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Accuracy and validity of IK4 handheld video keratometer measurements in children

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Abstract

The Infant Keratometer (IK4) is a custom handheld instrument that was designed specifically to allow measurement of corneal astigmatism in infants as young as 6 months of age. In this study, accuracy of IK4 measurements using standard toric surfaces was within 0.25 D. Validity measurements obtained in 860 children aged 3–7 years demonstrated slightly higher astigmatism measurements in the IK4 than in the Retinomax K+. Measurement success was 98% using the IK4. The IK4 may prove to be clinically useful for screening children as young as 3 years of age at high risk for corneal astigmatism.

Methods

Subjects

The subjects for our study were 923 members of the Tohono O'odham tribe (range, 3–7 years of age), a Native American tribe in which there is a high prevalence of astigmatism.^{1,2} This study was approved by the Tohono O'odham Nation and the Institutional Review Board of the University of Arizona and conformed to the requirements of the United States Health Insurance Portability and Accountability Act.

Apparatus

Four toric reference surfaces³ with toricity of 1.00 D, 3.00 D, 5.00 D, and 7.00 D were used to evaluate accuracy. The shapes of the diamond-turned torics (ClearTran, West Paterson, NJ) were verified with contact profilometry.

The Infant Keratometer (IK4) (Figure 1) consists of a single-ring (200 mm diameter) keratoscope with 12 infrared light emitting diodes (LEDs) attached to a custom telecentric

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telephoto lens and Sony TRV460 digital camcorder (Sony Electronics Inc, Tokyo, Japan) that captures data on video. The working distance is approximately 11.5 cm from the child's eye. Video data are scored by custom software that automatically scans the video and analyzes each frame for corneal alignment and image motion and automatically discards low-quality images. Selected frames were also reviewed manually for quality. For each selected frame, the positions of the LED spots are fitted to an ellipse and scaled by a calibrated magnification factor to recover the keratometry values.

Calibration constants for the software were established by imaging 2 plano-convex lenses (radii, 6.19 mm and 8.25 mm). Keratometry values for each frame were transformed into J0 and J45 components,⁴ and the median J0 and J45 across frames for each subject represented the final keratometry measurement. Median J0 and J45 values were also transformed into standard clinical notation.

The Retinomax K-Plus 2 (Nikon, Inc., Melville, NY, now manufactured by Right Manufacturing Co, Tokyo) is a handheld conventional keratometer and autorefractor with a working distance of approximately 5 cm.

Procedures

To evaluate accuracy, the toric surfaces were mounted in a rotation stage, the IK4 was aligned to each surface to bring the reflected LED spots into sharp focus, and a video of the spot pattern was captured. The axis of each surface was rotated to 7 different orientations (30° steps), and 10 video frames of each surface/orientation condition were scored and averaged in vector notation.

To evaluate validity, IK4 images were obtained for each child's right eye. Children were asked to fixate on the center green light in the display, and then the tester aligned the reflected images of the LEDs around the child's pupil through the monitor of the IK4 camcorder, moved forward or backward until the reflected ring was in sharp focus, and recorded a video (15–30 seconds). Cycloplegic drops (0.5% proparacaine, 2 drops 1% cyclopentolate) were instilled and at least 40 minutes later a keratometry measurement of each child's right eye was obtained with the Retinomax K-Plus 2. A complete cycloplegic eye examination was also conducted.

Results

For accuracy assessment, the mean cylinder measured with the IK4 for the toric surfaces was 1.19 D (standard deviation [SD], 0.27) for the 1.00 D toric, 2.81 D (SD, 0.09) for the 3.00 D toric, 4.86 D (SD, 0.36) for the 5.00 D toric, and 6.75 D (SD, 0.35) for the 7.00 D toric.

Data from 63 children were excluded from validity analyses (31 due to experimenter error, 11 refused dilation, 21 had ocular abnormalities). The mean age of the remaining 860 children was 4.8 years (SD = 1.3, n = 311 (age 3), 235 (age 4), 112 (age 5), 141 (age 6), 61 (age 7). IK4 measurement success rate was 97.9% (842/860 [96 (age 3), 98 (age 4), 99 (ages 5 and 6), and 100% (age 7)]; mean scoreable frames per subject, 55; SD, 42; range, 1–213). The Retinomax measurement success rate was 99.3% (854/860) children, with 837 children providing both IK4 and Retinomax data.

There were small but significant differences between mean IK4 and Retinomax measurements of J0 and J45 (IK4 – Retinomax = –0.11 D (SD, 0.25, 95% prediction limits –0.60 to 0.37) for J0, 0.12 D (SD 0.36, 95% prediction limits –0.58 to 0.83) for J45, and

-0.11 D (SD 0.49, 95% prediction limits -1.07 to 0.86) for astigmatism in clinical notation ($P < 0.001$). Data are plotted in Figure 2.⁵

IK4 and Retinomax corneal astigmatism measurements differed by <0.50 D in 93.3% of subjects for J0 and 83.9% of subjects for J45 (note: in vector notation, 0.50 D of astigmatism is equivalent to 1.00 D of astigmatism in clinical notation [eg, 0.50 D J0 = 1.00 D $\times$ 90 in clinical notation]). Over 95% measurements from the IK4 differed <1.00 D from Retinomax measurements in clinical notation.

Discussion

Measurement of toric surfaces indicated that the IK4 is accurate to 0.25 D. Validity data showed slightly higher measurements of astigmatism with the Retinomax. Variability between the 2 instruments may be related to differences in (1) dilation (only Retinomax measurements were obtained under dilation), (2) the size of the corneal measurement area, or (3) limits on measurement accuracy of either instrument. Measurement success rates for both instruments were high ($>98\%$).

Several design features of the IK4 make it promising for use in measuring corneal astigmatism in children younger than age 3 years: (1) continuous recording of keratoscopic video images increases the chance of capturing a few in-focus and centered frames, (2) it has a greater working distance than the Retinomax, and (3) the tester can view the eye on an instrument monitor (rather than through a view-finder), which allows the tester to interact with the child and follow the child's movements when aligning the instrument.

The results of the present study indicate that the IK4 is suitable for use in the study of astigmatism in early childhood. It may also be clinically useful for screening children as young as 3 years of age who are at high risk for corneal astigmatism.

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FIG 1.
The child's view (A) and a side view (B) of the IK4.

FIG 2. Bland-Altman⁵ plot for right eye IK4 vs Retinomax measurements of J0 (A), J45 (B), and cylinder in clinical notation (C). X-axis is mean of IK4 and Retinomax, y-axis is difference between IK4 and Retinomax measurements, and dashed lines are mean and have a 95% prediction interval.