CLINICAL EVALUATION OF THE HRK – 7000 AUTOREFRACTOMETER BASED ON THE SHACK - HARTMANN PRINCIPLE

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1. Introduction

Automated objective refractometers have been used since the late 1960s. As they are easy to operate, non invasive and quicker than other techniques of refraction, they are widely used in optometric and ophthalmic research, mostly as a starting point for subjective refraction. The aim of the study was to evaluate the repeatability and accuracy of a new generation autorefracto-keratometer (HRK-7000 Huvitz), based on wavefront aberrometry with non-cycloplegic and cycloplegic subjective refraction.

2. Methods

Participants: Right Eyes of 43 healthy myopes (mean age: 28±6 yrs). Mean spherical equivalent: R:-5.07±2.11D

Refraction measurements were assessed:

(a) Subjectively (manifest refraction) by a single practitioner.

(b) Objectively using HRK-7000 (3 automatic consecutive measurements) **i) without cycloplegia**

ii) with cycloplegia (cyclopentolate 1%)

Two individual measurements were taken, within 30 minutes, to estimate the Inter-test repeatability under cycloplegia.

Refractive error was converted into a vector representation[1] using Fourier decomposition in three components:

(1) Mean Spherical Equivalent (MSE),

(2) J_0 (astigmatism at 180° or 90°)

(3) J_{45} (oblique astigmatism at 45° or 135°)

Data analysis: Agreement between HRK-7000 and subjective measurements was evaluated using Bland-Altman[2] analysis. Statistical differences between various variables were estimated and analyzed using SPSS 17.0 (SPSS Inc., Chicago, IL,USA). P values < 0.05 were considered statistically significant.

Huvitz HRK-7000

The HRK-7000 auto Refracto-Keratometer, based on wavefront aberrometry, using the Hartmann-Shack principle. The refractive error is derived from the 2nd order wavefront aberrations (defocus, astigmatism) for a **4 mm pupil**. Wavefront sampling is achieved by a **25 micro-lenslet array** which creates a number of separate focal spots, providing a more detailed information on ocular refraction compared to standard refractometers.

3. Results: Repeatability & Accuracy

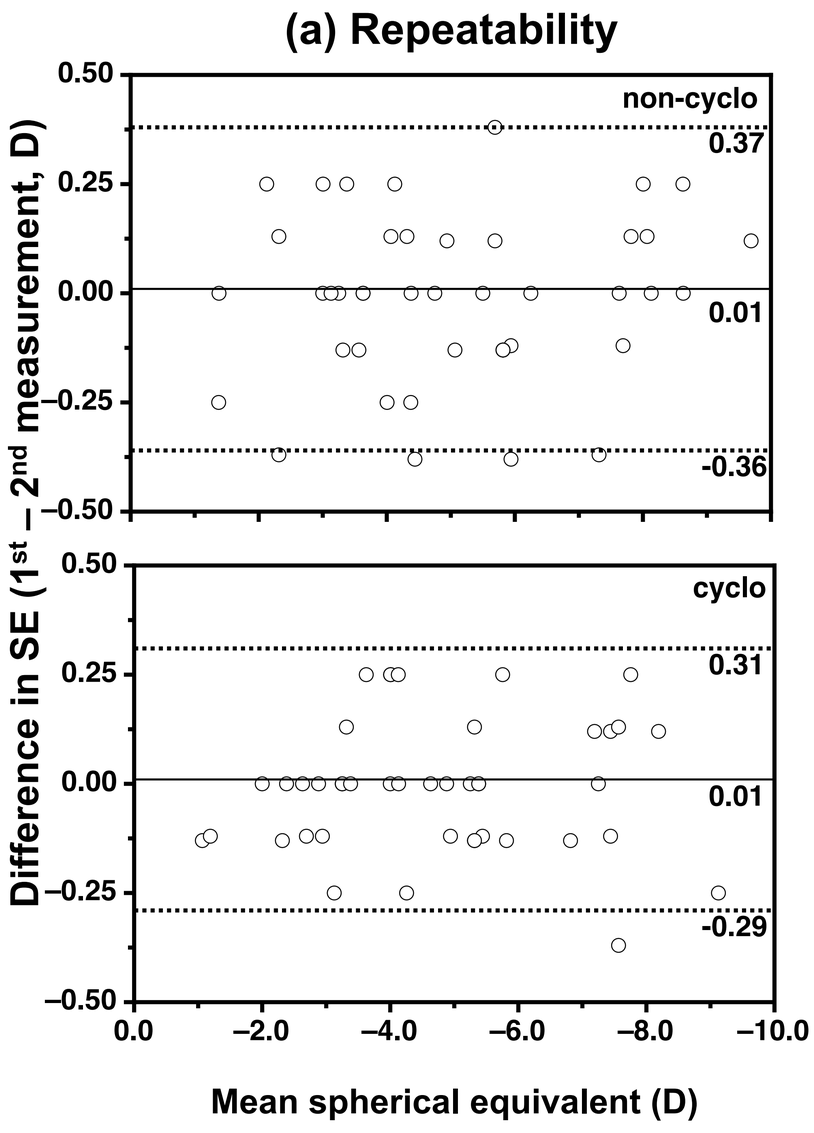

Figure (a): Mean Difference in spherical equivalent between the 1st and the 2nd measurement using HRK-7000 without cycloplegia (upper graph) and with cycloplegia (lower graph) as a function of the MSE (1st + 2nd measurement / 2). Figure (b): Bland Altman plots of the difference in SE between HRK-7000 and subjective refraction. The dashed line in the lower graph is the least square regression fit and the dotted lines are the 95% limits of agreement. The values correspond to average measures and 95% confidence limits

(a) Without cycloplegia, the mean difference between the 1st and 2nd measurement was **0.01**±0.19 D for S.E (p=0.92), **0.00**±0.09 D for the J_o (p=0.69) and **-0.01**±0.06 D for the J_{45} (p=0.62) component of the prescription.
In the presence of cycloplegia test-retest repeatability was **0.01**±0.15 D for S.E. (p=0.48), **0.02**±0.09 D for J_o (p=0.19) and **0.02**±0.07 D for J_{45} (p=0.09).

The average S.E. with HRK-7000 changed from -5.07±2.11 D to -4.75±1.99 D under cycloplegia, presenting a hyperopic shift in refraction (the average difference of the S.E. was **0.32**±0.30D, p<0.001)

(b) There was a statistical (but not clinical) significant difference between the HRK-7000 and subjective refraction. The average spherical equivalent difference was **0.11**±0.32 D (p=0.01) and **0.24**±0.24 D (p=0.001) without and with cycloplegia, respectively. Measurements of the S.E with HRK-7000 were less myopic than subjective refraction.

Without cycloplegia, the mean difference between HRK-7000 and subjective refraction was **-0.02**±0.12 D (p=0.287) and **0.05**±0.08 D (p=0.001) for the J_o and the J_{45} component respectively.
In the presence of cycloplegia, there was no significant difference with either the J_o:-0.01±0.13D (p=0.573) or the J_{45}:0.04±0.1D (p=0.06) component.

4. Conclusions

✓The HRK-7000 forms a fast and reliable objective refractive tool for general optometric practice and ophthalmic research.

✓HRK-7000 showed high repeatability in all components of sphero-cylindrical refraction, especially under cycloplegia.

✓There was no clinical difference between the results of the HRK-7000 (with a 4.0 mm pupil) and subjective refraction for either the spherical equivalent of the prescription or the J_o and J_{45} components.

✓HRK-7000 sphero-cylindrical refraction was in better agreement with the subjective refraction under cycloplegia, underestimating though the spherical component of the refractive error in high myopic eyes.

✓Future work on HRK-7000 could focus on its repeatability and accuracy on measuring pathological eyes, such as in keratoconus, or in post refractive surgery.

References

1. Thibos LN, Wheeler W, Homer D. Power Vectors: an application of Fourier analysis to the description and statistical analysis of refractive error. Optom Vis Sci 1997;74:367-75.

2. Bland JHS, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1986;1:307-10.

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