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## **Evaluation of the Spot Vision Screener in comparison with the orthoptic examination in visual screening in 3-5-year-old schoolchildren**

Evaluation du Spot Vision Screener en le comparant au bilan orthoptique dans le dépistage visuel des enfants de 3 à 5 ans en école maternelle

*Evaluation of the Spot Vision Screener*

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## **Evaluation of the Spot Vision Screener in comparison with the orthoptic examination in visual screening in 3-5-year-old schoolchildren**

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### **Abstract**

*Purpose.* – To evaluate the Spot Vision Screener (SVS) compared with the orthoptic examination for detection of amblyopia risk factors in preschools.

*Methods.* – This prospective study included children with a visual screening organized by the department of “Protection Maternelle et Infantile” (PMI) in Côte d’Or (Burgundy, France), between June 2017 and April 2018. All children were evaluated with the SVS followed by a clinical orthoptic examination. Results with the SVS were compared with those obtained by clinical orthoptic examination.

*Results.* – A total of 1236 subjects were included in the study from 100 preschools. The mean age of the children was  $3.6 \pm 0.7$  years, and 627 were female (50.7%). The orthoptic examination detected 308 (24.9%) children with subnormal visual acuity for age in one eye or both. In children with a history of prematurity, the orthoptic examination was more frequently abnormal ( $P = 0.002$ ), which was not seen with the SVS ( $P = 0.050$ ). The SVS screened 20 (1.6%) children with strabismus, while 40 (3.2%) were detected by orthoptic examination. At the end of the screening, the SVS detected 182 (14.7%) suspect patients while 311 (25.1%) suspect patients were detected after the orthoptic examination. Comparing SVS with orthoptic examination, agreement was fair ( $\kappa = 0.4$ ).

*Conclusion.* – The SVS can be a useful device for visual screening, but agreement with the orthoptic examination was only fair. The Spot vision screener should be used in conjunction with a clinical orthoptic examination.

**Key words**

Visual screening; Photoscreening; Spot Vision Screener; Amblyopia; Refraction

## **Résumé**

*Objectifs.* – Evaluer les capacités de dépistage des facteurs de risque d’amblyopie du Spot Vision Screener (SVS) en le comparant au bilan orthoptique chez les enfants en école maternelle.

*Matériel et méthodes.* – Etude prospective incluant des enfants ayant bénéficié d’un dépistage visuel organisé par la “Protection Maternelle et Infantile” (PMI) de Côte d’Or (Bourgogne, France) entre juin 2017 et avril 2018. Les enfants ont bénéficié d’une mesure de la réfraction sans cycloplégie via le SVS puis d’un bilan orthoptique. Les résultats du bilan orthoptique ont été comparés aux résultats du SVS.

*Résultats.* – Mille deux cent trente-six enfants d’âge moyen  $3,6 \pm 0,7$  ans, dont 627 de sexe féminin (50,7%) ont bénéficié du dépistage dans 100 écoles maternelles. Le bilan orthoptique a détecté 308 (24,9%) enfants présentant une acuité visuelle trop faible pour l’âge. Le bilan orthoptique était plus fréquemment anormal ( $P = 0,002$ ) chez les enfants avec des antécédents de prématurité mais pas le SVS ( $P = 0,050$ ). Le SVS a dépisté 20 (1,6%) enfants présentant un strabisme alors que 40 (3,2%) ont été dépistés après un bilan orthoptique. A l’issue du dépistage, le SVS a détecté 182 (14,7%) enfants considérés à risque d’amblyopie contre 311 (25,1%) bilans orthoptiques anormaux. En comparant les résultats du SVS avec ceux du bilan orthoptique, la concordance était modérée ( $\kappa = 0,4$ ).

*Conclusion.* – Le SVS semble être un dispositif utile dans le dépistage visuel, mais avec une concordance modérée en le comparant au bilan orthoptique. Sa place est probablement complémentaire du bilan orthoptique.

## **Mots Clés**

Dépistage visuel ; Photoscreening ; Spot Vision Screener ; Amblyopie ; Réfraction

## **Introduction**

Amblyopia is the most common cause of preventable vision loss in children with a prevalence estimated between 1 and 5% in preschoolers children [1–3]. The most common cause of amblyopia is refractive error followed by strabismus and the organic cause represents only 1% of them. It may negatively impact the live of patients, as they have twice the risk of developing bilateral visual impairment [4]. Also unilateral visual impairment can lead to functional significance like abnormal stereoacuity with difficulties in fine visuomotor actions and spatial representation [5]. So, early screening of amblyopia and its risk factors is a major challenge as the treatment effectiveness has an inverse relationship with age and can also reduce amblyopia prevalence [6–8]. Actually, in France, visual screening in children does not require cycloplegic refraction systematically. As determined by the 2002 report of the “Agence Nationale d’Accréditation et d’Evaluation en Santé” (ANAES), the cycloplegic refraction and fundus examination are recommended only for children with clinical situations predisposing to the occurrence of amblyopia risk factors (ARFs) like prematurity, low birth weight, neurological disorders, trisomy 21, craniosynostoses, infections in utero and medical history affecting their parents of amblyopia, strabismus or ocular tumours [9]. For children with any predisposition for amblyopic risk factors, a simple clinical examination without cycloplegic instillation is performed several times during childhood by the paediatrician or by a paramedical staff. The absence of cycloplegia which stays the gold standard to detect amblyopia risk factors is justified by the fact that paramedical staff like orthoptists are not legally allowed to use eyedrops without a medical prescription and the ophthalmologists are too few to assume mass screening [10].

Binocular devices have emerged the last few years to improve screening especially in low-cooperating or preverbal children [11]. The Spot Vision Screener (SVS) (Welch Allyn Inc, Skaneateles Falls, NY, USA) detects ARFs measuring ametropia, anisometropia and

ocular alignment without cycloplegic instillation. Some authors have previously evaluated this device. They found a good sensitivity for detecting ARFs: 89% for Garry *et al.* and 87% for Silbert *et al.* [12,13]. To obtain the measure, the SVS is handled at one meter from the child, which allows a decrease accommodation to the target. The American Academy of Pediatrics has recommended automated vision screener as an acceptable alternative to traditional vision screening in children 3 to 5 years of age [14,15]. In France, some orthoptists or paediatricians already use these devices but any recommendation has been proposed yet.

The present study aimed to assess the effectiveness of a binocular device, the Spot Vision Screener in children and to compare it with the traditional screening in France consisting of a clinical orthoptic examination with measurement of monocular visual acuity at school.

## **Methods**

We conducted a prospective study on children screened in Burgundy, from June 2017 to April 2018. This screening was organized by the department of “Protection Maternelle et Infantile” (PMI) in Côte d’Or, (Burgundy, France). One hundred infant schools were screened by one certified orthoptist. All children included in the study were between 2 and 6 years old. Few days before the screening, a form was distributed to the parents and they had to complete it in order to collect medical history about their children including prematurity, low birth weight, ophthalmic and neurological diseases, and family history of amblyopia.

### **Orthoptist Examination**

The screening day, all subjects underwent an age-appropriated monocular visual acuity evaluation with the scale of Cadet and then, a clinical orthoptic examination was performed by the same certified orthoptist including Bruckner test, cover test, Lang stereotest and ocular motility evaluation. Visual monocular acuity < 8/10, strabismus or ocular motility disorders were considered as an abnormal orthoptic examination and the child was referred for a complete ophthalmologic examination. When visual acuity measurement was impossible due to a lack of cooperation, the children were also referred to an ophthalmologist most of the time or a new examination was performed later.

### **Visual screening with the device**

Binocular photoscreening with the Spot Vision Screener was also performed. This device is a handheld photorefractor without instillation of a cycloplegic agent. Hyperopia, myopia, astigmatism, anisometropia, anisocoria, gaze deviation in primary position, media opacity and interpupillary distance were measured in approximately 2 seconds. The device is battery-operated, portable, and Wi-Fi enabled, with a touch screen and electronic data storage and transfer. The child looked at the display of twinkling lights and sound during the screen of the SVS indicated the good position “too far” or “to close”. The SVS, (PediaVision, Welch



Allyn, Skaneateles Falls, NY, USA), used specific parameters to generate a result (Table 1). Referral values for ametropia depended on the age of the child (Table 1). The result of the SVS could be “pass” when every data was normal, within the range or “refer” if a refractive error or any data exceeded the guidelines according to the age and when a complete eye exam was recommended. The SVS was able to detect refractive errors ranging between -7,5 dioptries (D) and +7,5 D of spherical equivalent (SE). If the measurement exceeded these values, the result was automatically “refer”.

### **Statistical analysis**

The following data were collected on an Excel spreadsheet and analysed. Descriptive statistics are given as means (with standard deviation) because the distribution of continuous variables was normal according to the Shapiro-Wilk test. Numbers (with percentages) are given for categorical variables. Results of the SVS were compared with results issued from clinical orthoptic examination using Chi-square test or Fisher exact test as appropriate and agreement was assessed by Cohen’s kappa. All analyses were conducted using the statistical analysis software Stata® (version 14, Stata Corps, College station, TX, USA). P-values < 0.05 were considered statistically significant and the tests were two-tailed.

## Results

A total of 1236 children were included, mostly of Caucasian origin. The mean age was  $3.6 \pm 0.7$  years, from 2.2 to 6.4 years. Six hundred twenty-seven (50.7%) were female, 20 (1.6%) had a medical history of preterm birth before 32 weeks of amenorrhea. All clinical characteristics of children are shown in Table 2. In our sample, 961 children (77.8%) had never seen any ophthalmologist before our study.

The SVS measured a mean SE of  $+0.35 \pm 0.7$  D in both eyes, with values ranging from -6.25 D to +6.00 D. The SVS detected 182 (14.7%) suspect patients and referred them for a complete ophthalmologic examination. Among the 182 cases referred, several ametropias or disorders could be present (Table 3). The SVS failed to measure the refraction in 1 (0.2%) child. The SVS detected 3 cases of anisocoria, among these cases, orthoptic examination was normal in 2 cases and in 1 case visual acuity was too weak but the anisocoria was not found.

Among the 1236 children screened, the orthoptic examination was abnormal in 311 (25.2%) cases. Complete description of the orthoptic examination is displayed in Table 4. Clinical examination revealed an interocular difference in visual acuity in 59 children that were not screened by the SVS. The orthoptic examination screened 2 cases of ptosis and in these cases the SVS was normal. In univariate analysis, in children with prematurity, the orthoptic examination was more frequently abnormal ( $P = 0.002$ ) but not the SVS ( $P = 0.050$ ).

The SVS screened 20 (1.6%) children with strabismus while 40 (3.2%) were detected after an orthoptic examination. Regarding strabismus detected by the orthoptist, the SVS detected 15 cases (37.5%). Among the 20 children with strabismus detected by the SVS, the orthoptic examination confirmed 15 cases (75%). Also, the orthoptic examination detected 6

cases of ocular motility disorders. Only one of these was detected by the SVS as a strabismus (Table 5).

Globally, the SVS and the clinical examination were normal in 889 (71.9%) cases, and were both abnormal in 122 (9.9%) cases. Among the 311 cases detected by the orthoptic examination, the SVS missed 189 (60.8%) cases, and the SVS detected 35 (2.8%) suspect patients that were not screened by the clinical examination, Table 6. The agreement between SVS and orthoptic examination was fair ( $\kappa= 0.4$ ).

## Discussion

This study was designed with the major objective of comparing a device of photoscreening with the actual screening reference method for detection of ARFs in France. We found that the SVS had a higher efficiency to measure refraction particularly in this young population compared to the traditional non-cycloplegic orthoptic examination that could be challenging for children with moderate cooperation or in case of language barriers. To our knowledge, the comparison between the SVS and the orthoptist examination without an instillation of a cycloplegic agent has been reported only once in a population of 168 children by Voide *et al.* [16]. They compared the SVS with a monocular refractor without instillation of a cycloplegic agent in combination with the orthoptic examination; they concluded that the SVS could be a useful device for screening but they also suggested that the SVS could cause over-referral by overestimating the astigmatism on the one hand and could miss amblyopic cases secondary to organic causes on the other hand.

The SVS detected 14.7% of ARFs in our population. These results were congruent with Donahue *et al.* who described 15% to 20% of ARFs after an ophthalmologic examination including cycloplegia in their paediatric population, as for Arnold *et al.* 21%  $\pm$  2% [15,17]. Our prevalence of ARFs with the SVS was also in agreement with the prevalence detected with the SVS by Arana *et al.* (12.3%) or by Matta *et al.* (14%) with another device of photoscreening, the PlusoptiX [18,19].

Regarding ametropias detected with the SVS, we found the same median SE (+0.25 D) than Voide *et al.*, which seems pertinent since the ethnicity and mean ages were the same in both populations. We found a high prevalence of astigmatism with the SVS according to the manufacturer referral values (11.2%). This is also congruent with several other studies [3,16,18,20,21]. The overestimation of the astigmatism compared to cycloplegic refraction (prevalence between 6% and 9%) may be due to the head position of the child during the

measurement [17]. We also found a very low prevalence of hyperopia (1.6%) compared with the prevalence described by Arnold *et al.* in a meta-analysis of children with a similar age (6.0%). Some studies have shown the tendency of the SVS to underestimate hyperopia, which could be related to the fact that the myopic shift secondary to accommodation is not totally reduced by the distance between the child and the SVS during measurement [21–23]. Barugel *et al.* found a very low sensitivity (27.3%) of the SVS to detect hyperopia when they compared the device with the refraction under cycloplegia. As we did, they also hypothesized an intrinsic technical weakness of the SVS for the detection of hyperopia [10]. This point is probably the principal limitation of the SVS in massive visual screening.

The absence of a reliability index with the SVS is another drawback already described by Voide *et al.* In our study, 35 (2.8 %) patients had an ametropia detected by the SVS but a normal orthoptic examination. In this context, a reliability index on the SVS could be a useful tool to find out if abnormal measures were consecutive to unreliable data or if a normal orthoptic examination was consecutive to accommodation which leads to a normal visual acuity despite ametropia [24]. Conversely, we found a substantial number of abnormal orthoptic examinations without any ARFs detected with the SVS (15.3%).

For strabismus, the prevalence in our population was higher with the clinical examination (3.2%) compared with the SVS (1.6%). Hashemi and colleagues described a prevalence of strabismus of 1.78% involving children < 20 years [25]. Peterseim *et al.* found a good sensitivity of the SVS (77.2%) and an excellent specificity (93.7%) for detecting strabismus [26]. As there was a minimal angle of 8<sup>Δ</sup> to be detected, we confirmed the SVS did not screen microstrabismus, neither ocular motility failure [16]. Some ocular motility disorders named “well-controlled deviations” (eg, Superior Oblique Palsy, Monocular Elevation Deficiency, Duane syndrome and Brown syndrome) had been already described in preschool vision screening guidelines. Some authors explained that these disorders were

neither typically associated with amblyopia development nor with rapid loss of stereopsis, thus they needed not be detected by a photoscreener [15]. Indeed, the device only allowed refraction measures in some positions around the primary gaze but did not estimate visual acuity or ocular motility. Furthermore, it was not able to detect any organic disease with clear media. In that regard, clinical examination is highly superior to detect ARFs and stays essential [16].

To detect ARFs, previous studies have shown that the SVS has a sensitivity about 85% and a specificity about 88% compared to the ophthalmologic examination with eyedrops [10,12,13,27,28]. In these studies, sensitivity and specificity were slightly different according to the age of their population and according to the chosen refractive thresholds. Arnold *et* Armitage compared the SVS and other devices of photoscreening using the 2003 guidelines of the AAPOS for detecting ARFs and found that all the photoscreeners (the SVS, the PlusoptiX, the iScreen and the GoCheckKids application) were capable of achieving a high degree of accuracy and had similar performances [29,30]. Compared with other devices, the efficiency of the SVS to obtain a measure in children is a major advantage [31,32].

In this study, the major limitation was the lack of cycloplegic retinoscopy examination considered as the gold standard, which explains that we could not extract any sensitivity or specificity of the SVS. However, it would have been complicated during this mass screening to perform an examination with cycloplegia. Furthermore, in our study, children were very young and the emmetropization process would have required a second cycloplegic refraction within 6 months. The visual screening was realized by a single orthoptist, which is also a limitation.

In conclusion, the SVS can be a useful device for visual screening, but comparison with the orthoptic examination agreement was fair. These two methods of visual screening do

not rely on the same parameters, therefore, the SVS should to be used in complement with a clinical examination.

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**Disclosure of interest**

The authors declare that they have no competing interest related to this work.



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**Table 1** Manufacturer criteria for the Spot Vision Screener, version 2.0.16.

Age	Anisometropia	Astigmatism	Myopia	Hyperopia	Anisocoria	Gaze	Gaze	Gaze	Gaze
Months	Dioptries	Dioptries	Dioptries	Dioptries	Millimeters	Vertical	Nasal	Temporal	Asymmetry
						Degrees	Degrees	Degrees	Degrees
6-12	1.50	2.25	2.00	3.50	1.00	8.00	5.00	8.00	8.00
12-36	1.00	2.00	2.00	3.00	1.00	8.00	5.00	8.00	8.00
36-72	1.00	1.75	1.25	2.50	1.00	8.00	5.00	8.00	8.00
72-240	1.00	1.50	1.00	2.50	1.00	8.00	5.00	8.00	8.00
240-1200	1.00	1.50	0.75	1.50	1.00	8.00	5.00	8.00	8.00

**Table 2** Baseline characteristics of children included in the study.

Main characteristics	Total (n = 1236)
Age (years)	3.6 ± 0.7
Sex, male	609 (49.3)
Prematurity < 32 weeks of amenorrhea	20 (1.6)
Low birth weight < 2100g	35 (2.8)
Previous visit with an ophthalmologist	275 (22.2)
Children referred by the orthoptist	190 (15.3)

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Continuous variables are expressed as mean ± standard deviation. Categorical variables are expressed as number (%).

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**Table 3** Results of amblyopia risk factors measured by the Spot Vision Screener.

Children referred by the Spot Vision Screener	182 (14.7) <sup>a</sup>
Astigmatism	138 (11.2)
Hyperopia	20 (1.6)
Myopia	9 (0.7)
Anisometropia	42 (3.4)
Strabismus	20 (1.6)
Esotropia	16 (1.2)
Exotropia	4 (0.3)
Anisocoria	3 (0.2)

Categorical variables are expressed as number (%).

<sup>a</sup> Several factors may be involved in a participant.

**Table 4** Results of the orthoptic examination.

Abnormal orthoptic examination	311 (25.2) <sup>a</sup>
Visual acuity < 8/10	308 (24.9)
Anisoacuity	128 (10.6)
Strabismus	40 (3.2)
Esotropia	19 (1.5)
Exotropia	21 (1.7)
Motility disorders	6 (0.5)
Ptosis	2 (0.2)
Symptoms (epiphora, headaches)	5 (0.4)

Categorical variables are expressed as number (%).

<sup>a</sup> Several factors may be involved in a participant.

**Table 5** Comparison between a complete orthoptic examination regarding ocular motility disorders and the Spot Vision Screener measures.

Disorders	Orthoptic examination	Spot Vision Screener referral criteria met
Superior Oblique Palsy	1	Normal
Möbius syndrome	1	Strabismus, astigmatism
Brown syndrome	2	Normal and astigmatism, respectively
Duane syndrome	1	Hyperopia
Nystagmus	1	Astigmatism, anisometropia

**Table 6** Agreement between the Spot Vision Screener and the orthoptic examination.

	Orthoptic examination abnormal	Orthoptic examination normal
Result of the Spot Vision Screener “refer”	122 (9.9)	35 (2.8)
Result of the Spot Vision Screener “pass”	189 (15.3)	889 (72.0)

Categorical variables are expressed as number (%).