Repeatability of the Sirius Imaging System and Agreement With the Pentacam HR

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ABSTRACT

PURPOSE: To assess measurement repeatability of corneal curvature, minimal corneal thickness, and anterior chamber depth obtained with the Sirius imaging system (Costruzioni Strumenti Oftalmici) and to assess its agreement with the Pentacam HR imaging system (Oculus Optikgeräte GmbH).

METHODS: Healthy individuals were prospectively recruited. To assess repeatability, eight consecutive measurements were performed in the right eye of healthy individuals with the Sirius. A single measurement was then performed consecutively with both systems. The anterior and posterior corneal radii (antR and posR, respectively), anterior chamber depth, and minimal corneal thickness were evaluated. Repeatability of Sirius was evaluated by calculating coefficients of variation (CoV). Agreement between Sirius and Pentacam was assessed by calculating 95% limits of agreement (LoA) and plotting Bland–Altman graphs.

RESULTS: Forty-five eyes from individuals (21 men, 24 women) aged 20 to 61 years were evaluated. The mean CoV was 0.37% and 1.32% for antR and posR at 3 mm, respectively, and 0.36% and 1.28% for antR and posR at 7 mm, respectively. For anterior chamber depth and minimal corneal thickness, the CoV was 0.56% and 1.69%, respectively. Calculated 95% LoA were −0.1 to 0.12 mm (mean difference: 0.018 mm) and −0.54 to 0.33 mm (mean difference: 0.1 mm) for antR and posR at 3 mm, respectively. For anterior chamber depth, 95% LoA was −0.23 to 0.09 mm (mean difference: 0.068 mm) and −9.61 to 33.44 μm (mean difference: 11.91 μm) for minimal corneal thickness.

CONCLUSIONS: The Sirius showed good to excellent repeatability for all measured parameters. Agreement analysis suggests that Sirius and Pentacam should not be used interchangeably. [*J Refract Surg*. 2012;28(7):493-497.]

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Corneal topography and thickness are important in diagnosing and evaluating progression of corneal ectatic disorders.[1] In addition, these parameters are vital when screening candidates for refractive surgery and identifying postoperative problems.[2]

Newer technologies, such as Scheimpflug topography, allow additional evaluation of the posterior corneal surface, thus enabling direct evaluation of elevation and thickness changes throughout the cornea.[3-5] The Pentacam HR (Oculus Optikgeräte GmbH, Wetzlar, Germany) uses a rotating Scheimpflug camera to image the anterior segment of the eye. It provides, in a single scan, anterior segment imaging (two- and three-dimensional), anterior and posterior corneal topography, complete corneal pachymetry, and lens densitometry. The repeatability of Pentacam central corneal thickness, corneal power, and anterior chamber depth measurements has been validated and the measurements were found comparable with other imaging modalities.[6-11]

The Sirius topography system (Costruzioni Strumenti Oftalmici, Florence, Italy) has been introduced recently. It combines two mechanisms of action, the Scheimpflug rotating camera with Placido disk topography.

The purpose of this study is to report our initial experience with the Sirius topography system, assess repeatability of its measurements, and assess the agreement with Pentacam HR measurements.

PATIENTS AND METHODS

Healthy individuals aged >18 years were prospectively recruited from among the medical personnel of the Assaf Harofeh Medical Center. Individuals with any ocular abnormality except mild myopia (<2.50 diopters [D]) were excluded, as were those with previous ocular surgery. Contact lens wearers

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were also excluded. All measurements were performed in the undilated right eye.

The Sirius topography system is a new device combining two Scheimpflug cameras and a Placido disk. It provides full analysis of the cornea and anterior segment, including curvature data of anterior and posterior corneal surfaces, corneal pachymetry, and corneal wavefront map. This system can measure more than 30 000 points of corneal surface (compared to 25 000 points measured by Pentacam) in approximately 5 seconds (compared to approximately 2 seconds using Pentacam).[6,12] Data of the anterior corneal surface are merged from both Placido and Scheimpflug scans using an unpublished proprietary method. Because the Placido disk does not scan the posterior corneal surface, the data of the posterior surface are based solely on Scheimpflug data.

The operating principles of the Sirius topography system are similar to that of Pentacam, which have been described previously.[6] Briefly, the patient is seated with the chin on a chinrest and forehead against the forehead strap and asked to fixate straight ahead on a fixation target. The operator visualizes two real-time images of the patient's eye on a computer screen; a profile image, which permits setting the instrument to the correct distance, and a frontal view, which permits correctly centering the instrument. Focusing is done by moving the joystick forward and back until the corneal apex is between two green lines. Centering is done by moving the joystick right and left until the reference cross is located within the green square. At this point, an adequate image can be obtained.[13] Whereas image acquisition is either manual or automatic with the Pentacam, the Sirius allows only manual image acquisition. We used the manual option of image acquisition with the Pentacam.

In the first experiment, the repeatability of the Sirius topography system was determined. Eight successive scans were obtained by the same operator (R.S.) in the right eye of each study participant. To ensure that measurements were independent, the participants were asked to sit back and the joystick was fully retracted and then realigned after each scan. After completing all scans, another operator (C.K.N.) assessed the acquisition quality parameter provided by the Sirius system for every scan. Acquisition quality takes into account the degree of motion compensation, centration, and anterior segment coverage. Only high-quality measurements (quality score $\geqslant$90%) were included for further analysis. The following parameters were assessed: anterior and posterior corneal radius of curvature at 3 and 7 mm (radius of curvature was defined as the average of the steepest and flattest meridians), anterior chamber depth (from endothelium), and minimal corneal thickness.

To assess the agreement between the Sirius and Pentacam, a second separate experiment was conducted by obtaining new single scans of both devices. Measurement was first made using the Pentacam. After 3 minutes of rest, measurement was made using the Sirius system. The quality of the measurements was assessed immediately by another operator and if it was not satisfactory according to the quality measures provided by the two devices, the first operator (R.S.) was asked to repeat scan acquisition. Analyzed parameters included anterior and posterior corneal radius of curvature at 3 mm, anterior chamber depth, and minimal corneal thickness.

In both devices, the corneal radius of curvature is the average of the steepest and flattest meridians.

Measurements with the two devices were performed in the same room and under the same conditions of dim light.

Statistical Analysis

The measured values of mean corneal radii of curvature, anterior chamber depth, and minimal corneal thickness of the two different instruments were processed and analyzed using an Excel spreadsheet (Excel version 2007; Microsoft Corp, Redmond, Washington). Normal distribution test and paired samples *t* test were performed with JMP statistical discovery software (version 8; SAS Institute, Cary, North Carolina).The Shapiro-Wilk W test was used to check for a normal distribution of quantitative data. Inter-device difference was evaluated using the paired samples *t* test and statistical significance was determined as $P<.05$.

To assess agreement and interchangeability between devices, the method suggested by Bland and Altman was used.[14] Differences between measurements were plotted against their mean, and the 95% limits of agreement (LoA) were determined as mean difference $\pm$2 standard deviations of the differences.

To assess repeatability of the Sirius, the coefficient of variation was calculated, which was defined as the standard deviation of the difference from the mean of the repeat measurements divided by the mean response. For each measured parameter, the coefficients of variation of each individual were calculated. The mean of these coefficients of variation was defined as the mean coefficient of variation of the specific parameter.

RESULTS

Forty-five healthy individuals (21 men, 24 women) aged 20 to 61 years (mean: 40.23$\pm$10.49 years) were prospectively recruited. Measurements of 45 right eyes were analyzed. In the first experiment, assessing repeatability of the Sirius imaging system, the mean

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TABLE 1

Mean Measured Values With the Pentacam and Sirius

Measured Value	Pentacam	Sirius	Mean Difference	*P* Value
Anterior corneal radius (mm)	7.73±0.26	7.72±0.26	0.01	.019
Posterior corneal radius (mm)	6.42±0.27	6.53±0.36	0.11	.001
Anterior chamber depth (mm)	2.91±0.31	2.97±0.29	0.06	<.001
Minimal corneal thickness (μm)	548.5±34	536.6±32	11.9	<.001

TABLE 2

Repeatability of the Sirius Imaging System

Measured Value	Mean Coefficient of Variation (%)
Anterior corneal radius	
3 mm	0.37
7 mm	0.36
Posterior corneal radius	
3 mm	1.32
7 mm	1.28
Minimal corneal thickness	1.69
Anterior chamber depth	0.56

number of eligible scans was 7.6. Some scans were excluded due to low quality measures as determined by the device. The mean measured values by the two instruments are reported in Table 1.

Regarding Sirius imaging system repeatability, the calculated mean coefficients of variation are presented in Table 2.

Agreement between instruments is presented as Bland–Altman plots for the measurements of anterior and posterior corneal radius, anterior chamber depth, and minimal corneal thickness (Fig).

DISCUSSION

Along with advances in refractive surgery, corneal imaging has become a rapidly advancing field and several devices have become commercially available providing ophthalmologists with more tools to assess the cornea and anterior segment.

Schiempflug technology is gaining importance and popularity as a reliable method for assessing the cornea and anterior segment. The newly available Sirius imaging system combines a rotating Scheimpflug camera and Placido disk topographer. Before a new instrument is accepted into routine clinical practice, it is important to know whether it provides consistent and reproducible measurements and whether its measurements are in agreement with previously available and familiar instruments.

In our study, both mean anterior and posterior corneal radii values of both devices were similar to previously reported data obtained by different technologies in healthy corneas. Dubbelman et al[15] reported an average anterior corneal radius of 7.79±0.27 mm and average posterior radius of 6.53±0.25 mm, and Ho et al[16] reported a similar average anterior radius of 7.75±0.28 mm and average posterior radius of 6.34±0.28 mm, both using the Pentacam. Fam and Lim,[17] using Orbscan II (Bausch & Lomb, Rochester, New York), reported averages of 7.87±0.25 mm and 6.46±0.26 mm for anterior and posterior corneal radius of curvature, respectively. Comparatively, similar values of anterior chamber depth were previously obtained by Pentacam, optical coherence tomography (OCT), and ultrasound biomicroscopy with averages of 2.87±0.4 mm, 2.97±0.31 mm, and 2.90±0.32 mm, respectively.[18,19] Minimal corneal thickness measurements in our study group were also close to previously reported data obtained by Orbscan II[20] with a mean of 537±37 µm in right eyes and also by Pentacam[21] with a mean of 535±33 µm. These data provide important evidence that the measured values in our study group reflect the normal distribution of these parameters in healthy eyes.

All measured parameters showed high repeatability with the Sirius imaging system. The mean coefficients of variation of anterior radius measurements (at 3 and 7 mm) and anterior chamber depth were <1% and showed better repeatability than posterior corneal radius and minimal corneal thickness (coefficients of variation >1%).

The differences between Pentacam and Sirius measurements were statistically significant for the four measured parameters: anterior and posterior corneal radii, anterior chamber depth, and minimal corneal thickness. To represent the results in a more clinically relevant and meaningful way, the results were plotted according to the method suggested by Bland and Altman.[14] The Bland–Altman plots show a variable range of inter-device differences for the parameters compared, with better agreement for anterior radius measurements

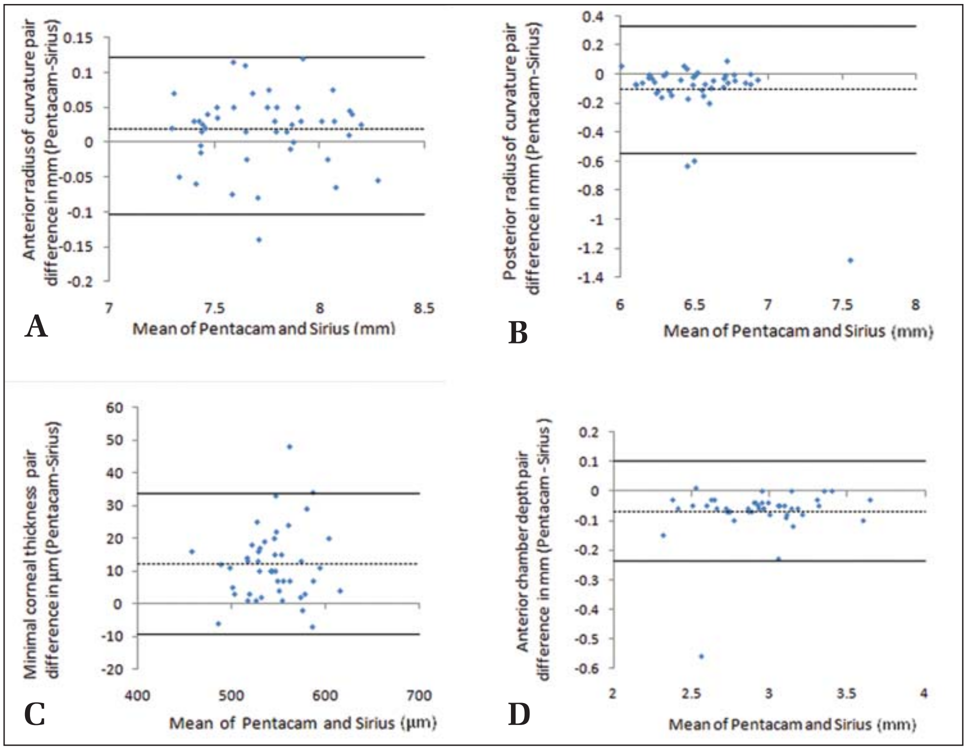

Figure. Bland–Altman plots for the four parameters measured by the Pentacam and Sirius. The mean difference is represented by the dotted line and 95% limits of agreement (LoA) are presented by the solid lines. **A)** Anterior corneal radius of curvature at 3 mm. **B)** Posterior corneal radius of curvature at 3 mm. **C)** Minimal corneal thickness. **D)** Anterior chamber depth. For measurement of anterior and posterior corneal radius, 95% LoA were −0.1 to 0.12 mm (mean difference: 0.018 mm) and −0.54 to 0.33 mm (mean difference: 0.1 mm), respectively. The 95% LoA were −0.23 to 0.09 mm (mean difference: 0.068 mm) for measurement of anterior chamber depth and −9.61 to 33.44 μm (mean difference: 11.91 μm) for measurement of minimal corneal thickness.

than posterior radius measurements. A similar observation was reported previously by Salouti et al,[22] who compared two Scheimpflug-based systems—Galilei (Ziemer, Port, Switzerland) and Pentacam. The authors attributed this discrepancy either to possible shortcomings of the systems in evaluating the posterior cornea or a similar systematic error of the two systems.

When considering intraocular lens (IOL) power calculations, the anterior radius plot emphasizes the importance of using Bland–Altman plots when comparing two different devices. If agreement between devices is assessed by only looking at the mean difference (0.01 mm), it appears that the agreement is excellent with negligible difference expected when calculating intraocular lens (IOL) power. But when considering the range of variation or 95% LoA of 0.2 mm, a resulting difference in IOL power calculation may be as large as approximately 1.00 D and therefore might be clinically significant. The inter-device difference in posterior corneal radius was larger and likely does not allow useful comparison in most clinical applications.

Range of variation of 0.32 mm in anterior chamber depth measurement may be too large for some clinical applications such as phakic IOL implantation. The two devices have similar eye-to-fixation point distances; however, the studied individuals are young (mean age ~40 years) and accommodation can change the measured anterior chamber depth. Thus, better agreement may be expected in older individuals.

Limits of agreement for minimal corneal thickness measurements might be too broad for corneal ectasia follow-up, as the difference between devices could be as large as ~43 µm.

For two individuals, the difference between Pentacam and Sirius posterior radius measurements was high as compared to the rest of the study group. Performing further analysis with group adjustment and omitting these outliers still results in significant inter-device difference. A similar situation was observed when examining the plot of anterior chamber depth, where inter-device difference in one individual was high compared to the remaining participants. Excluding this measurement may yield a 50% reduction in the range of variation difference (from ~0.34 to ~0.17 mm). In larger study groups, the influence of isolated "out of range" measurements might be largely reduced.

Possible causes of the difference between devices include different measurement accuracy standards, different reconstruction algorithms, and different points of measurement. The measurement principle could, in part, explain the difference in measurement of anterior radius but not the other parameters because Placido disk–based topographers do not measure the posterior radius.

Moreover, we noted that posterior radius and anterior chamber depth measurements of the Sirius were consistently higher than those of the Pentacam, whereas minimal corneal thickness measurements were con-

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sistently higher using the Pentacam. This observation may indicate that the difference could be due to a built-in shift between devices. Further investigation may reveal the source of this shift and possibly help establish an inter-device conversion formula. On the other hand, the Bland–Altman plot for the anterior radius showed no specific pattern of distribution.

This study is not the first to assess the measurements of the Sirius imaging system. Milla et al[12] found that pachymetric measurements with the Sirius were repeatable but not equivalent to those obtained with OCT. In this study, we compared additional parameters that reflect a broader spectrum of the Sirius utilities. Recently, Savini et al[23] compared the Sirius, Pentacam, and two other imaging devices and reported statistically significant differences in measurements of posterior corneal surface, corneal thickness, and anterior chamber depth. Our results essentially confirm these results based on a significantly larger sample.

It is important to emphasize that we measured only normal eyes with low astigmatism; therefore, the comparison data obtained between the two anterior segment imaging systems cannot be simply applied to eyes with pathological changes, high astigmatism, or postoperatively altered corneas. This issue requires further investigation.

The Sirius imaging system provided measurements of the anterior segment with good to excellent repeatability. The differences between the Sirius and Pentacam were clinically significant and it is recommended that these devices not be used interchangeably.

AUTHOR CONTRIBUTIONS

Study concept and design (C.K.N., Y.B., D.Z., I.A., Y.G.); data collection (C.K.N., R.Z.); analysis and interpretation of data (C.K.N., Y.B., Y.G.); drafting of the manuscript (C.K.N., R.Z.); critical revision of the manuscript (Y.B., D.Z., I.A., Y.G.); statistical expertise (Y.G.); administrative, technical, or material support (D.Z., I.A.); supervision (D.Z., I.A.)

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