities of imaging the anterior eye segment. Although some features are shared by other technologies, such as optical coherence tomography (OCT),¹⁻³ Scheimpflug cameras can provide several measurements that were not possible until a few years ago. They are able to assess the posterior corneal curvature, total corneal dioptric power (ie, the dioptric power of the whole cornea, including the anterior and posterior surfaces), and the anterior chamber depth and volume. They can also provide corneal pachymetric maps and cross-sectional images of the cornea, the natural lens, and intraocular lenses (IOLs).

The first commercially available instruments (EAS 1000, Nidek Co., Ltd., and SL-45, Topcon Corp.) were marketed at the end of the 1980s, more than 20 years after the Scheimpflug principle had been introduced in ophthalmology. These devices had little distribution because they were targeted more for experimental ophthalmology. The Scheimpflug principle was subsequently adopted by the Orbscan (Bausch & Lomb), a scanning-slit beam system that was marketed in 1995 and included several features that could aid the anterior eye segment surgeon. Measurements by the Orbscan system are reported to be repeatable and accurate, 19,10 although the reliability of posterior corneal curvature assessment after laser in

situ keratomileusis (LASIK) has been questioned. 11-13 In 2002, the first rotating Scheimpflug camera, the Pentacam (Oculus Optikgeräte GmbH), was introduced. Many early studies 14-21 found the instrument's automatic measurements to have good repeatability. More recently, in 2007, another instrument, the Galilei dual-Scheimpflug analyzer (Ziemer Group), was introduced. The instrument combines 2 rotating Scheimpflug cameras and a Placido topography system and has been shown to offer repeatable measurements. 22,23 Two other instruments were developed in the past few years; that is, the Sirius (Costruzione Strumenti Oftalmici) and the TMS-5 (Tomey Corp.). 24 This study assessed the repeatability of the automatic measurements provided by the Sirius instrument, which combines a single Scheimpflug camera and a Placido disk corneal topographer.

PATIENTS AND METHODS

Three groups of patients were prospectively recruited for this study: patients who had previous myopic photorefractive keratectomy (PRK) or LASIK, patients with a diagnosis of keratoconus based on classic slitlamp and corneal topography findings, ^{25,26} and patients with no history of refractive surgery and no sign of keratoconus. One eye of each patient was randomly selected. Three repeated consecutive measurements were taken by the same experienced examiner to assess intraobserver repeatability. All measurements were taken between 10 AM and 4 PM to minimize diurnal change. The study was performed in accordance with the ethical standards stated in the 1964 Declaration of Helsinki and approved by the local clinical research ethics committee. All patients provided informed consent.

Measurements with the Sirius system (version 2.0) were performed according to the manufacturer's guidelines. The device was brought into focus, and the patient's eye was aligned along the visual axis by a central fixation light. The patients were asked to sit back after each measurement, and the device was realigned before the subsequent measurement. The patients were instructed to blink completely just before each measurement.

The scanning process acquires a series of 25 Scheimpflug images (meridians) and 1 Placido top-view image. The ring edges are detected on the Placido image so that height, slope, and curvature data are calculated using the arc-step method

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with conic curves. Profiles of the anterior cornea, posterior cornea, anterior lens, and iris are derived from the Scheimpflug images. Data for the anterior surface from the Placido image and Scheimpflug images are merged using a proprietary method. All other measurements for internal structures (posterior cornea, anterior lens, and iris) are derived solely from Scheimpflug data.

The following values were evaluated in this study:

- 1. Mean simulated keratometry (K). This value is the arithmetic mean of the keratometric diopters (D) of the flattest and steepest corneal meridians. For each meridian, the keratometric diopters are calculated by averaging the axial curvature from the 4th to the 8th Placido ring. The curvature is converted in keratometric diopters using the customary keratometric index of 1.3375.
- 2. Mean posterior corneal curvature. This value is the arithmetic mean of the pair of meridians 90 degrees apart, with the greatest and least dioptric power in the 3.0 mm zone of the posterior corneal surface. The diopters of the steepest meridian and flattest meridian are calculated using the refractive indices of the cornea (1.376) and aqueous humor (1.336.)
- 3. *Mean pupil power*. This value is the total power of the cornea obtained by ray tracing through its anterior and posterior surfaces and a 4.5 mm diameter entrance pupil. The angle of refraction of incoming parallel rays is calculated using the Snell law and the following indices of refraction: 1.000 for air, 1.376 for cornea, and 1.336 for aqueous.
- 4. *Corneal asphericity*. This measurement is expressed as the asphericity (Q) values of the anterior and posterior corneal surfaces in the 8.0 mm zone. The Q value is zero when the curve is a circle, lies between -1 and zero when the curve is a prolate ellipse, and is higher than zero when the curve is an oblate ellipse.²⁷
- 5. Thinnest and central corneal thickness (CCT) measurements.
- 6. Aqueous depth and anterior chamber volume (ACV). Aqueous depth is the distance between the corneal endothelium and the anterior surface of the lens. The ACV is measured between the corneal endothelium and the anterior surface of the lens and is calculated on a maximum diameter of 12.0 mm.
- 7. Zernike coefficient Z(4,0) of the corneal optical path length difference (OPD). This value is the spherical aberration in the 5.0 mm pupil zone and is calculated considering the effect of both the anterior and posterior corneal surfaces; it is expressed in microns. Only Z(4,0) was studied because it is of particular interest to surgeons who implant aspheric IOLs.²⁸

Statistical Analysis

In the present study, the term *repeatability* was used according to the definition of the International Organization for Standardization, ²⁹ which considers it a part of accuracy. Accuracy includes trueness and precision. Trueness is the inverse of bias and is obtained by comparing the measurement result with the accepted reference (conventional true) value. Precision is the inverse of statistical uncertainty and is normally expressed in terms of the standard deviation (SD). The factors involved include (1) the operator, (2) the equipment used, (3) the equipment calibration, (4) the environment, and (5) the elapsed time between measurements. Precision has 2 conditions; that is, repeatability and reproducibility. Under repeatability conditions, factors such as 1

to 5 are considered constant and do not contribute to the variability of the measurement result. Under reproducibility conditions, those factors can vary. Repeatability and reproducibility are the 2 extremes of precision.

Repeatability was assessed by intrasession test–retest variability, the coefficient of variation (COV), and the intraclass correlation coefficient (ICC), as in a similar study evaluating the repeatability of a dual Scheimpflug analyzer.²³ Specifically, the following methods were used:

- 1. Intrasession test–retest variability (also known as repeatability). This was calculated by multiplying the pooled within-subject SD (s_w) by 2.77.³⁰ On the basis of repeatability, it can be expected that the difference between 2 measurements for the same subject will be less than 2.77 s_w for 95% of pairs of observations.
- 2. Coefficient of variation (COV). This was calculated as the $s_{\rm w}$ divided by the mean of the measurements and was expressed as a percentage. The COV was not calculated for parameters with both positive values and negative values.
- 3. Intraclass correlation coefficient (ICC). This is defined as the ratio of the between-subjects variance to the sum of the pooled within-subject variance and the between-subjects variance. The ICC, which approaches 1.0 when there is no variance between repeated measurements, was automatically calculated using PASW Statistics software (version 18.0, SPSS, Inc.) with the 2-way mixed model and absolute agreement. The ICCs ranging from 0 to 1 are commonly classified as follows: ICC less than 0.75 = poor agreement; ICC 0.75 to less than 0.90 = moderate agreement; ICC 0.90 and more = high agreement.

Because the within-subject SD of measurements with the investigated device was unknown, the sample size in the present study was established based on results in a previous study²³ in which 45 healthy subjects and 15 post-refractive patients were considered more than sufficient.

RESULTS

Ninety-four patients were examined. Seventeen patients (mean age 41.4 years \pm 6.9 [SD]) had previous myopic PRK or LASIK. Thirteen patients (mean age 41.7 \pm 15.8 years) had a diagnosis of keratoconus. The remaining 64 patients (mean age 56.4 \pm 17.3 years) had no history of refractive surgery and no signs of keratoconus. Table 1 shows the mean values for each measured parameter by groups.

Table 2 shows the results of the repeatability assessment. A COV of 0.6% or less and an ICC more than 0.99 (showing excellent repeatability) were achieved for most parameters, including mean simulated K, mean pupil corneal power, minimum and apex corneal thickness, and aqueous depth; ACV had a slightly higher COV (range 0.96% and 1.62%). No significant differences were found between normal unoperated eyes, post-refractive surgery eyes, and eyes with keratoconus, although the latter had slightly lower repeatability.

Similar values were observed for the mean posterior corneal power in control eyes and post-refractive

surgery eyes; however, measurements for this parameter in eyes with keratoconus yielded worse results (ie, a COV of 4.9% and an ICC of 0.868).

Repeatability was also high for anterior and posterior corneal asphericity measurements; the ICC was higher than 0.9 in all 3 groups. The COV of these parameters, however, was slightly higher (ie, worse) than the corresponding values of the abovementioned parameters. Spherical aberration measurements had the least repeatability, especially in normal eyes, in which the COV was 17.11% and the ICC was 0.806.

DISCUSSION

This study shows that the combination of Scheimpflug and Placido disk imaging provided by the Sirius leads to highly repeatable measurements of the anterior segment in normal eyes as well as in eyes with previous myopic excimer laser surgery and in eyes with keratoconus.

All corneal power measurements yielded a COV of less than 0.5% and an ICC of more than 0.99 in all 3 groups of eye; the only exception was posterior corneal power measurements in eyes with keratoconus. Test-retest variability for simulated K values in control eyes was 0.29 D. This means that the difference between 2 measurements in the same subject is expected to be less than 0.29 D for 95% of pairs of observations. Such a value has a relatively low clinical impact. Using the Hoffer Q formula, for example, a change in corneal power of 0.29 D would lead to a mean change of 0.40 D in IOL power (range 0.32 to 0.51 D in eyes with corneal power between 39.00 D and 46.00 D and axial length between 20.0 mm and 30.0 mm), which is within the commercially available IOL power dioptric steps. 32,33

The results for corneal power repeatability with the Sirius device are similar to those previously reported for another Scheimpflug camera combined with Placido topography (Galilei) for unoperated and postrefractive surgery eyes. Wang et al.²² and Savini et al.²³ obtained a COV of less than 0.6% and an ICC of more than 0.99 for simulated K, posterior corneal power, and total corneal power. Direct comparison with another commercially available Scheimpflug camera, the Pentacam, is difficult because most studies used methods different than those we used to evaluate repeatability.¹⁴ Three studies followed the same methods we did, at least in part. First, Kawamorita et al. 16 found a COV of 0.31% and 0.38%, respectively, for the flattest and steepest anterior corneal meridians in unoperated eyes. Second, Chen and Lam¹⁵ evaluated the anterior and posterior best-fit sphere at the 5.0 and 8.0 mm zones and found ICCs greater than 0.99. Third, Piñero et al.²¹ report an intraobserver

	Group						
Parameter	Control	Keratoconus	Post-refractive				
Simulated K (D)							
Mean \pm SD	43.37 ± 1.30	46.43 ± 1.67	39.00 ± 1.48				
Range	40.65, 46.31	43.93, 50.06	36.20, 41.83				
Posterior K (D)							
Mean ± SD	-6.12 ± 0.22	-6.96 ± 0.92	-6.13 ± 0.23				
Range	-6.74, 5.68	-8.93, -4.87	-6.51, -5.68				
Mean pupil power (D)							
Mean ± SD	43.11 ± 1.35	45.71 ± 1.33	38.13 ± 1.63				
Range	40.31, 46.18	43.25, 48.16	34.70, 41.33				
Minimum corneal thickness (μ	m)						
Mean ± SD	549.51 ± 29.29	467.11 ± 38.30	469.56 ± 51.08				
Range	464.28, 622.54	380.07, 530.22	367.47, 573.62				
Central corneal thickness (µm)							
Mean ± SD	552.79 ± 29.42	483.90 ± 37.63	471.72 ± 51.77				
Range	466.23, 626.56	405.37, 549.37	367.70, 577.89				
Aqueous depth (mm)							
Mean ± SD	2.90 ± 0.44	3.14 ± 0.25	3.07 ± 0.22				
Range	1.99, 3.86	2.62, 3.55	2.68, 3.44				
Anterior chamber volume (mn	n ³)						
Mean ± SD	143.53 ± 32.03	163.65 ± 23.64	168.71 ± 20.11				
Range	76.21, 196.65	119.40, 220.78	132.24, 200.87				
Anterior Q factor, 8.0 mm							
Mean \pm SD	-0.28 ± 0.12	-0.84 ± 0.41	0.76 ± 0.48				
Range	-0.83, 0.38	-2.76, 0.63	0.07, 1.74				
Posterior Q factor, 8.0 mm							
Mean ± SD	-0.28 ± 0.12	-1.10 ± 0.70	-0.30 ± 0.21				
Range	-1.42, 1.40	-3.69, 2.58	-0.84, 0.00				
Z(4,0) (μm)							
Mean ± SD	-0.12 ± 0.05	0.07 ± 0.20	-0.28 ± 0.13				
Range	-0.31, 0.04	-0.25, 0.53	-0.60, -0.14				

intra-visit test-retest repeatability of posterior corneal curvature between 0.078 D and 0.116 D (ICC between 0.980 and 0.986). These values are close to the ones achieved with the Sirius device.

To our knowledge, there are no studies evaluating the repeatability of corneal power measurements by the Pentacam device in eyes with keratoconus and just 1 study of post-refractive surgery eyes. After myopic LASIK, according to Jain et al., the coefficients of repeatability for the Pentacam mean anterior corneal curvature and posterior corneal curvature were 0.29% and 0.57%, respectively. Although direct comparison with our study is not possible because Jain et al. performed 5 (not 3) consecutive measurements and measured the radius in millimeters (not the power in diopters), the percentage of variability is extremely similar to the one achieved with the Sirius device

Other technologies to measure both anterior and posterior corneal curvatures and calculate the corneal

power are available. The Orbscan device, whose technology is usually referred to as slit-scanning topography (although the slit image is corrected for depth of focus by Scheimpflug rule motion of the slit in the object plane of the projectors), seems to provide less repeatable measurements, with ICC ranges between 0.70 and 0.93 in unoperated eyes.³⁴ Recently, Tang et al.³⁵ assessed the repeatability of Fourier-domain OCT, although their results are not comparable to ours because they relied solely on pooled SDs. If we divide the latter by the mean value of each parameter, we obtain a COV of 0.39% and 0.32% for the anterior corneal curvature and posterior corneal curvature, respectively, in normal eyes; 0.65% and 0.32% for the anterior corneal curvature and posterior corneal curvature, respectively, in post-LASIK eyes; and 0.63% and 1.11% for the anterior corneal curvature and posterior corneal curvature, respectively, in keratoconus eyes. These results are similar to those in the present study.

Table 2. Repeatability measurements obtained with Sirius compared with those obtained by 2 Scheimpflug camera systems in previous studies.

Parameter	Coefficient of Variation (%)			Test-Retest Repeatability			Intraclass Correlation Coefficient		
	С	K	Post	С	K	Post	С	K	Post
SimK (D)									
Sirius	0.24	0.32	0.32	0.29	0.41	0.34	0.994	0.992	0.993
Galilei ^{22,23}	0.12, 0.30	_	0.26	0.36	_	0.29	0.998	_	_
Pentacam ¹⁶	0.31, 0.38	_	_	_	_	_	_	_	_
Posterior corneal power (D)									
Sirius	0.30	4.90	0.31	0.05	0.94	0.05	0.993	0.868	0.993
Galilei ^{22,23}	0.35, 0.53	_	0.34	0.07-0.09	_	0.06	0.996	_	_
Pentacam ²¹	_	_	_	0.08, 1.11	_	_	0.980, 0.986	_	_
Corneal power by ray tracing	g (D)								
Sirius (mean pupil	0.28	0.46	0.43	0.34	0.58	0.45	0.992	0.976	0.991
power)									
Galilei ^{22,23} (total corneal	0.16-0.31	_	0.28	0.37	_	0.31	0.999	_	_
power)									
Minimal thickness (μm)									
Sirius	0.48	0.50	0.46	7.37	6.45	5.96	0.992	0.997	0.998
Galilei ²³	0.34	_	0.32	4.97	_	4.13	0.998	_	_
Pentacam ¹⁸	_	_	0.77	_	_	_	_	_	_
Central thickness (µm)									
Sirius	0.43	0.52	0.45	6.59	7.00	5.90	0.994	0.996	0.998
Galilei ²³	0.43	_	0.32	6.41	_	4.41	0.997	_	_
Pentacam ^{15,17,19}	0.48, 0.84	_	_	10.00	14.1	_	0.981, 0.987	_	_
Aqueous depth (mm)									
Sirius	0.49	0.60	0.39	0.04	0.05	0.03	0.999	0.994	0.997
Galilei ^{22,23}	0.61, 0.69	_	0.91	0.05, 0.12	_	0.08	0.999	_	_
Pentacam ²¹	0.5	_	0.98	_	_	_	_	_	_
Anterior chamber volume (m	m^3)								
Sirius	1.62	1.15	0.96	6.42	5.23	4.47	0.995	0.994	0.994
Galilei ²³	3.80	_	1.79	11.07	_	6.01	_	_	_
Pentacam ¹⁴	_	_	_	_	_	_	0.991	_	_
Anterior Q value, 8.0 mm									
Sirius	_	_	_	0.11	0.09	0.10	0.904	0.994	0.995
Posterior Q value, 8.0 mm									
Sirius	_	_	_	0.09	0.12	0.06	0.977	0.996	0.990
Pentacam ²¹	_	_	_	0.06, 0.08	_	_	0.984, 0.990	_	_
Z (4,0) (μm)							, , , , , , , , ,		
Sirius	_	_	6.79	0.06	0.08	0.05	0.806	0.981	0.980
Galilei ²³	16.68	_	_	_	_	_	0.981	_	_
Pentacam ³⁷	_						0.86		

C = control group; K = keratoconus group; Post = post-refractive surgery group

In eyes with keratoconus, the CoV was not calculated for Z (4,0) because measured values contained both negative and positive values. For the same reason, the CoV was not calculated for anterior and posterior Q values.

Measurements of central and thinnest corneal thickness by the Sirius device showed excellent repeatability, with a COV between 0.43% and 0.52% in the different subgroups (ICC always >0.99). Test–retest variability was approximately 6 μ m, a value with no clinical importance.

These results compare well with those previously reported for other Scheimpflug cameras. Using the Galilei device, our group found a COV ranging between 0.32% and 0.43% (with ICC >0.99) in a sample including operated eyes and post-refractive surgery eyes. Wang et al. Peport an even lower COV (0.25%) for the mean central corneal thickness (0.0 to 4.0 mm) in unoperated eyes. For the Pentacam, Nam et al. Peport a COV of 0.67% and 0.68% for corneal thickness at the apex and at the pupil center, respectively, in unoperated eyes. Chen et al. found a COV of 0.48% in unoperated eyes. Although this is

a direct comparison with our results, the results should be interpreted with caution because Chen et al. repeated the measurements 2 times instead of 3 times. Overall, the results obtained by the 3 Scheimpflug cameras are similar to those achieved by ultrasound pachymetry, for which the COV is reported to be 0.34% (ICC, 0.996).¹⁹

Repeatability of corneal thickness measurements in the present study was slightly worse than that recently reported for Fourier-domain OCT, for which the COV in virgin eyes was 0.26% and 0.31% for vertex measurements and pupil-centered measurements, respectively. The possible advantages of this technique over Scheimpflug imaging (not combined with Placido topography) are explained in detail in Nam et al.'s paper.¹⁹

In eyes with keratoconus, the repeatability of CCT measurements has been evaluated in a study by De Sanctis et al., 17 who measured it twice in the same session using the Pentacam device. The authors found a coefficient of repeatability (ie, test–retest variability) of 14.1 μ m compared with 7.0 μ m in the present study.

The repeatability of aqueous depth and, to a lesser extent, ACV measurements provided by Sirius device were very good in all 3 groups. Results were similar to or better than those previously obtained with the Galilei and Pentacam devices. ^{22,23}

Repeatability of the anterior and posterior corneal asphericity measurements was good, with an ICC greater than 0.9 in all groups. The results are close to those previously reported for the Pentacam device with respect to posterior corneal asphericity (ICC, 0.984 and 0.990 for the 2 observers in that study) and anterior corneal asphericity (test–retest variability, 0.11). 21,37

Spherical aberration measurements showed the least repeatability (ICC 0.806, 0.980, and 0.981 in normal eyes, post-refractive surgery eye, and keratoconus eyes, respectively) of those considered in this study. Relatively low repeatability of spherical aberration has also been reported for the Galilei and Pentacam devices, although the differences in the methods adopted by each author to measure aberrations and calculate repeatability hamper a direct comparison. 22,23,38,39 The first difference is related to the system used to report the measured value, which can be expressed as OPD or wavefront error, with opposite signs. By default the Galilei and Pentacam devices use the wavefront error approach, whereas in this study we adopted the OPD. As a consequence, the mean value is negative with Sirius device and positive with the Galilei and Pentacam devices. 40 The second difference concerns the corneal surface or surfaces analyzed. In the present study, as

well as in our study of the Galilei device,²³ spherical aberration was derived from both anterior and posterior surfaces. Other studies of the Pentacam device^{21,38,39} evaluated the spherical aberration generated by the anterior or posterior corneal surface only. Further differences include the pupil diameter and the axis of reference.

As suggested by Wang et al.,²² the relatively lower repeatability of spherical aberration may be related to changes in pupil center location in repeated measurements.

This study has limitations that warrant further investigation. First, we did not aim to compare the mean values of each parameter in each group of patients; hence, the discussion does not address these important issues, which will be the subject of future research. Second, this study did not include intervisit reproducibility, which may be of great interest in cases of progressive disease, such as keratoconus. Third, the group of eyes with keratoconus was not stratified according to the stage of the disease. Fourth, the Sirius device offers the opportunity to exclude data from the Placido disk so that anterior corneal curvature is examined by Scheimpflug imaging only. We did not take advantage of this feature, which deserves further study.

In conclusion, our data show that the Scheimpflug camera-Placido disk topography system used in this study provides repeatable measurements of anterior and posterior corneal power, corneal thickness, anterior aqueous depth and volume, corneal asphericity and, to a lesser extent, spherical aberration. Repeatability was similar to that reported for a Scheimpflug camera without a Placido disk (Pentacam) and a dual Scheimpflug camera combined with a Placido disk (Galilei). We therefore conclude that the measurements of the Sirius instrument can be relied on for everyday clinical use as well as for research purposes.

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