A comparison of plusoptiX A12 measurements with cycloplegic refraction

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PURPOSE To test the accuracy and reliability of the plusoptiX A12 in detecting amblyogenic risk factors.

METHODS We prospectively collected data on children undergoing screening with the plusoptiX A12, cycloplegic refraction, and complete ophthalmic examination. American Association for Pediatric Ophthalmology and Strabismus (AAPOS) 2013 guidelines for the detection of amblyogenic risk factors were used for plusoptiX A12 screening and comparison of the results of both examination modes.

RESULTS Data on 402 eyes of 201 children (mean age, 7.63 ± 3.41 years) was collected. Mean (with standard deviation) cycloplegic refraction results were as follows: sphere, 0.88 ± 1.5 D; cylinder, −0.61 ± 0.74 D; axis, 71.17 ± 71.04; and spherical equivalent, 0.68 ± 2.63. The plusoptiX A12 measurements were as follows: sphere, 0.58 ± 1.4 D; cylinder, −0.66 ± 0.77 D; axis, 77.3 ± 68.9; and spherical equivalent, 0.25 ± 1.3. We found a strong correlation (Pearson) for sphere (r = 0.91), cylinder (r = 0.81), and axis (r = 0.7). The mean difference of the myopic spherical component between the plusoptiX and cycloplegic refraction was −0.048 ± 0.55 (95% LoA, +1.04 to −1.14 D); for the hyperopic spherical component, 0.37 ± 0.93 (LoA, +2.20 to −1.45 D); and for the cylindrical component, 0.05 ± 0.32 (LoA, +0.68 to −0.57D). The sensitivity, specificity, positive and negative predictive values for myopia were, respectively, 86%, 93%, 82%, and 94%; for astigmatism, 85%, 98%, 88% and 98%; and for hyperopia, 40%, 100%, 100%, and 98%.

CONCLUSIONS The plusoptiX A12 accuracy is high in all subgroups but better in the myopic, astigmatic, and anisometropic subgroups. Reliability was lower in the hyperopic eyes, possibly resulting in underestimation of hyperopic refractive error. (J AAPOS 2016;20:310-314)

Amblyopia affects 1.6%-3.6% of the population.[1-4] According to several studies, screening for amblyopia and amblyogenic risk factors in children, followed by appropriate treatment, is effective in reducing the prevalence and severity of visual impairment in adults.[3-6] The American Academy of Pediatrics, the American Association for Pediatric Ophthalmology and Strabismus (AAPOS), and the American Academy of Ophthalmology recommend vision evaluation from birth.[5] In the past, vision screening incorporated traditional visual acuity tests with several shortcomings such as the need for a cooperative child, the results depending on the skills and experience of the examiner, and examinations that were time consuming.[6] Newer vision screening technologies—photoscreeners, autorefractors, and visual evoked potential–based systems—have been evaluated for their effectiveness in screening for amblyogenic risk factors. In order to compare data from various screening methods the Vision Screening Committee of AAPOS introduced referral criteria for automated preschool vision screening of amblyopia in 2003, which were updated in 2013.[6-10]

Many vision screeners have been found to be effective in referring children with risk factors for appropriate care. This study examined the newest autorefractometer, the plusoptiX A12 (Plusoptix Inc, Atlanta, GA), which measures refractive data, pupil size, pupil distance, and gaze deviation in real time and noninvasively.[8-10] The plusoptiX mobile autorefractor provides simultaneous examination of both eyes accurately and quickly with user-friendly and portable technology.[8]

Because of the large working distance of 1 meter. the plusoptiX is suitable for examining children and disabled patients. Earlier versions of the plusoptiX have demonstrated high accuracy (plusoptiX S08)[9] and high sensitivity in detecting amblyogenic risk factors (plusoptiX S04,[8] plusoptiX S08).[11] The plusoptiX A09 has also been compared

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Submitted August 20, 2015.
Revision accepted April 11, 2016.
Published online July 13, 2016.

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1091-8531/$36.00
http://dx.doi.org/10.1016/j.jaapos.2016.04.006

favorably to the SureSight autorefractor.[12] The purpose of the present study was to examine the accuracy of plusoptiX A12 as an autorefractor and to test its reliability in detecting amblyopic risk factors using AAPOS 2013 criteria.

Methods

This study was approved by the Chaim Sheba Medical Ethical Committee and followed the tenets of the Declaration of Helsinki. Data was collected prospectively during the plusoptiX A12 mobile autorefractor screening of children examined at the Pediatric Ophthalmology Clinic, Chaim Sheba Medical Center, a tertiary care medical center. All children underwent screening with the PlusoptiX A12 Mobile mobile autorefractor, both eyes are measured simultaneously from 1 meter away while the child fixates on the image of "a smiling face." The pupils were then dilated with mydriacyl and phenylephrine 2.5% once and then cyclopentolate 1% instilled 3 times at 20 minutes intervals; cycloretinoscopy was performed 20 minutes following the final instillation in addition to a complete ophthalmic examination. Exclusion criteria were uncooperativeness and refraction beyond the autorefractor limits.

We used the AAPOS updated guidelines for the detection of amblyogenic risk factors and compared the detection results of both examination modes.[7]

Statistical Analysis

Results were obtained from both patients' eyes. Refractive data was analyzed in negative cylindrical form and the spherical components. We used the paired *t* test, Pearson's correlation analysis, and Bland-Altman limits of agreement[13] to assess the agreement between the cycloplegic refraction and the plusoptiX A12. Agreement was evaluated by calculation of the mean of the differences between the techniques and the 95% limits of agreement. To assess how the plusoptiX A12 would perform in screening for the detection of amblyogenic risk factors, sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were determined according to the AAPOS criteria.[6,7] Statistical significance was defined as $P < 0.05$.

Results

We collected data on 402 eyes of 201 children (mean age, 7.63 ± 3.41 years; range, 1-17 years). Hyperopia was found in 286 eyes (71%), of which 24 eyes (8.4%) had hyperopia of >3.5 D. Myopia was found in 75 eyes (9%), of which 33 (44%) eyes had myopia >1.5 D. Emmetropia was found in 41 eyes (10%). Astigmatism was found in 56 eyes (14%), of which 56 eyes (100%) had more than 1.5 D of astigmatism. We divided the data into two subgroups in order to examine the accuracy of the plusoptiX separately: myopia, defined as sphere <0, and hyperopia, defined as sphere ≥0.

Table 1 describes the mean refractive components and standard deviation for cycloplegic refraction and plusoptiX A12 for all 402 eyes. Table 2 compares the both statistically. We found a significant difference for sphere, cylinder, axis, and spherical equivalent, although there is no difference in clinical implication between the tests. There was a strong correlation for sphere, cylinder, and axis.

Table 1. Cycloplegic refraction versus plusoptiX A12: refraction

Refractive component	Cycloplegic refraction, mean ± SD	plusoptiX A12, mean ± SD
Sphere	0.88 ± 1.5	0.58 ± 1.4
Cylinder	−0.61 ± 0.74	−0.66 ± 0.77
Axis	71.17 ± 71.04	77.12 ± 68.92
Spherical equivalent	0.68 ± 2.63	0.25 ± 1.31

SD, standard deviation.

Table 2. Cycloplegic retinoscopy versus plusoptiX A12 (N = 402)

Refractive component	Sphere	Cylinder	Axis
Difference, mean ± SD	0.29 ± 0.89	0.06 ± 0.33	−6.1 ± 38.18
P value (*t* test)	<0.001	<0.001	0.02
Pearson correlation (*R*)	0.81	0.91	0.7

SD, standard deviation.

Table 3. Cycloplegic retinoscopy versus plusoptiX A12: myopic, hyperopic, and astigmatic groups

Subgroup	Myopic spherical component	Hyperopic spherical component	Cylindrical component (myopic and hyperopic)
Difference, mean ± SD	−0.048 ± 0.55	0.37 ± 0.93	0.05 ± 0.32
P value (*t* test)	>0.05[a]	<0.05[b] >0.05[c]	<0.05
Pearson correlation (*R*)	0.85	0.62	0.91

SD, standard deviation.
[a]Sphere, cylinder, and axis.
[b]Sphere and cylinder.
[c]Axis.

Table 3 shows measurements separately for each group (myopia, hyperopia). In comparing two instruments or clinical tests, validity is generally expressed in terms of its agreements.[14] In this study, the mean differences, the standard deviations, and the 95% limits of agreement (LoA) refer to the spherical components, divided into myopia and hyperopia groups. The cylinder (the common component) is calculated for both groups. The mean difference of the myopic spherical component, the hyperopic spherical component and the cylindrical component, between the plusoptiX A12 and cycloplegic refraction is shown in Table 3.

The 95% limits of agreement between the two methods of obtaining the myopic spherical component were +1.04 D to −1.14D; the hyperopic spherical component, +2.20 D to −1.45 D; for the cylindrical component, +0.68 D to −0.57 D; and for the spherical equivalent, 5.03 D to −4.16 D.

Figure 1 and Figure 2 show the mean bias (ie, mean difference) and the 95% limits of agreement for the myopic spherical component, the hyperopic spherical component, and the cylindrical component respectively.