Calibration and Validation of the 2WIN Photoscreener Compared to the PlusoptiX S12 and the SPOT

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ABSTRACT

Purpose: Pediatricians are interested in the amblyopia detection ability of photoscreeners, whereas ophthalmologists ponder their value as autorefractors. The 2WIN (Adaptica, Padova, Italy) is a new device capable of estimating refractive error and ocular alignment by infrared photoscreening.

Methods: Sequential pediatric eye patients with a high (56% to 60%) prescreening prevalence of amblyopia risk factors were screened with the PlusoptiX S12 (PlusoptiX, Inc., Atlanta, GA), SPOT (PediaVision, Lake Mary, FL), and 2WIN photoscreeners before confirmatory examination adhering to American Association for Pediatric Ophthalmology and Strabismus guidelines and Alaska Blind Child Discovery institutional review board protocol. Instrument referral guidelines determined through phase 1 comparison was then applied on additional patients for validation in phase 2.

Results: Sixty-two children (age: 1 to 10 years, mean: 5.2 years) were screened with all three devices before cycloplegic examination. Refractive results were inconclusive due to pupil size, cooperation, and out-of-range values. Values for sensitivity (91% and 78%), specificity (71% and 59%), and inconclusive rate (10% and 13%) were found for PlusoptiX and SPOT. The 2WIN was calibrated for this age range (phase 1), yielding 71% sensitivity, 67% specificity, and a 5% inconclusive rate. Regression compared to examination for the PlusoptiX, SPOT, and 2WIN, respectively, were sphere (r^2: 0.76, 0.87, and 0.58), cylinder power (r^2: 0.67, 0.56, and 0.50), and cylinder axis (r^2: 0.71, 0.41, and 0.40). A preferred 2WIN instrument criteria set was determined from the receiver operating characteristic curve. In phase 2, with 117 patients comparing 2WIN to PlusoptiX A-09, sensitivity was 73% and 85%, specificity was 76% and 73%, and inconclusive rate was 8% and 12%, respectively. The three instant-interpreting photorefractors performed well on amblyopic children, with the 2WIN having low inconclusive results. The PlusoptiX outperformed the SPOT and 2WIN as an autorefractor, particularly with respect to astigmatism power and axis.

Conclusions: The new 2WIN is a promising addition to portable photoscreeners for amblyopia detection and estimating refractive error.

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INTRODUCTION

Photoscreening is endorsed by the American Academy of Pediatrics as an effective public health measure to quickly detect amblyopia in children too young to test with conventional, time-staking monocular visual acuity screening.[1] Pediatricians now have a Current Procedural Terminology (CPT) code 99174, by which they can be reimbursed for photoscreening.[2] The American Association for Pediatric Ophthalmology and Strabismus (AAPOS)

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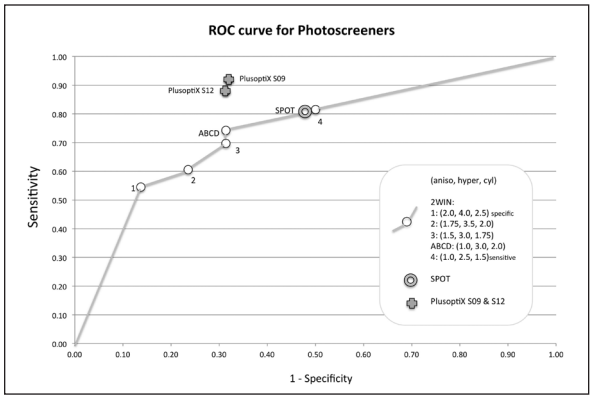

Figure 1. Receiver operating characteristic (ROC) curve for photoscreeners. The 2WIN photoscreener is manufactured by Adaptica, Padova, Italy. The PlusoptiXS12 photoscreener is manufactured by PlusoptiX, Inc., Atlanta, GA. The SPOT photoscreener is manufactured by PediaVision, Lake Mary, FL. ABCD = Alaska Blind Child Discovery; aniso = anisometropia; hyper = hyperopia; cyl = cylinder

has updated guidelines for age-based validation of photoscreeners[3] based on recent estimates of the prevalence of amblyopia risk factors.[4] Existing photoscreeners have been thus compared,[5] including two that employ rapid, multiradial infrared flash with internal computer interpretation: the PlusoptiX (table-top models S04, S08, S09, A09 autorefractometer, and now the hand-held S12; Nuremburg, Germany) and the Pediavision SPOT (Lake Mary, FL).[6-8]

A new remote binocular infrared autorefractor (2WIN; Adaptica, Padova, Italy) has been developed and marketed. Alaska Blind Child Discovery (ABCD) purchased a 2WIN for calibration to determine reasonable instrument referral criteria and comparative validation to apply these referral criteria to a subsequent set of patients. The validation statistics directly from a calibration study tend to overestimate the practical sensitivity and specificity of the instrument in actual subsequent screening, which was shown by the Welch Allyn SureSight's (Skaneateles Falls, NY) unrepeatable performance from phase 1 of the VIPS multicenter trial.[9]

Under ideal circumstances, a photoscreener is aimed at a child who fixes and focuses on the camera and then, from the acquired image series, software can find two pupils from which a refractive estimate can usually be derived. Unfortunately, in real-life screenings, not all children sit still and fix their gaze on the camera long and steadily enough. They also may not open eyelids to have adequately dilated, round pupils for the software to locate. The derived refractive error may exceed the estimation range of the instrument (common in the past with PlusoptiX). All of these result in "inconclusive" photoscreen results. Vision screen clinics and programs must deal with the reality of inconclusive interpretations. The majority of vision screen validation studies may report a portion to be "not readable," but exclude inconclusives from validation comparisons. Screening programs usually repeat a screening if they have an inconclusive instant result. Programs have the option to inform parents of a child with inconclusive results differently; they can regard each inconclusive as a "refer," a "pass," or a situation we fear. They can apologize to the parent that the screening "did not work" and hope that the child gets screened again in the future. ABCD has recently compared other photoscreeners and suggested new validation statistics.[5] As a result, the current study adds modified validation criteria highlighting the inconclusive impact, and considers such best factored as a "refer."[7]

PATIENTS AND METHODS

This HIPAA compliant study had ABCD Institutional Review Board approval from Providence Hospital.

Consecutive consented younger patients in a pediatric ophthalmology practice were screened in a random order using the PlusoptiX S12, the Pediavision SPOT, and the 2WIN. Instrument referral criteria were 2012 to 2013, specifically selected by ABCD (www.ABCD-Vision.org). The children then had a confirmatory eye examination for validation consistent with AAPOS guidelines.[3]

From this initial experience (phase 1), a receiver operating characteristic (ROC) curve was drawn. The ROC curve plots the inverse relationship between sensitivity and specificity based on different instrument referral cut-offs. **Figure 1** shows the ROC curve using irSensitivity and irSpecificity, regarding each inconclusive result as a "refer." We then selected our preferred ABCD referral criteria for the 2WIN, from which the second phase of the study could be done.

A subsequent set of patients in the same pediatric eye practice had PlusoptiX A-09 followed by 2WIN screening using phase 1 referral criteria as part of their confirmatory examination by 2013 AAPOS guidelines (phase 2). The examining pediatric ophthalmologist did not yet have access to the screening results performed by the technician at the time of cycloplegic refraction.

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TABLE 1

Validation of PlusoptiXS12 and SPOT With Calibration (Phase 1) and Then Validation (Phase 2) of 2WIN Photoscreeners[a]

	Phase 1			Phase 2	
Guidelines	**PlusoptiX S12**	**SPOT**	**2WIN**	**2WIN**	**PlusoptiX A09**
A	29	25	25	45	47
B	7	9	8	11	13
C	3	7	10	17	8
D	17	13	16	35	35
E	5	5	2	4	11
F	1	3	1	5	3
Sensitivity = A/(A+C)	91%	78%	71%	73%	85%
Specificity = D/(B+D)	71%	59%	67%	76%	73%
PPV = A/(A+B)	81%	74%	76%	80%	78%
NPV = D/(C+D)	85%	65%	62%	67%	81%
irSensitivity = (A+E)/(A+C+E)	92%	81%	73%	74%	88%
irSpecificity = D/(B+D+F)	68%	52%	64%	69%	69%
irAccuracy = (A+D+E+F)/total	84%	74%	71%	76%	82%
Prescreen-prev = (A+C+E)/(total)	60%	60%	60%	56%	56%
Total (A+B+C+D+E+F)	62	62	62	117	117

	Exam +	Exam -
Sc+	A	B
Sc-	C	D
Sci	E	F

PPV = positive predictive value; NPV = negative predictive value; Sc+ = screening refer; Sc- = screening pass; Sci = screening inconclusive

[a]Phase 1 is a comparison of the three portable, infrared, computer-interpreted photoscreeners on high-risk (pre-screen prevalence greater than 21%) children in a pediatric eye practice. Ir-statistics (irSensitivity) regard "inconclusive" results as if they were "refer"; inconclusives arise from lack of ability to obtain an image (patient cooperation) and lack of computer interpretation (ie, Asian eyelids). Instrument referral criteria for 2Win were then determined. Phase 2 used 2WIN with these referral criteria compared to a table-mounted PlusoptiX A09 using Alaska Blind Child Discovery referral criteria (**Table 2**).

The 2WIN photoscreener is manufactured by Adaptica, Padova, Italy. The PlusoptiX S12 and A09 photoscreeners are manufactured by PlusoptiX, Inc., Atlanta, GA. The SPOT photoscreener is manufactured by PediaVision, Lake Mary, FL.

RESULTS

Calibration (Phase 1)

Sixty-two children (age: 1 to 10 years, mean age: 5.2 years) were screened with the PlusoptiX S12 and SPOT and tested with the 2WIN in a random order. Some were determined to be "inconclusive" on the basis of lack of cooperation, no image, or on instrument read. Validation statistics are given in **Table 1**. The 2WIN was calibrated with referral criteria proposed in **Table 2**. In this ideal situation, 2WIN sensitivity would have been 92%, specificity 88%, and an inconclusive rate of 5%.

An ROC curve of irSensitivity versus irSpecificity is shown in **Figure 1**. Values for the SPOT, PlusoptiX S12, and PlusoptiX A09 are given for comparison. For given instrument referral cut-offs for the 2WIN (1 to 4 in the inset text box), the ROC curve was generated, allowing us to select our preferred instrument referral criteria for the 2WIN (ABCD).

Values of refractive error were compared for each autorefractor. Regression compared to examination for the PlusoptiX, SPOT, and 2WIN, respectively, were sphere (r^2: 0.76, 0.87, and 0.58), cylinder power (r^2: 0.67, 0.56, and 0.50), and cylinder axis (r^2: 0.71, 0.41, and 0.40). For astigmatism comparison, we excluded astigmatism less than 0.75 diopters (D).

Validation (Phase 2)

Validation statistics for 117 children, aged 4.7 ± 2.3 years (range: 0.5 to 10 years) from a pediatric

TABLE 2

2WIN Manufacturer and ABCD Recommendations for Instrument Referral Criteria

Criteria	Age 0 to 1 Year	Age 1 to 3 Years	Age 3 to 6 Years	ABCD 2WIN	ABCD PlusoptiX S12	SPOT
Hyperopia, D (sph)	> 3.5	> 3	< 2.5	Max ≥ 3	2.5	3
Myopia, D	> 2	> 2	< 1.25	≥ 2.25	2.25	2
Astigmatism, D (cyl)	> 2.25	> 2	< 1.75	≥ 2	2.25	2
Anisometropia, D (difference)	> 1.5	> 1	< 1.0	Δ SphEq ≥ 1	1	1
Anisocoria, mm (difference)	> 1	> 1	< 1	1.5	1.5	1
Gaze	> 6°	> 6°	> 6°	10°	10°	8°

ABCD = Alaska Blind Child Discovery; D = diopters; sph = sphere; cyl = cylinder; SphEq = spherical equivalent
The 2WIN photoscreener is manufactured by Adaptica, Padova, Italy. The PlusoptiX S12 photoscreener is manufactured by PlusoptiX, Inc., Atlanta, GA. The SPOT photoscreener is manufactured by PediaVision, Lake Mary, FL.

eye practice are given in **Table 1**. Refractive error was +1.3 ± 2 D sphere (range: -12 to +8) with an average 1.2 D cylinder (range: 0 to 5.5 D).

DISCUSSION

The three instant-interpreting photorefractors performed well on children with amblyopia, with the 2WIN having low inconclusive results. The 2WIN and the SPOT had similar ROC curves; however, we selected less sensitive and more specific referral criteria for the 2WIN given the unique and remote photoscreening needs in Alaska. The 2WIN has added template screens that include suggested thresholds for screening (**Table 1**). ABCD selected 2WIN instrument referral criteria similar to the manufacturer's choice of preschool age. With more years of computer-interpreted multiradial, infrared photoscreening experience since the similar PlusoptiX S04 (2004), the PlusoptiX S12 outperformed the SPOT and 2WIN, particularly with respect to astigmatism power and axis. The newer portable PlusoptiX was similar to the table-top PlusoptiX A-09, confirming the manufacturer's claims that the camera and the software should mirror each other.

CONCLUSION

The new 2WIN is a promising addition to several effective portable photoscreeners for rapid estimation of refractive error and amblyopia risk factor detection. We suspect validation will further improve with enhancements in the instruments and refinements in the computer-assisted instrument referral criteria.

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