



ORIGINAL ARTICLE

Single session, intrauser repeatability of anterior chamber biometric and corneal pachy-volumetric parameters using a new Scheimpflug + Placido device



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KEYWORDS

Scheimpflug imaging;
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Repeatability

Abstract

Purpose: To analyze single session, intrauser reliability of a Scheimpflug device for anterior chamber (AC) and corneal parameters.

Methods: In this observational study, 100 normal candidates underwent Scheimpflug analysis with Sirius 3D Rotating Scheimpflug Camera and Topography System (Costruzione Strumenti Oftalmici, Italy). Two scans in dark room conditions were performed by the same experienced user. The candidates were asked to keep both eyes closed for 5 min before the scans. Exclusion criteria were previous ocular surgery, corneal scarring and anterior segment/posterior segment anomalies. Only the right eyes were used for the analysis. Both corneal (central, minimum, and apical thickness, volume, horizontal visible iris diameter, and apical curvature) and anterior chamber (volume, depth, angle, horizontal diameter) measurements were evaluated.

Results: There was no difference in the means of repeated measurements ($p > 0.05$, ANOVA). Intraclass correlations between the measures were high and ranged from 0.995–0.997 for corneal to 0.964–0.997 for anterior chamber (AC) parameters. The precision of repeatability measures ($1.96 \times Sw$) was approximately 5μ for the central and minimum corneal thickness, 8μ for the apical corneal thickness, 0.06 mm for AC (anterior chamber) depth and less than 2° for the AC angle.

Conclusions: Sirius Scheimpflug system has high repeatability for both corneal and AC parameters in normal eyes.

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PALABRAS CLAVE

Adquisición de imágenes
Scheimpflug;
Cámara anterior;
Córnea;
Capacidad de repetición

Repetibilidad intra-usuario en una única sesión de las medidas de parámetros biométricos de la cámara anterior y volumétricos de la córnea utilizando un nuevo dispositivo Scheimpflug + Placido

Resumen

Objetivo: Analizar la repetibilidad intra-usuario en una única sesión del dispositivo basado en cámara Scheimpflug, en la medición de diversos parámetros para caracterizar la cámara anterior (CA) y la córnea.

Métodos: En este estudio observacional, se realizó a cien sujetos normales un análisis con cámara rotatoria de Scheimpflug utilizando el sistema Sirius 3D (Costruzione Strumenti Oftalmici, Italia). Se realizaron dos escaneos en condiciones de oscuridad por parte del mismo usuario experimentado. Se solicitó a los sujetos que mantuvieran ambos ojos cerrados durante los cinco minutos previos al escaneo. Los criterios de exclusión fueron: cirugía ocular previa, cicatrices en la córnea y anomalías de los segmentos anterior/posterior. Únicamente se utilizaron los ojos derechos en el análisis. Se evaluaron las mediciones tanto de la córnea (espesor central, mínimo y apical, volumen, diámetro horizontal del iris visible, y curvatura apical) como de la cámara anterior (volumen, profundidad, ángulo, diámetro horizontal).

Resultados: No se produjo diferencia en las medias de las mediciones repetidas ($p > 0,05$, ANOVA). Las correlaciones intra-clase entre las mediciones fueron elevadas, oscilando entre 0,995-0,997 para los parámetros de la córnea y 0,964-0,997 para los de la cámara anterior (CA). La precisión de las mediciones de repetición ($1,96 \times Sw$) fue de aproximadamente 5 micrones para el espesor central y mínimo de la córnea, 8 micrones para el espesor apical de la córnea, 0,06 mm para la profundidad de la CA (cámara anterior), e inferior a 2 grados para el ángulo de la CA.

Conclusiones: El Sistema Sirius, basado en el uso de una cámara Scheimpflug, tiene una elevada capacidad de repetición para las mediciones de los parámetros de la córnea y la CA en ojos normales.

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Introduction

Comprehensive anterior segment analysis units have been developed recently. In contrast to stand-alone cornea or anterior chamber units, these devices incorporate multiple functions including corneal topography, pachymetry, anterior chamber depth and volume in a single capture.¹⁻⁵ This has made these devices useful for the anterior segment practitioner.

One such group of devices is based on the principle of Scheimpflug imaging.⁶⁻⁸ There are multiple studies evaluating the repeatability of corneal parameters of Scheimpflug based instruments and their comparison with other devices such as ultrasound pachymetry and optical coherence tomography.⁹⁻¹⁵ However, there is less information on the repeatability of these devices for anterior segment anatomical and volumetric parameters such as the white to white diameter, anterior chamber diameter, depth, AC angle, corneal volume and AC volume.

In this current study, we evaluate the single user repeatability of a Scheimpflug device, Sirius 3D Rotating Scheimpflug Camera & Topography System [Costruzione Strumenti Oftalmici (CSO), Italy], for anterior chamber biometric and corneal parameters.

Methods

In this study, 100 consecutive candidates presenting for anterior segment analysis were assessed. The study had

the approval of the institutional review board and followed the tenets of declaration of Helsinki. The population pool consisted of patients for pre-refractive surgery workup, those for keratoconus screening, healthy volunteers and medical staff. Informed consent was obtained from all the candidates. Slit lamp assessment and clinical evaluation were done to rule out any anterior segment, and pupillary or retinal abnormalities. Cases having corneal scarring and anterior segment/posterior segment anomalies or a history of ocular surgery were excluded.

Sample size estimation

The a priori sample size was estimated by using expected difference in intraclass correlation (ICC), as has been proposed by Walter et al.¹⁶ We expected the ICC to be high based on the results of previous studies in the same field.^{9,10} For a power of 0.8 and an alpha (α) of 0.05, with 2 measurements per eye, the minimum sample size required to pick up difference of 0.1 between ICC of 0.9 and 0.8 was estimated.¹⁶ This number was a minimum of 46 eyes. The corneal parameters with Sirius have been studied in detail. However, there is less information available on the expected reliability of AC angle measurement and volume with the Sirius device. Thus, we wanted to keep adequate margin in the final sample size.¹⁶ Therefore, the final sample size was decided to be 100 eyes (approximately twice of the minimum required sample size). Depending on the stringency for accuracy, the confidence

Table 1 Descriptive statistics for repeated measures.

Parameter	Measurement number	N	Mean	Std. deviation	95% confidence interval for mean		Range		P value, one sample Kolmogorov-Smirnov test	P value, repeated measures ANOVA
					Lower Bound	Upper Bound	Minimum	Maximum		
Central corneal thickness (μ)	1	100	538.83	32.4	532.4	545.3	469	649	0.6	0.9
	2	100	538.77	32	532.4	545.1	470	647		
	Total	200	538.80	32.1	534.3	543.3	469	649		
Minimum corneal thickness (μ)	1	100	534.94	32.8	528.4	541.4	465	646	0.6	0.4
	2	100	534.58	32.4	528.2	541	465	641		
	Total	200	534.76	32.5	530.2	539.3	465	646		
Horizontal visible iris diameter (mm)	1	100	12.15	0.4	12.1	12.2	11.2	13.7	0.1	0.4
	2	100	12.15	0.4	12.1	12.2	11.2	13.7		
	Total	200	12.15	0.4	12.1	12.2	11.2	13.7		
Corneal apex thickness (μ)	1	100	567.53	45.9	558.1	576.7	482	695	0.3	0.9
	2	100	567.50	45.6	558.5	576.5	488	690		
	Total	200	567.52	45.7	561.1	573.9	482	695		
Corneal apex curvature (D)	1	100	45.52	2.2	45.1	46	39.9	53.9	0.9	0.1
	2	100	45.46	2.2	45	45.9	40	53.1		
	Total	200	45.49	2.2	45.2	45.8	39.9	53.9		
Anterior Chamber Depth (from endothelium) (mm)	1	100	3.16	0.3	3.1	3.2	2.2	3.7	0.2	0.1
	2	100	3.16	0.3	3.1	3.2	2.2	3.7		
	Total	200	3.16	0.3	3.1	3.2	2.2	3.7		
Anterior chamber volume (mm ³)	1	100	161.01	21.6	156.7	165.3	88	193	0.1	0.8
	2	100	161.12	21.7	156.8	165.4	90	194		

Table 1 (Continuación)

Parameter	Measurement number	N	Mean	Std. deviation	95% confidence interval for mean		Range		P value, one sample Kolmogorov-Smirnov test	P value, repeated measures ANOVA
					Lower Bound	Upper Bound	Minimum	Maximum		
Iridocorneal angle (°)	Total	200	161.07	21.6	158.1	164.1	88	194		
	1	100	43.41	5.7	42.3	44.5	30	55	0.1	0.1
	2	100	43.83	5.7	42.7	45	29	55		
Horizontal anterior chamber distance (mm)	Total	200	43.62	5.7	42.8	44.4	29	55		
	1	100	12.21	0.5	12.1	12.3	10.7	13.7	0.2	0.6
	2	100	12.24	0.5	12.1	12.4	10.7	13.8		
Corneal volume (mm ³)	Total	200	12.23	0.5	12.2	12.3	10.7	13.8		
	1	100	57.17	3.1	56.6	57.8	49.6	65.5	0.7	0.9
	2	100	57.19	3	56.6	57.8	49.8	64.8		
	Total	200	57.18	3	56.8	57.6	49.6	65.5		

interval for intra-measurement standard deviation (Sw) has been usually set less than 20% either side of Sw in previous studies on ophthalmic instrument reliability.^{17,18} With a sample size of 100, the confidence interval of Sw was estimated using the method suggested by JM Bland.¹⁹ It was found to be 13.9% for this study, which is clinically acceptable.¹⁹

Method of Scheimpflug analysis

Sirius 3D Rotating Scheimpflug Camera & Topography System with software suite Phoenix v2.1 (Costruzione Strumenti Oftalmici (CSO), Italy) was used in the assessment. An experienced optometrist (DS) performed all the tests. Two scans were performed sequentially in dark room conditions for both the right and the left eyes initially (the left eyes were excluded as explained later in the statistical analysis). Illumination related changes have been noted with the anterior chamber.^{20,21} Therefore, the candidates were advised to close the eyes before both tests for 5 min. This was done to standardize the illumination settings and measure the anterior chamber angle in non-accommodated state, as has been previously suggested by Radhakrishnan et al.²²

The anterior segment analysis output was generated and displayed as the glaucoma summary screenshot (Fig. 1). The "glaucoma summary" is a comprehensive output of the anterior segment biometrics of the eye. There is a large amount of information on the anterior segment biometry (Horizontal anterior chamber diameter, horizontal visible iris diameter, apex thickness and curvature) along with the traditional glaucoma related parameters (Anterior chamber (AC) angle, AC volume, AC depth, central corneal thickness). This output can be generated in all candidates, irrespective of them being normal or having an ocular pathology. All the candidates in this study were clinically normal as defined above and none of them had glaucoma or other ocular pathology except mild refractive error. The corneal parameters evaluated were: apex curvature and thickness, central and minimum thickness, horizontal visible iris diameter (white to white diameter) and corneal volume (for the central 10mm). The anterior chamber parameters evaluated were AC depth (from endothelium), iridocorneal angle, horizontal anterior chamber depth and anterior chamber volume (12 mm).

Statistical analysis

The data were entered into a MS Excel (Microsoft, Richmond, VA) sheet. Only the data for the right eyes were used to prevent skewing of correlation due to bilateral symmetry. The data were then transferred to SPSS 16.0 (SPSS Inc., Illinois) for the analysis. Measures of central tendency were used to display the descriptive data in mean $\pm$ standard deviation format. The difference of means between the two observations was computed using 'repeated measures one way analysis of variance' (repeated measures ANOVA).

The intra-measurement standard deviation (Sw) was calculated using the following equation described by Bland and Altman.²³⁻²⁵ $s_w^2 = \frac{1}{2n} \sum d_i^2$ where, n is the number of cases, and d_i is the difference between two measurements for the same subject i .

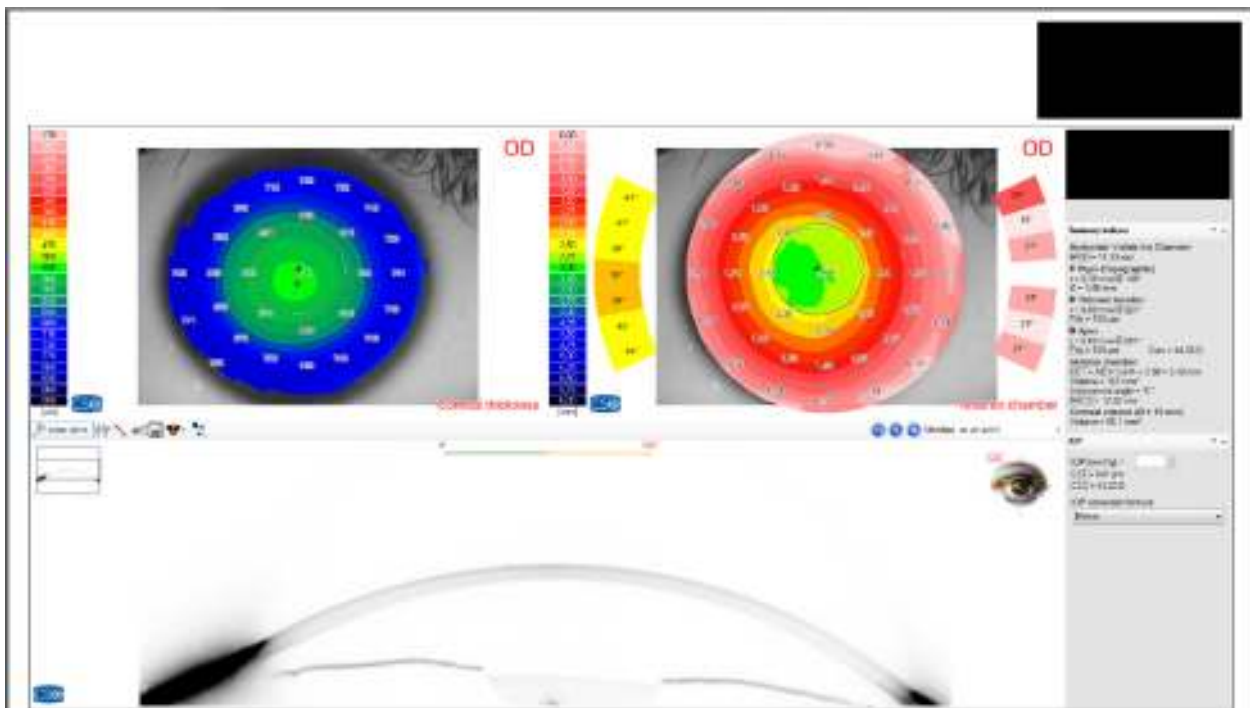


Figure 1 Output screenshot of the glaucoma summary mode of Sirius Scheimpflug analysis system (CSO, Italy) showing the measured parameters.

Precision was defined as difference between a subject's measurement and the true value for 95% of observations. It was computed as $1.96 \times Sw$.^{23–25}

Repeatability was computed as $2.77 \times Sw$ ($= \sqrt{2} \times 1.96 \times Sw$). The difference between the two observations for the same candidate is expected to be less than the value noted for repeatability for 95% pairs.^{23–25}

Results

Demography

There were 53 males and 47 females. The mean age was 29.9 ± 6.7 years [ranging from 18 to 44 years]. Only right eyes' measurements were used for analysis. All the measured variables followed normal distribution ($p > 0.05$, one sample Kolmogorov–Smirnov test) (Table 1).

Corneal parameters

There was no significant difference in the means of the repeated measures for all the 6 variables (p value > 0.05 , ANOVA) (Table 1). The precision of repeatability measures ($1.96 \times Sw$) was approximately 5μ for the central and minimum corneal thickness and 8μ for the apical corneal thickness (Table 2). Intraclass correlations (ICC) between the measures were high and ranged from 0.995 to 0.997 (Table 2).

Anterior chamber parameters

There was no significant difference in the means of the repeated measures for all the 4 variables (p value > 0.05 ,

ANOVA) (Table 1). The precision of repeatability measures ($1.96 \times Sw$) was 0.06 mm for AC depth and less than 2° for the AC angle (Table 2). ICC between the measures were high and ranged from 0.964 to 0.997 (Table 2).

Discussion

There are multiple comprehensive anterior segment analysis systems currently available. Many of these devices work on similar principles and therefore it is relevant to evaluate their interchangeability in clinical settings. In a recent study, Ramirez-Miranda et al. evaluated the repeatability, reproducibility, and agreement between three different Scheimpflug systems for 84 eyes of 42 patients.⁹ The Scheimpflug devices used were the Galilei G2 Dual Scheimpflug Analyzer (Ziemer Ophthalmic Systems AG, Port, Switzerland), Pentacam HR system (Oculus Optikgerate GmbH, Wetzlar, Germany), and Sirius 3D imaging system (Costruzione Strumenti Oftalmici, Florence, Italy). Good reliability was seen for all the three devices. Inter-device agreement analysis suggested that measurements for anterior radius of curvature, central corneal thickness, and anterior chamber depth from the Sirius 3D and Galilei G2 are interchangeable with those noted from the Pentacam HR. However, maximum anterior and posterior corneal elevation and total higher-order aberrations were not interchangeable.

In contrast, Shetty et al. used the same devices (Pentacam, Galilei and Sirius) in a study with a sample size of 55 eyes.²⁶ They found that the Pentacam, Galilei, and Sirius showed repeatable measurements for keratometry, thinnest corneal pachymetry and anterior chamber depth. The repeatability indices with Pentacam and Sirius

Table 2 Limits of agreement and intraclass correlations.

Parameter	Intrameasurement standard deviation (Sw)	Precision ($1.96 \times Sw$)	Repeatability ($2.77 \times Sw$)	Intraclass correlation (ICC)	ICC 95% limits (lower)	ICC 95% limits (upper)
Central corneal thickness (μ)	2.56	5.02	7.09	0.997	0.995	0.998
Minimum corneal thickness (μ)	2.87	5.62	7.95	0.996	0.994	0.997
Horizontal visible iris diameter (mm)	0.03	0.06	0.08	0.997	0.996	0.998
Corneal apex thickness (μ)	4.21	8.27	11.69	0.996	0.994	0.997
Corneal apex curvature (dioptries)	0.23	0.45	0.64	0.995	0.992	0.996
Anterior chamber depth (mm)	0.03	0.06	0.09	0.995	0.992	0.997
Anterior chamber volume (mm^3)	3.34	6.55	9.26	0.988	0.982	0.992
Iridocorneal angle ($^\circ$)	0.95	1.86	2.63	0.970	0.955	0.980
Horizontal anterior chamber depth (mm)	0.06	0.12	0.16	0.964	0.947	0.976
Corneal volume (mm^3)	0.69	1.36	1.92	0.973	0.960	0.982

Sw is intrameasurement standard deviation, computed as: $s_w^2 = 1/2n \sum d_i^2$. Where, n is the number of cases, and d_i is the difference between two measurement for the same subject i .^{17–19}

Statistical precision is the difference between a subject's measurement and the true value for 95% of observations and was defined as $1.96 \times Sw$.^{17–19}

Repeatability was defined as $2.77 \times Sw$ ($= \sqrt{2} \times 1.96 \times Sw$). The difference between the two observations for the same candidate is expected to be less than the value noted for repeatability for 95% pairs.^{17–19}

were better than those with Galilei.²⁶ There were significant differences in the measurements between the three devices. They concluded that these devices cannot be used interchangeably for anterior segment measurements in keratoconus patients. In a smaller study of 16 patients, De la Parra-Colín et al. further observed that even the Sirius and the Pentacam do not seem to be interchangeable, even though they are highly repeatable.²⁷

Therefore, the data on interchangeability are unequivocal as of now, and the devices need to be assessed separately to evaluate the repeatability.

We performed a focused literature search looking for the studies evaluating the device used in our study, the Sirius system. Maresca et al., evaluated right eyes of 35 normal candidates.²⁸ They found that the ICC for central corneal thickness was 0.97 for Sirius.²⁸ Similar repeatability for Sirius was noted by Huang et al.²⁹ Savini et al., evaluated the repeatability of the Sirius device for 64 normal eyes.³⁰ Their test-retest repeatability ($2.77 \times Sw$) and ICC were 7.37μ and 0.994 for minimum corneal thickness, 6.59μ and 0.992 for central corneal thickness, 0.04 mm and 0.999 for anterior chamber depth, and 6.42 mm^3 and 0.995 for anterior chamber volume.³⁰ In a larger study with 117 eyes, Montalbán et al. evaluated multiple shape factors with the Sirius.³¹

Additionally they also evaluated the repeatability of corneal thickness, white to white diameter and AC depth. Their ICC values were close to 1. Their intrameasurement standard deviation (Sw) was below 3μ for the central and minimum thickness. Their Sw for AC depth and white to white diameter were below 0.1 mm.³¹ The findings of these studies are comparable to ours.^{28–31} In fact, our study is a step further in the line of these previous studies and looks at the anterior chamber parameters and corneal parameters in a more detailed manner. The unique factors studied additionally in our study are horizontal anterior chamber diameter, anterior chamber angle, corneal volume, corneal apex thickness and steepness.

The use of Scheimpflug system to measure anterior chamber parameters such as AC depth and volume and horizontal anterior chamber diameter is a potentially useful addition. We also found these three parameters to be highly repeatable with ICC similar to those seen for corneal parameters in our study. The intra-measurement standard deviations were low and the precision and repeatability were clinically acceptable.

The reliability of AC angle measurement with Sirius was satisfactory and clinically acceptable. However, it remains to be seen if this method of measurement of AC angle is

comparable to the gold standard method of gonioscopy. In a recent report by the American Academy of Ophthalmology, it was observed that noncontact imaging using optical coherence tomography, Scheimpflug photography, or scanning peripheral anterior chamber depth analyzer is more attractive for large-scale primary angle closure screening than contact imaging using ultrasound biomicroscopy.^{30,32} The report further concluded that prospective longitudinal studies are needed to validate the diagnostic significance of the parameters measured by these instruments for identifying individuals at risk for primary angle closure.³² As of now, our study suggests that the measurement of anterior chamber bio-volumetric parameters is highly repeatable in normal, non-operated eyes. Further studies comparing various methods of anterior segment analysis can reveal further on the clinical utility of Scheimpflug analysis based parameters for diagnosis management of susceptible angles or glaucoma.

The purpose this study, like other repeatability studies, is to guide the clinician in regard to the expected variation in results. As an optometric service may use these devices, or interpret data from other service's scan reports, it would be useful to keep in mind the normal range of accuracy seen with this or other Scheimpflug device. With the knowledge of these ranges (Table 2), serial follow-ups can become more useful. For example, if one sees that there is a decrease in the AC depth or AC angle, it would be prudent to see if this is within the limits of variation. If it is outside these limits, a further clinical evaluation into the cause is recommended. If not, a repeat scan may be needed to confirm the change and then act accordingly. For example, a change of AC depth of 0.05 mm on follow-up may be a part of normal variation and needs to be reconfirmed, however, a change of 0.20 mm is outside the repeatability limits and is probably due to a change in the anatomy of the eye. Similarly a decrease of 5° in the AC angle or 10 μ in central/minimum or apical corneal thickness is more than expected on the repeatability parameters. Therefore, an optometrist can use these guidelines to diagnose and manage his or her patients better and to suspect early pathology and thus perform timely intervention.

In conclusion, our study suggests that Sirius Scheimpflug system has excellent intrauser repeatability and low intra-measurement standard deviations for corneal topographic and anterior chamber parameters in normal eyes. Further studies are required to analyze its inter-user repeatability in post-surgical eyes.

Declaration

Ethical disclosure: We have taken into account the "Ethical responsibilities" included in these guidelines, and among these: (a) procedures followed in the research are in accordance with the ethical guidelines of the committee responsible for human and animal experiments (institutional or regional) and in accordance with the World Medical Association and the Helsinki Declaration; (b) we guarantee the rights of their patients to the privacy and confidentiality in accordance with that described in the corresponding section of these guidelines, and that the article has avoided any kind of identification data in text or images and, In any event, (c) we are in possession of the informed consent by the patients

to take part in the study and the publication of the results in print and electronic (Internet) form in J Optom and that they have been declared as such in the EES.

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Conflicts of interest

The authors have no financial or proprietary interest in a product, method, or material described herein.

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