ARTICLE

Anterior Surface Measurements Correlation and Agreement Between Rotational Scheimpflug and Placido Disc-based Devices in Primary Eyes

Correlação e Concordância das Medições da Superfície Anterior entre Aparelhos Baseados em Disco de Plácido e em Scheimpflug Rotacional em Olhos Primários

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ABSTRACT

PURPOSE: To evaluate the inter-device agreement between Placido -based topography (Topolyzer Vario, WaveLight, Alcon Laboratories, Inc., Ft Worth, Texas, USA) and rotational Scheimpflug tomography (Oculyzer II, WaveLight, Alcon Laboratories, Inc., Ft Worth, Texas, USA) for measuring anterior corneal surface parameters.

METHODS: Fifty eyes from 50 subjects with no ocular disease were included in this study. The main outcome measurements were keratometric readings and anterior surface irregularity metrics derived from Fourier analysis (decentration, decentration axis and irregularity). Inter-device correlation and agreement between the two devices were assessed.

RESULTS: No statistically significant differences were detected among the parameters obtained by both devices (paired *t* test; $p > 0.05$). The 95% LoA between instruments were within the clinically relevant margins of discrepancy for the keratometric parameters. Seven (14%) and five (10%) eyes presented a difference greater than 0.5 D for the flat meridian (K1) and steep meridian (K2) parameters, respectively. Regarding corneal astigmatism, only three eyes (6%) presented a difference greater than 0.5 D between both devices. All the parameters selected from the Fourier analysis showed a lower level of correlation and a more extensive range of LoA compared to the keratometric variables.

CONCLUSION: Placido topography and Scheimpflug tomography showed good correlation and agreement for keratometric measurements, including corneal astigmatism. Based on the data derived from the Fourier analysis, the results recommend caution when selecting the data to plan the topography-guided customized ablation, especially in primary eyes, which calls for prospective studies, possibly using simulated models.

KEYWORDS: Cornea; Corneal Diseases; Corneal Topography

RESUMO

OBJETIVO: Avaliar a concordância entre aparelhos de topografia baseada no disco de Plácido (Topolyzer Vario, WaveLight, Alcon Laboratories, Inc., Ft Worth, Texas, EUA) e na tomografia de Scheimpflug rotacional (Oculyzer II, WaveLight, Alcon Laboratories, Inc., Ft Worth, Texas, EUA) para medir os parâmetros da superfície anterior da córnea.

MÉTODOS: Cinquenta olhos de 50 indivíduos sem doença ocular foram incluídos neste estudo. As principais medidas de resultado foram as medições queratométricas e parâmetros de irregularidade da superfície anterior derivadas da análise de Fourier (descentralização, eixo de descentralização e irregularidade). A correlação entre os dispositivos e a concordância entre os dois dispositivos foram avaliadas.

RESULTADOS: Não foram detectadas diferenças estatisticamente significativas entre os parâmetros obtidos pelos dois aparelhos (teste *t* pareado; $p > 0,05$). A LoA de 95% entre os instrumentos estava dentro das margens de discrepância clinicamente relevantes para os parâmetros ceratométricos. Sete (14%) e cinco (10%) olhos apresentaram diferença maior que 0,5 D para os parâmetros do meridiano plano (K1) e do meridiano íngreme (K2), respectivamente. Em relação ao astigmatismo corneano, apenas três olhos (6%) apresentaram diferença maior que 0,5 D entre os dois dispositivos. Todos os parâmetros selecionados da análise de Fourier apresentaram menor nível de correlação e maior amplitude de LoA em comparação com as variáveis ceratométricas.

CONCLUSÃO: A topografia da Plácido e a tomografia de Scheimpflug mostraram boa correlação e concordância para as medidas queratométricas, incluindo astigmatismo corneano. Com base nos dados derivados da análise de Fourier, os resultados recomendam precaução na seleção dos dados para o planeamento de ablações customizadas pela topografia, principalmente em olhos primários, o que requer estudos prospectivos, possivelmente utilizando modelos simulados.

PALAVRAS-CHAVE: Córnea; Doenças da Córnea; Topografia da Córnea

INTRODUCTION

The primary indications for topography-guided ablation treatments are enlargement of the optical zone or irregular astigmatism after other surgical procedures (such as penetrating keratoplasty and radial keratotomy) or due to corneal pathologies (including keratoconus and ectatic corneal diseases).[1-5] Interestingly, recent studies demonstrated the effectiveness of this approach for primary laser vision correction. Besides refractive error correction, this customized approach based on the anterior corneal surface helped to improve visual symptoms related to visual quality (including halos, glare and starbursts) by the reduction of the corneal irregularity or high-order aberrations.[6-8]

Previous studies investigated the reliability and accuracy of corneal surface measurements obtained by using distinct technologies systems.[9-11] In the present study, we included a Placido-disc based (Topolyzer Vario, WaveLight, Alcon Laboratories, Inc., Ft Worth, Texas, USA) and a rotational Scheimpflug camera (Oculyzer II, WaveLight, Alcon Laboratories, Inc., Ft Worth, Texas, USA) devices. The data derived from both systems may be used for customized ablation treatments with the EX500 excimer laser platform (WaveLight, Alcon Laboratories, Inc., Ft Worth, Texas, USA).[6-8,12]

This study aimed to evaluate the correlation and agreement of anterior corneal surface measurements, such as keratometry readings and irregularity indices based on Fourier analysis between two anterior segment imaging methods, a Scheimpflug rotational camera (Oculyzer II) and a Placido-based topographer (Topolyzer Vario).

PATIENTS AND METHODS

This report is a retrospective case series conducted in a private clinic (Sara Ribeiro Serviços Médicos Lda.; Fernando Faria Correia, Lda.) and followed the tenets of the Declaration of Helsinki. All participants provided written informed consent to be part of this study. The present study included one eye randomly selected from among 50 patients examined by an experienced surgeon (FFC) and considered good candidates to primary laser vision surgery based on their clinical and complementary exams. All patients enrolled had no history of ocular disease, surgery, trauma, or general disorders affecting vision, such as macular disease, diabetic retinopathy, or uveitis. Contact lens wearers were instructed to discontinue them three weeks before the clinical visit. All patients underwent a complete ophthalmic examination, which included corrected distance visual acuity measurement, noncontact tonometry, slit-lamp biomicroscopy, and dilated fundus examination. Each subject underwent examination with a Placido-based disk topographer (Topolyzer Vario) and a rotational Scheimpflug camera (Oculyzer II). Both systems were calibrated according to manufacturer recommendations before undertaking the scans. The Topolyzer Vario presents 22 rings and generates high-resolution data of the anterior corneal surface with 22 000 data points. The Oculyzer II device provided a three-dimensional reconstruction of the cornea by capturing 138 000 elevation points.

Regarding this system, the automatic release mode with the default setting of 25 images per acquisition was selected.

One technician with more than 5 years of experience in anterior segment diagnostic devices sequentially performed the ocular scans during the same session. The order of the examiner and the order of the device were randomized using a computer-generated random-numbers matrix. The eye to be included in the study was also randomized. Three scans were performed in a darkened room and the patient was asked to blink before each capture. The device was defocused, realigned, and focused between the measurements. For the present study, only good quality scans were included, defined as automated captures for the Topolyzer in which all of the reflected Placido rings were well-defined and free of artifacts. Regarding the Scheimpflug device, only scans with an "OK" in the quality scan box were selected. The same trained investigator (FFC) reviewed all measurements performed in each device.

For the statistical analysis, the same parameters provided by both devices were included. From the front surface of the cornea, the following variables were selected: flat keratometry (K1); steep keratometry (K2); corneal astigmatism magnitude and axis (astigmatism and axis); corneal asphericity at 6 mm (Q value). Both Placido-based and Scheimpflug systems included in this study provide radius of curvature measurements in the central 3.0-mm diameter area of the cornea. The corneal astigmatism was further converted into a vector representation, J0 (cylinder at 0º degree meridian) and J45 (cylinder at 45º degree meridian), by the method described by Thibos *et al.*[13]

Concerning the Fourier analysis of front sagittal curvature data, the following parameter were included in the analysis: decentration magnitude and axis (Decentration and Decentration axis, respectively); irregularity (Irregularity).[14] All results were analyzed using MedCalc software (version 14.12.02; MedCalc, Ostend, Belgium). A *p*-value of less than 0.05 was considered to be statistically significant. Data normality was confirmed using the Kolmogorov–Smirnov test. A paired t-test was performed to compare the mean values of the selected variables between the Oculyzer II and Topolyzer Vario systems. Significant correlations were also evaluated using the Pearson correlation, where R values smaller than 0.3 represented no correlation, between 0.3 and 0.6 expressed moderate correlation, and greater than 0.6 demonstrated high correlation. Bland-Altman plots were used to assess the agreement between the devices. Briefly, the mean difference and 95% limits of agreement (LoA) were calculated. This latter is the mean difference +/- 1.96 SD and represents the limits of the range for the 95% of differences between the devices. A narrower 95% LoA indicates superior agreement between both systems.

RESULTS

Fifty eyes randomly selected from 50 patients were analyzed in this study, of which 30 (60%) were right eyes. All eyes included in this study revealed mean corneal astigmatism inferior to 2.0 diopters (D) in both devices. Thirty-five (70%) of the eyes enrolled in this study were from female patients. Mean age of the subjects included in the study was 34.23 +/- 7.23.

The mean values provided by each instrument are described in Table 1. No statistically significant differences were detected among the parameters obtained by both devices (paired *t*-test; $p > 0.05$).

Table 1 – Parameters measured by Placido-based topography (Topolyzer Vario) and Scheimpflug-based tomography (Oculyzer II)

	Topolyzer Vario (Mean +/- SD)	Oculyzer II (Mean +/- SD)
K1 (D)	42.078 +/- 1.182	42.846 +/- 1.202
K2 (D)	44.174 +/- 1.432	44.130 +/- 1.565
Astigmatism (D)	1.242 +/- 0.709	1.276 +/- 0.563
Axis (degrees)	106.202 +/- 77.463	106.780 +/- 77.581
J0 (D)	-0.539 +/- 0.365	-0.550 +/- 0.389
J45 (D)	0.047 +/- 0.295	0.044 +/- 0.306
Corneal Asphericity (Q value)	-0.268 +/- 0.087	-0.269 +/- 0.074
Decentration magnitude (mm)	0.173 +/- 0.063	0.177 +/- 0.061
Decentration axis (degrees)	225.300 +/- 81.609	225.040 +/- 85.006
Irregularity (mm)	0.0159 +/- 0.005	0.0157 +/- 0.004

D = diopters; K1 = flat meridian keratometry, K2 = steep meridian keratometry, SD = standard deviation

The correlation and agreement between both instruments are shown in Table 2. Statistically significant correlations were found between the variables derived from the instruments. For K1, K2, and astigmatism parameters, the 95%

Table 2 – Agreement Between Placido-based topography (Topolyzer Vario) and Scheimpflug-based tomography (Oculyzer II)

	Correlation between devices (p)	Mean Difference +/- SD	95% LoA
K1 (D)	0.965 (< 0.001)	0.110 +/- 0.018	-0.51 to 0.73
K2 (D)	0.977 (< 0.001)	0.091 +/- 0.049	-0.52 to 0.70
Astigmatism (D)	0.848 (< 0.001)	-0.020 +/- 0.646	-0.62 to 0.58
Axis (degrees)	0.901 (< 0.001)	-0.578 +/- 0.332	-8.80 to 7.60
J0 (D)	0.863 (< 0.001)	0.011 +/- 0.396	-0.17 to 0.19
J45 (D)	0.913 (< 0.001)	-0.007 +/- 0.615	-0.19 to 0.17
Corneal asphericity (Q value)	0.736 (< 0.001)	0.001 +/- 0.907	-0.12 to 0.12
Decentration magnitude (mm)	0.579 (< 0.001)	-0.004 +/- 0.621	-0.12 to 0.11
Decentration axis (degrees)	0.580 (< 0.001)	-0.140 +/- 0.986	-111.0 to 110.7
Irregularity (mm)	0.545 (< 0.001)	0.001 +/- 0.840	-0.008 to 0.009

D = diopters, K1 = flat meridian keratometry, K2 = steep meridian keratometry, SD = standard deviation, LoA = limits of agreement

LoA between instruments were within the clinically relevant margins of the discrepancy. Seven (14%) and five (10%) eyes had a difference greater than 0.5 D for the K1 and K2 parameters, respectively. Regarding the corneal astigmatism magnitude (astigmatism), only three eyes (6%) presented a difference greater than 0.5 D between both devices. The mean axis (+/- SD) measurements provided by the Topolyzer and Oculyzer II were 106.202 +/- 77.463 and 106.780 +/- 77.581 degrees, respectively. Nine eyes (18%) had a greater than 5° difference between the devices. In vector terms, the data did not present statistically significant differences for the J0 (-0.01 D, 95% confidence interval [CI]: -0.04 to 0.01 D) and the J45 (-0.003 D, 95% CI: -0.03 to 0.03 D) components. Compared to the keratometric data, all the selected parameters derived from the Fourier analysis (decentration, decentration axis and irregularity) presented lower correlation coefficients. Bland-Altman analysis of these metrics is presented in Fig. 1 (A to C).

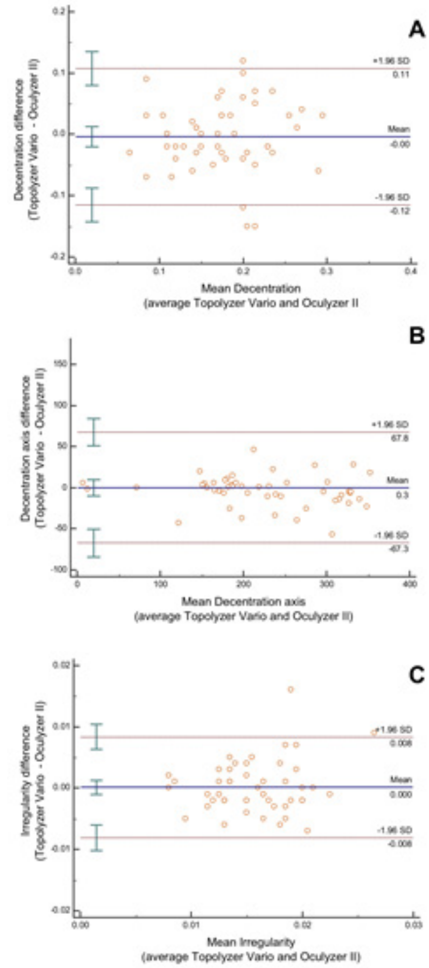

Figure 1 – Bland-Altman plot illustrates the level of agreement between Decentration (A), Decentration Axis (B) and Irregularity (C) measurements of Topolyzer Vario (WaveLight, Alcon Laboratories, Inc., Ft Worth, Texas, USA) and Oculyzer II (WaveLight, Alcon Laboratories, Inc., Ft Worth, Texas, USA). The red dashed horizontal lines represent the 95% limits of agreement.

DISCUSSION

In the present study, we focused on the corneal imaging devices from the Wavelight/Alcon company, consisting of a Placido disk and a rotational Scheimpflug camera (Topolyzer Vario and Oculyzer II, respectively). There was an overall good agreement between the two technologies, especially for keratometric readings. Interestingly, similar results were not verified with the irregularity data derived from the Fourier analysis (decentration and irregularity variables), which may have an impact on customized ablation planning.

The Topolyzer Vario is the same model that was earlier marketed by Oculus GmbH (Keratograph, Oculus GmbH, Wetzlar, Germany). A previous study described the accuracy of keratometry readings derived from this device.[18,19] This tool was also considered effective for topography-guided ablations to correct myopia, hyperopia, and mixed astigmatism.[8] The Oculyzer II is also marketed by the same company as the Pentacam (Oculus GmbH, Wetzlar, Germany). Previous studies revealed high repeatability and reproducibility in corneal curvature measurements provided by this rotational Scheimpflug camera.[9,20,21]

As mentioned in previous studies, corneal imaging devices are essential to select the candidates correctly, as well as to choose the surgical technique that is more appropriate to each patient.[9,10,15-17] With the increasing interest in customized ablations, the accuracy of preoperative scans has become even more important. Different companies allow the integration of data from Placido disk-based topographers, Scheimpflug tomographers, and wavefront sensors into the excimer laser platform, allowing the customization of the ablation to be applied. Concerning topography-guided ablations, the visual and refractive outcomes have shown superiority compared to conventional ablations in primary eyes, especially in terms of visual quality.[6] For example, Contoura® Vision (WaveLight, Alcon Laboratories, Inc., Ft Worth, Texas, USA) is a topography-guided LASIK, which had FDA-approval in 2013. It combines the Allegretto Wave Eye-Q 400 Hz (WaveLight, Alcon Laboratories, Inc., Ft Worth, Texas, USA) or the Wavelight EX500 excimer laser with the Placido disk data-driven by the Topolyzer Vario to create a customized ablation based. In addition, to correct the spherocylindrical error, this ablation type also reduces the magnitude of corneal irregularity or high-order aberrations that is based on the raw corneal data-driven by the imaging device. Other studies had also demonstrated the usefulness of the topography-guided ablations in therapeutic applications, such as in reducing high-order aberrations in patients with corneal ectasia.[1,5]

As mentioned previously, raw corneal data from both devices can be transferred to the excimer laser platform to allowed customized ablation. Our study aimed to analyze the correlation and agreement between these instruments in terms of anterior surface parameters.

Our results presented a good agreement for mean corneal measurements between both instruments (K1, K2, Astigmatism, J0 and J45). It is crucial to mention that the presented data might be influenced by the small sample size included in this study. Nevertheless, similar results were also described in previous studies. For example, Delrivo *et al* reported a good agreement for the corneal power and cylinder between a Placido topography (iTrace Visual Function Analyzer, Tracey Technologies, Houston, TX, USA) and a Scheimpflug tomography (Pentacam HR, Oculus Gmbh, Wetzlar, Germany) instruments.[22] Wang *et al* demonstrated excellent repeatability and reproducibility of anterior corneal power measurements by using eight different devices, including the Topolyzer and the Pentacam.[19] In the present study, the corneal asphericity variable revealed a lower correlation coefficient compared to other keratometry parameters. Regarding the agreement evaluation for this metric between the Topolyzer Vario and the Oculyzer II, similar findings were also described by the Savini *et al*.[23]

We also included parameters that provide information regarding corneal irregularity or optical quality. Both devices enable two distinct methods to evaluate this feature based on anterior surface curvature data. The Fourier analysis reconstructs wavefront data by decomposing the image into spatial frequency components that can be used to represent the irregular and regular astigmatism components simultaneously.[14,24,25] Otherwise, the Zernike analysis can be used to calculate higher-order wavefront aberrations by a mathematical sequence of polynomials that are orthogonal on the unit disk.[24,25] Different studies have reported controversy about the advantages of each method for representing corneal data, with no technique being considered the gold standard.[24,25] For the present study, we selected the data provided by the Fourier analysis, since it simplifies the description of the corneal surface irregularity. From this display, we excluded the spherical equivalent and the regular astigmatic values, since they correlate and are proportional to the keratometric spherocylindrical component.[14] The remaining metrics of the Fourier analysis have no keratometric equivalent and represent the irregular corneal astigmatism. Thus, these variables represent the data that are used by the excimer laser platform to design the topography-guided ablations to address the corneal surface irregularity. The Decentration metric represents the corneal tilt regarding the optical axis, similar to the comatic aberration from the Zernike polynomials. The Irregularity parameter characterizes the optical defects that degrade retinal image quality. We included these parameters in this study since both devices enable these data and interfere with the high-order aberration ablation profile.[5,8] Besides presenting a moderate correlation coefficients, the Decentration and Irregularity variables showed a wide range of LoA. Thus, we recommended precaution when selecting the raw corneal data from distinct technologies to customize the laser excimer ablation, especially in primary eyes. The presented results may derive from the small sample data, which can lead to lower correlation values that may not be clinically meaningful. Other reason that justify this finding is the inclusion of primary eyes with a minimal amount of corneal high-order aberrations that might induce a minimal effect on visual quality. This analysis should be performed in future studies including irregular corneas. The study also used devices with different measurement principles. The Topolyzer Vario is based on the tear film reflection of the Placido disk.[9] Thus, fluctuations in the tear film can interfere with the irregular astigmatism magnitude presented. Previous studies reported dynamic variations in corneal high-order aberrations after blinking, even in clinically healthy subjects.[26] Other factors may influence the quality of the Placido-disc exam, such as longer acquisition time, small palpebral opening, and shadows of the nose or the brow.[9,15] On the other hand, the Oculyzer II depends on elevation data derived from light scattering. The optical distortion correction related to Scheimpflug imaging may contribute to the reported findings.[9,27]

There are some limitations to the present study. The results are based on a relatively small number of eyes. Besides, the present study is limited to healthy subjects with normal corneas and proper fixation. From a practical point of view, despite both devices presented no statistically significant inter-device differences, our results still suggest awareness in selecting the preoperative corneal raw data for planning the topography-guided excimer ablation, once the analysis of the Fourier analysis parameters revealed a moderate correlation index and a wide range of LoA. In primary eyes undergoing customized laser vision correction, inadequate programming of the ablation may induce unexpected postoperative refractive errors due to misleading scans. In this regard, the refractive surgeon must become adapted to the available technology, to optimize visual and refractive results, as well as the surgical nomograms.[28] Further studies aiming to evaluate the impact of customized ablation based on distinct technologies should be designed.

ETHICAL DISCLOSURES

Conflicts of interest: Dr Ambrósio is consultant for Alcon, Zeiss and Oculus; Dr Faria-Correia is consultant for Alcon; Dr Lopes receives research funds from Oculus.

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Confidentiality of Data: The authors declare that they have followed the protocols of their work center on the publication of data from patients.

Protection of Human and Animal Subjects: The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the 2013 Helsinki Declaration of the World Medical Association.

Provenance and Peer Review: Not commissioned; externally peer reviewed.

RESPONSABILIDADES ÉTICAS

Conflitos de Interesse: Dr Ambrósio é consultor da Alcon, Zeiss e Oculus; Dr Faria-Correia é consultor da Alcon; Dr Lopes recebe financiamento de investigação da Oculus.

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Proteção de Pessoas e Animais: Os autores declaram que os procedimentos seguidos estavam de acordo com os regulamentos estabelecidos pelos responsáveis da Comissão de Investigação Clínica e Ética e de acordo com a Declaração de Helsínquia de 2013 da Associação Médica Mundial.

Proveniência e Revisão por Pares: Não comissionado; revisão externa por pares.

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