

## Repeatability and reproducibility of Orbscan II

Raul Martin,<sup>1</sup> Maria Izquierdo,<sup>2</sup>

Victoria de Juan,<sup>2</sup>

Guadalupe Rodriguez,<sup>2</sup>

Itziar Fernandez<sup>2</sup>

<sup>1</sup>IOBA-Eye Institute and School of Optometry, Department of Physics TAO; <sup>2</sup>IOBA-Eye Institute and School of Optometry, University of Valladolid, Valladolid, Spain

### Abstract

This study aimed to determine the repeatability and reproducibility of Orbscan for anterior and posterior best fit sphere (BFS), simulated keratometry (Sim-K), and central (CCT) and mid-peripheral (PCT) corneal thickness measurements in healthy eyes. Orbscan was performed in 40 healthy eyes (20 subjects) three consecutive times on each cornea during three visits scheduled over one week. Repeatability and reproducibility coefficients [Bland and Altman's coefficient (BAC), coefficient of variation (CV) and intraclass correlation (ICC)] were calculated for Orbscan anterior and posterior BFS, Sim-K and corneal pachymetry (central, superior, inferior, nasal and temporal locations). Repeatability was calculated using three consecutive measurements during each visit, while reproducibility was calculated using the average of the measurements obtained at each visit. High repeatability was found for all Orbscan measurements ( $r^2 < 0.01$ ;  $P > 0.05$ , two-way ANOVA) with BAC and CV  $< 1\%$  (except in PCT coefficients; from 0.97% to 1.67%) and ICC close to 0.98-0.99 for all visits. High reproducibility was also found for all Orbscan measurements ( $r^2 < 0.01$ ;  $P > 0.05$  two-way ANOVA). BAC values were less than 1% for both BFS and Sim-K, and between 1.21 and 2.20% for corneal pachymetry. CV values were less than 1% (except in superior, nasal and temporal PCT, where they ranged from 1.06 to 1.30%). ICC was close to 0.98-0.99 for all measurements. The BAC of reproducibility was higher than the CV of reproducibility. PCT showed less repeatability and reproducibility than CCT. The Orbscan provides non-invasive, repeatable and reproducible measurements of anterior and posterior BFS, simulated keratometry and central and mid-peripheral pachymetry in healthy eyes.

### Introduction

Computerized videokeratography can be used to determine corneal topography and is considered essential in keratoconus diagnosis.<sup>1-4</sup> This technique also has many important applications in refractive surgery, including pre-operative screening, surgical planning, postoperative assessment and patient follow up,<sup>5-8</sup> and in contact lens (CL) fitting,<sup>9,10</sup> where it is used in orthokeratology,<sup>11</sup> corneal refractive therapy<sup>12</sup> and CL fit on irregular corneas.<sup>13,14</sup> Corneal thickness, which is one of the most used indicators to assess ocular health and is used to determine intraocular pressure (IOP) measurements in the diagnosis and follow up of glaucoma,<sup>15</sup> can also be measured using computerized videokeratography.

The Orbscan II topography (Bausch & Lomb Surgical) is a scanning slit (light)-based optical reflectance instrument capable of taking several images of different corneal sections for 3-dimensional reconstruction of corneal shape using the anterior and posterior corneal surfaces [best fit sphere (BFS)] and the corneal thickness at any point.<sup>16,17</sup> Orbscan II combines the scanning slit with Placido-ring videokeratography to obtain the advantages of both systems and to generate curvature-based (corneal power) maps.<sup>18-20</sup> Because Orbscan II acquires data using hybrid slit-scan and Placido ring technology, it offers detailed information on corneal curvature, power and thickness that can be acquired by non-invasive exploration that does not require topical anesthesia or corneal touch.

Other techniques commonly used to explore the corneal surface have a variety of limitations. For example, with standard keratometry, only four points of the paracentral area are used for the calculation of corneal curvature.<sup>21</sup> Standard (Placido's rings-based) corneal topographers provide a global measure of anterior corneal surface but do not provide information about posterior corneal surface or corneal pachymetry.<sup>22</sup> Ultrasound pachymetry is commonly used to determine corneal thickness,<sup>15,16,23-25</sup> but the measure depends critically on the technician's experience and requires topical anesthesia.<sup>23</sup>

Most published studies have focused on the reproducibility and repeatability of Orbscan pachymetry measurements,<sup>17,24,25</sup> while there is relatively little information concerning other types of Orbscan measurements, such as corneal curvature (anterior and posterior BFS) and simulated keratometry (corneal power). Measurements of these parameters are critically important in the diagnosis of corneal pathology, in refractive surgery<sup>1-6</sup> and in CL fit.<sup>2,9-14</sup> Other studies

Correspondence: Raul Martin, IOBA Eye Institute, Paseo Belen 17 - Campus Miguel Delibes E-47011 Valladolid, Spain.  
Tel. +34.983.423.559 - Fax: +34.983.423.274.  
E-mail: raul@ioba.med.uva.es

Key words: Orbscan II, repeatability, reproducibility, BFS, simulated keratometry, pachymetry.

Acknowledgments: the authors would like to thank Soraya Fonseca and Sofia Martin (IOBA Eye Institute, University of Valladolid, Spain) for their help throughout this project. Authors have no financial involvement with products in this manuscript. The Human Sciences Ethical Committee of the University of Valladolid in Spain approved this study.

None of the authors have a financial or proprietary interest in any material or method mentioned.

Received for publication: 10 October 2011.

Revision received: 19 December 2011.

Accepted for publication: 21 December 2011.

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Optometry Reports 2012; 2:e1  
doi:10.4081/optometry.2012.e1

have focused on comparing the use of Orbscan before and after corneal surgery with other corneal exploration techniques.<sup>26,27</sup>

The aim of this study is to determine the repeatability and reproducibility of Orbscan for anterior and posterior BFS, simulated keratometry and central and mid-peripheral corneal thickness measurements in healthy eyes.

### Materials and Methods

The investigation used a one-week prospective study design.

### Subjects

Twenty subjects were enrolled in the study (14 women; 6 men). The mean age was  $20.3 \pm 2.2$  years (range 18-25). The spherical equivalent refractive error ranged from +2.00 D to -4.75 D ( $-1.60 \text{ D} \pm 1.75 \text{ D}$ ), and none of the patients exhibited anisometropia greater than 1.00 D. Wearing of CL was not permitted during the study. Subjects were excluded if they had active ocular-surface disease, such as significant dry eye, papillary conjunctivi-

**Table 1. Summary of Orbscan measurements over all study visits.**

	Anterior BFS (mm)	Posterior BFS (mm)	K Maximum (D)	K Minimum (D)	Central CT (mm)	Superior CT (mm)	Inferior CT (mm)	Nasal CT (mm)	Temporal CT (mm)
Measure 1	8.00±0.17	6.52±0.15	43.90±0.92	42.94±1.12	571±46	624±38	605±36	632±43	586±40
Measure 2	8.01±0.16	6.52±0.15	43.90±1.00	42.96±1.15	572±45	626±41	605±36	635±43	585±40
Measure 3	8.00±0.17	6.51±0.14	43.90±0.95	43.02±1.10	572±46	627±38	607±40	635±39	585±41
Mean±SD	8.00±0.17	6.52±0.14	43.90±0.94	42.97±1.11	572±45	626±38	606±36	634±41	585±40
Measure 1	7.99±0.16	6.53±0.14	43.83±0.96	42.90±1.10	573±47	633±41	606±39	636±42	586±42
Measure 2	8.00±0.16	6.52±0.15	43.82±1.00	42.89±1.11	573±48	635±38	608±37	636±45	592±45
Measure 3	8.00±0.17	6.52±0.15	43.81±0.95	42.92±1.11	574±45	634±38	607±40	638±45	583±43
Mean±SD	8.00±0.16	6.52±0.15	43.82±0.95	42.91±1.10	573±47	634±38	607±38	637±43	587±42
Measure 1	8.00±0.16	6.52±0.15	43.76±0.88	42.82±1.05	570±48	628±39	605±40	634±44	587±42
Measure 2	7.99±0.16	6.52±0.16	43.84±0.92	42.84±1.07	572±47	629±41	603±36	634±46	586±42
Measure 3	8.00±0.16	6.54±0.15	43.72±0.94	42.85±1.25	573±47	635±39	603±33	635±43	587±41
Mean±SD	8.00±0.16	6.53±0.15	43.78±0.90	42.84±1.06	572±47	631±39	604±36	634±43	586±41

SD, standard deviation; BF, best fit sphere; D, diopter; CT, corneal thickness.

tis, corneal opacities, current medication that could affect ocular physiology, astigmatism (>2.00 D), or if they had previously worn EW lenses. Subjects had vision correctable to 20/20 in each eye. Informed consent was obtained from each subject after approval was granted by the Human Sciences Ethics Committee of the University of Valladolid. All subjects were treated in accordance with the Declaration of Helsinki.

### Instrumentation

Orbscan (Bausch & Lomb, Rochester, NY, version 3.12) was performed three consecutive times (after completely realigning the Orbscan) on each cornea during each visit, and the mean was used as the final value at each study visit. The Orbscan procedure has been described previously<sup>28</sup> and the instrument was calibrated by the manufacturer. Anterior and posterior BFS (millimeter), simulated keratometry (diopters) in the main corneal meridians at the 3.0 mm zone and central and mid-peripheral corneal thickness (microns) were collected in each Orbscan exploration (using standard pachymetry map provided by the Orbscan in every assessment). Mid-peripheral corneal thickness was collected at 2.5 mm from the closest limbus in four different corneal locations: at superior, inferior, nasal and temporal corneal positions. To determine the thickness of the cornea, Orbscan uses an algorithm that involves multiplying the corneal thickness by an acoustic factor of 0.92. The same operator took all Orbscan measurements during all visits.

### Procedure

For the study, three visits were scheduled over one week. During the initial visit (day 0), participants were screened according to the inclusion and exclusion criteria. The pro-

**Table 2. Analysis of repeatability of three measurements taken each visit (anterior and posterior BFS, maximum and minimum keratometry, and central and mid-peripheral pachymetry).**

Method	Mean of Diff	SD of Diff	r <sup>2</sup>	P*
BFS anterior (visit 1) n=36				
Measure 1	0.00	0.02	0.000	0.989
Measure 2	0.00	0.02	-	-
Measure 3	0.00	0.03	-	-
BFS anterior (visit 2) n=36				
Measure 1	0.00	0.01	0.0000	0.987
Measure 2	0.00	0.02	-	-
Measure 3	0.00	0.02	-	-
BFS anterior (visit 3) n=36				
Measure 1	0.00	0.01	0.000	0.975
Measure 2	0.00	0.02	-	-
Measure 3	0.00	0.02	-	-
BFS posterior (visit 1) n=36				
Measure 1	0.00	0.03	0.000	0.912
Measure 2	-0.01	0.03	-	-
Measure 3	0.01	0.03	-	-
BFS posterior (visit 2) n=36				
Measure 1	0.00	0.02	0.000	0.994
Measure 2	0.00	0.02	-	-
Measure 3	0.00	0.02	-	-
BFS posterior (visit 3) n=36				
Measure 1	0.00	0.02	0.000	0.941
Measure 2	0.00	0.03	-	-
Measure 3	-0.01	0.02	-	-
K max (visit 1) n=36				
Measure 1	0.02	0.20	0.000	0.941
Measure 2	0.02	0.19	-	-
Measure 3	-0.05	0.16	-	-
K max (visit 2) n=36				
Measure 1	-0.01	0.14	0.000	0.998
Measure 2	0.00	0.20	-	-
Measure 3	0.01	0.17	-	-
K max (visit 3) n=36				
Measure 1	0.01	0.16	0.000	0.852
Measure 2	-0.07	0.17	-	-
Measure 3	0.05	0.19	-	-
K min (visit 1) n=36				
Measure 1	0.04	0.18	0.000	0.945
Measure 2	0.01	0.16	-	-
Measure 3	-0.05	0.17	-	-

To be continued on next page.

cedures governing the study were explained, and informed consent was obtained. Baseline Orbscan corneal topography measurements were taken. During the second visit (on Day 3) and the third visit (on Day 7) Orbscan corneal topography was performed.

Total time for acquiring all measurements did not exceed 15 min for each subject. This was to minimize the effect of diurnal variation of pachymetry.<sup>29,30</sup> To ensure that corneal circadian changes did not influence the measurements, all visits related to the study took place between 4 p.m. and 8 p.m., which is the time of the day when the eye is most physiologically stable.<sup>30,31</sup>

### Statistical analysis

Statistical analysis was performed using the SPSS 14.0 (SPSS Chicago, Illinois, USA, EEUU) statistical package for Windows.

Repeatability and reproducibility of Orbscan were calculated for anterior and posterior BFS, simulated keratometry of the main corneal meridians, and central and mid-peripheral (superior, inferior, nasal and temporary) pachymetry.

We used the definitions of reproducibility and repeatability of the British Standards Institution<sup>32,33</sup> as recommended by Bland and Altman.<sup>34</sup>

### Repeatability

Repeatability is the condition in which independent test results are obtained by the same method on identical test items in the same laboratory by the same operator using the same equipment with the shortest time lapse possible between successive sets of readings.<sup>34</sup> We investigated repeatability by obtaining three Orbscan measurements in each study visit.

There are different ways to express repeatability; the most commonly used are Bland and Altman's coefficient of repeatability, the coefficient of variation (CV), and intraclass correlation coefficient (ICC) of repeatability.

The Bland and Altman's coefficient of repeatability was calculated as the standard deviation (SD) of the difference from the mean of the repeat measurements divided by the average response. The CV of repeatability was calculated by dividing the standard deviation by the mean value. Finally, the ICC of repeatability was calculated based on the repeated-measures analysis of variance.

As suggested by Bland and Altman,<sup>34</sup> graphs of the differences against means were plotted to ascertain that there was no relation between the differences and the range of measurement and to check that the differences between measurements were approximately normally distributed. Limits of agreement were calculated (mean±two standard

**Table 2. Continued from previous page.**

Method	Mean of Diff	SD of Diff	r <sup>2</sup>	P*
K min (visit 2) n=36				
Measure 1	0.00	0.13	0.000	0.995
Measure 2	0.01	0.14	-	-
Measure 3	-0.01	0.14	-	-
K min (visit 3) n=36				
Measure 1	0.02	0.17	0.000	0.992
Measure 2	0.00	0.39	-	-
Measure 3	-0.01	0.47	-	-
Central CT (visit 1) n=36				
Measure 1	0.90	3.88	0.000	0.989
Measure 2	-0.35	4.34	-	-
Measure 3	-0.55	4.07	-	-
Central CT (visit 2) n=36				
Measure 1	0.81	3.81	0.000	0.988
Measure 2	0.11	3.87	-	-
Measure 3	-0.92	3.99	-	-
Central CT (visit 3) n=36				
Measure 1	1.23	4.10	0.000	0.979
Measure 2	-0.19	4.17	-	-
Measure 3	-1.05	4.72	-	-
Superior CT (visit 1) n=36				
Measure 1	1.60	11.10	0.000	0.947
Measure 2	-0.20	10.08	-	-
Measure 3	-1.40	9.26	-	-
Superior CT (visit 2) n=36				
Measure 1	0.57	7.98	0.000	0.991
Measure 2	-0.68	9.94	-	-
Measure 3	0.10	7.30	-	-
Superior CT (visit 3) n=36				
Measure 1	2.68	9.62	0.000	0.722
Measure 2	1.65	9.26	-	-
Measure 3	-4.32	8.54	-	-
Inferior CT (visit 1) n= 36				
Measure 1	1.06	8.16	0.000	0.949
Measure 2	0.54	5.20	-	-
Measure 3	-1.60	9.54	-	-
Inferior CT (visit 2) n= 36				
Measure 1	0.65	5.23	0.000	0.991
Measure 2	-0.60	6.72	-	-
Measure 3	-0.05	5.46	-	-
Inferior CT (visit 3) n= 36				
Measure 1	-1.36	9.49	0.000	0.962
Measure 2	0.92	8.56	-	-
Measure 3	0.44	6.29	-	-
Nasal CT (visit 1) n= 36				
Measure 1	1.83	6.61	0.000	0.949
Measure 2	-1.08	6.97	-	-
Measure 3	-0.75	6.96	-	-
Nasal CT (visit 2) n=36				
Measure 1	0.38	7.70	0.000	0.972
Measure 2	0.99	5.61	-	-
Measure 3	-1.37	9.59	-	-
Nasal CT (visit 3) n=36				
Measure 1	0.26	12.47	0.000	0.991
Measure 2	0.54	7.63	-	-
Measure 3	-0.80	9.36	-	-
Temporal CT (visit 1) n= 36				
Measure 1	-0.35	6.37	0.000	0.998
Measure 2	0.06	6.09	-	-
Measure 3	0.29	7.24	-	-
Temporal CT (visit 2) n=36				
Measure 1	0.79	7.44	0.000	0.719
Measure 2	-4.52	12.71	-	-
Measure 3	3.73	9.00	-	-
Temporal CT (visit 3) n=36				
Measure 1	-0.36	5.94	0.000	0.988
Measure 2	0.86	5.86	-	-
Measure 3	-0.50	6.34	-	-

CT, corneal thickness; diff, differences; SD, standard deviation. \*P: two-way analysis of variance (ANOVA).

deviations).<sup>34</sup> The two-way random effects ANOVA model was used to detect differences in corneal values (anterior and posterior BFS, simulated keratometry and central and mid-peripheral corneal thickness) between each Orbscan measurement.  $P < 0.05$  was considered statistically significant.

### Reproducibility

Reproducibility is the condition in which independent test results are obtained during different sessions or by different operators on identical test items in the same laboratory using the same equipment between successive sets of readings.<sup>32-34</sup>

The reproducibility was calculated using the average of the Orbscan final value (BFS, simulated keratometry and corneal pachymetry) calculated in each visit.

There are different ways to express reproducibility; Bland and Altman's coefficient of reproducibility, the normalized standard deviation or CV of reproducibility, and ICC of reproducibility are the most commonly used.<sup>33</sup>

The Bland and Altman's coefficient of reproducibility was calculated as the SD of the differences between pairs of measurements obtained during different sessions, divided by the average of the means of each pair of readings.<sup>34</sup> The CV of reproducibility was calculated by dividing the standard deviation by the mean value obtained at each of the three visits. Finally, the ICC of repeatability was calculated based on the repeated-measures analysis of variance of the three visits.

Graphs of the differences against means, as suggested by Bland and Altman,<sup>34</sup> were plotted and limits of agreement were calculated (mean  $\pm$  two standard deviations).

The two-way random effects ANOVA model was used to detect differences in corneal value (anterior and posterior BFS, simulated keratometry and central and mid-peripheral corneal thickness) between each scheduled visit.  $P < 0.05$  was considered statistically significant.

## Results

Table 1 summarizes all Orbscan measurements (anterior and posterior BFS, simulated keratometry, and central and mid-peripheral corneal thickness) obtained in all study visits.

### Repeatability

The results of the repeatability of three measurements of anterior and posterior BFS, simulated keratometry, and central and mid-peripheral corneal pachymetry (superior, inferior, nasal and temporal) made with the

Orbscan are summarized in Table 2. Good repeatability ( $r^2 < 0.01$ ) and statistically insignificant differences between measurements (two-way ANOVA  $P > 0.05$ ) were observed for all Orbscan measurements. Table 3 shows limits of agreement, Bland and Altman's coefficient of repeatability, CV and ICC obtained in each visit. All Orbscan measurements showed high repeatability in all study visits.

In the Figures, the Bland-Altman plot comparing Orbscan anterior and posterior BFS repeatability (Figure 1), simulated keratometry repeatability (Figure 2), and central and mid-peripheral pachymetry repeatability (Figure 3A-C) are represented.

### Reproducibility

The reproducibility of measurements of the anterior and posterior BFS, simulated keratometry, and central and mid-peripheral corneal pachymetry measurements taken over three visits is summarized in Table 4. Good repeatability ( $r^2 < 0.01$ ) and statistically insignificant differences between visits (two-way ANOVA  $P > 0.05$ ) were observed for all Orbscan measurements.

Table 5 shows limits of agreement, Bland and Altman's coefficient of reproducibility, CV and ICC obtained along all visits. All Orbscan measurements showed a high reproducibility in one week of follow up.

Figure 4 shows the Bland-Altman plot comparing the reproducibility of anterior and posterior BFS, and simulated keratometry

**Table 3. Orbscan repeatability coefficients. Limits of agreement (Lo A), coefficient of variation of repeatability (CV) Bland and Altman's coefficient of repeatability (BA CR) and intraclass correlation coefficient (ICC) of Orbscan measurement over three visits are shown.**

	Diff $\pm$ SD	Lo A	CV (%)	BA CR (%)	CCI
<b>Anterior BFS (mm) n=36</b>					
Visit 1	0.00 $\pm$ 0.02	0.05 to -0.05	0.30	0.29	0.99
Visit 2	0.00 $\pm$ 0.02	0.03 to -0.03	0.23	0.21	0.99
Visit 3	0.00 $\pm$ 0.02	0.03 to -0.03	0.22	0.20	0.99
<b>Posterior BFS (mm) n=36</b>					
Visit 1	0.00 $\pm$ 0.03	0.06 to -0.06	0.48	0.45	0.97
Visit 2	0.00 $\pm$ 0.02	0.04 to -0.04	0.38	0.34	0.98
Visit 3	0.00 $\pm$ 0.02	0.05 to -0.05	0.39	0.30	0.98
<b>K maximum (D) n=36</b>					
Visit 1	0.00 $\pm$ 0.18	0.4 to -0.4	0.45	0.42	0.98
Visit 2	0.00 $\pm$ 0.17	0.3 to -0.3	0.41	0.39	0.98
Visit 3	0.00 $\pm$ 0.18	0.4 to -0.4	0.41	0.41	0.98
<b>K minimum (D) n=36</b>					
Visit 1	0.00 $\pm$ 0.17	0.4 to -0.4	0.43	0.41	0.98
Visit 2	0.00 $\pm$ 0.14	0.3 to -0.3	0.36	0.32	0.99
Visit 3	0.00 $\pm$ 0.37	0.7 to -0.7	0.51	0.84	0.94
<b>Central CT (mm) n=36</b>					
Visit 1	0.00 $\pm$ 4.11	8.2 to -8.2	0.78	0.74	0.99
Visit 2	0.00 $\pm$ 3.83	7.6 to -7.6	0.74	0.71	0.99
Visit 3	0.00 $\pm$ 4.40	8.8 to -8.8	0.84	0.81	0.99
<b>Superior CT (mm) n=36</b>					
Visit 1	0.00 $\pm$ 10.15	20.3 to -20.3	1.68	1.67	0.96
Visit 2	0.00 $\pm$ 8.42	16.8 to -16.8	1.35	1.37	0.97
Visit 3	0.00 $\pm$ 9.58	19.1 to -19.1	1.58	1.59	0.97
<b>Inferior CT (mm) n=36</b>					
Visit 1	0.00 $\pm$ 7.86	15.7 to -15.7	1.08	1.29	0.97
Visit 2	0.00 $\pm$ 5.81	11.6 to -11.6	1.02	0.97	0.98
Visit 3	0.00 $\pm$ 8.21	16.4 to -16.4	1.34	1.34	0.97
<b>Nasal CT (mm) n=36</b>					
Visit 1	0.00 $\pm$ 6.91	13.8 to -13.8	1.13	1.11	0.98
Visit 2	0.00 $\pm$ 7.80	15.6 to -15.6	1.31	1.26	0.98
Visit 3	0.00 $\pm$ 9.94	19.9 to -19.9	1.23	1.44	0.97
<b>Temporal CT (mm) n=36</b>					
Visit 1	0.00 $\pm$ 6.53	13.1 to -13.1	1.25	1.11	0.98
Visit 2	0.00 $\pm$ 6.27	12.6 to -12.6	1.38	1.75	0.97
Visit 3	0.00 $\pm$ 6.03	12.1 to -12.1	1.12	1.12	0.98

Diff, difference mean; SD, standard deviation; BFS, best fit sphere; D, diopter; CT, corneal thickness.

measurements. Figure 5 shows the reproducibility of Orbscan central and mid-peripheral pachymetry.

## Discussion

In this study, each patient underwent the Orbscan procedure on three different days in the same week, in order to provide information on the repeatability and reproducibility of Orbscan measurements of anterior and posterior BFS, simulated keratometry, and central and mid-peripheral corneal thickness. This was carried out because although the repeatability and precision of Orbscan pachymetry has been extensively reported,<sup>7,16,17,24,25</sup> there is little information available about the repeatability and reproducibility of Orbscan curvature and corneal power measurements. This information could be very useful in the follow up of eye examination patients with respect to screening corneal pathologies, refractive surgery and follow up of wearers of contact lenses.

## Repeatability

The repeatability of the Orbscan was determined with three consecutive measurements of each cornea on three different visits. Three successive measurements were used for obtaining values of repeatability which were more reliable than those obtained taking only two measurements, following the recommendations of other authors.<sup>25</sup>

Bland and Altman's coefficient of repeatability, the CV and ICC were all calculated because they are the coefficients most used in the literature<sup>25,35,36</sup> and also because there is still no consensus on the choice of coefficient to be used.

The Orbscan provided repeatable measurements for all the parameters evaluated, with coefficients of repeatability lower than 1.0% for anterior and posterior BFS, simulated keratometry and central thickness pachymetry (Table 3). These results are in agreement with previous reports.<sup>25,35,37</sup>

Similar to previous reports,<sup>28,29</sup> our pachymetry data showed that mid-peripheral corneal thickness is less repeatable (close to 1%). However, we found better repeatability than was found in another study, with a CV of 2.5% for peripheral pachymetry.<sup>17</sup> The loss of repeatability in the peripheral cornea with the Orbscan could be explained by the fact that there are fewer slits projected onto the peripheral areas during acquisition than in the central corneal region, where overlapping of projected slits increases the resolution of the measurement occurs.<sup>17</sup> Jonuscheit *et al.*<sup>25</sup> reported that repeatability is, at least indirectly, related to the central anterior corneal

**Table 4. Analysis of reproducibility over three visits (anterior and posterior BFS, maximum and minimum keratometry, and central and mid-peripheral pachymetry).**

Method	Mean of Diff	SD of Diff	r <sup>2</sup>	P Value *
BFS anterior n=36				
Visit 1	0.00	0.02	0.000	0.965
Visit 2	0.00	0.02	-	-
Visit 3	0.00	0.02	-	-
BFS posterior n=36				
Visit 1	-0.01	0.02	0.000	0.874
Visit 2	0.00	0.02	-	-
Visit 3	0.00	0.01	-	-
K maxima n=36				
Visit 1	0.08	0.15	0.000	0.509
Visit 2	-0.02	0.13	-	-
Visit 3	-0.06	0.13	-	-
K minima n=36				
Visit 1	0.07	0.14	0.000	0.679
Visit 2	0.00	0.13	-	-
Visit 3	-0.07	0.17	-	-
Central CT n=36				
Visit 1	-0.50	4.01	0.000	0.953
Visit 2	1.13	3.96	-	-
Visit 3	-0.64	3.60	-	-
Superior CT n=36				
Visit 1	-4.46	8.85	0.000	0.308
Visit 2	3.62	7.12	-	-
Visit 3	0.48	6.69	-	-
Inferior CT n=36				
Visit 1	0.20	5.02	0.000	0.807
Visit 2	1.56	5.82	-	-
Visit 3	-1.76	5.01	-	-
Nasal CT n=36				
Visit 1	-0.86	6.76	0.000	0.889
Visit 2	1.66	6.71	-	-
Visit 3	-0.80	6.79	-	-
Temporal CT n=36				
Visit 1	-0.86	4.51	0.000	0.959
Visit 2	0.78	6.87	-	-
Visit 3	0.08	6.34	-	-

CT, corneal thickness; Diff, differences; SD, standard deviation. \*P value: two-way analysis of variance (ANOVA).

**Table 5. Orbscan reproducibility coefficients. Limits of agreement (Lo A), Coefficient of variation of reproducibility (CV), Bland and Altman's coefficient of reproducibility (BA CR) and intraclass correlation coefficient (ICC) of Orbscan measurement over three visits are shown.**

n=36	Diff±SD	Lo A	CV (%)	BA CR (%)	ICC
Anterior BFS (mm)	0.00±0.03	-0.1 to 0.1	0.23	0.41	0.99
Posterior BFS (mm)	-0.01±0.03	-0.1 to 0.1	0.26	0.40	0.99
K maximum (D)	0.10±0.24	-0.4 to 0.6	0.34	0.55	0.99
K minimum (D)	0.09±0.25	-0.4 to 0.6	0.37	0.60	0.99
Central CT (µm)	0.09±6.76	-13.4 to 13.6	0.73	1.21	0.99
Superior CT (µm)	-3.53±13.86	-31.3 to 24.2	1.30	2.20	0.98
Inferior CT (µm)	1.30±9.30	-17.3 to 19.9	0.97	1.55	0.99
Nasal CT (µm)	-0.04±11.76	-23.6 to 23.5	1.16	1.88	0.99
Temporal CT (µm)	-0.62±10.33	-21.3 to 20.0	1.06	1.75	0.99

Diff, difference mean; SD, standard deviation; BFS, best fit sphere; D, diopter; CT, corneal thickness.

curvature. Our posterior BFS repeatability results agree with those of Maldonado,<sup>35</sup> who reported a CV of 0.5% and an ICC of 0.98 in 22 post-myopic LASIK eyes. These results suggest that myopic LASIK might not influence Orbscan repeatability.<sup>35</sup> However, Oshika *et al.* found a CV of 0.18% and 0% for anterior and posterior surfaces, respectively, with an artificial spherical cornea.<sup>38</sup>

The fact that the coefficients calculated in each visit showed no differences, suggests

that the Orbscan offers repeatable measures of anterior and posterior BFS, simulated keratometry, and central and mid-peripheral corneal pachymetry.

The most repeatable parameters were central corneal thickness, anterior and posterior curvature (BFS) and simulated keratometry, each of which displayed coefficients lower than 1%. These results were similar to previous reports.<sup>25,35</sup> However, mid-peripheral corneal thickness showed coefficients higher

than 1%. This lack in the Orbscan peripheral pachymetry repeatability has been previously described.<sup>17,25,28</sup>

## Reproducibility

There are few studies at present that report the Orbscan's reproducibility in healthy corneas.<sup>24,34</sup> We found that the coefficients of reproducibility (Bland-Altman and CV) in the healthy eyes in this study were lower than 2.0% for all the parameters evaluated (Table 5). This reproducibility coefficient was determined with the final value of each of three visits (calculated with the mean value of three Orbscan assessments). This suggests that the Orbscan can be useful for monitoring topographic corneal changes in prospective studies.<sup>28,39</sup> The lowest coefficient of reproducibility compared with the coefficients of repeatability calculated in each visit could be related to physiological corneal changes (circadian changes). To minimize the effects of diurnal variation on pachymetry, all the measurements were performed at the same time of day, because Giráldez-Fernández found 2.5% of circadian corneal thickness variation in central and peripheral cornea.<sup>40</sup>

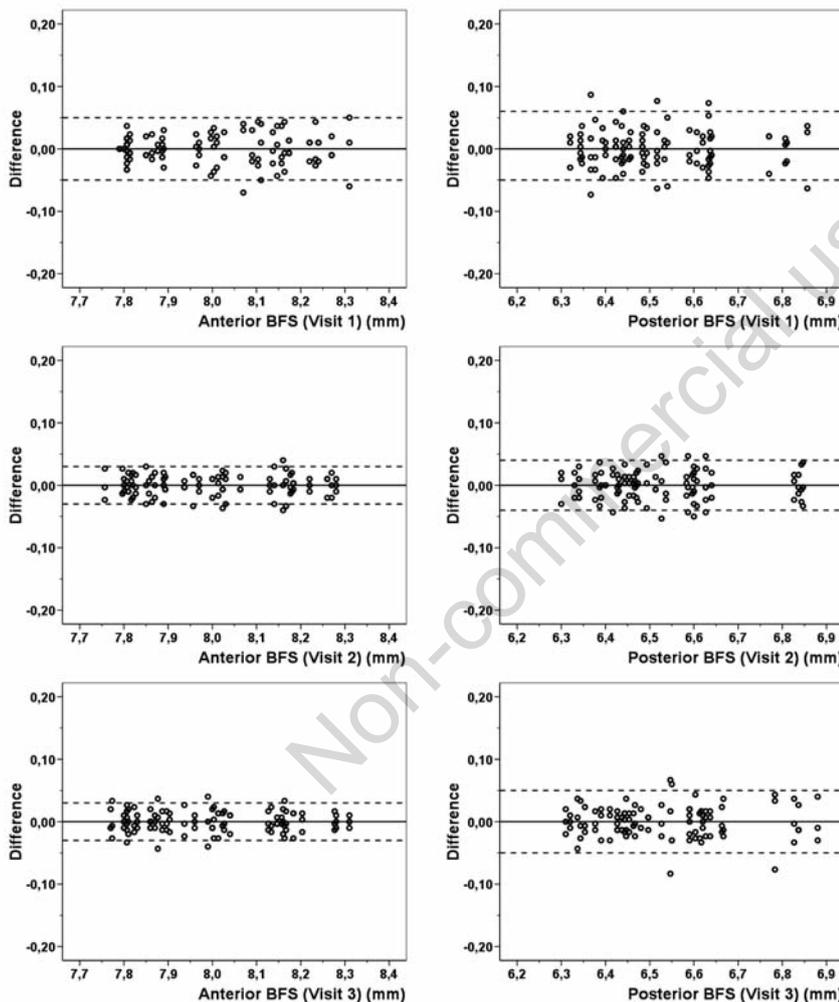
Posterior BFS reproducibility CV (0.26%) was lower than that reported previously after refractive surgery (0.68%<sup>35</sup> to 1.22%<sup>41</sup>). This difference suggests that myopic LASIK corneal surface could have some influence in Orbscan posterior analysis and is in agreement with other studies in which some limitations of scanning-slit corneal topography in eyes treated with excimer laser keratorefractive surgery were found.<sup>18,42,43</sup>

BFS (anterior and posterior) and simulated keratometry showed higher reproducibility (Bland-Altman and CV) than corneal thickness (central and mid-peripheral). This difference could be explained because circadian variations of the cornea may mainly affect corneal thickness and may have a low effect on the curvature and the power of the cornea.<sup>30,31</sup>

Finally, the Bland-Altman coefficient of reproducibility was two times higher than the CV for all corneal measurements (Table 5). This difference suggests that these coefficients are not interchangeable and emphasizes the need to establish a consensus to facilitate comparison between the results of different studies.

## Clinical implications

The repeatability and reproducibility of Orbscan measurements is of paramount importance in many situations because important clinical decisions are based on Orbscan topography. Changes in simulated keratometry, in anterior and posterior curva-



**Figure 1.** Bland-Altman plot comparing Orbscan best fit sphere (BFS) repeatability in all visits (left anterior BFS and right posterior BFS). For anterior BFS (left), the mean difference in the 1<sup>st</sup> visit (top-left) was 0.00 mm±0.02 mm and the limit of agreement (LoA) ranged from 0.05 mm to -0.05 mm (SD±2); in the 2<sup>nd</sup> visit (middle left) the mean difference was 0.00 mm±0.02 mm and LoA ranged from 0.03 mm to -0.03 mm; in the 3<sup>rd</sup> visit (lower left) the mean difference was 0.00 mm±0.02 mm and LoA ranged from 0.03 mm to -0.03 mm. For posterior BFS (right) the mean difference in 1<sup>st</sup> visit (top-right) was 0.00 mm±0.03 mm; limit of agreement (LoA) ranged from 0.06 mm to -0.06 mm (SD±2), in 2<sup>nd</sup> visit (middle-right) was 0.00 mm±0.02 mm; LoA ranged from 0.04 mm to -0.04 mm and in 3<sup>rd</sup> visit (below-right) was -0.00 mm±0.02 mm; LoA ranged from 0.05 mm to -0.05 mm.

ture, or in corneal pachymetry may be early indicators of corneal pathology (diagnosis<sup>44</sup> and keratoconus progression<sup>45</sup>), iatrogenic ectasia post corneal refractive surgery,<sup>7,35</sup> contact lens-induced corneal swelling,<sup>46,47</sup> and orthokeratology.<sup>11</sup> These changes could also be useful in myopia progression studies,<sup>25</sup> and in the study of corneal thickness and IOP relationship in glaucoma patients.<sup>15,48</sup>

We were unable, however, to find any previous analysis of Orbscan repeatability and reproducibility in the literature, because previous studies focused on comparison of

corneal pachymetry with different instruments<sup>24,25</sup> or on the study of posterior curvature after corneal refractive surgery.<sup>35</sup> To our knowledge, this study is, therefore, the first to investigate the repeatability and reproducibility of Orbscan anterior and posterior BFS, simulated topography, and central and mid-peripheral pachymetry in healthy eyes over one week with more than two visits.

The current results can serve as repeatability and reproducibility (of curvature, power and thickness of the cornea) control data or as a reference for future clinical studies. However, these results should be inter-

preted with caution because of the limitations of the Orbscan apparatus, the absence of a *gold-standard* to compare the corneal measurements, the experimental methodology, and the effect of circadian corneal changes, but they provide reference coefficients to facilitate the clinical use of Orbscan corneal assessment.

It will, nevertheless, be necessary to check the reproducibility of the technique in irregular or opaque corneas or in unhealthy eyes, since a decrease in the reliability of the instrument has been described in such patients.<sup>41</sup>

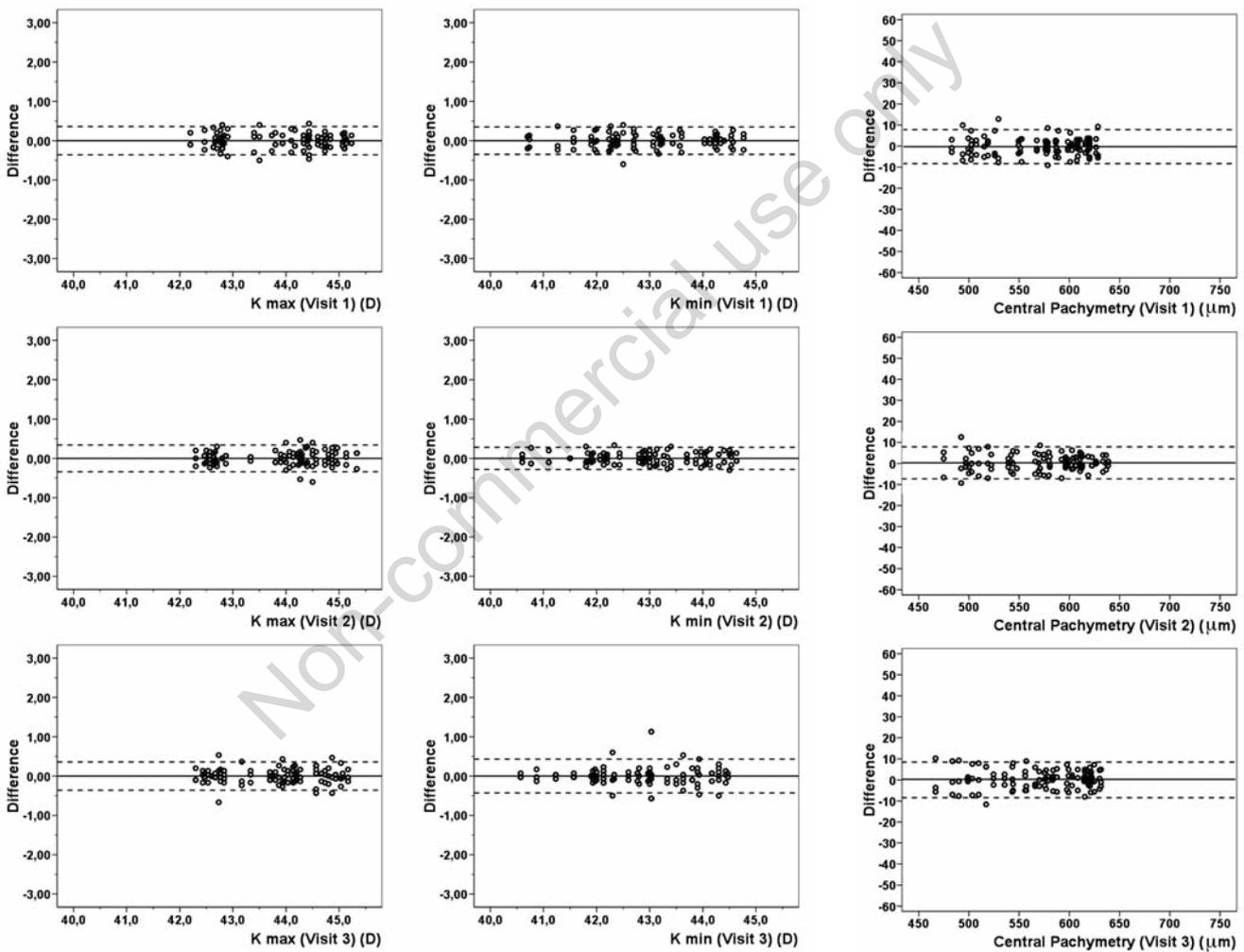


Figure 2. Bland-Altman plot comparing Orbscan simulated keratometry repeatability in all visits (left maximum keratometry (K max) and right minimum keratometry (K min)). For K max (left) the mean difference in 1<sup>st</sup> visit (top left) was 0.00 mm±0.18 mm and the limit of agreement (LoA) ranged from 0.40 mm to -0.40 mm (SD±2); in 2<sup>nd</sup> visit (middle left) was 0.00 mm±0.17 mm and LoA ranged from 0.30 mm to -0.30 mm; in the 3<sup>rd</sup> visit (lower left) was 0.00 mm±0.18 mm and LoA ranged from 0.40 mm to -0.40 mm. For K min (right) the mean difference in 1<sup>st</sup> visit (top-right) was 0.00 mm±0.17 mm; limit of agreement (LoA) ranged from 0.40 mm to -0.40 mm (SD±2), in 2<sup>nd</sup> visit (middle right) was 0.00 mm±0.14 mm; LoA ranged from 0.30 mm to -0.30 mm and in 3<sup>rd</sup> visit (lower right) was 0.00 mm±0.37 mm; LoA ranged from 0.70 mm to -0.70 mm.

Figure 3 (A). Bland-Altman plot comparing Orbscan central pachymetry repeatability over all visits. The mean difference in 1<sup>st</sup> visit (top) was 0.00 mm±4.11 mm; limit of agreement (LoA) ranged from 8.20 mm to -8.20 mm (SD±2), in 2<sup>nd</sup> visit (middle) was -0.00 mm±3.83 mm; LoA ranged from 7.60 mm to -7.60 mm and in 3<sup>rd</sup> visit (b) was 0.00 mm±4.40 mm; LoA ranged from 8.80 mm to -8.80 mm.

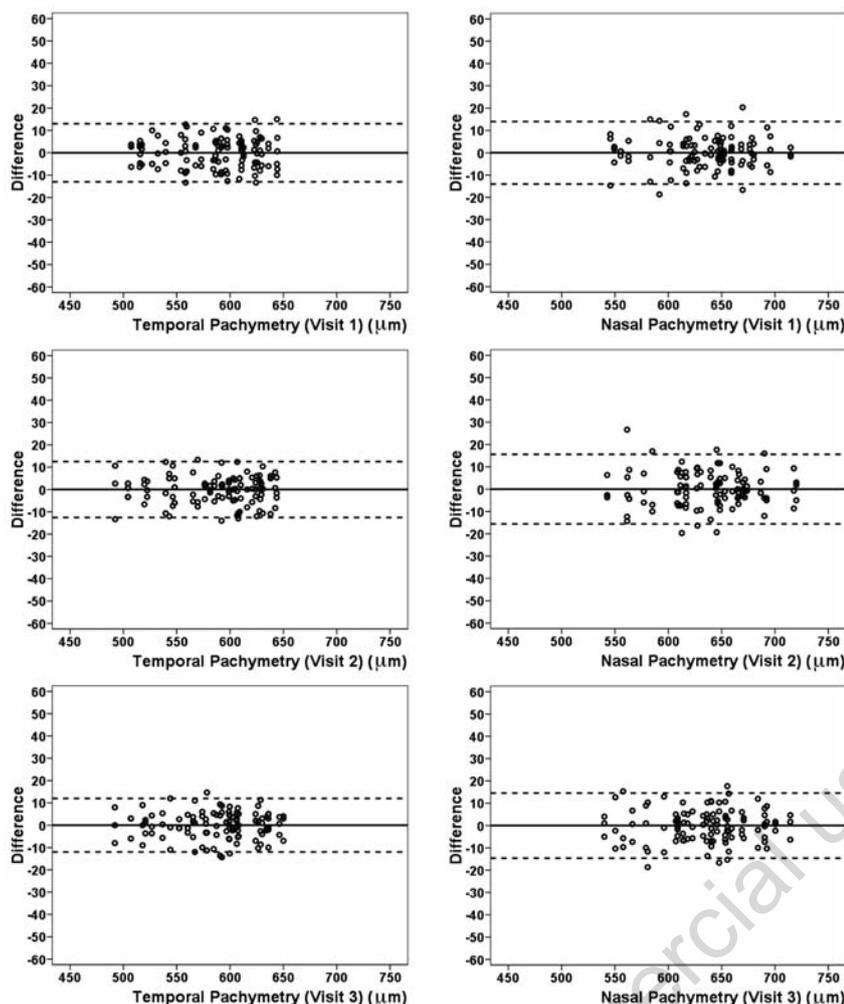


Figure 3 (B). Bland-Altman plot comparing Orbscan mid-peripheral pachymetry repeatability over all visits (left temporal pachymetry and right nasal pachymetry). To temporal pachymetry (left) the mean difference in 1<sup>st</sup> visit (top-left) was 0.00 mm±6.53 mm; limit of agreement (LoA) ranged from 13.10 mm to -13.10 mm (SD±2), in 2<sup>nd</sup> visit (middle-left) was 0.00 mm±6.27 mm; LoA ranged from 12.60 mm to -12.60 mm and in 3<sup>rd</sup> visit (below-left) was 0.00 mm±6.03 mm; LoA ranged from 12.10 mm to -12.10 mm. To nasal pachymetry (right) the mean difference in 1<sup>st</sup> visit (top-right) was 0.00 mm±6.91 mm; limit of agreement (LoA) ranged from 13.80 mm to -13.80 mm (SD±2), in 2<sup>nd</sup> visit (middle-right) was 0.00 mm±7.80 mm; LoA ranged from 15.60 mm to -15.60 mm and in 3<sup>rd</sup> visit (below-right) was 0.00 mm±9.94 mm; LoA ranged from 19.9 mm to -19.90 mm.

## Conclusions

The Orbscan provides repeatable and reproducible measurements of anterior and posterior BFS, simulated keratometry, and central and mid-peripheral (superior, inferior, nasal and temporal) pachymetry. It is a non-invasive, repeatable and reproducible technique for corneal topography evaluation in healthy eyes.

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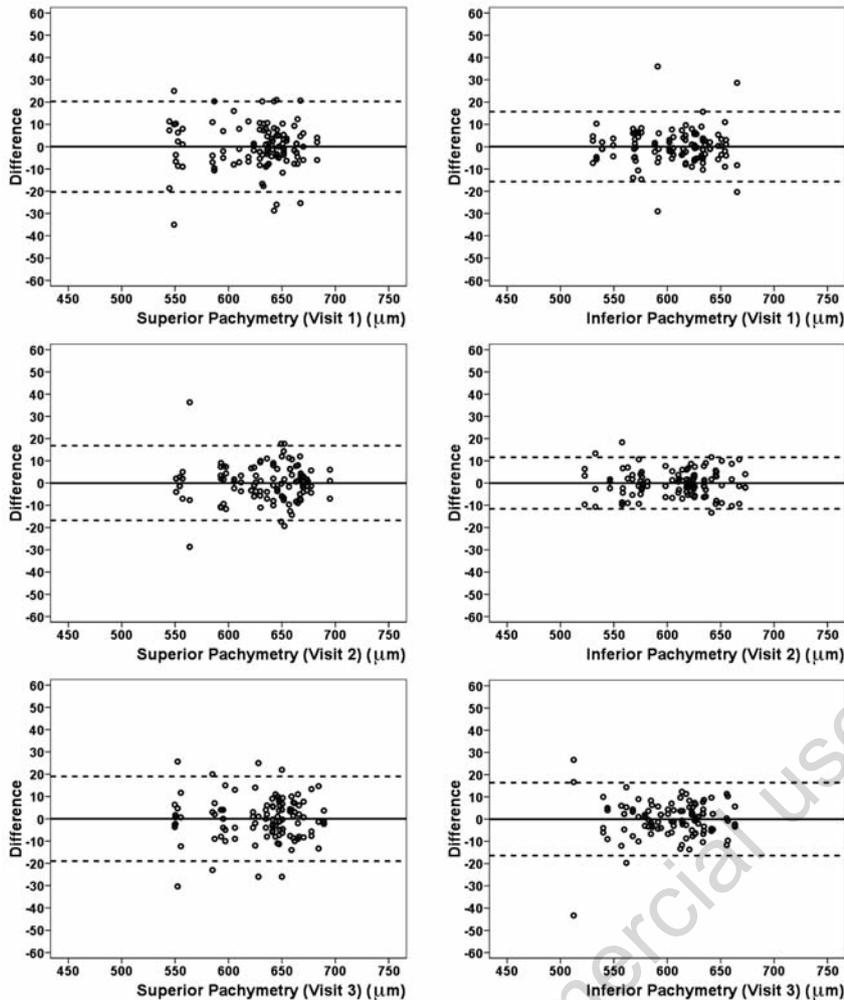


Figure 3 (C). Bland-Altman plot comparing Orbscan mid-peripheral pachymetry repeatability over all visits (left superior pachymetry and right inferior pachymetry). For superior pachymetry (left) the mean difference in 1<sup>st</sup> visit (top-left) was 0.00 mm±10.15 mm; limit of agreement (LoA) ranged from 20.30 mm to -20.30 mm (SD±2), in 2<sup>nd</sup> visit (middle-left) was 0.00 mm±8.42 mm; LoA ranged from 16.80 mm to -16.80 mm and in 3<sup>rd</sup> visit (below-left) was 0.00 mm±9.58 mm; LoA ranged from 19.10 mm to -19.10 mm. For inferior pachymetry (right) the mean difference in 1<sup>st</sup> visit (top-right) was 0.00 mm±7.86 mm; limit of agreement (LoA) ranged from 15.70 mm to -17.70 mm (SD±2), in 2<sup>nd</sup> visit (middle-right) was 0.00 mm±5.81 mm; LoA ranged from 11.60 mm to -11.60 mm and in 3<sup>rd</sup> visit (lower right) was 0.00 mm±8.21 mm; LoA ranged from 16.40 mm to -16.40 mm.

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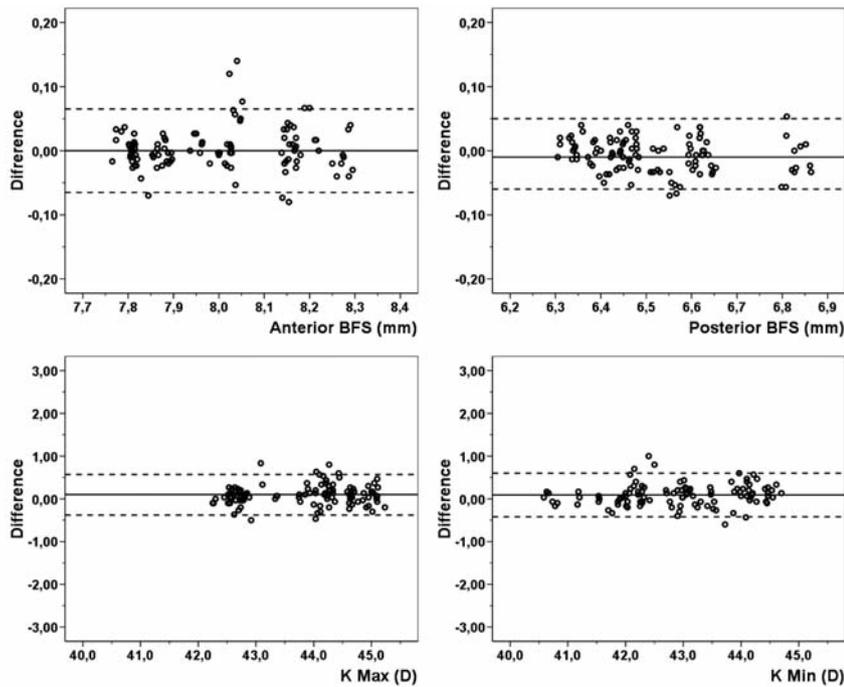
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**Figure 4.** Bland-Altman plot comparing Orbscan best fit sphere (BFS) and simulated keratometry reproducibility over three visits. For anterior BFS (top-left) the mean difference was  $0.00 \text{ mm} \pm 0.03 \text{ mm}$ ; LoA ranged from  $0.10 \text{ mm}$  to  $-0.10 \text{ mm}$ . For posterior BFS (top-right) the mean difference was  $-0.01 \text{ mm} \pm 0.03 \text{ mm}$ ; LoA ranged from  $0.10 \text{ mm}$  to  $-0.10 \text{ mm}$ . For maximum simulated keratometry (K max) (lower left) the mean difference was  $0.10 \text{ mm} \pm 0.24 \text{ mm}$ ; LoA ranged from  $0.60 \text{ mm}$  to  $-0.40 \text{ mm}$ . For minimum simulated keratometry (K min) (right-below) the mean difference was  $0.09 \text{ mm} \pm 0.25 \text{ mm}$ ; LoA ranged from  $0.60 \text{ mm}$  to  $-0.40 \text{ mm}$ .

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