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ARTÍCULO ORIGINAL

Efficacy of Orbscan II® and Pentacam® topographers by a repeatability analysis when assessing elevation maps in candidates to refractive surgery

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Introduction: Anterior and posterior corneal elevations are measurements used to detect keratoconus suspects.
Purpose: To determine the efficacy of Orbscan II® and Pentacam® when assessing their elevation maps.
Materials and methods: The efficacy of the Orbscan II and Pentacam measuring the anterior and posterior corneal elevations were evaluated in a sample of 68 eyes. The concordance between the two devices and the coefficient of repeatability were measured following the parameters of the British Standard Institution by the Bland-Altman concordance analysis and the Lin concordance correlation coefficient.
Results: The coefficient of repeatability at the point of maximum anterior elevation was 68.29% with the Orbscan and 24.20% with the Pentacam. The concordance correlation coefficient was 0.64 (CI 95%: 0.48-0.76) with the Orbscan and 0.94 with the Pentacam (CI 95%: 0.91-0.96). The coefficient of repeatability at the point of maximum posterior elevation was 38.7% with the Orbscan and 68.0% with the Pentacam. The concordance correlation coefficient was 0.69 with the Orbscan (CI 95%: 0.55-0.80) with a precision of 0.71 and an accuracy of 0.97, and 0.24 with the Pentacam (CI 95%: 0.00-0.45) with a precision of 0.24 and an accuracy of 0.99.
Conclusions: Measurement of the point of maximum posterior elevation is better with the Orbscan II and less precise with the Pentacam. The random error can be reduced by using the mean of three assessments and can serve as a guide in the search of diagnostic devices with minimum absolute relative error in all measurements.

Key words: cornea, corneal topography, keratoconus, reproducibility of results, selection bias, efficacy

Eficacia del Orbscan II y Pentacam en la evaluación de los mapas de elevación en candidatos a cirugía refractiva mediante un análisis de repetibilidad

Introducción. La elevación posterior es una de las medidas usadas para detectar pacientes con sospecha de queratocono.
Objetivo. Determinar la eficacia del Orbscan II y Pentacam en la evaluación de los mapas de elevación.
Materiales y métodos. Se evaluaron 68 ojos con Orbscan II y Pentacam. Con parámetros del *British Standard Institution*, se midieron el coeficiente de repetibilidad mediante un análisis de concordancia con el método de Bland-Altman y el coeficiente de correlación de concordancia de Lin. Se midió la concordancia entre ambos equipos.
Resultados. El coeficiente de repetibilidad del punto de máxima elevación anterior en Orbscan fue de 68,29% y de 24,20% en Pentacam. El coeficiente de correlación de concordancia fue de 0,64 (IC95% 0,48-0,76) en Orbscan y en Pentacam fue de 0,94 (IC95% 0,91-0,96). El coeficiente de repetibilidad del punto de máxima elevación posterior en Orbscan fue de 38,69% y en Pentacam fue 68,03%. El coeficiente de correlación de concordancia en Orbscan fue de 0,69 (IC95% 0,55-0,80) con una precisión de 0,71 y una exactitud de 0,97, y en Pentacam fue de 0,24 (IC95% 0,00-0,45) con una precisión de 0,24 y una exactitud de 0,99.

Conclusiones. La eficacia de Orbscan II y Pentacam en la evaluación del punto de máxima elevación posterior resulta afectada por la imprecisión de la medida y es peor en el Pentacam. Este error aleatorio se puede manejar usando la media de tres mediciones y nos orienta a la búsqueda de equipos en los que el error relativo absoluto sea el menor posible en todas las medidas que ofrezca.

Palabras clave: córnea, topografía de la córnea, queratocono, reproducibilidad de resultados, sesgo de selección, eficacia.

The assessment of the radius at the point of maximum anterior and posterior elevation can be taken from the elevation maps shown by topographers such as the Orbscan II (Bausch & Lomb Surgical, Rochester, USA), Pentacam (Oculus, Wetzlar, Germany), or the very new rasterstereography topographer (Galilei, Ziemer Group, Port, Switzerland.)

This evaluation is part of the preoperative evaluation of patients who are going to refractive surgery, and is used to establish if corneas are normal, or with keratoconus. Other preoperative measurements are keratometry, pachymetry. The difference between the upper and lower half from the cornea and other more complex radii obtained from topographers data based on Placido disk, slit scanning, Scheimpflug cameras or combinations of these systems. Laser-Assisted *in situ* Keratomileusis (LASIK) is contraindicated when keratoconus is suspected or confirmed due to a possible biomechanical decompensation and corneal ectasia.

Regarding anterior and posterior elevations values reported, Rao, *et al.* (1) considered 12 µm as the maximum anterior elevation radius and 40 µm as the normal Orbscan II limit of maximum posterior elevation radius. Although the posterior corneal surface is not optically as important as the anterior one, it has been considered structurally more fluid and a more sensitive indicator of abnormality (2).

Likewise, there are publications about the repeatability of the Pentacam determining the posterior curvature radius after a refractive surgery (3), repeatability of the Pentacam assessing the corneal power in curvature maps, corneal thickness, anterior chamber and pupil (4), repeatability of the Orbscan and Pentacam measuring the corneal thickness (5), and repeatability of the Pentacam establishing the anterior and posterior sphere of reference (6). However, studies were not found that reported the repeatability of the maximum anterior and posterior elevation points assessed by the Orbscan or Pentacam--the two usual assessments achieved preoperatively before refractive surgeries.

Before comparing the elevation maps given by the Orbscan and Pentacam, repeatability determined by the precision and accuracy of their measurements must be characterized. The level of confidence on the information provided by these devices depends on the efficacy of both devices--defined as the difference between what was measured and the real value (7). The purpose of the current work is to establish the confidence and repeatability of the best sphere of reference (BFS) and of the radius at the point of maximum anterior and posterior elevation achieved by the Orbscan II and the Pentacam by means of the coefficient of repeatability (CR) and the Lin's concordance correlation coefficient (CCC).

Materials and methods

Patients consulting the Refractive Surgery Unit by the first time at the Clínica de Oftalmología de Cali (Colombia) between May 5 and May 10, 2006 were included in the study because the four topographic devices were available during that time. The sample size was fixed at 90 eyes because this number constituted the institutional weekly historical average during the 12 months prior to this research. After the initial

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recruitment of 90 eyes, 78 eyes from 41 patients satisfied the inclusion criteria. At this stage, 12 eyes from 8 patients were excluded, 6 eyes because suspected keratoconus and 6 eyes for incomplete data. Abnormal suspicious corneas, and with keratoconus were excluded because they may provide extremely variable data that will be difficult to compare with normal corneas. From the 78 eyes remaining, 10 eyes were also excluded from 5 patients who did not agree to participate in the study. The final eligible sample was 68 eyes from 36 patients.

The average age was 35 years (range, 20 to 45 years). These were candidates for refractive surgery and had normal corneas based in their refraction, slit lamp examination, pachymetry, slit scanning topography (Orbscan II), single Scheimpflug topography (Pentacam) and Placido disc topography (Scout and Tomey). Topographic exams were performed by skilled and experienced staff. The results were assessed in a blinded design. Patients coming to the refractive surgery unit received a consecutive number by personnel not involved in the study. Exams were not identified regarding to their age, gender, race, and origin of patients or to the practitioner who requested the test, allowing a camouflage of information for operators and researchers.

When the patients were using contact lenses, they were instructed to stop 15 days prior to the topographic examinations. The Orbscan II and Pentacam maps with poor centering were repeated to avoid errors of the BFS. Automatic established Orbscan II parameters were used for the float BFS elevation maps centered to the apex defined by this system. The Orbscan II BFS was obtained from a 10-mm-diameter area and its Placido disc data were used to obtain the curvature maps. With the Pentacam, a 10-mm-diameter area was also used to calculate the float BFS fixed to the apex defined by the Scheimpflug system but the curvature maps were derived from the elevation data.

To measure the repeatability of each device, parameters from the British Standard Institute were followed (8,9). Three measurements per eye from each patient and each device were taken by the same operator between 8:00 am and 5:00 pm. Two consecutive measurements per eye from each patient and each device were taken by the same operator. The concordance between the measurements per device was calculated using the coefficient of repeatability (CR) of Bland Altman (10) obtained from the repeated measurements taken under identical conditions. The CR was defined as the standard deviation (SD) of the mean difference from the repeated measurements divided by the mean value. The confidence intervals of 95% (CI 95%) were obtained from the limits of agreement (LOA) of the mean differences (difference mean ± 1,96 x standard deviation). The agreement, precision and correction factor of the measurement trend was assessed using the concordance correlation coefficient (CCC) of Lin (11,12). The correlation coefficient of Pearson was used to assess the linear association between measurements. Normal data was defined by means of the skewness and kurtosis coefficients. The t-test level of significance was $p<0.005$. In addition, the concordance between both devices was calculated using the Bland Altman and Lin tests. The analysis was done using the Medcalc software, version 9.4.2.0.

Ethical matters

The protocol of this research was approved by the Institutional Medical Committee from the Clínica de Oftalmología de Cali. An informed authorization was signed by patients according to the Resolution 8430 of 1993.

Results

Radius of the anterior sphere of reference

The mean radius of the anterior BFS from the Orbscan II and Pentacam is shown in table 1. The data showed a normal distribution. The mean difference between the repeated means was -0.009 (CI 95%: -0.019 to 0.001, SD =±0.04) with the Orbscan II and -0.002 (CI 95%: -0.007 to 0.001; SD =±0.01) with the Pentacam. The concordance limits are shown in table 2.

The coefficient of repeatability, the concordance correlation coefficient, the accuracy and the

Table 1. Means of the radius of BFS and anterior and posterior elevations provided by the Orbscan II and Pentacam.

Corneal Radius	Orbscan II Mean ± SD	Pentacam Mean ± SD	Value of p
raBFS	7.90 mm ±0.24 CI 95%: 7.84-7.96	7.95 mm ±0.23 CI 95%: 7.89-8.01	p <0.0001
rpBFS	6.52 mm ±0.24 CI 95%: 6.46-6.57)	6.69 mm ±0.24 CI 95%: 6.63-6.75	p <0.0001
rMEA	9.27 µm ±3.49 CI 95%: 8.41-10.14	11.50 µm ±4.26 CI 95%: 10.44-12.55	p <0.0001
rMEP	27.81 µm ±6.69 CI 95%: 26.15-29.47	29.50 µm ±6.81 CI 95%: 27.81-31.19	p=0.20

raBFS: mean of the radius of the anterior sphere of reference
rpBFS: mean of the radius of the posterior sphere of reference
rMEA: mean of the radius at the point of maximum anterior elevation
rMEP: mean of the radius at the point of maximum posterior elevation
SD: standard deviation
CI: confidence interval

precision from the repeated measurements with the Orbscan II and Pentacam are shown in table 3. The difference of means between the Orbscan II and Pentacam was -0.04 (CI 95%: -0.05 to -0.03, SD =±0.04). The range of LOA agreement was -0.13 to 0.04. The CCC was 0.96.

Radius of the posterior sphere of reference

The mean radius of the posterior BFS from the Orbscan II and Pentacam is shown in table 1. The data showed a normal distribution. The difference of means was -0.014 (CI 95%: -0.028 to 0.000; SD =±0.05) with the Orbscan II and 0.000 (CI 95%: -0.009 to 0.010; SD=±004) with the Pentacam. The range of agreement are shown in table 2.

The coefficient of repeatability, the concordance correlation coefficient, the accuracy and the precision from the repeated measurements with the Orbscan II and Pentacam are shown in table 3.

The difference of means between Orbscan II and Pentacam was of -0.17 (CI 95%: -0.20 to -0.14; SD =±0.11). The range of LOA agreement was -0.39 to 0.04. The CCC was of 0.71.

Radius at the point of maximum anterior elevation

The mean radius at the point of maximum anterior elevation in the Orbscan II and Pentacam is shown in table 1. The data showed a normal distribution. The difference of means was -0.184 (CI 95%: -0.986 to 0.617; SD =±3.23) with the Orbscan II and 0.138 (CI 95%: -0.214 to 0.491; SD =±1.42) with the Pentacam. The limits-of-agreement are shown in table 2.

The coefficient of repeatability, the concordance correlation coefficient, the accuracy and the precision from the repeated measurements with the Orbscan II and Pentacam are shown in table 3. The difference of means between Orbscan II and Pentacam was -2.22 (CI 95%: -3.09 to -1.35; SD =±3.50). The range of LOA agreement was -9.08 to 4.64. The CCC was of 0.51.

Radius at the point of maximum posterior elevation

The mean radius at the point of maximum posterior elevation in the Orbscan II and Pentacam is shown in table 1. The data showed a normal distribution. The difference of means was 1.35 (CI 95%: -0.007 to 2.71; SD =±5.49) with the Orbscan II and 0.23 (CI 95%: -2.30 to 2.76; SD =±10.24) with the Pentacam. The limits-of-agreement are shown in table 2.

The coefficient of repeatability, the concordance correlation coefficient, the accuracy and the precision from the repeated measurements of Orbscan II and Pentacam are shown in table 3. The difference of means between Orbscan II and Pentacam was -1.69 (CI 95%: -4.31 to 0.93;

Table 2. Limits-of-agreement (LOA) of the mean differences between repeated measurements of Orbscan II and Pentacam calculated with the Bland-Altman's method.

Corneal radius	Mean	SD	LOA
raBFS Orbscan II	-0.009	0.042	-0.092/0.073
raBFS Pentacam	-0.002	0.018	-0.038/0.032
rpBFS Orbscan II	-0.014	0.057	-0.127/0.097
rpBFS Pentacam	0.000	0.041	-0.080/0.080
rMEA Orbscan II	-0.184	3.235	-6.525/6.156
rMEA Pentacam	0.138	1.423	-2.652/2.929
rMEP Orbscan II	1.353	5.492	-9.411/12.119
rMEP Pentacam	0.230	10.245	-19.849/20.31

raBFS: radius from the anterior sphere of reference
rpBFS: radius from the posterior sphere of reference
rMEA: radius at the point of maximum anterior elevation
rMEP: radius at the point of maximum posterior elevation
SD: standard deviation

Table 3. Measurement of coefficients of repeatability provided by the Orbscan II and Pentacam. Precision and accuracy from the repeated measurements.

Corneal radius	CR %	CCC	Precision	Accuracy
raBFS Orbscan II	1.04	0.98	0.98	0.99
raBFS Pentacam	0.44	0.99	0.99	0.99
rpBFS Orbscan II	1.71	0.97	0.97	0.99
rpBFS Pentacam	1.20	0.98	0.98	0.99
rMEA Orbscan II	68.29	0.64	0.64	0.99
rMEA Pentacam	24.20	0.94	0.94	0.99
rMEP Orbscan II	38.69	0.69	0.71	0.97
rMEP Pentacam	68.03	0.24	0.24	0.99

CR: repeatability measured by the coefficient of repeatability
CCC: Lin's concordance correlation coefficient
raBFS: radius of the anterior sphere of reference
rpBFS: radius of the posterior sphere of reference
rMEA: radius at the point of maximum anterior elevation
rMEP: radius at the point of maximum posterior elevation

SD =±10.60). The range of LOA agreement was -22.47 to 19.08. The CCC was of -0.22.

Discussion

With the Orbscan II we found a mean radius of the anterior and posterior BFS and a mean radius at the point of anterior and posterior maximum elevation (table 1) similar to those found by Fam, *et al.* in normal patients (13). However, we found a mean radius at the point of anterior and posterior maximum elevation with the Orbscan II and Pentacam different from those found by Hashemi, *et al.* (14). In this latter study, the values with the Pentacam, 6.80 µm and 17.98 µm respectively, corresponded to an adjustment of a BFS from an area with 6 mm, as the authors have indicated; however, the values with the Orbscan II, 14.07 µm and 32.87 µm respectively, seem to correspond to an adjustment of a BFS with 10 mm and not 6 mm as the authors show.

Chen, *et al.* found a good intrasession and intersession repeatability of the anterior and posterior BFS radius with the Pentacam, but they used the Cronbach test, indicated for psychological studies. Therefore, we believe this study did not accomplish the standards agreed for the analysis of this type of comparisons

(8-10). Furthermore, they suggested that taking an average of several exams is better than an individual reading, probably because this is a way to compensate statistically for the imprecision of the exam.

The coefficient of repeatability, the concordance correlation coefficient, the precision and accuracy of the radius of the anterior and posterior BFS with the Orbscan II and Pentacam were excellent, as shown by the standard deviation of differences and the lower LOA. Therefore, both topographers were efficient in providing the value of these variables and their measurements can be considered reliable.

The radius at the Pentacam's maximum anterior elevation point showed a poor CR, although it had excellent CCC, precision and accuracy. The CR of 1.42 was established by the standard deviation of the means differences of 1.42, with lower LOA of -2.652 and an upper LOA of 2.929. These findings have significant clinical importance because the difference among measurements can be until 3, a close value found for the standard deviation of the group mean (±4.26).

The radius at the Orbscan's maximum anterior elevation point showed a poor CR determined by its regular precision and the standard difference of the difference of means of 3.23, with a lower LOA of -6.525 and an upper LOA of 6.156. These findings implied a wide variability of the result and therefore a clinical impact.

The CR from the radius at the point of maximum posterior elevation from Orbscan II and Pentacam was poor at the expense of the precision and the great SD from the differences of the means. It was worst in the case of Pentacam where the LOA of -19.849 at the lower limit and 20.31 at the upper limit gave differences up to 20 µm between exams with the same device, same patient and same examiner.

Our results on the precision measured with the Lin 's CCC and the SD from the differences measured by the Bland Altman test were in agreement with the assessments by repeated measurements. The SD indicated the level of precision of our findings, with the lesser standard deviation indicating greater precision (7).

Comparing the Orbscan II and the Pentacam, we found differences between the radius of the anterior and posterior BFS, and the radius at the point of maximum anterior elevation with the t-test and the concordance test. The radius at the point of maximum posterior elevation did not show significant differences (t-test), but the concordance test showed a very high standard deviation with a consistent significant clinical limit of difference between both topographers.

Quisling, *et al.* (15) compared the Orbscan II and the Pentacam equaling parameters in both devices and found differences among eyes with keratoconus at the radius of the point of maximum posterior elevation, even though they did not find differences at the radius of the posterior BFS. Although their study used random samples, their results may have potential selection biases or information; therefore the inference to the general population is limited and the data is only applicable to the population studied. Because little information is available in the literature, our results are a great import because show an approximation to the real precision of the radius of the anterior and posterior BFS and the radius at the point of maximum anterior and posterior elevation taken with the Orbscan II and Pentacam. Furthermore, since the sample population did not differ from the at large population, the use of normal corneas in our research strengthens this approximation.

This is the first comparative study about the repeatability of the radius at the point of maximum anterior and posterior elevation provided by the Orbscan II and the Pentacam in patients with normal, unexplored corneas. It shows how the imprecision of this measurement appreciably affects the efficacy of Orbscan II and Pentacam during the preoperative evaluation of refractive surgery. The imprecision with the Pentacam (0.24) was worst. In contrast to the excellent accuracy of the same measurement, we discarded systematic errors from the examiner, with the calibration of the device or with the assessed persons. The imprecision of the maximum

posterior elevation with the Pentacam (0.24) was worst. In contrast, we found an excellent accuracy of the same measurement, thus we discarded systematic errors from the examiner, in the callibration of the device or the assessed persons. This concept guides our search for new devices that provide better resolution and, with different technological combinations, may show the least absolute relative error in a given measurement.

Conflict of interest

The authors do not have any commercial interest in products or companies described in this study.

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