An Evaluation of SPOT Vision Screening Efficacy for Children in South Dakota

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Abstract

Background: Amblyopia is a preventable, sight stealing disorder with a prevalence of approximately 2-4 percent in the U.S. pediatric population. Identifying efficacious, early stage screening modalities is of critical importance to sustain quality of vision and quality of life. This project assessed the quality of screening methods used in the Children's Vision Screening Initiative (CVSI), administered by Northern Plains Eye Foundation in collaboration with Western South Dakota Lions Clubs, by comparing to data collected in follow-up appointments at professional eye care clinics.

Methods: Data from 120 cases for children ages 6 months-12 years collected between February 2014 to July 2016 were compared. Only cases that had undergone initial screening by CVSI using a SPOT photoscreener device and that attended a subsequently scheduled eye care professional referral follow-up appointment were evaluated. SPOT screening performance measures on detecting amblyopia risk factors and the accuracy of refractive error data were evaluated.

Results: Review of professional evaluations showed that 23 percent of cases referred by SPOT screening had detectable amblyopia and 82 percent of all cases referred were found to be in need of further therapy as a result of examination findings. The SPOT device showed fair sensitivity and good specificity in the detection of astigmatism (76 percent/86 percent), strabismus (50 percent/96 percent), and anisometropia (75 percent/90 percent).

Conclusion: Vision screening performed using the SPOT device represents a valuable modality that is easily employable and can provide tremendous benefit to children in the state of South Dakota.

Background

Amblyopia is a preventable, sight stealing disorder for younger age groups. Various studies report the prevalence of amblyopia in the U.S. pediatric population to be approximately between 2-4 percent.[1-4] This is suspected to be disproportionately increased in rural areas where there is reduced access to health care.[5] South Dakota is a state where finding ways to improve health care access to rural populations is a priority. Yet, it represents one of only eight states (Arkansas, Hawaii, Idaho, Montana, North Dakota, South Carolina, New Hampshire) that does not have a designated pediatric vision screening policy.[6]

Amblyopia is commonly stratified into three main categories that include strabismic, refractive, and stimulus deprivation (congenital cataract, corneal opacity, etc.).[7,8] Strabismus and refractive error (anisometropia or ametropia) tend to be more commonly seen disorder causes for amblyopia with strabismus being identified as the primary cause in approximately 50 percent of unilateral amblyopia cases.[7] Other contributing risk factors include child congenital (maternal use of alcohol, drugs, or smoking during pregnancy; premature birth; small for gestational age) and development (developmental delay) history as well as family history of a first degree relative. There are many options for addressing risk factors in

amblyopia and therapy choice depends greatly on the primary cause identified. The end goal of management is to achieve improvement in visual acuity which may be addressed in a stepwise strategy of (1) addressing potential causes of visual deprivation, (2) visually significant refractive error correction, and (3) promoting use of the amblyopic eye.[7] These may be achieved through many methods including optical correction, patching, pharmacological or optical penalization, surgery, and vision therapy techniques.[7,8]

Amblyopia can be readily prevented during a child's early developmental years and is easily treated prior to age 5. Beyond this age cap a decline in intervention efficacy has been found to occur.[1,6] Therefore identifying efficacious, early stage screening modalities is of critical importance to sustain quality of vision and quality of life for patients into their later years.

Autorefractors (photoscreeners) represent a great advancement in the area of pediatric vision screening. Their use has been endorsed by numerous agencies including the U.S. Preventative Task Force, American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, and the American Association of Certified Orthoptists.[9] In the last decade, photoscreeners have been employed successfully and with increasing frequency by several countries evaluating children for risk factors of amblyopia.[2,10] Further, a number of studies evaluating the efficacy of the SPOT photoscreener in detecting amblyogenic risk factors have found this device to be of valuable use as a screening modality.[11-14]

This study represents a continuation of initial efforts performed in the study by Terveen et al.[1] that seeks to inspect the efficacy of screening-generated referrals obtained using the SPOT photoscreener. The goal of this project is to provide an age-based comparison of screening data collected as part of the Children's Vision Screening Initiative (CVSI), which is administered by Northern Plains Eye Foundation (NPEF) in collaboration with the Western South Dakota Lions Clubs. The primary objective of this study is to compare the accuracy of refractive measurements obtained by the SPOT photoscreener during routine NPEF CVSI screening efforts to those obtained in professional eye care clinics using cycloplegic refraction methods. The accuracy of potential conditions listed by the SPOT device to reflecting the actual diagnosis realized on professional follow-up will also be inspected. Secondary objectives are to assess the study population demographics and assess the benefits to screening based on subject outcomes from provider referral appointments.

Materials and Methods

Study Design

Institutional Review Board approval was obtained from The University of South Dakota Sanford School of Medicine, and the study conforms to the requirements of the U.S. Health Insurance Portability and Accountability Act of 1996. Data from the 120 cases collected between February 2014 to July 2016 was evaluated for children that had (1) been screened positive for one or more risk factors in an initial SPOT screening by CVSI and (2) also attended a subsequent professional referral follow-up appointment. The data compared was from inputs generated by Vision Screening Summary reports obtained using the SPOT photoscreener device and data from Eye Care Professional Evaluation Forms (PEF) completed by eye care professionals in South Dakota who were referred children deemed at risk through preliminary CVSI SPOT screening outcomes.

The process of data collection allowed for inclusion of children ages 6 months through 12 years to whom CVSI free vision screenings were administered by NPEF's non-medical staff and Lions Clubs volunteers associated with NPEF's CVSI project. Screening was carried out on an annual basis during the collection period of this study in 6 different communities of the Black Hills region (Rapid City, New Underwood, Custer, Piedmont, Sturgis, and Whitewood). NPEF is a non-profit 501(c)(3) organization, based in Rapid City, South Dakota, whose mission is to protect and preserve vision and restore sight for people of the Northern Plains. Through CVSI, NPEF strives to make vision screenings accessible to children across the region, leading to timely diagnosis and appropriate intervention. All NPEF staff and Lions Clubs volunteers underwent background checks and formal CVSI training on the techniques of vision screening and how to properly administer screenings using the SPOT device. All Lions Clubs volunteers were proctored by experienced staff of NPEF. CVSI follows an established process for administering the screenings, wherein standardized CVSI Free Vision Screening Consent Forms, provided by CVSI, must be completed, signed, and dated by the parent/guardian prior to their child's free vision screening and only those children with completed, signed, and dated consent forms

are allowed to be screened by CVSI. All SPOT Vision Screening Summary results are compiled by CVSI and information, inclusive of the SPOT Vision Screening Summary result, is mailed to the parent/guardian at the address provided on their child's consent form. In all cases wherein a complete eye exam was recommended on the SPOT Vision Screening Summary, additional information was provided by CVSI to the parent/guardian on the condition(s) cited from the SPOT Vision Screening Summary result printout report. This, along with available regional eye care professionals, instructions on scheduling an appointment, support agencies providing financial assistance for families in need, and an PEF, is given to the parent/guardian who is then instructed to give it to their eye care professional at the time of the child's eye exam appointment. After a child is seen by an eye care professional, the provider is encouraged to fill out the PEF and forward it to NPEF.

Device and Procedures

The SPOT photoscreener (Welch Allyn, Co.), Figure 1, is a handheld device that was introduced in 2011 as a vision screening tool able to be easily employed by both professional and layperson alike. It works through harnessing a patient's optical reflex using infrared photoemissions to obtain binocular refractive errors along with pupillary and gaze measurements. All measurements may be obtained on the device without any need for cycloplegia or pupillary dilation. The reported accuracy by Welch Allyn for various refractive error measurements on the SPOT photoscreener is ±0.25-0.50D for sphere, ±0.50-1.00D for cylinder, and ± 5 degrees for cylinder axis.

To perform an assessment, subjects are placed approximately 1 meter from the device, which harnesses attention through a series of noises and random visual patterns, as a sequence of measures are obtained in multiple meridians in the course of a few seconds. The device can be easily programmed to evaluate for operator designated cut-off values to assist in the decision process for making a referral. It additionally hosts a very user-friendly manner of data presentation on a 4.5-inch touch screen display that may be stored on the device or wirelessly sent to either a printer or other medium of electronic storage for data integration into an Excel-based format.

Figure 1. Image of the SPOT photoscreener model used by CVSI for pediatric screening

Data Analysis/Statistics

Descriptive statistics were utilized to stratify and assess patient population demographic information evaluated in this study. SPOT screening performance measures of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic odds ratio (DOR) were determined on the detection capabilities for three key amblyopic risk factors (strabismus, astigmatism, and anisometropia).

In order to compare refractive error data quality between SPOT screening field results and PEFs where cycloplegic refraction technique was used, the univariate measures (sphere, cylinder, axis) were transformed into power vector notation detailed by Thibos et al.[15] using a spreadsheet calculation methodology described by Miller.[16] The conversion to vector notation permits the representation of a sphero-cylinder lens as a single point in three-dimensional dioptric space with the three axes corresponding to separate lens powers. These representative lens powers include the spherical equivalent (M) and two Jackson cross-cylinder lenses at 0 degrees (J_0) and 45 degrees (J_{45}). Such conversion renders the standard clinical notation of refractive measurements using a spherocylindrical format of S/C x A where S (sphere), C (cylinder), and A (axis) to a form that has been proven amenable for performing statistical analysis.[15-19]

Once data had been converted to power vector form, the 95 percent confidence interval (CI) was generated on the means for SPOT and PEF refractive error vector data (M, J_0, J_{45}) for both the right and left eye using a T distribution. Additionally, the calculated probability using a two-tailed T test of means was also computed to detect for difference between refractive error measurements.

Results

Of the 120 cases evaluated in this study, 53 percent (n=63) were male and 47 percent (n=57) were female. The average age was 72 months (6 years) with a range from 18 months to 134 months. The age distribution of the study population, Table 1, was grouped according to the amblyopia risk factor categories found in the automated

screening guidelines by Donahue et al.[9] Racial demographics are presented in Table 2.

The average time taken for a child to reach an initial appointment with an eye care professional after being identified in a CVSI screening exam was 85 days with the shortest follow-up being nine days and the longest 686 days. The treatment outcomes resulting from patient initial appointments to their eye care professional referrals stratified by age category are provided in Table 3. The most common outcome from referral was glasses alone (77 percent) followed by no intervention (17.5 percent).

After professional evaluation, it was discovered that 23 percent (N=27) of the 120 cases referred by SPOT screening were later diagnosed with amblyopia in their eye care professional examination. Of these 27 cases the majority, 55 percent (N=15), were diagnosed in children older than 6 years. The 27 cases diagnosed with amblyopia have been stratified according to age and race in Table 4.

Performance evaluation of the SPOT device on achieving an appropriate assessment of potential conditions when compared against final diagnoses made on eye care professional follow-up demonstrated good specificity for each of the amblyopia risk factors examined. Table 5 SPOT screening results showed comparable sensitivity in the detection of refractive amblyopia risk factors which included astigmatic (76 percent) and anisometropic (75 percent) causes. Detection of strabismus showed a much lower sensitivity coupled with a low PPV. The Positive Likelihood ratio for astigmatism (5.5), anisometropia (7.5), and strabismus (14.3) as well as the Negative Likelihood ratio at 0.28, 0.28, and 0.52 for each risk factor, respectively, were calculated.

The results of power vector comparison analysis between SPOT and PEFs are shown in Table 6. Comparison of the right eye M power vector between SPOT and PEF patient data was detected to show a mean difference in refractive error measurement ($p<0.01$). Left eye M power vector comparison between SPOT and PEF data also showed reasonable difference ($p=0.05$). For all other power vectors contrasted (J_0 and J_{45}) on either eye no statistically significant difference was detected.

Table 1. SPOT screening population age distribution

Age categories: (months)	Toddlers (12-30)	Early preschool (31-48)	Late preschool/kindergarten (49-72)	School-aged children (>72)
TOTAL (n/%):	**4 / (3%)**	**11 / (9%)**	**56 / (47%)**	**49 / (41%)**
Male (n)	2	6	29	26
Female (n)	2	5	27	23

Table 2. SPOT screening referral population racial demographics

Race	N (%)
White	60 (50%)
American Indian	26 (22%)
Black/African American	3 (2.5%)
Hispanic	3 (2.5%)
Asian	1 (0.5%)
Other*	2 (1.5%)
Unknown+	25 (21%)

*One individual self-identified into multiple racial categories white/American Indian/Hispanic/Hawaiian/Pacific Islander and the remaining individual designated other without identifying.
+Patient race was not designated on Eye Care Professional Evaluation Form.

Table 3. Treatment outcomes from SPOT screening referrals

Age categories: (Months)	Toddlers (12-30)	Early preschool (31-48)	Late preschool/kindergarten (49-72)	School-aged children (>72)
TOTAL (n/%):	4/ (3%)	11 / (9%)	56 / (47%)	49/ (41%)
Glasses (n)	2	9	42	39
Glasses and patching (n)	0	0	2	0
Glasses and vision therapy (n)	0	0	1	0
Surgery (n)	0	0	0	1
Vision therapy (n)	0	0	0	1
Other (n)*	0	0	2	0
None (n)	2	2	9	8

*Two patients were scheduled for future follow-up at one and five months without mention of treatment plan or goals.

Discussion

The results of this study demonstrate the importance of identifying techniques aiding the early detection of amblyopic risk factors in children that can lead to the loss of vision and a diminished quality of life. Out of the 27 cases presenting with some detectable degree of amblyopia confirmed through eye care professional follow-up in this study over half were found in children beyond the age of 6 years old. This combined with the observation that the majority of screening referrals were composed of children in the "Late Preschool/Kindergarten" age category, along with the fact that most treatment interventions occurred

Table 4. Amblyopia diagnosis demographics by age and race

Age categories: (Months)	Toddlers (12-30)	Early preschool (31-48)	Late preschool/kindergarten (49-72)	School-aged children (>72)
TOTAL (n/%):	1 / (4%)	1 / (4%)	10 / (37%)	15/ (55%)
White (n)	1	1	5	13
American Indian (n)	0	0	2	2
Hispanic	0	0	1	0
N/A*	0	0	2	0

*Patient race not declared on the Eye Care Professional Evaluation Form.

Table 5. SPOT screening performance on detection of select amblyopia risk factors compared to eye care professional evaluation forms

Risk factor	Sensitivity*	Specificity*	PPV*	NPV*	DOR*
Astigmatism	76%	86%	96%	44%	19.5
Strabismus	50%	96%	43%	97%	27.5
Anisometropia	75%	90%	60%	94%	27

DOR = diagnostic odds ratio; PPV = positive predictive value; NPV = negative predictive value. *Values calculated from a positive-screened cohort.

Table 6. Power vector comparison of refractive error measurements**

Eye	Measurement		Mean	SD	CI	P-value
OD						
	M	SPOT	0.25 D	1.34 D	0.26	0.006
		PEF	0.90 D	2.02 D	0.39	
	J_0	SPOT	0.63 D	0.66 D	0.13	0.401
		PEF	0.56 D	0.60 D	0.12	
	J_{45}	SPOT	0.10 D	0.37 D	0.07	0.477
		PEF	0.07 D	0.27 D	0.05	
OS						
	M	SPOT	0.31 D	1.56 D	0.30	0.05
		PEF	0.81 D	2.11 D	0.40	
	J_0	SPOT	0.51 D	0.70 D	0.13	0.786
		PEF	0.49 D	0.64 D	0.12	
	J_{45}	SPOT	-0.02 D	0.33 D	0.06	0.802
		PEF	-0.03 D	0.26 D	0.05	

CI = 95 percent confidence interval; J0 =Jackson cross-cylinder lens equivalent at 0 degrees; J45 = Jackson cross-cylinder lens equivalent at 45 degrees; M = spherical equivalent; OD = right eye; OS = left eye; PEF = Eye Care Professional Evaluation Form refractive error (performed using cycloplegic technique); SD = standard deviation.
**Power vector refractive error statistics are generated from pool of 108 patients since 12 cases had no refractive error measurements reported on Eye Care Professional Evaluation Forms to compare with SPOT results.

in this age group, further helps to show the impact that can be made through early identification permitting subsequent intervention. It is also noteworthy to observe that in this study 82 percent (n=99) of cases referred to eye care professionals were found to be in need of additional therapy as a result of examination findings.

Even though 23 percent of all children referred for amblyopic risk factors had detectable amblyopia discovered in their professional follow-up appointment, most were treated with glasses alone. This is an important observation, as typically only children with severe amblyopia are treated initially with more intensive measures, which explains why only a few children received any other treatment. Given that early stages of amblyopia can usually be remedied by correcting the underlying risk factor condition, most eye care professionals will do a trial treatment with glasses alone at the initial visit. Treatment is further augmented by close follow-up at two to three months after the glasses are provided. This strategy allows time to see if a condition may be corrected and can also help to confirm whether or not a more permanent visual deficit exists by increasing the visual acuity data available to support a diagnostic decision.

A recent guideline put out by the American Association for Pediatric Ophthalmology and Strabismus Vision Screening Committee emphasized how the screening effort for amblyopic risk factors must be looked at as a continuous process during a child's visual development.[9] Early screening allows for increased opportunity to address visual disparities sooner with improved likelihood of a positive outcome. Further, a serial screening process can allow for more rapid detection and treatment referral of children either prior to or at earlier stages of amblyopia which long-term may result in less financial and temporal cost through decreased provider visits for children found to require treatment. This is a rational concept when one considers that beyond the age of 5 years the window of opportunity for recovering vision lost to developed amblyopia is much narrower and may be more refractory to treatment than at earlier stages.[2,9]

The number of photoscreener options presently available is extensive and has been well described in a prior review.[20] Quality assessment of photoscreeners in both clinical and field settings has been evaluated by many studies which have shown good agreement in refractive error estimation when compared to the gold standard of cycloplegic

refractive measurements in professional offices.[2,5,20,21] Overall, the results of this study on examining performance measures for the SPOT device's amblyopia risk factor detection capabilities and refractive error estimation are similar to findings by others examining it and additional photoscreener models in community and clinic based screening efforts.[2,3,5,12,20,21]

Important limitations of this study to recognize are the retrospective nature and that an initially positive-screened cohort was evaluated. Given this, it is important to note that screening test performance measures did not include normal-screened children as they were not referred for professional follow-up. Therefore, the false negative and true negative quantities depicted in the data represent children who were referred initially with at least one possible risk factor and were instead found to have either additional risk factors or a completely different risk factor upon completion of their professional follow-up evaluation.

Conclusion

This quality assessment of the screening efforts by NPEF in the CVSI project using the SPOT device has identified highly favorable preliminary results. This has been demonstrated both in terms of the quality in SPOT device performance on the identification of amblyopic risk factors, capacity for measuring refractive errors, and through screening follow-up benefit that is reflected in the high percentage of children who received treatment on referral to professional eye care services. Vision screening performed using the SPOT device represents a valuable modality that is easily employable and can provide tremendous benefit to children of the state of South Dakota. It provides a way to help further ensure the healthy development of vision for children by allowing for timely and effective professional referral when needed.

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