Published in final edited form as:

J AAPOS. 2015 December ; 19(6): 521–525. doi:10.1016/j.jaapos.2015.09.004.

High specificity of the Pediatric Vision Scanner in a private pediatric primary care setting

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Abstract

Purpose—To determine the specificity of the Pediatric Vision Scanner, a binocular retinal birefringence scanner, in its intended setting, a pediatric primary care office.

Methods—A total of 102 preschool children (age 2–6 years) were screened during a well-child pediatric visit using the Pediatric Vision Scanner and the SureSight Autorefractor and completed a masked comprehensive pediatric ophthalmic examination (gold standard examination).

Results—Based on the gold standard examination, one child had anisometropic amblyopia, and the remaining 101 had no amblyopia or strabismus. Specificity of the Pediatric Vision Scanner was 90% (95% CI, 82%–95%) while specificity of the SureSight was 87% (95% CI, 79–93%). Combining these results with the sensitivity of the devices determined in our previous study conducted in a pediatric ophthalmology office setting, the positive likelihood ratio for the Pediatric Vision Scanner was 10.2; for the SureSight, 5.0. The negative likelihood ratio for the Pediatric Vision Scanner was 0.03; for the SureSight, 0.42, a significant difference.

Conclusions—The Pediatric Vision Scanner had high specificity (90%) in screening for amblyopia and strabismus as part of a pediatric well-child visit. Likelihood ratio analysis suggests that affected children have a high probability of being correctly identified by the Pediatric Vision Scanner. The high level of confidence conferred by Pediatric Vision Scanner screening may remove an important barrier to vision screening in pediatric primary care.

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Presented in part as a poster 41st Annual Meeting of the American Association for Pediatric Ophthalmology and Strabismus, New Orleans, Louisiana, March 25–29, 2015.

The authors have no financial interest in any screening device.

Amblyopia is the most common cause of monocular visual impairment, affecting 2%–4% of children age 6 years and younger.^{1,2} Delayed detection and treatment can lead to permanent vision loss.^{3–6} Young children are unlikely to be aware of decreased vision in one eye; thus, the primary aim of preschool vision screening is the detection of amblyopia. Strabismus is the most common amblyogenic risk factor.^{7,8} Even in the absence of amblyopia, strabismus can disrupt the development of normal binocular vision, detrimentally affect fine motor skills, and have psychosocial consequences.^{9–13} Preschool vision screening could help identify children with the targeted conditions of amblyopia or strabismus who might benefit from early interventions. The U.S. Preventative Service Task Force recommends vision screening at least once for children between 3 and 5 years of age and specifically mentions automated screening devices as an appropriate technology for this age range to overcome the low success and high rate of over-referral associated with visual acuity testing in young children.¹⁴ However, most automated screening devices are not designed to screen for amblyopia and strabismus; rather, they screen for amblyogenic risk factors, including hyperopia and anisometropia. As such, they reduce the cost-effectiveness of screening due to high false-positive rates,^{15,16} which was cited by pediatricians as a major barrier to preschool vision screening.¹⁷ Therefore, there is a need for a vision screening technology that directly tests for the targeted conditions of amblyopia and strabismus.

The Pediatric Vision Scanner (Rebiscan Inc, Cambridge, MA) directly detects strabismus and amblyopia by analyzing binocular scans for the presence or absence of a characteristic signature of bifoveal fixation, namely, retinal birefringence.¹⁸ Based on 5–10 scans completed within 5 sec, the Pediatric Vision Scanner generates a binocularity score; a score >60% is characteristic of steady, bifoveal fixation.¹⁸ We previously published a study that screened 300 children aged 2–6 years for the targeted conditions of strabismus and amblyopia in a pediatric ophthalmology private practice setting using both the Pediatric Vision Scanner and the SureSight Autorefractor (Welch Allyn Inc, Skaneateles Falls, NY).¹⁹ The sensitivity of the Pediatric Vision Scanner in that setting was 97% (95% CI, 94%–100%), significantly higher than the SureSight sensitivity of 63% (95% CI, 54%–72%) when using Silverstein-Vanderbilt criteria.²⁰ The Pediatric Vision Scanner also demonstrated better specificity than the SureSight (87% [95% CI, 80%–95%] vs 70% [95% CI, 59%–81%]). Although positive and negative likelihood ratios were used to infer the expected accuracy of the Pediatric Vision Scanner in a pediatric primary care screening setting, there remains a question of whether specificity can be adequately estimated based on data obtained from an enriched cohort. The purpose of the present study was to evaluate the performance of the Pediatric Vision Scanner—in particular, the specificity—in its intended setting, a pediatric primary care office.

Materials and Methods

Consecutive male and female children aged 2–6 years and scheduled for a pediatric well-child visit enrolled at Plano Pediatrics (a pediatric primary care practice in Plano, TX) 1–2 mornings per week. Children under the care of an ophthalmologist or with developmental delay were excluded. Eligible children were identified by clinical staff, and their parent(s) were invited to discuss the study with the researcher. Informed consent was obtained from parents who agreed to participate in the study. The research protocol was approved by the

Institutional Review Board of the University of Texas Southwestern Medical Center and conformed to the requirements of the Health Insurance Portability and Accountability Act of 1996.

Procedure

All children were tested in the pediatric clinic using both the Pediatric Vision Scanner and the SureSight. To avoid bias, test order was varied according to a random number table. Total test time for both screening tests was less than 5 minutes. Testing procedures were performed by research staff and have been published previously.¹⁹ Briefly, both tests were performed with room lights dimmed at a testing distance of 30–40 cm (Figure 1). For the Pediatric Vision Scanner, a background measurement was obtained with eyes closed, and the 2.5–5 second data scan performed immediately afterward. If a usable measurement could not be obtained, an “unable to perform” result was recorded. For the SureSight, data collection continued until at least 5 usable measurements (ie, reliability score ≥ 6) were obtained for each eye. If 5 measurements with reliability scores ≥ 6 could not be obtained, an “unable to perform” result was reported. Both devices generated a “refer” (+) or “pass” (–) result per manufacturer recommendations (Silverstein-Vanderbilt criteria²⁰ to evaluate the SureSight data).

Gold Standard Examination (GSE)

Regardless of the screening result, whether “pass,” “refer,” or “unable to perform,” all patients were referred to the Center for Pediatric Ophthalmology & Adult Strabismus, Plano, Texas, for a complimentary, comprehensive eye examination (GSE). The examination was performed by one of two fellowship-trained pediatric ophthalmologists. Examination elements included monocular distance visual acuity assessment, cover testing for strabismus, and cycloplegic retinoscopy. Evaluation of anterior segment and binocular indirect ophthalmoscopy were also performed. If the child was too young to provide monocular distance visual acuity, amblyopia was assessed by fixation preference. Examiners did not have access to screening results.

Data Analysis

Based on the results of the GSE, children were classified as positive or negative for strabismus/amblyopia. Sensitivity, specificity, and 95% confidence intervals were determined for each of the screening devices. Likelihood ratios were also determined (details below).

Sample Size

Considering that patients under the care of an ophthalmologist would be excluded, we estimated that $<2\%$ of children enrolled—at most, half of the estimated disease prevalence—would be affected by strabismus and/or amblyopia. We chose a sample size of 100 patients to obtain adequate confidence intervals for estimating specificity, with the understanding that any effort to obtain realistic estimates of sensitivity in this well-child setting would be require prohibitively large enrollment numbers. The protocol was therefore designed to continue until 100 children had participated in screening and *completed* the GSE. Prior

studies have reported that only 38%–48% of children who fail a vision screening will report for a comprehensive eye examination,^{21–23} even when the pediatric ophthalmologist is a member of the same multispecialty practice as the pediatricians who perform the vision screening.²² Considering the expected low attendance at the GSE, and further considering that most families in the present study would not have the imperative of a screening failure referral to motivate them to take the time to schedule the GSE, it was anticipated that only 20%–40% of patients would obtain the GSE and that screening of up to 300 patients would be required to achieve the desired sample size of 100 children with completed GSEs.

Primary Outcome

The primary outcome was specificity of the Pediatric Vision Scanner for detection of the targeted conditions, strabismus and amblyopia, in children 2–6 years of age. Specificity was assessed with the SureSight in the same cohort of children. Because the prevalence of the targeted conditions of strabismus and amblyopia were expected to be so low in the well-child cohort screened in the present study, the sensitivity of the Pediatric Vision Scanner and the SureSight obtained from the previous study¹⁹ that included the enriched population was used to calculate the positive likelihood ratio (LR+; sensitivity/[1-specificity], ie, how much more likely a child with strabismus/amblyopia will get a refer [+] result than an unaffected child) and the negative likelihood ratio (LR–; [1-sensitivity]/specificity, ie, how much less likely a child with strabismus/amblyopia will get a pass [–] result than an unaffected child).

Results

A total of 293 children were enrolled and screened. The GSE was completed by 102 (35%) children at a mean with standard deviation of 100 ± 81 days after the screening visit. Mean age of children who completed the GSE was 3.6 years (range, 2–6 years). One child (1%) had anisometropic amblyopia, and the remaining 101 had no amblyopia or strabismus.

Both devices had similar “unable to perform” rates of 6%–7%, primarily in ages 2–3 (Table 1). An “unable to perform” result indicates the child was uncooperative and the test was not completed. All children who were “unable to perform” on either device had no strabismus or amblyopia diagnosed on GSE. Both devices detected the one patient with anisometropic amblyopia. The 2×2 contingency table characterizing the performance of the two devices is presented in Figure 2. Specificity for the Pediatric Vision Scanner was 90% (95% CI, 82%–95%), whereas while specificity of the SureSight was 87% (95% CI, 79%–93%).

Combining these results with the sensitivity of the devices determined in the previous study,¹⁹ the positive and negative likelihood ratios were determined (Table 2). The LR+ of 10.2 suggests that a Pediatric Vision Scanner refer (+) outcome provided a large increase in the likelihood that the targeted conditions of strabismus or amblyopia were present, and the LR– of 0.03 suggests that a Pediatric Vision Scanner pass (–) outcome provided a large decrease in the likelihood that the targeted conditions of strabismus or amblyopia were present. LR+ for SureSight was not significantly lower at 5.0, but LR– was significantly higher than at 0.42, providing only moderate decrease in the likelihood that the targeted conditions of strabismus or amblyopia were present in children who received a pass (–) result.

Discussion

Pediatric Vision Scanner vision screening for amblyopia and strabismus as part of a pediatric well-child visit had high specificity (90%). The specificity of the Pediatric Vision Scanner in the pediatric setting was comparable to our previous study,¹⁹ in which we reported 87% specificity in a large cohort (n = 300) tested in an ophthalmology practice enriched for high disease prevalence. In the pediatric setting, the specificity of the Pediatric Vision Scanner was not significantly higher than the 87% specificity of the SureSight. Both devices detected the 1 case of anisometropic amblyopia, but sensitivity could not be meaningfully determined in this nonenriched population. In our previous study of an enriched population of 300 children aged 2–6 years screened in a pediatric ophthalmology setting,¹⁹ sensitivity of the Pediatric Vision Scanner was determined to be 97%, significantly higher than the SureSight sensitivity of 63% when using Silverstein-Vanderbilt criteria.²⁰

All children who screened with the Pediatric Vision Scanner and the SureSight were referred for the gold standard examination (GSE) by a pediatric ophthalmologist. However, only 1 in 3 patients tested ultimately appeared in the ophthalmology office for the GSE. This is a recognized problem with any vision screening program. Even if the GSE is free, parents must take time off work to appear for the appointment, and they may not be aware—even in the case of a failed screening—of the importance of early detection and treatment of amblyopia and strabismus. Overall, our completed GSE rate was comparable with that in other published studies,^{17,21–23} and there was no reason to assume that any systematic errors could have led to bias in the patients who did receive GSE. Although we cannot know whether the children who did not attend the GSE had amblyopia or strabismus, our finding of 1 of 102 children (1%) who completed the GSE affected with amblyopia is consistent with the published prevalence of 2.5%.^{1,2}

Because sensitivity could not be meaningfully determined in the present study, we combined the data with our previous study¹⁹ to allow for estimation of positive and negative likelihood ratios. The differences in LR+ and LR– have important consequences when screening a population with a condition that has low prevalence. The LR+ of 10.2 for the Pediatric Vision Scanner is consistent with a refer outcome, providing strong or conclusive evidence that the targeted condition of strabismus or amblyopia is present. On the other hand, the LR+ of 5.0 for the SureSight provides a moderate but not conclusive increase in the likelihood that strabismus or amblyopia is present. The higher level of confidence conferred by Pediatric Vision Scanner screening may remove an important barrier to vision screening in pediatric primary care. A recent survey of 377 US pediatricians reported that a high false positive rate was one of two major barriers to implementing regular vision screening.¹⁷ A high rate of false positive referrals also contributes to higher health care costs, parental anxiety, and a lack of confidence in screening results. Lower confidence in screening results may reduce both the number of children referred to ophthalmologists by the pediatrician and the number of families who follow the referral recommendation of their pediatrician to schedule an ophthalmology examination for their child.^{17,24}

The LR– of 0.03 for the Pediatric Vision Scanner was significantly lower than the LR– of 0.42 for the SureSight and represents a very low probability that a child with the targeted

condition of strabismus or amblyopia will receive a pass outcome; that is, affected children have a high probability of being correctly identified by the Pediatric Vision Scanner. The LR – of 0.42 for the SureSight represents a moderate probability that children affected by the targeted conditions will be missed by SureSight screening. The ability to accurately identify amblyopia and strabismus early is important because, although there is some evidence that treatment can be somewhat effective into the teenage years and adulthood,^{25–27} optimum vision outcomes depend on intervention by age 7 years.^{28,29}

The key to effective preschool vision screening is ensuring that the screening program fits its purpose.¹⁵ The underlying concept of the Pediatric Vision Scanner is fundamentally different than that for devices that screen for amblyogenic risk factors. The Pediatric Vision Scanner is supposed to identify and refer children with amblyopia or strabismus. There is no evidence that early detection of *risk factors* results in better vision outcomes than early detection of amblyopia and strabismus. A program of annual testing, when performed using a device like the Pediatric Vision Scanner that has good testability and high sensitivity and specificity, should reduce the likelihood that any child with significant amblyopia or strabismus will be missed.

Acknowledgments

Institutions at which study was conducted: Retina Foundation of the Southwest & Plano Pediatrics

Supported by grants from the Thrasher Research Fund (#8481) and the National Eye Institute (EY022313).

The Pediatric Vision Scanner was loaned to the Retina Foundation of the Southwest for the duration of the study by Rebiscan Inc.

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FIG 1.
Testing with the Pediatric Vision Scanner (A) and the SureSight (B).

n = 95

PVS REFER (+)

PVS PASS (-)

GSE + GSE -

GSE +	GSE -
1	9
0	85

n = 96

PVS REFER (+)

PVS PASS (-)

GSE + GSE -

GSE +	GSE -
1	12
0	83

FIG 2.

Contingency table results for Pediatric Vision Scanner (PVS) and SureSight (SS). *GSE*, gold standard examination result; +, positive for strabismus and/or amblyopia; -, negative for strabismus and/or amblyopia.

Table 1

Number of children with “unable to perform” result

Age, years	Number	Pediatric Vision Scanner, n (%)	SureSight, n (%)
2	29	5 (17)	4 (14)
3	20	2 (10)	1 (5)
4	27	0	0
5	15	0	1 (7)
6	11	0	0
Total	102	7 (7)	6 (6)

Table 2

Likelihood ratios for Pediatric Vision Scanner (PVS) versus SureSight (SS)

	LR+ (95% CI)	LR- (95% CI)
PVS	10.2 (5.5–18.9)	0.03 (0.01–0.07)
SS	5.0 (2.9–8.6)	0.42 (0.34–0.51) *

CI, confidence interval; *LR+*, positive likelihood ratio; *LR-*, negative likelihood ratio.* Significant difference in LR- for the PVS vs SS ($P < 0.05$).