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ORIGINAL ARTICLE

Validation of refraction and anterior segment parameters by a new multi-diagnostic platform (VX120)

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KEYWORDS

Scheimpflug imaging;
Precision;
Repeatability;
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Validity

Abstract

Background: The VX120 (Visionix Luneau, France) is a novel multi-diagnostic platform that combines Hartmann–Shack based autorefractive, Placido-disk based corneal-topography and anterior segment measurements made with a stationary-Scheimpflug camera. We investigate the agreement between different parameters measured by the VX120 with accepted or gold-standard techniques to test if they are interchangeable, as well as to evaluate the repeatability and reproducibility.

Methods: The right-eyes of healthy subjects were included in the study. Autorefractive of the VX120 was compared to subjective refraction. Agreement of anterior segment parameters was compared to the Sirius (CSO, Italy) including autokeratometry, central corneal thickness (CCT), iridocorneal angle (IA). Inter and intra-test repeatability of the above parameters was assessed. Results were analyzed using Bland and Altman analyses.

Results: A total of 164 eyes were evaluated. The mean difference between VX120 autorefractive and subjective refraction for sphere, spherical equivalent (SE), and cylinder was 0.01 ± 0.43 D, 0.14 ± 0.47 D, and -0.26 ± 0.30 D, respectively and high correlation was found to all parameter ($r > 0.75$) except for J_{45} ($r = 0.61$). The mean difference between VX120 and the Sirius system for CCT, IA, and keratometry (k_1 and k_2) was -3.51 ± 8.64 μ m, $7.6 \pm 4.2^\circ$, 0.003 ± 0.06 mm and 0.004 ± 0.04 mm, respectively and high correlation was found to all parameter ($r > 0.97$) except for IA ($r = 0.67$). Intrasession repeatability of VX120 refraction, CCT, IA and keratometry yielded low within-subject standard deviations. Inter-session repeatability showed no statistically significant difference for most of the parameters measured.

Conclusions: The VX120 provides consistent refraction and most anterior segment measurements in normal healthy eyes, with high levels of intra and inter-session repeatability.

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PALABRAS CLAVE

Imágenes de Scheimpflug; Precisión; Repetibilidad; Auto-refracción; Validez

Validación de los parámetros de refracción y segmento anterior mediante una nueva plataforma multi-diagnóstica (VX120)

Resumen

Antecedentes: VX120 (Visionix Luneau, Francia) es una plataforma multi-diagnóstico novedosa que combina la auto-refracción basada en Hartmann–Shack, la topografía corneal mediante discos de Plácido, y las mediciones del segmento anterior realizadas mediante cámara de Scheimpflug. Analizamos la concordancia entre los diferentes parámetros medidos por VX120 con las técnicas aceptadas o de referencia, para probar si eran intercambiables, y evaluamos la repetibilidad y reproducibilidad.

Métodos: Se incluyeron en el estudio los ojos derechos de sujetos sanos. Se comparó la auto-refracción de VX120 con la refracción subjetiva. La concordancia de los parámetros del segmento anterior se comparó con la del sistema Sirius (CSO, Italia), incluyendo autoqueratometría, espesor corneal central (ECC) y ángulo iridocorneal (AI). Se valoró la repetibilidad inter e intra-prueba de los parámetros anteriores. Los resultados se analizaron mediante el método de Bland–Altman.

Resultados: Se evaluó un total de 164 ojos. La diferencia media entre la auto-refracción de VX120 y la refracción subjetiva para esfera, equivalente esférico (EE), y cilindro fue de $0,01 \pm 0,43D$, $0,14 \pm 0,47D$ y $-0,26 \pm 0,3D$, respectivamente, encontrándose una elevada correlación entre todos los parámetros ($r > 0,75$) excepto para J_{45} ($r = 0,61$). La diferencia media entre VX120 y el sistema Sirius para ECC, AI, y queratometría (k_1 y k_2) fue de $-3,51 \pm 8,64 \mu m$, $7,6 \pm 4,2^\circ$, $0,003 \pm 0,06 mm$ y $0,004 \pm 0,04 mm$, respectivamente, encontrándose una elevada correlación entre todos los parámetros ($r > 0,97$) excepto para AI ($r = 0,67$). La repetibilidad intra-sesión de la refracción VX120, ECC, AI y queratometría reflejó desviaciones estándar bajas entre sujetos. La repetibilidad inter-sesión no reflejó una diferencia significativa para la mayoría de los parámetros medidos.

Conclusiones: VX120 aporta medidas consistentes de refracción y de la mayoría de las mediciones del segmento anterior en ojos sanos normales, con elevados niveles de repetibilidad intra e inter-sesión.

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Modern optometry and ophthalmology require the data from several instruments to offer the patient a complete ocular exam, especially when refractive or cataract surgery or contact lens fitting are going to be planned.¹ This clinical procedure can be simplified using multi-diagnostic platforms that integrate several technologies in the same device to measure different anatomical and optical parameters of the eye.¹ These types of diagnostic platforms facilitate a complete characterization of the corneal structure, including the analysis of the shape and optical aberrations of the two corneal surfaces, distribution of thickness and even a volumetric analysis of the cornea.¹

The VX120 (Visionix Luneau, Chartres, France) is new non-invasive multi-diagnostic platform that combines refraction (Hartmann–Shack based autorefractometer),^{2,3} simulated keratometry (based on Placido disk videokeratography),^{3,4} non-invasive stationary Scheimpflug based pachymetry and Hartmann–Shack wavefront aberrometry as well as other functions not investigated in this study.^{4,5}

One common issue with new instrumentation is to test its accuracy. Accuracy may be described by two terms: trueness and precision.⁶ Trueness refers to the closeness between the mean of many results and the true value. For measurements of the eye, there are few true or accepted reference values.⁶

Therefore, new instruments should be assessed for agreement with other existing instruments or gold standard tests. This concept is also called validity.⁷

Precision refers to the closeness between repeated measurement that are influenced by five factors: (1) Observer, (2) Instrument used, (3) Instrument calibration, (4) Environment and (5) Time interval between measurements.⁶ The concept of precision has two components: repeatability and reproducibility. Repeatability is the variability in which the above five factors are kept constant.⁶ This is also known as intra-test repeatability.⁷ Reproducibility is the variability when one or more of the above five factors vary.⁶ When time is varied, this is called inter-test repeatability.⁷

Piñero et al. (2017)⁴ evaluated the intra-test repeatability of several functions of the VX120 system in 107 healthy subjects and found that the device provides consistent measurements of keratometric measurements, corneal eccentricity, and third- and fourth-order corneal aberrations. Likewise, the same research group has demonstrated recently that the VX120 system is also able to provide consistent measurements of anatomical parameters of the anterior segment, such as anterior chamber depth, central and peripheral pachymetry and iridocorneal angle.⁵ However, validity has yet to be assessed for this device.

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