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Comparison of Objective and Subjective Refractive Surgery Screening Parameters Between Regular and High Resolution Scheimpflug Imaging Devices

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Abstract

Purpose—To compare objective and subjective metrics from regular and high resolution Scheimpflug devices (Pentacam, Oculus, Inc.) to determine their equivalence and interchangeability for refractive surgery screening.

Setting—Emory Vision at Emory University, Atlanta, GA, USA

Design—Retrospective comparative case series.

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Randleman, Akhtar, Lynn: None

Ambrosio: Consultant to Oculus and Alcon-Wavelight

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Klyce: (relevant) Abbott Medical Optics, Alcon, Oculus, Topcon, Tomey, Nidek.

Methods—One hundred eyes from 50 consecutive screened refractive surgery patients evaluated with both high resolution (HR) and regular (REG) devices were evaluated. Objective parameters evaluated included keratometry (K), central corneal thickness (CCT), and device-generated keratoconus screening indices (KI). Evaluations by masked expert reviewers subjectively graded images as normal, suspicious, or abnormal.

Results—Keratometry values were not significantly different (Anterior K (HR) 1.21 ± 1.13 vs. (REG) 1.15 ± 1.16 , $P = 0.73$, Posterior K (HR) 0.34 ± 0.23 vs. (REG) 0.35 ± 0.23 , $P = 0.67$). CCT was significantly thinner in the HR group (514.7 ± 26.6 vs. 527.6 ± 27.6 , $p < 0.0001$) with limits of agreement of -12.9 to $+17.5$ microns. Most KI were more suspicious for HR than REG except index of height asymmetry (IHA) and index of height deviation (IHD). Subjectively, 60% of cases received the same score, HR was more suspicious in 30%, and REG was more suspicious in 12% of cases, with only slight subjective agreement ($\kappa = 0.26$ to 0.31) between technologies.

Conclusions—Regular and high resolution Scheimpflug imaging devices generated different objective values and significantly different subjective interpretations with poor inter-reviewer agreement. The high resolution device provided a more conservative overall output. For refractive surgical screening the two devices are not interchangeable.

Corneal topography and tomography have both gained importance in screening to determine patient suitability to undergo corneal refractive surgery.¹ A variety of devices and strategies have been employed, including Placido-based topography,^{2–7} scanning slit beam topography and tomography,^{8–10} Scheimpflug tomography^{11, 12} dual Scheimpflug tomography,^{13, 14} anterior segment ocular coherence tomography (OCT),^{15, 16} and combined Placido topography and OCT.¹⁷

Scheimpflug imaging provides more information than Placido imaging alone, with purported advantages compared to other screening devices, including regional and relational corneal thickness and posterior surface evaluations.¹⁸ Additionally, Scheimpflug technology should be less affected by tear film alterations for curvature mapping than Placido imaging and less affected by corneal scarring for thickness evaluations than scanning-slit imaging.¹⁹ However, the superiority of Scheimpflug imaging over other technologies remains to be determined.

Among Scheimpflug imaging devices, the Pentacam (Oculus, Inc.) has been utilized clinically for many years and is the subject of numerous reports in the literature comparing this technology to other technologies^{19–22, 23–26} and evaluating the repeatability and reproducibility of the Pentacam high resolution (HR) device.²⁷

Currently, two Pentacam models are available for refractive surgery screening; these include the regular and the high-resolution devices. These devices are reportedly interchangeable based on the company's marketing information (<http://www.pentacam.com>) for all primary screening metrics. However, in our clinical experience the devices have appeared to provide different objective data, especially with regard to corneal thickness, and subjective analysis of the scans appeared to be leading experienced reviewers to different interpretations with some regularity. Despite numerous studies on other aspects of the Pentacam technology and

comparison between Scheimpflug and other imaging devices, we could find no comparative studies directly comparing the two devices.

The purpose of this study was, therefore, to compare the objective and subjective screening metrics generated from the Pentacam HR and Pentacam devices to determine their equivalence and interchangeability. Specifically, the clinical question to be answered was the following: Are these devices equivalent for refractive surgery patient screening?

METHODS

This retrospective study was approved by the Emory University Institutional Review Board. All patients presented for refractive surgery evaluation to Emory Vision, a part of the Emory Eye Center at Emory University, Atlanta GA.

All patients included in this study had both eyes evaluated by Scheimpflug imaging with both the Pentacam high resolution (HR) and Pentacam regular and devices. Both devices were purchased in the same year (2006) at the same time and have been used equivalently in clinical practice throughout that time. Both machines have equivalent service records and calibration schedules. All scans for review were generated directly from the computer information in an identical fashion using identical scales. A single scan from each device was used for evaluation.

In addition to Scheimpflug imaging, each patient had measurement obtained with scanning-slit and Placido Topography (Orbscan II, Bausch & Lomb) and a complete clinical examination. Imaging was performed on the same day by the same technician for every patient visit. Patients were excluded if they had an abnormal evaluation and were deemed by one author (JBR) not to be candidates for LASIK based on the propensity of testing performed. Additionally, patients with corneal scars, significant tear film abnormalities, or other factors that may adversely affect quality and reproducibility of corneal imaging were excluded.

Objective Evaluation

Objective parameters evaluated and compared included keratometry values, central corneal thickness values, and keratoconus screening indices. Keratometry values included anterior and posterior K values (K flat, K steep, K average, steepest K), and axes (front axis flat, back axis flat). Keratoconus screening indices included index of surface variation (ISV), index of vertical asymmetry (IVA), keratoconus index (KI), central keratoconus index (CKI), index of height asymmetry (IHA), index of height decentration (IHD), and small radius of curvature (Rmin).

Subjective Evaluation

For subjective evaluations, four expert reviewers (RA, WD, RK, SK) were asked to interpret the images obtained by both Pentacam models in a blinded fashion. The reviewers were instructed that they would be reviewing Scheimpflug images obtained during the preoperative evaluation for refractive surgery but were not told any other patient-related or device-related details. They specifically did not know that two separate devices were being

used or compared. After all identifying patient information was removed, each scan was sent electronically to each reviewer. Each reviewer reviewed the exact same copy of the computer-generated images retrieved directly from the devices as JPEG images without alterations. Figures 1 & 2 are representative maps evaluated in the study.

The scans were arranged by patient and device, meaning that each reviewer was able to review both the right and left eyes from the same patient taken from one device at the same time, but the scans were randomized so that scans taken from each device were not readily identifiable or comparable for any individual eye or patient. Reviewers used a standard, mutually agreed upon subjective three point scoring system scoring system (1 = normal, 2 = suspicious, 3 = abnormal). The scans sent for reviewer evaluation included: Sagittal curvature (0.5 D relative scale), Front (2.5 μm scale) and Back (5.0 μm scale) elevations, and Pachymetry map (Absolute 10 μm scale). There was no variation in these parameters for any patient scans. All maps included routine numerical data views and color scales.

Statistical Methods

The agreement of the measurements from the high resolution and regular devices was assessed using the following methods. A paired t test used to compare the mean difference between the two devices to determine if there was a systematic shift in the difference between the devices. A Bland-Altman plot was used to graphically depict the agreement between the two devices. The extent of agreement was calculated in two ways.²⁸ First, the 95% limits of agreement were calculated as the mean difference between the tests $\pm$ 2 standard deviations of the difference between the two tests. The limits of agreement can be interpreted as the range in which 95% of the differences between the two devices would fall. Second, the extent of agreement was also characterized as the width of the 95% prediction limits from a linear regression analysis of the high resolution device versus the regular device. For all the parameters evaluated, the 95% prediction limits from the regression analysis were virtually identical over the range of the measurements and were also very similar to the 95% limits of agreement calculate as described above. Therefore the regression results are not presented in the paper. The difference between the axis measurements of the two devices was calculated and presented as the percent of patients with differences within 5, 10, 20, and 30 degrees. The agreement between the subjective scores from the two devices was assessed using a kappa statistic for each of the reviewers. The characterization of the agreement based on the kappa statistic followed the guidelines proposed by Byrt.²⁹ All data analyses were performed with SAS Version 9.2 (SAS Institute, Cary NC).

RESULTS

One hundred eyes from 50 consecutive patients were evaluated. Average patient age was 39.5 ± 10.4 years (23 to 58 years) with 50 males and 50 females included.

Keratometric Comparisons

Keratometric data are shown in Table 1. Mean keratometric astigmatism values were not significantly different from one another for anterior (1.21 ± 1.13 vs. 1.15 ± 1.16 , $P = 0.73$)

or posterior (0.34 ± 0.23 vs. 0.35 ± 0.23 , $P = 0.67$) values. The mean differences between the HR and Regular devices for Front Flat, Front Steep and Back Steep values were significantly different from 0 but not clinically relevant, with less than 0.1D for the mean difference of any parameter. Bland-Altman plots for Front Flat K values (Figure 3) and Front Steep K values (Figure 4) demonstrate that the limits of agreement fell between -0.58 to 0.40 D for Flat K and -0.63 to 0.55 D for Steep K values. The limits of agreement for Back Flat K and Back Steep K were even tighter with limits of agreement of ± 0.22 D for both. In comparing anterior axis measurements, 38% fell within 5 degrees, 59% within 10 degrees, 77% within 20 degrees, and 85% within 30 degrees.

Corneal Thickness Comparisons

Corneal thickness data are shown in Table 2. Corneal thickness values were significantly thinner by 12.9 microns on average with the HR device than the Regular device ($p < 0.0001$). As shown in Figure 5, 21% of cases had > 20 micron differences between devices. The high resolution device measured thinner than the regular device in 95% of cases.

Keratoconus Indices Comparisons

Keratoconus indices data are shown in Table 3. Average values obtained from the high resolution device were greater (more suspicious) than those from the regular device values for each variable except IHA and IHD. All indices were significantly different except IVA and IHA. As assessed by the Bland-Altman plots, the variation of the differences between the two devices was reasonably constant over the range of the measurements for each of the indices.

Reviewer's subjective evaluation comparative outcomes are shown in Table 4. There was only slight agreement between technologies for each reviewer. In comparing the specific scores obtained (Figures 6), reviewers rated more high resolution device images as suspicious than regular device images. There were minimal differences between reviewers in terms of the number of scans determined to be different from one another.

Discussion

The results of this study show that the regular and high resolution versions of the Pentacam Scheimpflug tomography units were neither equivalent nor interchangeable for refractive surgical screening based on either objective or subjective parameters. While no definitive conclusion could be drawn from this data set regarding the relative superiority of one unit to the other, both objective metrics and subjective evaluations found the HR device to be a more conservative screening device; central corneal thickness values were thinner, most keratoconus indices were higher (more suspicious), and reviewer scores were skewed towards the HR output appearing more suspicious in cases where differences existed. We are not aware of any other study specifically comparing these technologies in a refractive surgery screening population.

We did find good clinical agreement for most keratometric values, suggesting these two devices may be equivalent for cataract surgical evaluations. There were significant differences with regard to steep axis; however, as many patients had minimal astigmatism

(Table 1) these differences may not be clinically relevant. A recent analysis found similarly good agreement in corneal power and worse agreement in axis between Placido and Scheimpflug imaging.³⁰ This suggests that the two devices are likely equivalent to one another for cataract surgical planning, including toric IOL power determinations.

The most striking differences found between technologies were corneal thickness measurements. As shown in Table 2 and Figure 5, these differences were frequently clinically relevant. Average central thickness difference was nearly 13 microns between devices, and 21% had differences greater than 20 microns. Values were usually thinner when measured by the high resolution device. Previous studies have found good repeatability of thickness measurements with the high resolution device,³¹ and have found these measurements to be well correlated with other devices, including dual Scheimpflug and ultrasound measurements.³²

Significant differences were also found between devices for most keratoconus indices. The high resolution device generated on average higher (more suspicious) values; however, this was less consistent or predictable than thickness measurement differences. The value of these keratoconus indices in refractive surgery remains to be determined; some studies have found these indices to be useful in distinguishing suspect corneas,³³ while other reports have not shown them to be useful.³⁴

The masked reviewers usually subjectively scored scans generated by the high resolution device as more suspicious than images generated by the regular device in cases where they found a difference. The scans most frequently received the same subjective score, and more than ten percent of cases had a higher (more suspicious) score generated from the regular device. There were no major differences between reviewers in the way they scored the images (Figure 6) despite the completely subjective nature of the scoring system implemented in this study. In clinical practice, output from either device can be customized to include the information deemed most relevant for screening purposes; however, in this study all reviewers had to review the same images regardless of their individual preferences in order to standardize the images evaluated. It is unclear what effect this standardization had on the subjective outcomes. Further, there was a small, inadvertent, difference in the colors assigned to the anterior and posterior elevation output. It is also unclear what if any influence this may have had on scoring. A recent study highlighted differences found in subjective grading when largely different color step scales (0.5 D and 1.5 D) were employed for anterior curvature maps.³⁵ However, since the differences were similar between reviewers despite subjective analysis, and because the subjective data matched well with objective differences in found, it is unlikely that these differences had any meaningful affect on the outcome of the study.

This study has direct clinical relevance, as many iterations of Scheimpflug imaging devices are now available, both unique devices from different manufacturers and variations of the same technology from individual manufacturers. Marketing information states that the devices should be interchangeable for the metrics evaluated in this study, which was clearly not the case. A recent case report highlighted the differences in output and screening

performance between the Oculyzer and the Pentacam Device when using the same captured data to process output from both machines.^{36, 37}

The current study did not directly compare the findings from either device with other technologies such as Placido imaging, thickness measures utilizing ultrasound or OCT, or dual Scheimpflug imaging devices. This could have provided greater information in terms of the relative accuracy for either device but was beyond the scope of this study for additional device comparisons and was not feasible for certain measurements due to the retrospective nature of the study.

We acknowledge that we cannot confirm the relative superiority of one device over the other for refractive surgery screening neither relative to their accuracy in the screening process nor in terms of appropriately categorizing patients based on surgical risk. However, the high resolution version of the Pentacam was clearly a more conservative screening device than the regular version. Since refractive surgery is an elective procedure, we believe that minimizing risk of complications is paramount and erring on the side of caution is warranted. Therefore, we recommend use of the high resolution device for refractive surgical screening. Further, we cannot determine which device is better to use for comparative studies with other technologies; however, again, we can state that the two are not interchangeable for important comparative metrics, including corneal thickness values and keratoconus indices. It is our collective opinion that the high resolution device is likely the better device to utilize for comparative analyses, but further study would be needed to confirm that hypothesis.

In summary, we found that the regular and high resolution imaging devices generated different objective variables and subjective analysis resulted in significantly different interpretations and poor inter-reviewer agreement. Therefore, for refractive surgical screening the two devices are not interchangeable.

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WHAT WAS KNOWN

- A variety of devices are available for preoperative refractive surgery patient screening, including different Scheimpflug devices.
- There is limited information on the interchangeability of these devices

WHAT THIS PAPER ADDS

The Regular and High Resolution Scheimpflug devices studied were not interchangeable for either objective or subjective screening metrics. The High resolution device provided a more conservative evaluation.

Figure 1.

Scheimpflug image generated by the regular device. There is an asymmetric pattern on sagittal curvature, central corneal thickness is 564 microns, maximal anterior elevation is +4 microns, and maximal posterior elevation is +11 microns. Color step scales are: Anterior elevation (2.5 micron), Posterior Elevation (5.0 microns), Sagittal Curvature (0.50 D relative scale), Corneal Thickness (10 microns, Absolute scale). For anterior and posterior elevations, green is set at zero, positive values begin with light yellow colors, and negative values begin with light blue colors. Average subjective score was 1.25, with three reviewers scoring the image as normal and one scoring as suspicious.

Figure 2.

Scheimpflug image from the same eye as Figure 1 generated by the high resolution device. There is an asymmetric pattern on sagittal curvature that is more apparent, central corneal thickness is 540 microns, maximal anterior elevation is +4 microns, and maximal posterior elevation is +10 microns. Color step scales are: Anterior elevation (2.5 micron), Posterior Elevation (5.0 microns), Sagittal Curvature (0.50 D relative scale), Corneal Thickness (10 microns, Absolute scale). For anterior and posterior elevations, positive values begin with light green colors, and negative values begin with dark green colors. Average subjective score was 2, with all four reviewers scoring the image as suspicious.

Figure 3.

Bland Altman Plot of the Anterior Flat keratometry values. Limits of agreement for the high resolution and regular device measurements fell between -0.58 to $+0.40$ D with a relatively uniform distribution.

Figure 4.

Bland Altman Plot of the Anterior Steep keratometry values. Limits of agreement for the high resolution and regular device measurements fell between -0.63 to 0.55 D with a relatively uniform distribution.

Figure 5.

Bland-Altman Plot of Corneal Thickness measurements. Limits of agreement for the high resolution and regular device measurements fell between -30.47 to $+4.61$ microns. Most measurements fall below zero, indicating that for most eyes thickness values obtained with the high resolution device were lower than those obtained with the regular device. More than 20% of eyes had differences of more than 20 microns.

Figure 6.

Bar graph showing the comparative subjective responses for all reviewers (All) and by reviewer (1–4). Overall, in 58% of cases comparative high resolution and regular maps received the same subjective score, in 14% the regular scan received a higher (more suspicious) score, and in 28% the high resolution scan received the higher score. There were no major differences in scores between reviewers.

Table 1

Corneal Curvature Descriptive Statistics

Parameter	HR		Regular		<u>Mean Difference</u> [*]	<u>SD of Difference</u>	<u>LOA</u> [†]	<u>P</u> [‡]
	<u>Mean</u>	<u>SD</u>	<u>Mean</u>	<u>SD</u>				
Front K								
K Steep (D)	44.63	1.40	44.67	1.40	-0.04	0.29	0.59	0.23
K Flat (D)	43.47	1.32	43.56	1.32	-0.09	0.24	0.49	0.001
Steepest K (D)	45.35	1.61	45.53	1.67	-0.18	0.54	1.08	0.001
Back K								
K Steep (D)	-6.43	0.32	-6.46	0.34	0.04	0.11	0.22	0.001
K Flat (D)	-6.13	0.25	-6.13	0.25	0.00	0.11	0.22	0.99

HR = high resolution device, Regular = regular device, SD = standard deviation, D = diopters, LOA = limits of agreement

^{*} Positive mean values indicate HR > Regular. Negative values indicate Regular > HR.

[†] LOA = $2 \times (\text{SD of Difference})$. The 95% limits of agreement can be calculated as the Mean Difference $\pm$ the LOA value in the table.

[‡] The p-value for the paired t test comparing the mean of HR to the mean of Regular.

Table 2

Corneal Thickness Comparisons

Parameter	HR		Regular		SD of Difference	LOA [‡]	p [‡]
	Mean	SD	Mean	SD			
CCT (µm)	514.71	26.66	527.64	27.66	8.77	17.54	< 0.001

HR = high resolution device, Regular = regular device, SD = standard deviation, CCT = central corneal thickness, LOA = limits of agreement

* Positive mean values indicate HR > Regular. Negative values indicate Regular > HR.

[‡]LOA = 2 × (SD of Difference). The 95% limits of agreement can be calculated as the Mean Difference ± the LOA value in the table.

[‡]The p-value for the paired t test comparing the mean of HR to the mean of Regular.

Table 3**Keratoconus Screening Descriptive Statistics**

Parameter	HR		Regular		Mean Difference *	SD of Difference	LOA †	p ‡
	Mean	SD	Mean	SD				
ISV	20.160	9.14	19.440	9.11	0.72 0	3.36	6.72	0.035
IVA	0.1542	0.08	0.1516	0.08	0.0026	0.05	0.11	0.63
KI	1.0338	0.02	1.0269	0.02	0.0069	0.02	0.03	<0.001
CKI	1.0074	0.01	1.0051	0.01	0.0023	0.01	0.01	0.002
Rmin	7.4485	0.25	7.4191	0.26	0.0269	0.09	0.17	0.003
IHA	3.9210	4.11	4.4280	4.77	-0.5070	2.86	5.73	0.080
IHD	0.0080	0.01	0.0095	0.01	-0.0016	0.01	0.01	0.027

ISV = index of surface variation, IVA = index of vertical asymmetry, KI = keratoconus index, CKI = central keratoconus index, Rmin = small radius of curvature, IHA = index of height asymmetry, IHD = index of height decentration, HR = high resolution device, Regular = regular device, SD = standard deviation, LOA = limits of agreement

* Positive values indicate HR > Regular. Negative values indicate Regular > HR.

† LOA = $2 \times (SD \text{ of Difference})$. The 95% limits of agreement can be calculated as the Mean Difference $\pm$ the LOA value in the table.

‡ The p-value for the paired t test comparing the mean of HR to the mean of Regular.

Table 4

Reviewer Subjective Scores & Agreement

Reviewer	Subjective Score Scale*	HR (n)	Regular (n)	Kappa	Agreement
1	1 (N)	31	50	0.26	Slight
	2 (S)	55	41		
	3 (A)	14	9		
2	1 (N)	36	47	0.31	Slight
	2 (S)	42	32		
	3 (A)	22	21		
3	1 (N)	28	44	0.34	Slight
	2 (S)	51	35		
	3 (A)	21	21		
4	1 (N)	15	16	0.28	Slight
	2 (S)	65	74		
	3 (A)	20	10		

* Subjective reviewer scale used by each reviewer:

N = Normal, score = 1

S = Suspicious, score = 2

A = Abnormal, score = 3