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Validation of the Pediatric Vision Scanner in a normal preschool population

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Abstract

Purpose—To assess the Pediatric Vision Scanner (PVS), a handheld vision screening device designed to test for amblyopia and strabismus, in a general pediatric population.

Methods—In this prospective study, trained research staff screened 300 eligible children 24–72 months of age with no known eye conditions for amblyopia and strabismus using the PVS. A pediatric ophthalmologist masked to PVS screening results then performed a comprehensive eye examination. Sensitivity and specificity of the PVS was calculated with a 95% confidence interval.

Results—Based on the gold standard eye examination, 6 children (2%) had amblyopia and/or strabismus. The PVS detected all 6 cases, yielding a sensitivity rate of 100% (95% CI, 54% −100%). The PVS referred 45 additional children (15%) who had normal ophthalmic findings, yielding a specificity rate of 85% (95% CI, 80%−89%). The median acquisition time for the PVS was 28 seconds.

Conclusions—The PVS detected amblyopia with high sensitivity in a nonenriched pediatric population. The device would allow children with amblyopia and/or strabismus to be referred to an eye care specialist as early as 2 years old. Given its short acquisition time, the PVS can be implemented in a pediatric clinic with minimal impact on workflow.

Amblyopia is the leading cause of unilateral vision impairment in young children, with a prevalence of 2%−5%.[1] Regular vision screening is recommended at an early age, with age-appropriate methods to detect preventable vision loss conditions.[2–4] Treatment is most effective when initiated at a young age, but standard visual acuity testing has been shown to be less reliable in children <5 years of age.[5]

Guidelines developed by the American Academy of Pediatrics and the American Association for Pediatric Ophthalmology and Strabismus include instrument-based screening, as appropriate, for children ≤5 years of age.[6] However, most instrument-based

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screening devices detect amblyogenic risk factors, not amblyopia directly—leading to false positives and unnecessary referrals.

The Pediatric Vision Scanner (PVS; Rebiscan Inc [dba Rebion], Boston, MA) was developed to meet the need for direct detection of amblyopia in children. The PVS is an innovative handheld vision screening device designed to test for amblyopia and strabismus. It can be operated by a lay user with minimal training. The PVS uses retinal polarization scanning, a laser probe that senses eye fixation by analyzing the pattern of nerve fibers in the retina.[7–9] The device therefore screens for strabismus and amblyopia by directly detecting reduced bifoveal fixation. Loss of bifoveal fixation may be an early sign of amblyopia. The detection of abnormal bifoveal fixation acts as a proxy for potential amblyopia which must be confirmed by clinical examination.

The PVS device has been shown to be very sensitive and specific in an enriched ophthalmology clinic population. To date, only one study has been performed in a general pediatric setting; that study, which showed 90% specificity, was limited by low follow-up, with only 35% of children screened by the PVS subsequently undergoing a gold standard examination.[10,11] The purpose of the current study was to assess the performance of the PVS in a general pediatric care clinic setting and to compare the results to a gold-standard examination conducted by a pediatric ophthalmologist.

Subjects and Methods

Kaiser Permanente Southern California (KPSC) Institutional Review Board approval was obtained for this study, which adhered to the tenets of the Declaration of Helsinki and was registered on ClinicalTrials.gov (NCT02536963).

Phase I

Before initiating the main study, we conducted a feasibility study from January 2016 to April 2016 in which we recruited 40 children ages 96–132 months at well-child visits. Interested participants visited an on-site ophthalmology clinic immediately following their well-child visit where trained research staff screened children using the PVS, and a pediatric ophthalmologist conducted an examination comprising visual acuity (using a standard wall chart), sensorimotor status (including stereopsis), color vision, and autorefraction (manifest refraction performed for significant refractive errors). While this phase of the study did not yield sufficiently powered validation results, we determined that the study was feasible based on our ability to successfully implement study procedures without interrupting pediatric clinic workflow.

Phase II

After demonstrating feasibility, we recruited 318 clinical trial participants during previously scheduled visits at two Kaiser Permanente Southern California pediatric clinics from October 2016 to January 2019. We chose a sample size of 300 to obtain adequate confidence intervals for estimating specificity. We also sent letters and placed phone calls to parents of eligible children who lived in cities proximal to the two clinics. We considered children eligible if they were at least 24 months old, less than 72 months old, had not visited an

ophthalmologist (because this could indicate a preexisting eye condition and/or introduce biased eye examination results if the physician had seen the patient before), and had no cognitive and/or developmental disability (ICD-10 codes Z82.79 and F84.0).

Interested participants either visited an on-site ophthalmology clinic immediately following their pediatric visit or made an appointment at one of two KPSC ophthalmology clinics. We completed all study activities during one appointment. Research staff described the study to parents and obtained informed consent, collected parent-reported demographic data about each participant, screened each participant using the PVS, and documented PVS results, test acquisition time, and participant cooperation. We performed testing in a dimly lit room with the child seated on a chair or on parents' laps. Per manufacturer recommendations, staff first measured a background calibration measurement from the face with closed eyes. We then asked the child to open both eyes and fixate on the smiley face target within the device while the binocular retinal polarization scan was performed. The PVS displayed results which we interpreted as either "pass" or "refer" based on validated recommendations.[12] We defined acquisition time as time from when the research staff picked up the PVS to when the result is generated, and defined cooperation as "excellent" or "fair" based on staff discretion (eg, a patient who listens to instructions and completes the examination on the first try would be "excellent," whereas a patient who moves his/her head around during testing would be "fair"). A pediatric ophthalmologist masked to the PVS result then performed a gold standard eye examination according to standard clinical methods comprising visual acuity, stereopsis, motility evaluation, examination of anterior segment, cycloplegic retinoscopy, and dilated fundus examination. Possible results were recorded as follows: normal, normal with risk factors, suspected binocular vision deficit, suspected amblyopia, amblyopia, strabismus, and amblyopia and strabismus. Results were mutually exclusive. To compare the PVS results to the gold standard eye examination, we performed a validation characteristics analysis with a 95% confidence interval. We used the same methods for subgroup analysis when stratifying by cooperation. To calculate positive and negative predictive values of the instrument we used an assumed prevalence of 5% of amblyopia and strabismus to account for our cohort having excluded patients with known ophthalmic conditions.

Results

Of the 318 children enrolled in the study, 18 were excluded from analysis; we were unable to obtain reliable PVS results from 3 children due to device malfunction and from 8 children due to lack of cooperation. An additional 7 patients left the clinic before completing the eye examination. Of the 300 children included in the analysis, 141 were female (47%) and 149 were male (53%). The median age was 48 months. With regard to race, 121 participants (40.3%) were non-Hispanic white, 80 (26.7%) were Hispanic, 73 (24.3%) were Asian, 8 (2.7%) were black, and 18 (6%) were "other" or "more than one race" (Table 1).

Based on the gold standard eye examination, 6 children (2%) had amblyopia, 2 of whom (0.67%) had strabismus (Table 2). The PVS referred all 6 patients, yielding a sensitivity rate of 100% (95% CI, 54%−100%). The PVS referred 45 additional children (15%) who had normal ophthalmic findings, yielding a specificity rate of 85% (95% CI, 80%−89%).

When stratified by cooperation, specificity increased to 91% (95% CI, 86%−95%) among the 178 children (59.3%) with “excellent” cooperation (Table 3). Specificity did not change when stratified by child age. The overall positive predictive value was 26.0% (95% CI, 12.4%−32.4%); the negative predictive value, 100% (95% CI, 97.1%−100%). The median acquisition time for the PVS was 28 seconds (range, 8–249).

Discussion

Screening preverbal children with instrument-based screening can be fraught with poor specificity, false positives, and unnecessary referrals.[13] In a prior study examining the PVS in a similar primary care cohort, Jost and colleagues[11] reported data for 100 children; however, they screened nearly 300 children, with only one-third presenting for follow-up examination. In their study, 1 patient who had amblyopia on examination was also detected on PVS screening. The small numbers in this study precluded meaningful sensitivity interpretation. Our specificity is consistent with their reported specificity of 90%.

In the current study, the PVS demonstrated excellent sensitivity and good specificity for detection of amblyopia and strabismus. It is difficult to compare these results with sensitivity-specificity data from the Vision in Preschoolers (VIP) study[14] and other published studies, which tend to report sensitivity-specificity for detecting risk factors and not for disease.[15–18] However, when specificity was set at 90%, the VIP study found that the sensitivity of an autorefractor or photoscreener for detecting at least one “targeted condition” ranged from 51% to 68%.[14]

Of note, the PVS had a 100% negative predictive value. Thus, a normal or “pass” result provides a high degree of confidence that amblyopia and poorly controlled strabismus are not present. While the negative predictive value was excellent, the positive predictive value of the device for detecting amblyopia or strabismus was 26%. A pattern emerged when analyzing the subset of patients that generated false positives. Patients who were judged to have “excellent” cooperation with the PVS had a specificity of 91%, compared with only 75% for those children judged to have “fair” cooperation. We do not know whether simply retesting the group of children with fair cooperation might have improved the specificity result. One possible workflow when using this device on a large-scale for mass screening would be to retest children at a follow-up appointment if the child was uncooperative and received a “refer” result, assuming there were no other clinical reasons for referral.

Another key finding is the short acquisition time, which was as little as 8 seconds in highly cooperative and engaged patients. From a clinical operations and practice management perspective, the short acquisition time will make it much easier to integrate vision screening with this device as part of a pediatric well-child visit.

This study has several limitations. Although it included the largest number of unenriched pediatric patients to date evaluated by both the PVS and ophthalmologic examination, the power of the study was at the minimum threshold to allow for evaluation of statistical significance. This is because of the low prevalence of amblyopia, with a further reduction in affected patients due to exclusion criteria eliminating those who were already under the

care of an ophthalmologist. A critical characteristic of any vision screening modality is that it must not disrupt the busy workflow of a pediatric clinic. Although the acquisition time of the device was short, this was based on trained research staff performing the examination, which may not reflect the real-world conditions under which the device is intended to be used. An additional limitation was the lack of a comparison with existing photoscreening devices; during study design, we chose not to add to the complexity and cost of the present study, given the low published accuracy of these devices. Finally, we note that the PVS used in this study was a prototype that is not commercially available; the commercially available retinal polarization scanning device is known as blinq (Rebion).

The PVS can be an important part of a vision screening strategy for both preverbal and verbal children during the amblyogenic period. The device allows for the detection of amblyopia and strabismus in children as young as 24 months old. With its short acquisition time, the PVS can be easily integrated into the clinic workflow of a pediatrician. A “pass” result is highly reliable in informing the clinician that amblyopia and strabismus are not present. One possible limitation of the device is that reduced cooperation may reduce the specificity and positive predictive value. Poorly cooperative children who are referred may need to be rescreened to improve accuracy.

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Table 1.

Study population at baseline (N = 300)

Characteristic	Value
Age, years	
Mean ± SD	4.0 ± 1.16
Median (IQR)	4 (3.0, 5.0)
Range	2.0 −6.0
Sex, no. (%)	
Female	141 (47)
Male	159 (53)
Race/ethnicity, no. (%)	
White, non-Hispanic	121 (40.3)
Black, non-Hispanic	8 (2.7)
Hispanic	80 (26.7)
Asian, non-Hispanic	73 (24.3)
Other, non-Hispanic	18 (6)

IQR, interquartile range; *SD*, standard deviation.

Table 2.

Outcomes by PVS result

	Pass, n = 249	Refer, n = 51	Total, N = 300
PVS test length, seconds			
Mean	35.6	42.4	36.7
Median	28	29	28
Range	8.0 −222.0	14.0 −249.0	8.0 −249.0
Exam result, no. (%)			
Normal	241 (96.8)	41 (80.4)	282 (94)
Normal (with risk factors)	4 (1.6)	2 (3.9)	6 (2)
Suspected binocular vision deficit	4 (1.6)	2 (3.9)	6 (2)
Amblyopia only	0 (0)	4 (7.8)	4 (1.3)
Strabismus only	0 (0)	0 (0)	0 (0)
Amblyopia with strabismus	0 (0)	2 (3.9)	2 (0.7)

Table 3.

Validation characteristics by cooperation with 95% confidence

Amblyopia and/or strabismus, no or yes						
	Fair cooperation		**Excellent cooperation**		**Total**	
	No, n = 120	**Yes, n = 2**	**No, n = 174**	**Yes, n = 4**	**No, N = 294**	**Yes, N = 6**
PVS pass	90	0	159	0	249	0
PVS refer	30	2	15	4	45	6
Validation characteristics						
	Fair cooperation		Excellent cooperation		Total	
Sensitivity	1.00 (0.16, 100)		1.00 (0.40, 1.00)		1.00 (0.54, 1.00)	
Specificity	0.75 (0.66, 0.82)		0.91 (0.86, 0.95)		0.85 (0.80, 0.89)	
PPV	0.17(0.02, 0.23)		0.37 (0.13, 0.51)		0.26 (0.12, 0.32)	
NPV	1.00 (0.94, 1.00)		1.00 (0.97, 1.00)		1.00 (0.97, 1.00)	

CI, confidence interval; *NPV*, negative predictive value; *PPV*, positive predictive value.

[a]Assumed prevalence of 5% of amblyopia and strabismus.