Evaluation of the Spot Vision Screener for children with limited access to ocular health care

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PURPOSE To compare the sensitivity, specificity, and referral rate of the Spot Vision Screener (Welch Allyn Inc, Skaneateles Falls, NY) with the gold standard cycloplegic measurements acquired using the Retinomax in a population of underprivileged children and teenagers with limited access to medical care.

METHODS Children were recruited for the study by social workers in the vicinity of Robert Debre Hospital, Paris, France. Refractive errors (hyperopia of ≥ +2.00 D spherical equivalent [SE]; myopia of ≤ −0.50 D SE; astigmatism of ≥1.00 D between the two main meridians; anisometropia of ≥1.00 D SE difference between eyes) were assessed using the Spot Vision Screener and the Retinomax. Sensitivity (true positive rate), specificity (true negative rate), and referral rate of this Spot Vision screening program were evaluated.

RESULTS A total of 82 eyes of 41 subjects (19 males) were included; mean age was 126 months of age (range, 48-246). The sensitivity of the Spot Vision Screener for the detection of refractive errors was 82.35%; specificity was 91.67%. The sensitivity of the Spot Vision Screener to detect hyperopia, myopia, astigmatism, and anisometropia was 27.27%, 84.61%, 78.57%, and 66.67%, respectively. Its specificity to detect hyperopia, myopia, astigmatism, and anisometropia was 100%, 98.55%, 89.71% and 94.29%, respectively.

CONCLUSIONS The specificity of the Spot Vision Screener to detect refractive errors was found to be relatively high (>90%). However, its low sensitivity for hyperopia seems to remain a major limitation of the device, because hyperopia is particularly important to detect in children given its high prevalence and possible adverse consequences. Global programs using cycloplegic measurements should be considered an alternative. (J AAPOS 2019;23:153.e1-5)

The prevalence of refractive errors in children is as high as 50%.[1] Uncorrected refractive errors are a major cause of visual impairment and must be screened[2-4]; moreover, they represent the second most common cause of blindness worldwide.[5] In 2011 the World Health Organization estimated that 284 million individuals, mostly living in countries with limited access to ocular healthcare, were visually impaired and that 43% of them had uncorrected refractive errors.[6] Early and systematic visual screening is necessary in children to prevent amblyopia during the critical period of visual development.[7,8] After the end of this sensitive period, screening remains important, because uncorrected refractive errors can impair school performance: uncorrected refractive errors can lead to low vision,[9] and hyperopia itself can be associated with significantly worse performance in tests of early literacy, even with normal visual acuity, in preschoolers[10] as well as in school-age children.[11] Screening can be performed by direct measurement of visual acuity in verbal children. However, it can be challenging in cases of language barriers, moderate cooperation, or mental retardation. Moreover, visual acuity can be "normal" even in cases of significant ametropia, and especially in case of hyperopia. Indeed, Fotouhi and colleagues[12] reported that more than 10% of children with a visual acuity of ≥20/20 were hyperopic. Uncorrected refractive errors can be responsible for symptoms such as asthenopia.[13] However, most children do not complain of their vision or of visual fatigue.[14]

Today, refraction under cycloplegia using autorefractometers is the gold standard for the detection of refractive errors, but it requires the use of eyedrops. In France, paramedical staff is not legally allowed to use such eyedrops without a doctor's prescription, which makes cycloplegic refraction both costly and time consuming. This legal constraint also limits the dissemination of cycloplegic screenings of ametropia. For these reasons, automated noncycloplegic photoscreeners such as the Spot Vision Screener (Welch Allyn Inc, Skaneateles Falls, NY) have

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been developed over the last decade. When a photoscreener is used, a positive result leads to medical referral, and complete examination, including cycloplegic refraction, is performed to confirm the ametropia. Photoscreeners are recommended by the American Association of Pediatric Ophthalmology and Strabismus (AAPOS) for the screening of amblyopia risk factors in children aged 6 months to 3 years and as an alternative to visual acuity screening with vision charts in children aged 3-5 years.[15]

The Spot Vision Screener has been previously evaluated in preschool children referred to hospitals.[16,17] The purpose of this study was to evaluate the accuracy of the Spot Vision Screener for the screening of refractive errors in children and teenagers with limited access to medical care during a dedicated day. Sensitivity, specificity, and overall referral rate of the Spot Vision Screener were assessed in comparison with cycloplegic autorefraction using the Retinomax K+3 (Luneau, Luneau SAS 1, Prunay le Gillon, France).

Subjects and Methods

The study was approved by the Legal and Ethics Committee of Assistance Publique Hôpitaux de Paris, France. Children ≥ 4 years of age with poor access to medical care were referred to Robert Debré University Hospital, Paris, for refractive error screening during a full-day dedicated session. Consecutive and nonselected asymptomatic children were recruited by social workers in the vicinity of the hospital. The purpose of this screening campaign was to diagnose refractive errors and provide glasses when deemed necessary.

The same orthoptist (GB) performed noncycloplegic refraction measurements using the Spot photoscreener in all patients. In addition, in the absence of contraindications, cycloplegic refraction using the Retinomax K+3 autorefractometer was independently evaluated by an ophthalmologist 45 minutes after the last instillation of cyclopentolate (total of 3 instillations per eye every 5 minutes). Slit-lamp and fundus examinations were systematically performed in all cases. Glasses were prescribed when deemed necessary by the physician. Complete ophthalmological assessment was advised in case of strabismus or any other eye abnormality.

The Spot Vision Screener is a handheld automated photoscreener. From a distance of 1 meter, this device measures spherical and cylindrical errors, ocular alignment, and interpupillary distance. It detects spherical errors, according to the manufacturer, from −7.50 to +7.50 D, and cylindrical errors up to 3.5 D. The Retinomax K+3 is a handheld refractor that provides sphere, cylinder, and keratometric measurements of each eye separately from a distance of 5–10 cm. According to the manufacturer, it can detect spherical error from −18 D to + 23 D and cylindrical errors up to 12 D.

Refraction results from the Spot Vision Screener and the Retinomax (under cycloplegia) were compared. Cycloplegic autorefraction using the Retinomax was considered the gold standard. The following refractive errors were detected: hyperopia, myopia, astigmatism, and anisometropia. Considering the age of our population (≥4 years), diagnostic thresholds of clinically significant ametropia were chosen as follows:

- Hyperopia: ≥ +2.00 D spherical equivalent (SE)
- Myopia: ≤ −0.50 D SE
- Astigmatism: ≥1.00 D difference between the two main meridians
- Anisometropia: ≥1.00 D SE difference between eyes

Refraction values were considered abnormal when cycloplegic autorefraction results using the Retinomax were beyond these thresholds. The sensitivity (true positive rate) and specificity (true negative rate) of the Spot Vision Screener to detect refractive errors were calculated based on the comparison with the cycloplegic measures. The number of referrals was assessed.

True positives are patients with measurements above the thresholds with both devices, and true negatives are those with measurements below the thresholds with both devices. False positives are the patients with measurements above the thresholds with the Spot Vision Screener but below with the Retinomax K+3, and false negatives are the patients with measurements below the thresholds with the Spot Vision Screener but above with Retinomax K+3.

A Bland-Altman plot was used to depict the concordance between both devices.

Table 1. Description of the study population

Number of subjects (male/female)	41 (19/22)
Mean age, months (range)	126 (48-246)
Median age, months	120
Mean SE, Spot Vision Screener, D (range)[a]	−0.22 (−7.75 to +3.50)
Mean SE, Retinomax, D (range)	0.05 (−17.25 to +4.00)

D, diopter; *SE*, spherical equivalent.
[a]SE can be above or below the apparatus limits of ±7.00 D because astigmatism was assessed negative in negative diopters.

Results

A total of 82 eyes of 41 subjects (19 males) were examined. The mean age at inclusion was 126 months (range, 48-246 months). The mean SE was −0.22 ± 1.88 D with the Spot Vision Screener and +0.05 ± 3.07 D with the Retinomax K+3 (Table 1). On clinical examination, 1 child was found to have an abnormal fundus corresponding to the presence of peripheral pigment abnormalities, and 3 children had strabismus ($>10^{\Delta}$).

Using the previously described thresholds, ametropia was detected in 34 eyes of 17 children with cycloplegic autorefraction, which corresponds to a rate of refractive errors of 41.46%. Of these 17 children, the Spot Vision Screener categorized 14 children above one of the thresholds (true positives), which corresponds to a sensitivity of 82.35%. On the other hand, of the 24 patients who were not found to have refractive errors on cycloplegia, it detected 22 presumably emmetropic patients, corresponding

Table 2. Sensitivity and specificity of Spot Vision Screener for refractive error detection

	Detected with Spot Vision Screener	Diagnosed by Retinomax	TP	FP	TN	FN	Sensitivity (TP/TP+FN), %	Specificity (TN/TN+FP), %
Refractive errors overall	16	17	14	2	22	3	82.35	91.67
Hyperopia	3	11	3	0	71	8	27.27	100
Myopia	12	13	11	1	68	2	84.61	98.55
Astigmatism	18	14	11	7	61	3	78.57	89.71
Anisometropia	6	6	4	2	33	2	66.67	94.29

FN, false negatives; *FP*, false positives; *TN*, true negatives; *TP*, true positives.

to a specificity of 91.67%. Overall, the Spot Vision Screener detected ametropia in 16 children, leading to a 39.02% referral rate. Of these 16 children, 2 did not show any significant refractive error on cycloplegic measurements (false positives). On the other hand, 3 children with proven refractive errors were not detected by the Spot Vision Screener (false negatives). Further, of the 14 true positives, 1 patient was referred by the Spot Vision Screener for astigmatism when the correct diagnosis was anisometropia. In another case, the it detected bilateral myopic astigmatism when the correct refraction was bilateral hyperopia without astigmatism.

The analysis of each refractive error showed the following results (Table 2). The Spot Vision Screener detected 3 eyes above hyperopia thresholds. Compared to the cycloplegic autorefraction, which detected 11 hyperopic eyes, the sensitivity of the Spot Vision was 27.27% (3/11) and its specificity was 100%. The Spot Vision detected 12 eyes above myopia thresholds, including 1 false positive. Compared to the cycloplegic autorefraction, which categorized 13 eyes as myopic, the sensitivity of the Spot Vision was 84.61% (11/13); its specificity was 98.55%. The Spot detected 18 eyes above astigmatism thresholds, including 7 false positives. Compared to the cycloplegic autorefraction, which diagnosed 14 eyes with astigmatism, the sensitivity of the Spot was 78.57% (11/14); its specificity was 89.71%. The Spot detected spherical anisometropia in 6 children, including 2 false positives. Compared to the cycloplegic autorefraction, which assessed 6 children with anisometropia, the sensitivity of the Spot Vision was 66.67% (4/6); its specificity was 94.29%.

Bland Altman analysis showed a mean of the differences of spherical equivalents of 0.29 (−2.84; +3.43) between the Retinomax and the Spot Vision Screener (Figure 1). The differences between devices appear to be greater for hyperopia than for myopia. The plots representing the correspondence between the spherical equivalents measured with the Retinomax and the Spot Vision (for hyperopia, myopia, and astigmatism) are shown in Figure 2.

Figure 2A shows that the number of false negatives is higher than the number of true positives for hyperopia (low sensitivity), whereas it is the opposite for myopia. Figure 2B shows that the number of true positives is higher than the number of false negatives for astigmatism.

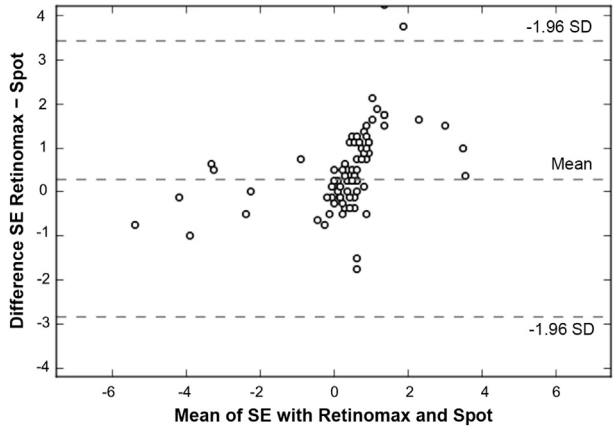

FIG 1. Bland Altman Plot for SE with Retinomax and Spot Vision Screener. *SD*, standard deviation; *SE*, spherical equivalent.

Discussion

Early treatment of refractive errors is advised to avoid visual complications; for instance, hyperopia needs to be treated correctly to avoid esophoria and esotropia,[18] and early detection of myopia can halt its evolution.[19,20] Detection and correction of refractive errors is also important to avoid amblyopia in young children during the critical period of visual development. In our study, the sensitivity of the Spot Vision Screener to detect refractive errors was found to be 82.35%; the specificity, 91.67%. These values are similar to previously published data: 80% and 74% in Silbert and Matta[16] (children 1-6 years); 89% and 71% in Garry and Donahue[17] (children 24 months to 9 years [mean, 5.16 years]); 87.7% and 75.9% in Peterseim and colleagues[3] (children 11-221 months [mean, 72 months]). It should be noted that these studies used the 2013 AAPOS criteria in younger populations than in the present study.

The sensitivity of the Spot Vision Screener to detect hyperopia, myopia, astigmatism, and anisometropia was 27.27%, 84.61%, 78.57%, and 66.67%, respectively. The sensitivity of the Spot Vision Screener to detect myopia was high (>80%), in accordance with previously published data. On the other hand, its detection of hyperopia, astigmatism, and spherical anisometropia was low (<80%), leading to a high rate of false negatives. The most interesting and novel finding of this report is related to

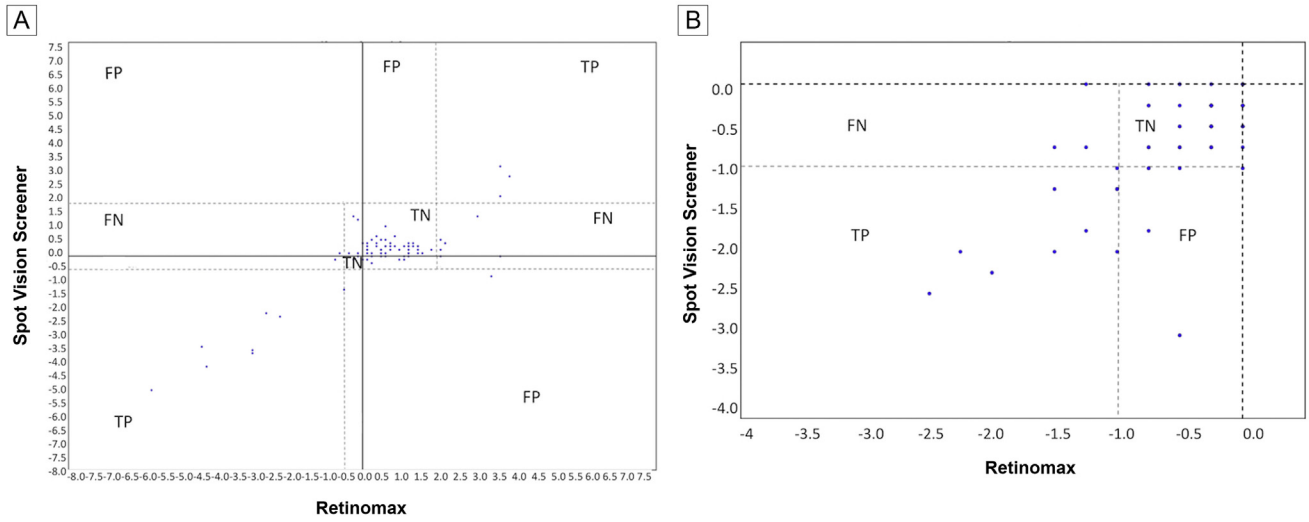

FIG 2. Retinomax K+3 measurements vs Spot Vision Screener measurements. A, Plot of spherical equivalent. B, Astigmatism. *FN*, false negatives; *FP*, false positives; *TN*, true negatives; *TP*, true positives.

hyperopia. The sensitivity for hyperopia was found to be as low as 27.27%. One of the possible reasons for this finding could be the fact that accommodation might remain significant without cycloplegia, even with distant noncontact devices such as the Spot Vision Screener. Another possible explanation could be the intrinsic technical weakness of the Spot Vision Screener for the detection of hyperopia. This constitutes one of the main limitations of this device in screening for refractive errors, which are the main amblyopia risk factors.

Sensitivity of any screening program must be high enough to avoid as many false negatives as possible. A positive screening does not necessarily result in glasses prescription; it does, however, encourage the clinician to adopt a more cautious approach, particularly if symptoms are present during the follow-up.

Our study showed that the specificity of the Spot Vision Screener to detect hyperopia, myopia, astigmatism, and anisometropia was 100%, 98.55%, 89.71%, and 94.29%, respectively, which is acceptable (>90% except for astigmatism, although very close).

The referral rate of this Spot Vision screening program was 39.02%, which is only slightly below the rate of refractive errors in the studied population (41.46%). The patients in this study were older overall than in other studies, which makes any comparison regarding the referral rate difficult to interpret. The mean age in our study was 126 months (48-246 months) compared to 5.16 years (24 months to 9 years) in the studies of Garry and Donahue[17] (referral rate, 70.32%) and 1-6 years in Silbert and Matta[16] (referral rate, 64.24%). The rate of referrals in refraction studies depends not only on the prevalence of ametropia but also on the refractive thresholds. In 2013 the AAPOS defined the thresholds for amblyopia risk factors above which the patients screened with noncycloplegic refractometers should be referred for cycloplegic refractometry. These thresholds are designed to increase the specificity (true negative rate), and therefore avoid false positives (Table 3).

We did not use the AAPOS 2013 criteria for automated preschool vision screening; rather, we chose a hyperopia threshold of +2.00 D (instead of +3.50 D), a myopia threshold of −0.50 D (instead of −1.50 D), and astigmatism and anisometropia thresholds of 1.00 D (instead of 1.50 D). Because we studied a population of school-age children, we chose thresholds corresponding to those we use in our clinical practice for the prescription of glasses. In theory, these chosen thresholds should have increased the number of positive detections, in turn increasing the referral rate.

We believe that the thresholds we chose were appropriate in this real-life setting, which included both consecutive and nonselected subjects. The thresholds also correspond to the age of our population; we believe that even if a hyperopia of +2 D does not require glasses in a 4-year-old without any ophthalmological pathology, it must be considered in a teenager, because it can impair his or her school performance.[21]

There are limitations to this study that must be highlighted. First, the power of this study could be increased with a larger sample. However, it is noteworthy that this study mimics a real-life setting corresponding to a single-day screening program of consecutive and nonselected patients. Second, this series included patients of various ages (young subjects with amblyopia risk factors and older subjects beyond the end of the critical period), which might have induced some degree of heterogeneity. However, the primary purpose was to assess refractive errors regardless of age, from kindergarten, where such errors already lead to low vision and amblyopia, to high school and university.[2,4,9] Also, the combination of visual acuity and refraction measurements could have increased the accuracy of visual impairment

Table 3. 2013 AAPOS Vision Screening Committee amblyopia risk factor criteria[13]

Age, months	Anisometropia, D	Hyperopia, D	Astigmatism, D	Myopia, D
12-30	>2.5	>4.5	>2.0	> −3.5
31-48	>2.0	>4.0	>2.0	> −3.0
>48	>1.5	>3.5	>1.5	> −1.5

detection.[22] However, we chose to focus only on refractive errors because measures of visual acuity would have been less reliable because of the marked language barrier in our population. Another limitation is that this study did not include children with > +4 D of hyperopia, which limits our conclusions regarding high hyperopia. Finally, all measurements were performed by medical professionals (ophthalmologists and orthoptists); the results might be different if performed by nonspecialists, as can be the case in mass screening programs. Despite these limitations, our study provides an encouraging example of the use of a photoscreener during a dedicated day for the detection of refractive errors in a socioeconomically disadvantaged population of school-aged children.

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