

Intrasession repeatability of refractive and ocular aberrometric measurements obtained using a multidiagnostic device in healthy eyes

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Purpose: To evaluate the intrasession repeatability of refractive and ocular aberrometric measurements obtained using a new multidiagnostic device in healthy eyes.

Patients and methods: A total of 107 eyes of 107 patients, age ranging from 23 to 65 years, were enrolled in this study. A complete eye examination was performed in all eyes, including an ocular examination using the VX120 system. Three consecutive measurements were obtained using this device to assess the intrasession repeatability of different refractive and ocular aberrometric parameters. The within-subject standard deviation (S_w), intrasubject precision ($1.96 \times S_w$), and intraclass correlation coefficient (ICC) were calculated.

Results: S_w and intrasubject precision for refractive data were below 0.12 and 0.20 D, respectively, in all cases. The ICC ranged from 0.947 for the J_{45} power vector component to 0.997 for the sphere. Concerning aberrometric measurements S_w and intrasubject precision values were below 0.05 μm and 0.10 μm , respectively. Likewise, the ICC ranged from 0.805 for the quadrafoil root mean square to 0.954 for the primary spherical aberration. Poor correlations were found between most of the refractive parameters and their S_w ($-0.033 \leq r \leq 0.053$, $p \geq 0.064$). Moderate and significant positive correlations were found between the magnitude of the aberrometric parameters evaluated and their S_w ($r \geq 0.446$, $p < 0.001$).

Conclusion: The new multidiagnostic device evaluated is able to provide consistent measurements of refraction and ocular aberrations in healthy eyes. Future studies should confirm if this consistency is also observed in highly aberrated eyes.

Keywords: ocular aberrations, refraction, Scheimpflug imaging, VX120 system, intrasession repeatability

Introduction

Multidiagnostic devices based on corneal and anterior segment imaging techniques have become a crucial tool in the clinical practice of ophthalmology and optometry, with a great variety of applications, such as corneal curvature and pachymetric analysis, detection of ectatic corneal conditions, anatomical study of the anterior segment prior to phakic intraocular lens implantation, and densitometric analysis of the crystalline lens.¹ One of the main features of these devices is the clinical characterization of the ocular optics, providing a measurement of objective refraction and ocular aberrations.^{2,3} Some studies have evaluated the consistency of refractive and aberrometric measurements provided by different models of devices measuring ocular refraction and aberrations.²⁻⁹ Nonconsistent aberrometric measurements in the clinical practice can lead to incorrect clinical decisions. In refractive surgery, it has been shown that

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the variability of aberrometric measurements can be a major limitation of a truly successful wavefront-guided excimer laser procedure.⁹ Specifically, surgeons should consider treating higher order aberration (HOA) magnitudes that are more than the intrasession repeatability values (2.77 times of the intrasession standard deviation).⁹ Recently, a new multidagnostic platform has been developed that provides automatic measurements of corneal topography, corneal, internal and ocular aberrations, pachymetry, anterior chamber depth, iridocorneal angle, pupil diameter under different luminance conditions, and intraocular pressure (IOP), which is the VX120 system (Visionix-Luneau Technologies, Chartres, France). To this date, there are no scientific studies evaluating the consistency of any type of measurements provided by this device. Only Shneor et al¹⁰ evaluated the consistency of refractive measurements provided by a previous version of the aberrometer included in the VX120 multidagnostic system. The aim of the present study was to evaluate the intrasession repeatability of refractive and ocular aberrometric measurements obtained using this multidagnostic device in a sample of normal healthy eyes.

Patients and methods

Patients

A total of 107 healthy eyes of 107 patients with age ranging from 23 to 65 years were included in this study. We used the same sample previously evaluated in a study conducted by our research group to analyze the consistency of corneal topographic measurements provided by the VX120 system.¹¹ All subjects were selected randomly from patients attending the Optometric Clinic of the University of Alicante, where this investigation was developed. Only 1 eye from each subject was chosen randomly for the study according to a random number sequence (dichotomic sequence, 0 and 1) in order to avoid the potential interference of the correlation that often exists between the 2 eyes of the same person. Inclusion criteria were age of >18 years, refraction error between +5.00 and -10.00 D, and eyes without pathology. The exclusion criteria were previous ocular surgery, glaucoma, <18 complete consecutive Placido rings projected on the cornea and, therefore, considered for the corneal analysis, pseudophakia, corneal ectatic diseases, and any other type of pathological condition of the eye. All patients were informed previously about the study and signed an informed consent document in accordance with the tenets of the Declaration of Helsinki. An approval for the performance of the study was obtained from the ethics committee of the University of Alicante (Spain).

Ocular examination

A complete eye examination was performed in all cases that included measurement of uncorrected visual acuity and objective refraction, air tonometry and corneal topographic and anterior segment analysis with the multidagnostic device VX120 (VX120 system, Visionix-Luneau Technologies). All tests were performed by a single experienced examiner (ALN). In all cases, 3 consecutive measurements of objective refraction and ocular aberrations were obtained using the multidagnostic system in order to assess their intrasession consistency. Aberrometric data were calculated by the device for a 5 mm pupil aperture by default and, therefore, included in the analysis this way.

VX120 system

The VX120 system is a multidagnostic platform that combines a Hartmann–Shack aberrometer, a Placido disk corneal topographer, a Scheimpflug imaging-based system, and an air tonometer. The Hartmann–Shack aberrometer of the VX120 system measures 1,500 points in 0.2 seconds in an area ranging from 2.0 to 7.0 mm of diameter. The Scheimpflug imaging-based system uses monochromatic blue light of 455 nm to obtain pachymetric measurements with a resolution of $\pm 1 \mu\text{m}$ and iridocorneal angle measurements with a resolution of $\pm 1^\circ$. The Placido disk system projects 24 rings on the corneal surface, measuring >100,000 points. The combination in 1 device of all these technologies allows obtaining tangential and axial curvature data of the anterior corneal surface, a biometric estimation of various anterior segment structures, measurement of corneal, internal, and ocular wavefront aberrations, visual quality simulations, corneal pachymetry maps, and IOP measurements.

Statistical analysis

The statistical analysis was performed using the software SPSS version 15.0 for Windows (SPSS, Chicago, IL, USA). Normality of all data distributions was confirmed by means of the Kolmogorov–Smirnov test. Then, parametric statistics was always applied. Intrasession repeatability for each refractive and aberrometric parameter evaluated was assessed by means of the following statistical variables: the within-subject standard deviation (S_w) of the 3 consecutive measurements, intrasubject precision ($1.96 \times S_w$), and the intraclass correlation coefficient (ICC). The within-subject standard deviation (S_w) is a simple way of estimating the size of the measurement error. The intraobserver precision was defined as ($\pm 1.96 \times S_w$) and this parameter indicates how large is the range of error of the repeated measurements for 95% of observations. Finally,

the ICC is an analysis of variance-based type of correlation that measures the relative homogeneity within groups (between the repeated measurements) in ratio to the total variation. The ICC will approach 1.0 when there is no variance within repeated measurements, indicating that total variation in measurements is due solely to variability in the parameter being measured. Furthermore, Pearson correlation coefficients were used to assess the correlation between the different parameters evaluated. All statistical tests were 2-tailed, and p -values <0.05 were considered statistically significant.

Refraction notation

The spherocylindrical refractions obtained were converted to vectorial notation using the power vector method described by Thibos and Horner.¹² Using this procedure, any spherocylindrical refractive error can be expressed by 3 dioptric powers: M , J_0 , and J_{45} , M being a spherical lens equal to the spherical equivalent of the given refractive error, and J_0 and J_{45} 2 Jackson crossed cylinders equivalent to the conventional cylinder. These numbers are the coordinates of a point in a 3-dimensional dioptric space (M , J_0 , and J_{45}). The length of this vector is a measure of the overall blurring strength B of a spherocylindrical refractive error.

According to the power vector method, manifest refractions in conventional script notation (S [sphere], C [cylinder] $\times \phi$ [axis]) were converted to power vector coordinates and overall blurring strength (B) by the following formulae: $M = S + C/2$; $J_0 = (-C/2) \cos(2\phi)$; $J_{45} = (-C/2) \sin(2\phi)$; and $B = (M^2 + J_0^2 + J_{45}^2)^{1/2}$.

Results

The study involved 107 eyes of 107 subjects with a mean age of 47.8 years (ranging from 23 to 65 years). A total of 45.8% (49) subjects were male and 54.2% (58) were female. Table 1 summarizes the outcomes of the intrasession repeatability analysis for all refractive measurements. The S_w and intrasubject precision for refractive data were below 0.12 and 0.20 D in all cases. The ICC ranged from 0.947 for the J_{45} power vector component to 0.997 for the sphere. Concerning the aberrometric measurements (Table 2), S_w and intrasubject precision values were below 0.05 and 0.10 μm , respectively. Likewise, the ICC ranged from 0.805 for the quadrafoil root mean square (RMS) to 0.954 for the Zernike term corresponding to the primary spherical aberration.

Table 3 displays the coefficients of correlation of all relationships between the magnitudes of the different refractive and aberrometric parameters evaluated and their associated S_w . As shown, no statistically significant correlations of

Table 1 Summary of the intrasession repeatability outcomes for the refractive measurements obtained by means of the VX120 system

Refractive parameter	Overall mean (SD) Overall median (range)	S_w (°)	Pr (°)	ICC (range 95% CI)
Sphere (D)	-0.43 (2.02) 0.00 (-7.00 to 6.00)	0.05	0.11	0.997 (0.996 to 0.998)
Cylinder (D)	-0.40 (0.75) 0.00 (-4.00 to 0.00)	0.10	0.19	0.959 (0.944 to 0.971)
J_0 (D)	0.06 (0.35) 0.00 (-0.99 to 1.85)	0.04	0.07	0.975 (0.965 to 0.982)
J_{45} (D)	0.01 (0.23) 0.00 (-1.00 to 0.81)	0.03	0.07	0.947 (0.926 to 0.962)
B (D)	1.40 (1.65) 1.00 (0.00 to 7.34)	0.09	0.18	0.995 (0.993 to 0.996)

Abbreviations: S_w , within-subject standard deviation; J_0 and J_{45} , power vector components; B, overall blurring strength; Pr, intrasession precision $1.96 \times S_w$; SD, standard deviation; ICC, intraclass correlation coefficient.

Table 2 Summary of the intrasession repeatability outcomes for the aberrometric measurements obtained by means of the VX120 system

Aberrometric parameter	Overall mean (SD) Overall median (range)	S_w (°)	Pr (°)	ICC (range 95% CI)
HOA RMS (μm)	0.23 (0.13) 0.19 (0.07 to 0.73)	0.04	0.09	0.922 (0.893 to 0.945)
Primary coma RMS (μm)	0.12 (0.09) 0.09 (0.02 to 0.51)	0.03	0.06	0.939 (0.916 to 0.957)
Trefoil RMS (μm)	0.13 (0.09) 0.10 (0.02 to 0.48)	0.03	0.06	0.940 (0.918 to 0.957)
Z_4^0 (μm)	0.06 (0.09) 0.04 (-0.12 to 0.44)	0.03	0.05	0.954 (0.936 to 0.967)
Secondary astigmatism RMS (μm)	0.04 (0.04) 0.03 (0.01 to 0.20)	0.02	0.03	0.861 (0.808 to 0.901)
Quadrafoil RMS (μm)	0.04 (0.03) 0.03 (0.01 to 0.16)	0.01	0.03	0.805 (0.731 to 0.861)

Abbreviations: S_w , within-subject standard deviation; Pr, intrasession precision $1.96 \times S_w$; Z_4^0 , Zernike term corresponding to the primary spherical aberration; SD, standard deviation; ICC, intraclass correlation coefficient; HOA, higher order aberrations; RMS, root mean square.

sphere, J_0 , J_{45} , and B measurements with their S_w associated were found ($-0.033 \leq r \leq 0.053$, $p \geq 0.064$). A poor but statistically significant correlation was found between cylinder and its S_w ($r = -0.194$, $p = 0.045$). Concerning aberrometric data, moderate and significant positive correlations were found between the magnitude of the aberrometric parameters evaluated and their S_w ($r \geq 0.446$, $p < 0.001$). No significant correlations were found between the magnitude of sphere and cylinder and the S_w corresponding to the different aberrometric parameters evaluated ($-0.171 \leq r \leq 0.131$, $p \geq 0.078$).

Table 3 Summary of correlations between different refractive and aberrometric parameters and their within-subject standard deviation (S_w) associated

	Correlation Pearson coefficient	P-value
Sphere with S_w	0.053	0.589
Cylinder with S_w	-0.194	0.045
J_0 with S_w	-0.033	0.739
J_{45} with S_w	0.024	0.807
B with S_w	0.180	0.064
HOA RMS with S_w	0.469	<0.001
Primary coma RMS with S_w	0.588	<0.001
Trefoil RMS with S_w	0.449	<0.001
Z_4^0 with S_w	0.506	<0.001
Secondary astigmatism RMS with S_w	0.446	<0.001
Quadrafoil RMS with S_w	0.554	<0.001

Abbreviations: S_w , within-subject standard deviation; J_0 and J_{45} , power vector components; B, overall blurring strength; Z_4^0 , Zernike term corresponding to the primary spherical aberration; HOA, higher order aberrations; RMS, root mean square.

Discussion

New multidagnostic devices combining Scheimpflug imaging with other technologies are very useful in clinical setting for obtaining a complete analysis of the anatomical and optical properties of different anterior segment structures.¹ One of the main advantages of these devices is that the measurement procedure is not time- and space-consuming in spite of measuring a very large number of parameters.¹ Likewise, the consistency and reliability of the measurements obtained are high.¹ Recently, a new multidagnostic equipment has been developed and commercially released, the VX120 system, that combines several technologies to obtain not only refractive, aberrometric, and corneal topographic measurements in 1 measurement session but also IOP and a great variety of anatomical parameters. In the present study, we have evaluated the consistency of refractive and ocular aberrometric measurements provided by this new device in a normal healthy population. To our knowledge, this is the first scientific study evaluating the reliability of measurements obtained using this new multidagnostic system.

The intrasession repeatability of the refractive measurements was excellent, with S_w and intrasubject precision below 0.12 and 0.20 D, respectively, and ICC values of 0.947 or better. These results are similar and even better than those reported for other modalities of aberrometers.^{13–16} S_w values of 0.18, 0.20, 0.10, and 0.20 D have been reported with a ray tracing aberrometer (iTrace; Tracey Technologies) for sphere, J_0 , J_{45} , and spherical equivalent also in a sample of healthy eyes, respectively.¹⁶ S_w values of 0.25 and 0.08 D have been

reported for the magnitude of sphere and cylinder measured with a new generation Hartmann–Shack aberrometer (iDesign; Abbott Medical Optics).¹⁴ Segura et al¹⁵ calculated the ICC for 3 repeated refractive measurements in healthy eyes obtained with the WAM-5500 autorefractometer (Grand Seiko Co.) and a ray tracing aberrometer (iTrace; Tracey Technologies) and found values of 0.999 and 0.904 for sphere and cylinder with the autorefractometer and values of 0.998 and 0.939 with the aberrometer. Therefore, the multidagnostic equipment evaluated was able to provide in our series consistent measurements of refraction. Furthermore, the variability of consecutive measurements (S_w) of refraction was not correlated with the magnitude of measurements. This means that the consistency of refractive measurements in high myopes was as good as in low or moderate myopes, hyperopes, or emmetropes.

Concerning ocular aberrometric measurements, high levels of intrasession repeatability were also found, with S_w and intrasubject precision values below 0.05 and 0.10 μm , respectively, for all aberrometric parameters evaluated. Additionally, ICC values were over 0.90, except for secondary astigmatism (ICC=0.861) and quadrafoil RMS (ICC=0.805). These outcomes are better than those reported for other types of aberrometers.^{4,14,17} Prakash et al¹⁴ found with a new generation Hartmann–Shack aberrometer S_w values of 0.18, 0.05, 0.06, and 0.06 μm for consecutive repeated measures of HOA RMS, primary coma RMS, trefoil RMS, and the Zernike term corresponding to primary spherical aberration (6 mm pupil), respectively. López-Miguel et al⁴ found ICC values of >0.87 for repeated measurements of ocular aberrations with a device combining Hartmann–Shack aberrometry and Placido disk corneal topography, except for primary coma (ICC=0.75) and third-order aberration RMS (ICC=0.72; 6 mm pupil). Therefore, the multidagnostic device evaluated was able to provide consistent measurements of ocular aberrations in healthy eyes. The magnitude of the aberrometric parameters evaluated was significantly lower than the precision values ($1.96 \times S_w$) or intrasession repeatability coefficients ($2.77 \times S_w$) associated with them, which suggests that this device is capable of providing useful measures for performing truly successful wavefront-guided laser procedures.⁹

Moderate and statistically significant positive correlations were found among the magnitude of the aberrometric parameters evaluated and the S_w values associated with them. This means that the consistency of aberrometric measurements may be somewhat more limited in highly aberrated eyes. This is consistent with the outcome reported in another study evaluating the consistency of internal aber-

rations measured with another integrated system combining a Hartmann–Shack aberrometer and a Placido disk corneal topographer.³ In that study, the authors found that the consistency of some internal aberrometric measurements was limited by the level of aberration.³ In our series, the consistency of aberrometric measurements was within acceptable levels in all cases in spite of this moderate correlation between aberration magnitude and S_w . Future studies should confirm if these same acceptable levels of consistency of aberrometric measurements are observed in highly aberrated eyes.

The results of this study have only demonstrated that the multidagnostic platform evaluated is able to provide consistent measurements of refraction, which is crucial for an instrument to be used in clinical practice. Future studies are being performed to demonstrate the interchangeability of the objective measurement of refraction provided by this device and the subjective measurement. Likewise, the interchangeability of this device with other autorefractometers and aberrometers should also be evaluated in future studies. Finally, the evaluation of consistency of refractive and aberrometric measurements should also be done in aberrated eyes, such as keratoconus and postsurgical eyes.

Conclusion

The new multidagnostic device evaluated is able to provide consistent measurements of refraction and ocular aberrations in healthy eyes. The consistency of refractive measurements is not dependent on the magnitude of the refractive error, with the same precision ability for moderate to high myopic eyes and for hyperopes. The intrasession repeatability of aberrometric measurements is high in a healthy normal population. Future studies should be conducted to confirm if this level of intrasession repeatability for ocular aberrations is also observed in highly aberrated eyes, such as keratoconus.

Disclosure

The authors report no conflicts of interest in this work.

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