Validity of the Spot Vision Screener in detecting vision disorders in children 6 months to 36 months of age

Gayathri Srinivasan, MS, OD, Diane Russo, OD, MPH, Christopher Taylor, BSc, PhD, Anthony Guarino, PhD, Paulette Tattersall, DipPharm, Msc, and Bruce Moore, OD

PURPOSE To evaluate the Spot Vision Screener in detecting targeted vision disorders compared to cycloplegic retinoscopy in children <3 years of age.

METHODS Children, ages 6 months to 36 months underwent vision screening using the Spot Vision Screener. Results were compared to results of comprehensive eye examinations. Validity of the Spot was evaluated by calculating the area under the curve (AUC); the receiver operating characteristics (ROC) were used to determine optimal sensitivity and specificity for detection of targeted vision disorders.

RESULTS A total of 249 children were included. The AUC for detecting targeted vision disorders as defined by the study specific criteria using the Spot was 0.790. Compared to cycloplegic retinoscopy, the Spot underestimated hyperopia by 1.02 D (95% CI, 0.86–1.17 D). For hyperopia ≥4.5 D spherical equivalent (n = 10), the mean difference between the Spot and cycloplegic retinoscopy was 3.46 D (95% CI, 1.95–4.98 D). In contrast, the Spot overestimated astigmatism compared to cycloplegic retinoscopy (−1.00 D vs −0.48 D; $P < 0.001$) by −0.52 D (95% CI, 0.43–0.62 D).

CONCLUSIONS The Spot Vision Screener showed good overall validity in detecting targeted vision disorders. It was within 0.5 D and 1 D of cycloplegic retinoscopy with regard to low hyperopia and astigmatism. Higher hyperopic spherical equivalent refractive errors showed larger differences in mean values between the Spot and cycloplegic retinoscopy. (J AAPOS 2019;23:278.e1-6)

Validity of vision screening in preschool children (4-6 years of age) and vision screening methods has been widely studied.[1-5] However, few studies have evaluated the efficacy of vision screening methods in children below 3 years of age. Instrument-based screening is recommended for children <3 years of age by the American Academy of Ophthalmology (AAO) and the American Academy of Pediatrics (AAP).[6] Instrument-based vision screening techniques use autorefraction or photorefraction to assess the refractive status of the eyes, which can then be compared to a normative database. Photorefraction uses a camera to capture images from both eyes simultaneously within a few seconds to screen for amblyogenic refractive errors.

The Spot Vision Screener (Welch Allyn, Skaneateles Falls, NY) is a handheld photorefractor that uses infrared technology to obtain (a) refractive error measurement, (b) ocular alignment, and (c) pupil sizes from both eyes simultaneously. It is presently marketed as a vision screener and an autorefractor. Its sensitivity has been reported to be 81.8%-89.8%; its specificity, 70.4%-88%.[7-11] The age range of the samples in these studies is between 6 months and 16 years and includes children from enriched populations. Of interest are 2 studies that evaluated the performance of the Spot in detecting hyperopia in young children. Peterseim and colleagues,[11] using two different photorefractors, found that the Spot underestimated hyperopia by 1.35 D compared with cycloplegic retinoscopy in a sample of high-risk children aged 1-16 years. Recently, Feldman and colleagues[12] reported that the sensitivity and specificity of the Spot in detecting hyperopia compared to cycloplegic retinoscopy in 2- to 12-year-olds increased with higher degrees of hyperopia in their enhanced population (sensitivity to detect > +2.50 D hyperopia and > +4.00 D hyperopia was 23.81% [95% CI, 8.22%-47.17%] and 33.33% [9.92-65.11%, 95% CI], resp.). The authors concluded that in their preliminary, small-scale study (n = 109), the Spot was "only marginally useful in detecting high hyperopia." The purpose of this study was to evaluate the validity of the Spot Vision Screener in detecting targeted vision disorders, with

Author affiliations: New England College of Optometry, Boston, Massachusetts
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Correspondence: Gayathri Srinivasan, MS, OD, 424 Beacon Street, Boston, MA 02115 (email: srinivasang@neco.edu).

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Table 1. 2013 AAPOS criteria for amblyogenic risk factors

Age, months	Hyperopia, D	Astigmatism, D	Myopia, D	Anisometropia, D
12-30	>4.5	>2.0	>−3.5	>2.5
31-48	>4.0	>2.0	>−3.0	>2.0
>48	>3.5	>1.5	>−1.5	>1.5
All ages	Manifest strabismus >8 PD Media opacity >1 mm			

AAPOS, American Academy of Pediatric Ophthalmology and Strabismus; *D*, diopters; *PD*, prism diopter.

particular attention to hyperopia, in children 6 months to 3 years of age recruited from a general population. Performance of the Spot was evaluated using receiver operating characteristics (ROC) in addition to sensitivity and specificity measures, because the ROC is more beneficial in assessing the performance of a screening test over a range of sensitivity and specificity values.[13] Evaluating the performance of commonly used vision screening tests recommended for use in children <3 years of age is an important step toward bridging the evidence gap in vision screening efficacy in this age group.[14]

Subjects and Methods

The Institutional Review Board at the New England College of Optometry approved the study, which conformed to the requirements of the US Health Insurance Portability and Accountability Act of 1996 and to the tenets of the Declaration of Helsinki. Children between the ages of 6 and 36 months from Early Head Start programs across Greater Boston were invited to participate in the study. Investigators traveled to participating sites and performed all study procedures on the New England College of Optometry On-Sight mobile vision clinic. The study coordinator, who was trained on the Spot Vision Screener version 2.1.4 (Welch Allyn, Skaneateles Falls, NY), performed the vision screenings and was unaware of the results of the comprehensive eye examination. The device screen displayed binocular refraction, ocular alignment, and pupillary diameter and made one of the following recommendations based on the built-in criteria: "All measurements in range" or "Complete eye exam recommended."

After the children underwent vision screening, 2 masked investigators performed standard comprehensive eye examinations (CEE), which consisted of assessment of fixation (using fix and follow), extraocular motility, pupillary evaluation, cover test at distance and near, ocular health evaluation, and cycloplegic retinoscopy. Cycloplegia was achieved using 2 drops of cyclopentolate hydrochloride 1% instilled 5 minutes apart, with retinoscopy performed 30-45 minutes after the last drop instillation. The results of the screening were then compared to cycloplegic retinoscopy that was performed either on the day of the screening or within 6 months prior to the screening. Parental informed consent was obtained prior to vision screening and eye examination. Parents signed release forms to obtain eye examination records if they were conducted elsewhere within the past 6 months.

Several studies in the past evaluating the efficacy of the Spot Vision Screener used the 2013 AAPOS Vision Screening Committee guidelines[15] to determine criteria for pass/fail for comprehensive eye examinations (Table 1). The current study evaluated the agreement of the Spot and cycloplegic retinoscopy based on two criteria: the AAPOS 2013 vision screening criteria for amblyogenic risk factors (ARFs) and a study-specific criteria for targeted vision disorders modified from the Vision in Preschoolers (VIP) study[1] (Table 2). Modifications include definitions of hyperopia (>4.50 in any meridian) and myopia (>2 D in any meridian), based on the population-based Multi-Ethnic Pediatric Eye Disease Study,[16] which showed that in children 6-35 months of age, the defined levels of hyperopia and myopia were found in the lower end of the 95% range.

Data Collection and Analysis

The following data were collected from each participant: age, sex, race/ethnicity, testability of the Spot (yes/no), results of the vision screening (pass/fail), and comprehensive eye examination, including strabismus evaluation and cycloplegic retinoscopy. Testability was defined as the ability to obtain measurements in one or both eyes after three consecutive attempts for each eye. Efficacy of the Spot was evaluated by calculating the area under the curve (AUC), whereas the ROC evaluated the performance of the device over a range of sensitivity and specificity values to determine optimal performance. All statistical analyses were calculated by SPSS version 25 (IBM, Chicago, IL).

Results

A total of 242 children participated in the study. Mean age (with standard deviation) was 23.7 ± 8.24 months (range, 6-36 months). The characteristics of children participating in the study are summarized in Table 3. Seventy-one children (30.86%) were receiving early intervention services. The types of vision disorders in this cohort and the

Table 2. Study specific criteria for targeted vision disorders

Vision disorders	Criteria[a]
Refractive error	
Hyperopia	>4.50 D in any meridian
Myopia	>2.00 D in any meridian
Astigmatism	>1.50 D between principal meridians
Anisometropia	
	1.50 D interocular difference in hyperopia
	3.00 D interocular difference in myopia
	1.50 D interocular difference in astigmatism
	Antimetropic difference 1.00 D and one eye 1.00 D of hyperopia
	Antimetropic difference 3.00 D and one eye 2.00 D of myopia
Strabismus	Any heterotropia in primary gaze
Media opacity	Any media opacity obscuring the visual axis

[a]Adapted from Vision In Preschoolers Study.[1]

Table 3. Descriptive characteristics of study participants

Characteristic	No. (%)
Age, months	
6-11	27 (11.1)
12-17	31 (12.8)
18-23	54 (22.3)
24-29	57 (23.5)
30-36	73 (30.1)
Mean ± SD	23.7 ± 8.24
Sex	
Female	105 (43.3)
Male	137 (56.6)
Ethnicity	
Hispanic or Latino	86 (35.5)
Not Hispanic or Latino	156 (64.4)
Race	
White	44 (18.1)
African American	35 (14.4)
Asian	5 (2)
Multiple/Other	97 (40)
Not available	61 (25.20)
Enrolled in early intervention	
Yes	71 (29.33)
No	171 (70.66)
Refractive error, D	
Hyperopia (more hyperopic eye)	
+1.00 to < +2.00	110 (52.88)
+2.00 to < +3.00	61 (29.32)
+3.00 to < +4.00	24 (11.53)
≥ +4.00	17 (8.01)
Hyperopia (less hyperopic eye)	
+1.00 to < +2.00	104 (54.45)
+2.00 to < +3.00	56 (28.86)
+3.00 to < +4.00	19 (9.94)
≥ +4.00	16 (8.24)
Myopia (more myopic eye)	
0.00 to < −1.00	8 (80)
−1.00 to < −2.00	2 (20)
−2.00 to ≤ −3.00	0
Myopia (less myopic eye)	
0.00 to < −1.00	15 (88.23)
−1.00 to < −2.00	2 (11.76)
−2.00 to ≤ −3.00	0
Astigmatism (more astigmatic eye)	
0.00 to < −1.00	193 (75.39)
−1.00 to < −2.00	46 (17.96)
−2.00 to ≤ −3.00	15 (5.85)
≤ −3.00 D	2 (0.78)
Astigmatism (less astigmatic eye)	
0.00 to < −1.00	204 (80.31)
−1.00 to < −2.00	36 (14.17)
−2.00 to ≤ −3.00	13 (5.11)
≤ −3.00 D	1 (0.39)
Anisometropia (SE)	
0.00 to <1.00	227 (97.84)
1.00 to <2.00	5 (2.15)
2.00 to ≤3.00	0

D, diopter; *SD*, standard deviation; *SE*, spherical equivalent.

Table 4. Prevalence of targeted vision disorders[a]

Vision disorders	No. (%)
Refractive error, D	
Hyperopia	
> +4.50 in any meridian	13 (5.6)
Myopia	
> −2.00 in any meridian	0
Astigmatism	
>1.50 difference between meridian	22 (9.5)
Anisometropia	
>1.50 for hyperopia	0
> −3.00 for myopia	0
> −1.50 for astigmatism	1 (0.43)
Strabismus	7 (3.0)

[a]Study specific criteria (see Table 2).

prevalence of targeted vision disorders are shown in Tables 3 and 4, respectively.

Testability of the Spot was positive in 230 children (94.2%), of whom the Spot referred 43 children (18.6%): 34 (14.7%) for refractive error, 3 (1.3%) were for strabismus, and 6 for refractive error and strabismus (2.6%). For the purposes of sensitivity and specificity analysis, data from the remaining 12 children (5 of the 12 children were enrolled in early intervention) who were untestable using the device, were categorized as fail, because a VIP study[17] found that preschool children who were untestable using VIP screening tests were more likely to have vision problems than children who passed the tests. The sensitivity and specificity of the device to detect targeted vision disorders using the study specific criteria was 66.7% (95% CI, 49.7%-80.4%) and 84.8% (95% CI, 79.1%-89.3%,), respectively. The sensitivity and specificity of the device to detect ARFs using the 2013 AAPOS criteria in children 12-36 months of age (n = 215) was 78.3% (95% CI, 55.8%-91.7%) and 84.5% (95% CI, 78.4%-89.1%), respectively (Table 5). Data from the remaining 27 children ages 6-11 months were excluded from sensitivity and specificity analysis using the 2013 AAPOS criteria, because it is established for children ages 12 months and above.

ROC Analysis

The ROC curve for detecting targeted vision disorders using the study specific criteria is shown in Figure 1. AUC was 0.790 (95% CI, 0.70%-0.88). An AUC of >0.9 is considered excellent; 0.8-0.9, very good; 0.7-0.8, good; 0.6-0.7, average; and <0.6, poor.[18] Kappa analysis was conducted to test the agreement of results (pass/fail) between those of the CEE using the 2013 AAPOS criteria (Table 1) and Spot Vision Screener, yielding a coefficient of 0.459, or fair to moderate agreement. Similar analysis for the CEE results using the study specific criteria yielded a κ of 0.46, or fair to moderate agreement. A Fisher r to z transformation indicated no statistically significant difference between the κ values.

Table 5. Sensitivity and Specificity of the Spot Vision Screener

Criteria	Sensitivity (95% CI)	Specificity (95% CI)
Study specific criteria	66.7% (49.7-80.4)	84.8% (79.1-89.3)
2013 AAPOS criteria	78.3% (55.8-91.7)	84.5% (78.4-89.1)

CI, confidence interval.

Agreement of Refractive Error Between the Spot and Cycloplegic Retinoscopy

Given that hyperopia and astigmatism were the most prevalent targeted disorders found in this cohort (Table 4), we evaluated the level of agreement in detecting hyperopia (spherical equivalent calculated using sphere + [cylinder/2]) and astigmatism between the Spot (prior to cycloplegia) and cycloplegic retinoscopy (Table 6). As expected, the Spot underestimated hyperopia compared to cycloplegic retinoscopy (0.92 vs 1.94; $P < 0.001$), with a mean difference of 1.02 D (95% CI, 0.86-1.17. See eSupplement 1. This underestimation was more pronounced in children with spherical equivalent of ≥4.5 D ([n = 10], 2.23 D vs 5.69 D; $P = 0.001$), showing a mean difference of 3.46 D (95% CI, 1.95-4.98). In contrast, the Spot overestimated astigmatism compared to cycloplegic retinoscopy (−1.00 vs −0.48; $P < 0.001$), with a mean difference of −0.52 D (95% CI, 0.43-0.62). Of the 13 subjects with hyperopia on CEE (>4.50 D in any meridian; See eSupplement 1), 4 subjects were referred by the Spot for hyperopia, and 5 were referred for other reasons (astigmatism, gaze, anisometropia).

Discussion

In this study, the sensitivity of the Spot to detect ARFs using the AAPOS 2013 guidelines in children 12-36 months of age was 78.3%; the specificity, 84.5%. Using study-specific criteria in detecting targeted vision disorders in children 6-36 months of age, the sensitivity was 66.7% and the specificity was 84.8%. An analysis of level of agreement between the AAPOS criteria and the study-specific criteria for subjects in the 12- to 36-months age range yielded no significant difference. The AUC for detecting targeted vision disorders was 0.790 (95% CI, 0.70-0.88). The testability of the device was 94.3%.

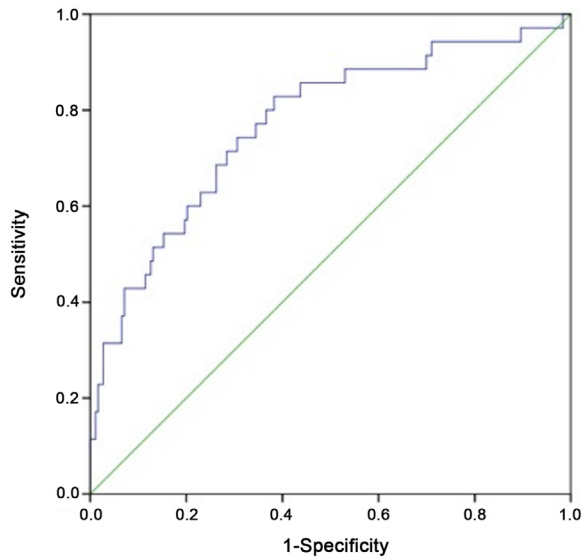

FIG 1. Receiver operating characteristics for detection of amblyogenic risk factors.

Since its introduction in 2011, the validity of the Spot has been studied[7-11] in children 6 months to 12 years of age. Peterseim and colleagues[8] evaluated the effectiveness of the Spot Vision Screener in a cohort of 444 children (mean age, 72 months; range, 12-221 months) and reported that the sensitivity and specificity of the Spot in the 12- to 30-months group were 81.8% and 56.7%, respectively, whereas in the 31- to 48-months group, the sensitivity and specificity were 82% and 76.2%, respectively. Recently, Forcina and colleagues[10] studied the validity of the Spot Vision Screener in 184 children (age range, 6-36 months) and reported that the overall sensitivity and specificity for detection of ARFs was 89.8% and 70.4%, respectively. Both of these studies used the 2013 guidelines from the AAPOS Vision Screening Committee.[15] In general, the higher sensitivity and lower specificity reported by the previous studies in comparison to the current study (with the study-specific criteria and the AAPOS criteria) is likely due to the inclusion of an enriched sample of wider age ranges.

To our knowledge, this is the first study to report ROC analysis of the Spot in this age group. We found good AUC (0.790) for detection of vision disorders in this young cohort. Using a different definition of targeted vision disorders, the VIP study[19] evaluated the accuracy of the Retinomax and SureSight autorefractors using ROC analysis and found very good AUCs of 0.87 and 0.84, respectively, in 3-year-olds (n = 885).

We found an overall underestimation of spherical equivalent refractive error by the Spot (1.02 D) compared with cycloplegic retinoscopy, with a higher level of underestimation for SE of ≥4.5 D (3.46 ± 2.12 D). Photorefractors are meant to be used before cycloplegia in a screening setting and are therefore probably susceptible to variability in accommodation, particularly when used in young children. Peterseim and colleagues[11] reported that the Spot underestimated hyperopia by 1.35 D compared with cycloplegic retinoscopy in a cohort of high-risk children 1-16 years of age. Although their subjects included children with developmental delay and Down syndrome, a population with known accommodative dysfunction,[20] the Plusoptix (Plusoptix Inc, Atlanta, GA) photoscreener underestimated hyperopia by a smaller amount (0.64 D) compared to cycloplegic retinoscopy in that same study.

The underestimation we observed in our small subsample of children with moderate hyperopic refractive error (n = 10) could have clinical implications: infants[21] and preschoolers[22] with moderate hyperopia have larger

Table 6. Level of agreement between Spot Vision Screener and cycloplegic retinoscopy

	No. children	Spot, mean ± SD	CR, mean ± SD	Mean difference ± SD	*P* value	95% CI
Sphere, D	230	0.92 ± 0.99	1.94 ± 1.32	1.02 ± 1.19	<0.001	0.86-1.17
Cylinder, D	230	−1.00 ± 0.80	−0.48 ± 0.67	−0.52 ± 0.73	<0.001	0.43-0.62
SE ≥ 4.5 D	10	2.23 ± 2.57	5.69 ± 0.89	3.46 ± 2.12	0.001	1.95-4.98

CI, confidence interval; *CR*, cycloplegic retinoscopy; *D*, diopter; *SD*, standard deviation; *SE*, spherical equivalent.

accommodative lags. The increased accommodative effort from uncorrected hyperopia, and consequently the risk of esotropia,[23] have been previously reported. Atkinson and colleagues[24] reported that hyperopic infants (≥+3.50 in any axis) identified at 9 months of age continued to show deficits in visuocognitive and visuomotor abilities until 5.5 years of age compared to controls. Additionally, the recent Vision in Preschoolers – Hyperopia in Preschoolers (VIP-HIP) study showed that uncorrected hyperopia of ≥4.0 D in preschoolers is associated with poor literacy skills[25] and reduced visual function,[26] making this group of children important to detect in any screening program.

Given the association between accommodative lag and moderate hyperopia in preschool and school-age children, and reduced visual function in moderate hyperopia in preschoolers, a vision screening device that could measure accommodation and is compatible for use in this young cohort could facilitate early detection of significant hyperopia. Regardless, because any screening technique can produce false negative results, it is important to remember that parents/caregivers who have concerns regarding a child's vision should be recommended to receive a comprehensive eye examination.

Literature Search

PubMed was searched on September 3, 2019, without language or date restriction using the following terms *Spot Vision Screener*, *ROC curve*, and *0-3 years*.

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