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Cover Page Footnote

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Abstract

Purpose: This study sought to further validate the efficacy of the SPOT^{TM} photoscreener version (v) 3.0.0500 as a screening device for amblyopia risk factors (ARF).

Methods: This was a cross-sectional study from five different western South Dakota outpatient clinics. Data from 610 eyes of 305 children aged 6 months to 13.5 years collected between July 2018 to September 2018 were analyzed, using both the out-of-box referral criteria and the 2013 American Association for Pediatric Ophthalmology and Strabismus (AAPOS) referral criteria. Optometrist (eye care provider or ECP) cycloplegia practice patterns were deferred to each clinics' specific protocols. Power vector and Bland-Altman plot analyses were performed.

Results: The average age of the 305 children in the study population is 99.6 months (~8.3 years), with a total of 42% of these subjects receiving no dilating drops prior to testing. From these cases, the SPOT^{TM} v3.0.0500 photoscreener evaluation parameters for detecting ARFs using the out-of-box referral criteria yielded an overall sensitivity (SN) of 95.2%, specificity (SP) of 91.9%, positive predictive value (PPV) of 81.6%, and negative predictive value (NPV) of 98.1%; the SPOT^{TM} v3.0.0500 photoscreener evaluation parameters for detecting ARFs using the 2013 AAPOS referral criteria yielded an overall SN of 96.3%, SP of 92.4%, PPV of 82.1%, and NPV of 98.6%.

Conclusions: With SN and NPV values exceeding 95%, this study supports the efficacy of the SPOT^{TM} v3.0.0500 photoscreener as a pediatric screening device to detect ARFs. Power vector analyses help to provide further objective comparisons of refractive measurements between photoscreening devices and refractive examinations.

Introduction

Amblyopia's Impact

Amblyopia is a significant cause of pediatric vision loss but is preventable and treatable with early recognition.[1-5] Strabismus, anisometropia spherical equivalent, and occlusion are all considered risk factors for amblyopia (ARF) in young children. Other ARFs include premature birth, maternal substance abuse during pregnancy, and family history of amblyopia in a first-degree relative.[6] The consequences of untreated amblyopia may be permanent and often begin in childhood with slower reading,[7] decreased fine motor skill functioning,[8] and adverse emotional ramifications.[9,10] If the non-amblyopic eye is injured or affected by disease, long-term visual performance consequences include impaired facial perception,[11] increased risk of bilateral vision impairment,[12] as well as total blindness.[13] As of 2020, eight states, including South Dakota, are without a designated pediatric vision screening policy.[14] To date, a comprehensive proposal has never been brought forward to the South Dakota State Legislature.

Amblyopia Treatment and Screening Efforts

Standard of amblyopia care entails guiding therapy based upon identified risk factors. Efficacious strategies, ideally within the first decade of life, include optimizing refractive correction, removing physical occlusions, correcting the strabismic eye with surgery, and penalizing the non-amblyopic eye (pharmacologically or through occlusive patching).[15-18] Without adequate optic input during this critical period, the visual cortex fails to develop properly and vision is permanently impaired.[19] In 2017, the United States Preventive Services Task Force published its updated evidence report, recommending vision screening for all patients aged 3-5 years old, with growing support for ARF screening under the age of 3.[20-25] Therefore, early screening and tailored therapy remain atop eye care providers' priorities in the management of amblyopia.

SPOT^{TM} Photoscreening

Photoscreening is the process of interpreting photos to screen for ocular defects associated with amblyopia. Photoscreening devices and vision screening initiatives have been extensively studied and continue to be shown to be cost-effective, efficient, and effective methods for ARF detection.[5] As such, photoscreening devices have been endorsed by the American Academy of Pediatrics, the American Academy of Ophthalmology, the American Association of Certified Orthoptists, the Children's Eye Foundation, and the American Association for Pediatric Ophthalmology and Strabismus (AAPOS).[26,27]

The current study evaluates the SPOT[TM] v3.0.0500 photoscreener (Welch Allyn, Skaneateles Falls, New York, USA). Several SPOT[TM]-related studies have looked at photoscreener evaluation parameters using different referral criteria, albeit with varying study designs and software versions: SPOT[TM] v1.0.3 software (SN 89-92%, SP 41-71%),[28] SPOT[TM] v1.1.50 software (SN 86%, SP 90%),[29] SPOT[TM] v1.1.51 software (SN 80-89%, SP 74-88%, PPV 88%, NPV 61%),[28,30-33] SPOT[TM] v2.0.16 software (SN 85-93%, SP 70-91%, PPV 58-82%, NPV 79-99%),[22,34,35] SPOT[TM] v2.1.4 (SN 84-94%, SP 62-80%, PPV 52-62%, NPV 86-96%),[36-38] SPOT[TM] v3.0.04.06 (SN 61%, SP 95%, PPV 76%, NPV 90%),[39] and SPOT[TM] version not specified (SN 86%, SP 70%, PPV 79%, NPV 79%).[40] To the authors' knowledge, photoscreener evaluation parameters in pediatric populations have yet to be published using the SPOT[TM] v3.0.0500 software.

Study Objectives
The primary objective of this study is to compare the collected screening data from the updated SPOT[TM] v3.0.0500 software with same-day optometrists' (eye care provider or ECP) analyses by constructing 2x2 tables to calculate photoscreener evaluation parameters and provide validation of the SPOT[TM] efficacy. A secondary objective is to assess the study population demographics. A tertiary objective is to obtain power vector analysis on the data as a point of comparison for future studies. Lastly, in conjunction with previous South Dakota SPOT[TM] publications,[3,6,41,42] state leaders could use this information to support legislation requiring childhood vision screenings in states like South Dakota, without such laws in place.

Patients and Methods

Study Design and Data Collection
This cross-sectional study represents a continuation of efforts in collaboration with Northern Plains Eye Foundation (NPEF) and its Children's Vision Screening Initiative (CVSI). The mission of NPEF is to protect and preserve vision and restore sight for people of the Northern Plains; this geographical area includes all of South Dakota, Northeastern Wyoming, Southeastern Montana, Southwestern North Dakota, and Northwestern Nebraska. The primary research mission of NPEF CVSI is to assess the efficacy of the SPOT[TM] photoscreener, which has been supported in four publications to date.[3,6,41,42] The current study was approved by The University of South Dakota Sanford School of Medicine's Institutional Review Board and conformed to the requirements of the United States Health Insurance Portability and Accountability Act of 1996. Informed consent was obtained from the parents (or guardians) of patients presenting for a routine yearly pediatric eye examination from their local optometrist.

Patients aged 6 months to 13.5 years who received both the SPOT™ screening and comprehensive eye examination on the same day were included in this analysis. Voluntary participation in the study came from twelve experienced ECPs, at five different eye clinics, in three western South Dakota communities – Rapid City, Belle Fourche, and Pierre. Following same-day training from experienced NPEF staff, optometric technicians at each eye clinic were responsible for conducting the SPOT™ screening prior to the subject's routine, yearly, comprehensive eye examination by the patient's local optometrist. The ECPs were asked to complete a comprehensive eye examination for each subject, in accordance with their clinics' protocol. The ECPs were masked to all SPOT™ screening results. Each clinic collected SPOT™ and ECP data from July 2018 to September 2018. NPEF staff followed an established process for organizing and digitally uploading the data to a secure database.

Device
Introduced in 2011, the SPOT™ photoscreener (Welch Allyn, Co.) is a user-friendly, handheld, noninvasive, touchscreen, portable, rechargeable device. Its infrared camera captures the patient's reflected (red) reflex, and in seconds, the user can obtain binocular refractive error, pupillary size, and gaze measurements. The device is held about three feet from the subject while lights and sounds are emitted from the device to attract the patient's attention. All measurements may be obtained on the device without any need for physical contact with the child, verbal input from the child, or pupillary dilation/cycloplegia of the child.

The effectiveness of the SPOT™ photoscreener to separate patients into a group that requires more extensive ECP evaluation supports its use as a screening tool. The subject receives either a "screening complete" (screen negative) or "complete eye exam recommended" (screen positive) designation based upon preset cutoff values for ARFs. For simplicity, a "screening complete" result will be referred to as "pass" and a "complete eye exam recommended" result will be referred to as "referral" henceforth. These referral criteria can be manually programmed based on desired cutoff values for levels of astigmatism, strabismus, and anisometropia. Welch Allyn reports the following accuracy measurements for the refractive error measurements of SPOT™: ±0.25-0.5D for sphere (S), ±0.50-1.00D for cylinder (C), and ±5 degrees for cylinder axis (A). The SPOT™ software v3.0.0500 was used in this study, and Welch Allyn conducts regular software updates to optimize SPOT™ performance. Functional advantages of SPOT™ include the ability to change referral criteria based on user's needs, simultaneous binocular screening, direct estimate of refractive error, concomitant detection of media opacities, concomitant detection of strabismus, as well as instantaneous results.[5,28,30-32,35] The

primary functional disadvantages of SPOT^{TM} are overestimation of astigmatism and underestimation of moderate to severe hyperopia.[5,29,43,44]

Data Analysis and Statistics
First, collective demographic information (age, race, gender) was calculated using descriptive statistics. Second, 2x2 tables were constructed, beginning with ARF status assignment to help address inter-ECP examination variability. ARF status for each subject was determined by comparing the ECP's S and positive C measurements to those listed in the 2018 Pediatric Ophthalmology/Strabismus (POS) Preferred Practice Pattern Panel (PPPP) refractive treatment criteria. The subject was deemed to have an ARF present if any of the four ARF criteria (anisometropia, astigmatism, myopia, and/or hyperopia) exceeded the values listed in Table 4C for either eye. Next, the S and positive C obtained from the SPOT^{TM} photoscreener were compared to the referral criteria values in Table 4A (adapted SPOT^{TM} v3.0.0500 out-of-box) and gold standard, cycloplegic exam cutoff values in Table 4B (adapted 2013 AAPOS) to determine true positives (TP), true negatives (TN), false positives (FP), and false negatives (FN). Standard calculations for SN, SP, PPV, and NPV were subsequently performed.

Finally, in an effort to further objectively compare refractive error data quality between SPOT^{TM} photoscreening results and ECP refraction measurements for statistical significance, the univariate, clinical measures of S, C, A were transformed into power vector notation of spherical equivalent lens of a refraction in diopters (M), vertically-oriented Jackson Cross-Cylinder (JCC) at 0 degrees with power J_0 (J_0), and obliquely oriented JCC at 45 degrees with power J_{45} (J_{45}).[45] The clinical (S, C, A) to vector (M, J_0, J_{45}) conversion (C2V) was performed in Microsoft Excel; this C2V notation input may be performed in either plus cylinder notation or minus cylinder notation.[46] For this study, power vector analysis was carried out with S, C, A values in negative cylinder. For readability purposes, J_0 and J_{45} values are color coded blue and red, respectively, in all tables and figures henceforth.

Once in power vector format, a two-tailed, Student T-test, with a 95% confidence interval (CI) was generated for both the left eye (OS) and the right eye (OD), using the mean differences from the M, J_0, and J_{45} values as calculated from SPOT^{TM} and ECP's refractive (S, C, A) measurements. This arithmetic was carried out using the following Microsoft Excel functions: "=.CONFIDENCE.T" and "=.STDEV.P".[47] For each measurement, if the standard deviations of the ECP and SPOT^{TM} differed by double (or more) the other, unequal variances were assumed; otherwise, equal variances were assumed. The spherical equivalent was calculated for each subject using the following formula: [ECP's S measurement] + [(0.5)*(ECP's C

measurement)]; this calculation is the same in positive or negative cylinder astigmatism values.

Mean, standard deviation (SD), 95% CI, and p-values were rounded to two-significant figures. For this study, the evaluation parameters SN, SP, PPV, NPV were calculated following conversion to plus cylinder.

To further objectively compare SPOT^{TM} and ECP refractive error measurements, Bland-Altman analysis was performed on the J_0 and J_{45} power vector data for OD and OS. The Bland-Altman plot methods have been described previously.[48,49] The Bland-Altman scatter plots show average ECP and SPOT^{TM} power vector values for each eye plotted against the ECP minus SPOT^{TM} differences for the same eye. The mean bias is calculated as the average of the differences plotted on the y-axis while the upper and lower limits of agreement (LOA) are calculated and plotted as ± 1.96 SD from the mean bias also on the y-axis. In this study, bias refers to the average discrepancy between the SPOT^{TM} and ECP refractive error measurements.

Results

From July 2018 through September 2018, a total of 317 children presented to their local optometrists' outpatient clinics in western South Dakota for routine evaluation. Subjects were excluded from data analysis if there was no consent form signed, if the SPOT^{TM} result was not obtained, or if there was not clear refractive information documented on the ECP's form. Ultimately, data was analyzed from 610 eyes of 305 patients (Figure 1). These subjects were evaluated at the following five western South Dakota clinics: 70% (N=213 subjects) Drs. Tucker-Kudrna-Holec-Young Eye Care Centre, 16% (N=48 subjects) Central Dakota Eyecare, 9.2% (N=28 subjects) Independent Eyes, 3.9% (N=12 subjects) Redwater Eye Care, and 1.3% (N=4 subjects) Black Hills Regional Eye Institute. This study population consisted of 45% male and 55% female, with an average age of 99.6 months (~8.3 years), ranging from 6 months to 162 months (~13.5 years), with 78% of subjects being over 73 months (~6.1 years) (Table 1). Dilation of the subjects was performed according to each clinic's preferred protocol (Table 2). White (73%) and American/Indian/Alaska Native (14%) composed the subjects' racial demographic majority (Table 3). The average age of the 11 subjects – representing 3.6% of the total population screened – diagnosed with amblyopia was 98 months (~8.1 years). The out-of-box SPOT^{TM} v3.0.0500 referral criteria settings, the 2013 AAPOS referral criteria, and the 2018 POS PPPP guidelines are juxtaposed in Table 4.
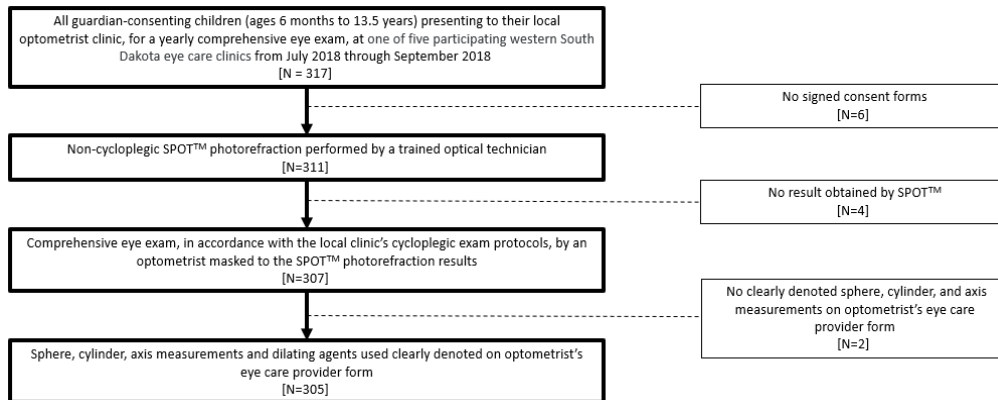
Figure 1: Flow chart depicting selection of the 305 subjects analyzed for this study.

Table 1: SPOT™ photoscreening population age and gender distributions.

		Age categories (months)				
		Infants (6-11)	Toddlers (12-30)	Early preschool (31-48)	Late preschool – kindergarten (49-72)	School – aged (73 - 162)
Gender	**Total** N= 305; 100%	2; 0.66%	4; 1.3%	14; 4.6%	47; 15%	238; 78%
	Male N=137; 45%	1	1	4	22	109
	Female N=168; 55%	1	3	10	25	129

Table 2: Summary of methods of dilation used during eye care professional examination.

Dilating eye drops used	N (%)
No dilation	128 (42%)
Tropicamide (Mydriacyl) 1%	106 (35%)
Cyclopentolate (Cyclogel) 1%	28 (9.2%)
Tropicamide (Mydriacyl) 1% + Phenylephrine (Neofrin) 2.5%	24 (7.9%)
Tropicamide (Mydriacyl) 1% + Norpholedrine (Paremyd) 0.25%	12 (3.9%)
No information provided	4 (1.3%)
Cyclopentolate (Cyclogel) 2.5%	3 (0.98%)

Table 3: SPOT™ photoscreening population racial demographics. ^17 subjects identified as more than 1 ethnicity. ⁺Subject race was not designated on eye care professional evaluation form. %, percentage of total study population.

Race	N (%)	N Diagnosed with Amblyopia (%)
White	223 (73%)	9 (3%)
American Indian/Alaska Native	43 (14%)	2 (0.7%)
Unknown⁺	17 (5.6%)	0
Other^	17 (5.6%)	0
Hispanic	3 (0.98%)	0
Asian	1 (0.33%)	0
Black/African American	1 (0.33%)	0
Native Hawaiian/Other Pacific Islander	0 (0.00%)	0

Table 4: Adapted pediatric refractive referral or treatment criteria. Listed values are the minimum for referral or treatment. Anisometropia refers to the difference in spherical equivalent measurements between eyes. D, diopters. v, version.

A) Adapted pediatric refractive referral criteria for the SPOT™ photoscreener v3.0.0500. The limit of detected myopia and hyperopia is –7.50 D and 7.50 D, respectively. The fourth age cohort is published as 73-240 months but assumed to be > 73 months for our data analysis. v, version.

B) Adapted 2013 American Association for Pediatric Ophthalmology and Strabismus gold standard, cycloplegic exam cutoff criteria. The first age cohort is published as 12-30 months, but this range is assumed to be < 30 months, for the purposes of the current study. All ages manifest strabismus > 8 prism diopters in primary position as well as all ages with a media opacity > 1 millimeter should be referred for an eye care professional examination.

C)) Adapted 2018 Pediatric Ophthalmology/Strabismus Preferred Practice Pattern Panel recommended refractive treatment criteria. Because there are no scientifically rigorous published data for guidance, these values are based on an expert consensus of professional experiences and clinical impressions. The fourth age cohort is published as 36-47 months, but this range is assumed to be ≥ 36 months, for the purposes of the current study. Listed anisometropia values are without strabismus present. *, if myopia present. **, if hyperopia or astigmatism present. ***, if esotropia present. ****, if astigmatism present. *****, if hyperopia present.

Table 4A. Adapted SPOT™ photoscreener (v3.0.0500) manufacturer refractive referral criteria.				
Age Range (months)	Anisometropia (D)	Astigmatism (D)	Myopia (D)	Hyperopia (D)
6-12	1.50	2.25	-2.00	3.50
12-36	1.00	2.00	-2.00	3.00
37-72	1.00	1.75	-1.25	2.50
> 73	1.00	1.50	-1.00	2.50

Table 4B. Adapted 2013 American Association for Pediatric Ophthalmology and Strabismus Vision Screening Committee gold standard, cycloplegic exam cutoff criteria.				
Age Range (months)	Anisometropia (D)	Astigmatism (D)	Myopia (D)	Hyperopia (D)
< 30	2.50	2.00	-3.50	4.50
31-48	2.00	2.00	-3.00	4.00
> 48	1.50	1.50	-1.50	3.50

Table 4C. Adapted 2018 Pediatric Ophthalmology/Strabismus Preferred Practice Pattern Panel refractive treatment criteria.				
Age Range (months)	Anisometropia (D)	Astigmatism (D)	Myopia (D)	Hyperopia (D)
< 12	4.00 * 2.50 **	3.00	-5.00	6.00 2.00 ***
12-23	3.00 * 2.00 **	2.50	-4.00	5.00 2.00 ***
24-35	3.00 * 2.00 **** 1.50 *****	2.00	-3.00	4.50 1.50***
≥ 36	2.50 * 1.50 **	1.50	-2.50	3.50 1.50 ***

Our reported SPOT^{TM} v3.0.0500 photoscreener evaluation parameters using the out-of-box referral criteria yielded an overall SN of 95.2%, SP of 91.9%, PPV of 81.6%, and NPV of 98.1%. The SPOT^{TM} v3.0.0500 photoscreener evaluation parameters using the 2013 AAPOS referral criteria yielded an overall SN of 96.3%, SP of 92.4%, PPV of 82.1%, and NPV of 98.6%. These results are summarized in Table 5.

Table 5: SPOT™ v3.0.0500 photoscreener evaluation parameters using different referral criteria. The SPOT™ referral and pass screens varied based on whether the SPOT™ v3.0.0500 referral criteria or the 2013 AAPOS referral criteria was used as the cutoff criteria for determining screen positive and screen negative. The 2018 Pediatric Ophthalmology/Strabismus Preferred Practice Pattern Panel consensus opinion treatment criteria was applied to eye care professionals' refractions and used to determine subjects' amblyopia risk factor (ARF) status. Table 4 delineates the cutoff values for each of these criteria. AAPOS, American Association for Pediatric Ophthalmology and Strabismus. v, version. SN, sensitivity. SP, specificity. PPV, positive predictive value. NPV, negative predictive value.

	SPOT™ photoscreener v3.0.0500: out-of-box referral criteria		SPOT™ photoscreener V3.0.0500: 2013 AAPOS referral criteria	
	ARF present	ARF not present	ARF present	ARF not present
SPOT™ referral (screen positive)	80	18	78	17
SPOT™ pass (screen negative)	4	203	3	207
Evaluation parameters of SPOT™ v3.0.0500	*SN = 95.2%*	*SP = 91.9%*	*SN = 96.3%*	*SP = 92.4%*
	PPV = 81.6%	*NPV = 98.1%*	*PPV = 82.1%*	*NPV = 98.6%*

The results of power vector comparison analysis between SPOT™ v3.0.0500 and ECP examinations provide a novel comparison of power vector data (Table 6).[46] Statistically significant differences were only found between OD J_0 and J_{45} (*p=0.019* and *p=3.8E-6*, respectively) as well as OS M and J_{45} (*p=0.025* and *p=7.9E-10*, respectively). The magnitude of differences (MOD) was calculated to be OD MOD 0.74 and OS MOD 0.80. The vector difference in diopters (VDD) was calculated to be OD VDD 1.0 and OS VDD 1.1.

*Table 6: Power vector comparison of refractive error measurements from entire study population. MOD, magnitude of differences. VDD, vector difference in diopters. D, diopters. CI, 95% confidence interval for the population mean, using a Student's T-distribution. *, statistically significant (p≤0.05). J_0, Jackson Cross-Cylinder lens equivalent at 0°. J_{45}, Jackson Cross-Cylinder lens equivalent at 45°. M, spherical equivalent. OD, right eye. OS, left eye. ECP, eye care professional (refractive error from cycloplegic evaluation form). SD, standard deviation.*

Eye	Measurement		Mean (in D)	SD (in D)	95% CI	p-value
OD						
N=305 eyes of 305 patients	M	SPOT	**0.13**	1.2	0.13	**0.061**
		ECP	**0.33**	1.5	0.17	
	J_0	SPOT	**0.43**	0.64	0.072	**0.019***
		ECP	**0.31**	0.61	0.068	
	J_{45}	SPOT	**0.14**	0.26	0.029	**3.8E-6***
		ECP	**0.05**	0.24	0.027	
	MOD	SPOT	**0.74**			
		ECP				
	VDD	SPOT	**1.0**			
		ECP				
OS						
N= 305 eyes of 305 patients	M	SPOT	**0.13**	1.2	0.14	**0.025***
		ECP	**0.39**	1.6	0.18	
	J_0	SPOT	**0.32**	0.59	0.066	**0.23**
		ECP	**0.26**	0.59	0.066	
	J_{45}	SPOT	**0.090**	0.25	0.028	**7.9E-10***
		ECP	**-0.040**	0.26	0.030	
	MOD	SPOT	**0.80**			
		ECP				
	VDD	SPOT	**1.1**			
		ECP				

In the Bland-Altman analysis (Figures 2-5), SPOT^{TM} consistently shows mean bias of greater astigmatism power vector values, and therefore cylinder values, compared to ECP. This leads to negative mean bias, which is consistent throughout the range of average measurements between ECP and SPOT^{TM}, meaning there is no proportional bias to the measurements.
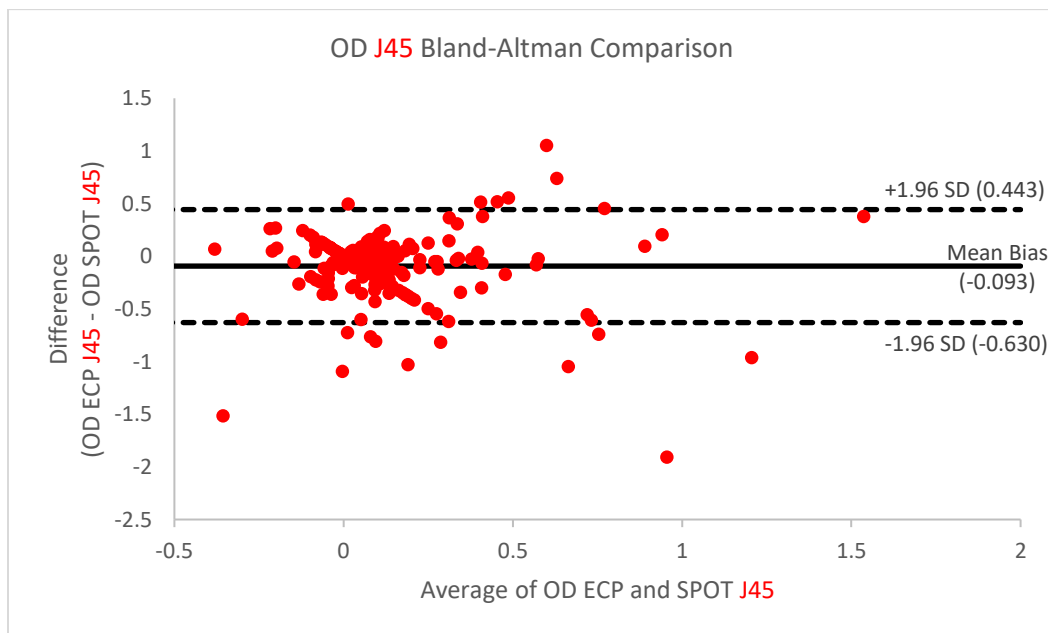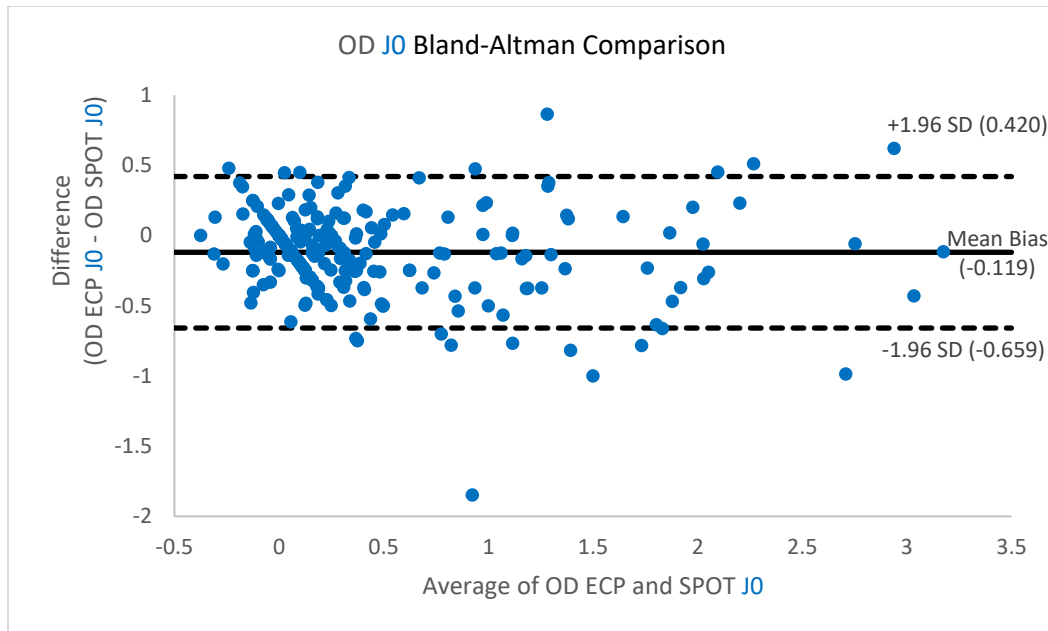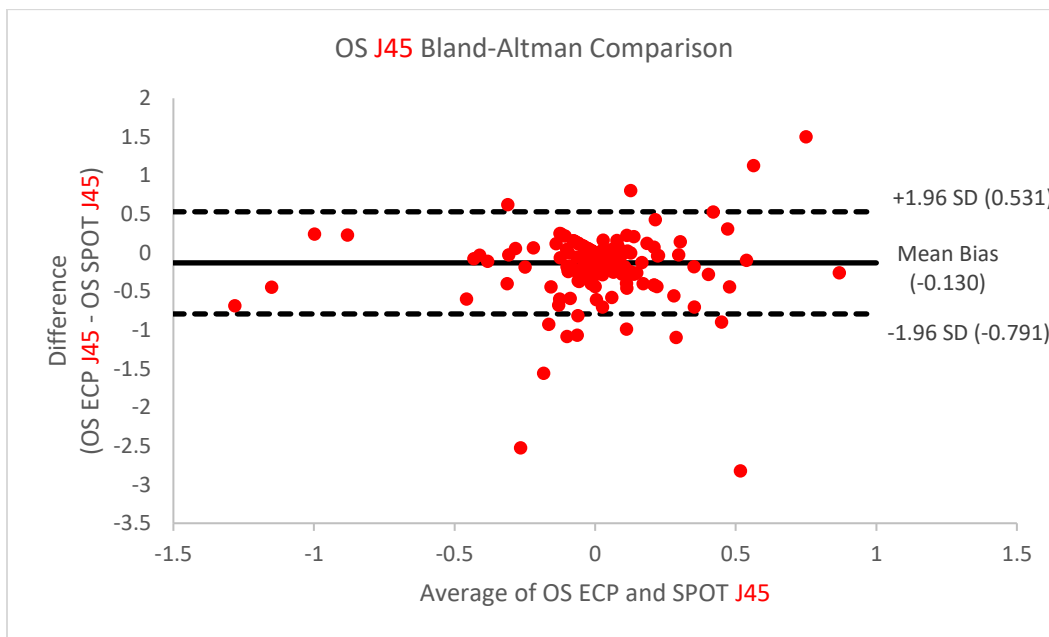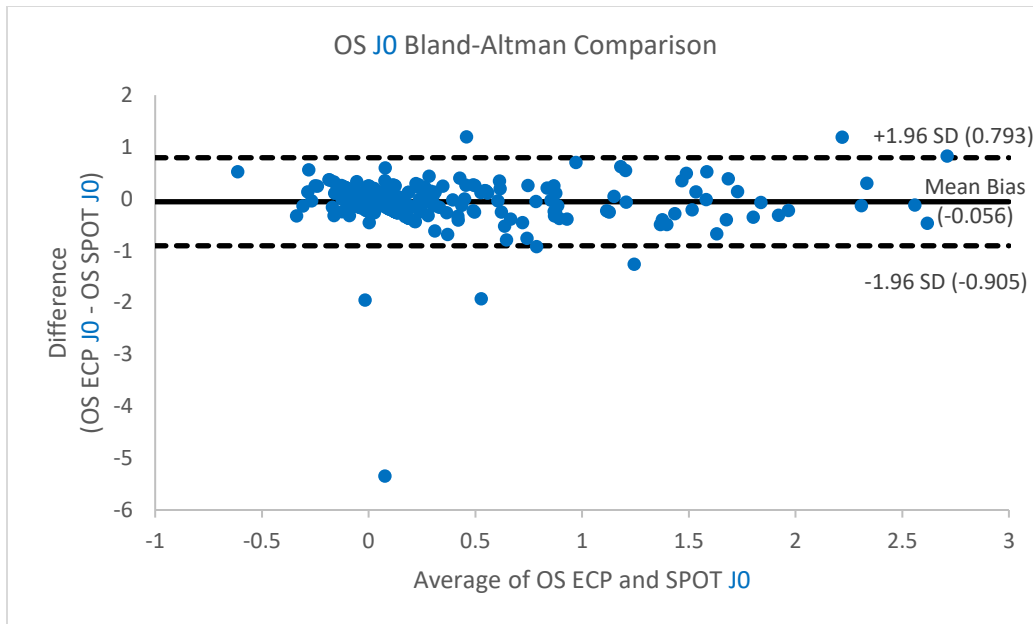
Figures 2-5: Bland-Altman plots comparing OD and OS J_0 (blue) and J_{45} (red) power vector values for ECP and SPOT^{TM} refractions. J_0, Jackson Cross-Cylinder lens equivalent at 0°. J_{45}, Jackson Cross-Cylinder lens equivalent at 45°. OD, right eye. OS, left eye. ECP, eye care professional (refractive error from cycloplegic evaluation form). SPOT^{TM}, refractive error from SPOT^{TM} Photoscreener device. SD, standard deviation.

Discussion

Towards Routine Use of the SPOT^{TM} Photoscreener and Power Vector Analysis
With SN and NPV exceeding 95%, this study certainly supports the efficacy of the SPOT^{TM} v3.0.0500 software as a screening device in western South Dakota. The favorable screening parameters obtained in this study provide significant validation for use in this geographic area. As with any photoscreening device, there remains a need to continually refine criteria parameters; our study, and others like it, help to provide guidance to this end. In this process of optimizing photoscreener referral parameters/rates appropriate for these pediatric office locations and age of child, other objective screening data, namely power vector analyses, may represent a promising step in the right direction to help decrease the burden of inappropriate referrals and unnecessary expenses.

The power vector values of M, J_0, J_{45}, MOD, and VDD provide specific, complimentary information to more completely optimize SPOT^{TM} photoscreening use. Furthermore, Bland-Altman analysis of J_0 and J_{45} allow for a generalizable comparison of ECP and SPOT^{TM} refractive error measurements. Thus, evidence-based refinement of multiple objective parameters may help to support standardized definitions of photoscreener outcome variables and customize photoscreening data in a population-specific manner for the purpose of routine photoscreener use.

Assumptions Regarding ECP Recommendations and SPOT^{TM} Photoscreening Results
Developing standardized definitions of SPOT^{TM} photoscreening outcome variables require making consistent assumptions. For the current study, these assumptions were necessary to ensure valid counts of TP, TN, FP, and FN in the post hoc analysis of the ECP recommendations (Table 5). Throughout the study, we were mindful of differences in ECPs' practice patterns as well as the nuances specific to unique patient situations. ECPs are known, for many evidence-based reasons, to prescribe ARF-preventing interventions at refractive targets below ARF thresholds in preferred practice guidelines. Therefore, instead of letting the decision from the ECP determine the ARF status columns in Table 5, we applied the 2018 POS PPPP findings to the S and C measurements documented by the ECP to decide whether an ARF was present or not. For the rows in Table 5, a SPOT^{TM} photoscreening "referral" (screen positive) indicates the subject should be referred for ECP examination, while "pass" (screen negative) indicates subject screening is complete.

Interpreting SPOT^{TM} Photoscreener Results

Comparing SPOT^{TM} photoscreener evaluation parameters of SN, SP, PPV, and NPV values in our study with those reported in previous studies should be interpreted with a few considerations in mind. Each photoscreener study is performed with nuanced differences in subject population, study designs, photoscreener product/software updates, and across diverse clinical environments. In the end, as a screening tool, photoscreener use is not intended to "outperform" other populations or supplant yearly optometric eye examinations, but rather photoscreeners serve as an accessible first step to potentially sight-saving care, particularly in underserved populations.

Interpreting Power Vector Analyses

For this study, the common language of Thibos et al. and the readily performed C2V calculations described by Miller were used to interconvert the refractive measurements of S, C, and A into power vector notation of M, J_0 , J_{45}, respectively.[45,46] Our study helps to serve as one benchmark comparison for power vector values, but additional studies are warranted to establish normal ranges for these values as well as the p-values that imply both statistical and clinical significance.

Clinical application of power vectors facilitates more standardized descriptions of refractive error.[45,47,50,51] These power vector calculations allow for a consolidated understanding and objective comparison of numerical data from multiple refractions, beyond photoscreener brand and ECP practice preferences. Augmented understanding and application of power vectors allow for more precise control of photoscreener experimental protocols and extraction of more meaning from refractive data. As photoscreening continues to increase in use and software updates refine screening parameters based on evidence in a patient population-specific manner, the need grows for a common language to facilitate clear communication across providers and technologies.[5] We expect clinical protocols for photoscreening devices, as dictated by the published evidence, to integrate use of power vectors and its associated terminology.

The power vector analysis of our data differed slightly from the previous western South Dakota power vector analysis.[6] While the previous study reported $p \leq 0.05$ in both eyes (OU) M values, our study reports statistical significance with the same p-value definition in the values of OD J_0, OD J_{45}, OS M, and OS J_{45}. When attempting to reconcile these findings, it is important to remember a few items. First, the current study did not mandate the gold-standard cycloplegic exam. Cycloplegic refraction reveals uncorrected refractive status of children by preventing the child's ability to accommodate. For the purposes of this study, we accepted the limitation

of not administering cycloplegic drops to every patient in order to increase clinics' participation in the study. Next, the average age of our study population was 99.6 months compared to the 72 months previously reported.[6] What may be statistically significant in an older patient population may not be statistically significant in another. Likewise, the clinical significance of these statistically significant power vector analysis values remains to be determined. Lastly, conducting multiple hypothesis tests without proper adjustment to the alpha value (kept at 0.05 for both performance parameter and power vector analysis) runs the risk of increasing type 1 (alpha) error. While p-values are conventionally chosen and generally accepted in the scientific community at 0.05, by definition, this number itself is still a value that is chosen arbitrarily and may not necessarily be appropriate for power vector analysis. Accounting for this multiplicity (multiple testing) problem could be addressed by tweaking the alpha value for the performance parameters (SN, SP, PPV, NPV) versus the power vector analysis (M, J_0, J_{45}), once the statistical and clinical significance interplay is better understood.

In addition to M, J_0, J_{45}, two other power vector values carry clinical significance. The MOD, and associated VDD, are currently used to help identify representative refractions as a form of median measurement,[46] because MOD and VDD can be followed over time to lend validity to various refractions. In this way, MOD and VDD values can identify the extent of dispersion in a set of observations of different refractions from multiple providers/photoscreening devices and have threshold values set for MOD and VDD. Thus, as MOD and VDD increase in magnitude, confidence is increased that the refractions being compared are objectively changing in a meaningful manner. For this study, the similar median values for the average MOD OD (0.74D) and OS (0.80D) and similar median values for the average VDD OD (1.0D) and OS (1.1D) suggest similar magnitude power vectors of the SPOT™ photoscreener and the ECP (Table 6). However, the clinical utility of MOD and VDD may be found in calculating these values for multiple refractions for the same patient over time.

Limitations and Future Directions
There are limitations of our study. This study focused on detection of ARFs as a means of further validating the latest version of the SPOT™ device for screening purposes. However, given the predominance of school-aged children (≥73 months of age) included, intervening to prevent ARFs may not be as feasible as it is in younger populations (<48 months of age) who are still in the critical period for visual development. Recent evidence suggests the primary screening focus for SPOT™ in school-aged children may shift from amblyopia prevention to detecting visual disturbances, such as refractive error.[38]

Next, despite a significant sample size, subjects were only evaluated at one time in space. Following fewer patients over multiple visits during a time span of years may provide valuable insight in helping to further interpret MOD and VDD threshold values for changing refractive prescriptions.

The current study proportionally reflects the racial demographics of five western South Dakota optometry offices (Table 3). Future studies may consider sampling from broader populations. Efforts to yield wider applicability of findings may include patient sampling across South Dakota, as well as from ophthalmology and pediatrician office visits. Furthermore, evaluation in more geographically isolated areas with even fewer eye care providers per square mile than western South Dakota (viz. Native American reservations) may help further elucidate information on patient populations with the least access to eye care and a paucity of eye health resources. These populations may have the most to benefit from photoscreening technologies, given the barriers to follow-up eye care that disproportionally affect certain populations.[42]

The enhancing effects of cycloplegic dilation on photoscreening are known.[39] However, approximately 42% of our subjects did not receive dilation. Future studies may focus on eliminating this possibly confounding variable with stricter control of dilation practices. Furthermore, comparing photoscreening results with recommendations among different health professionals (e.g., pediatricians, optometrists, and ophthalmologists) might lend insight into inter-specialty practice patterns.

Cycloplegic refraction is the gold standard for assessing refractive errors. It has been reported the SPOT[TM] photoscreener overestimates the degree of astigmatism, regardless of the dilation/cycloplegic status of the subject being screened;[5,39,43,44] indeed, our study did find higher J_0 values – corresponding with the magnitude of astigmatism – for the SPOT[TM] device compared to the ECP examination. Additionally, a myopic shift leading to underestimation of moderate to high hyperopia is a commonly accepted limitation of the SPOT[TM] device if cycloplegia is not considered.[29,39,52] Thus, key stakeholders – photoscreener researchers, eye care-related non-profit organizations, school nurses, advanced practice providers, optometrists, pediatricians, and ophthalmologists – need to account for these considerations when designing clinical protocols to routinely and effectively employ photoscreeners. Specifically, 3 of the 4 FN screens in the current study may

have been accounted for by recognizing the SPOT^{TM} device's underestimation of hyperopia.

The SPOT^{TM} photoscreening device will no doubt continue to play a role in the future of pediatric vision screening. It will be important to continually refine its use, especially in a time of increased telemedicine and a global pandemic. Ultimately, we hope this manuscript will contribute to increasing use and understanding of both the SPOT^{TM} photoscreening device and power vector analyses, as well as helping to support legislation of pediatric vision screening policies in states such as South Dakota, without current laws in place mandating childhood eye examinations.

Acknowledgements

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