

BRIEF COMMUNICATION

2020 Evaluation of Portable Vision Screening Instruments

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Amblyopia is the most common cause of preventable visual impairment in children and occurs as a result of unilateral or bilateral impairment in best-corrected visual acuity. Early diagnosis and proper treatment are crucial to prevent poor visual outcomes in adulthood. Advances in technology have provided more objective diagnostic tools, which can now be used by a wide range of healthcare providers. Here, we highlight tools that have gained popularity in the past two decades and compare clinically relevant parameters to guide primary care providers seeking to incorporate instrumental vision screening in pediatric patient care.

INTRODUCTION

Amblyopia occurs when a decrease in visual stimulation results in suboptimal development of the visual pathways in the brain. Studies have shown that the prevalence of amblyopia is between 2-6% in the general pediatric population [1-3] and up to 20% in certain populations at risk of developing this condition [4,5]. Risk factors for developing amblyopia include refractive errors (myopia, astigmatism, hyperopia), anisometropia (unequal refractive error leading to better vision in one eye compared to the other), strabismus (crossed eyes), and media opacities. Screening ensures early identification of children who are at risk so that they may be treated while there is significant plasticity in the developing visual pathways – typically until age 7 [6]. Although traditional screening

tools such as letter and symbol charts are available, they can be time-consuming, erroneous, and challenging in younger children or those with disabilities.

The advent of instrumental vision screening has provided primary and eye care providers with more objective tools to detect amblyopia risk factors, especially in preverbal children as young as 6 months [7]. These instruments are also useful for pediatric ophthalmologists in screening children with disabilities, for which the standard cycloplegic retinoscopy examination might be difficult. In this article, we highlight the most common vision screening instruments in 2020 and compare statistical measures of utility and clinically relevant parameters to guide providers seeking to incorporate these instruments into their practices.

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Abbreviations: ARFs, Amblyopia Risk Factors; NPV, Negative Predictive Value; PPV, Positive Predictive Value; SN, Sensitivity; SP, Specificity.

Keywords: Amblyopia, Amblyopia Risk Factors, Vision Screening, Instrumental Vision Screening, Preventive Ophthalmology

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2013 GUIDELINES				
Age (months)	Refractive Errors			
	Astigmatism	Hyperopia	Anisometropia	Myopia
12-30	>2.0D	>4.5D	>2.5D	>-3.5D
31-48	>2.0D	>4.0D	>2.0D	>-3.0D
>48	>1.5D	>3.5D	>1.5D	>-1.5D
	Nonrefractive Errors			
All	Manifest strabismus >8PD in primary position			
	Media opacity >1mm			
2003 GUIDELINES				
Age (months)	Refractive Errors			
All	Anisometropia (spherical or cylindrical) > 1.5			
	Hyperopia > 3.50 D in any meridian			
	Myopia magnitude > 3.00 D in any meridian			
	Astigmatism > 1.5 D at 90° or 180° > 1.0 in oblique axis (> 10° eccentric to 90° or 180°)			
	Visual Acuity per age appropriate standards			
	Nonrefractive Errors			
	Any manifest strabismus			
	Any media opacity > 1 mm in size			
	Ptosis ≤ 1 mm margin reflex distance*			

* Margin-reflex distance is the distance from the corneal light reflex to the upper lid margin and is a standard objective measurement of ptosis

Figure 1. American Association of Pediatric Ophthalmology and Strabismus (AAPOS) Amblyopia Risk Factors (ARFs) Guidelines.

METHODS

Amblyopia risk factors (ARFs) were obtained from the guidelines drafted by the American Association for Pediatric Ophthalmology and Strabismus (AAPOS) and the American Academy of Ophthalmology (AAO) in 2003 and 2013 [7,8]. We subsequently conducted a web search for “vision screening instruments” and included portable pediatric instruments that screened for amblyopia risk factors (ARFs). Once the instruments were selected, we obtained cost, conditions screened, as well as several clinically useful parameters for each instrument. The cost of equipment was obtained from online vendors (Active Forever, Alibaba.com, CME Corp, Jaken Medical, Medex Supply, Medical Device Depot, Serfinity Medical, and Tiger Medical) and/or company representatives. The clinically useful parameters we obtained include the presence of an EMR interface, battery life (after being fully charged), the transmission of protected health information (PHI), remote analysis of data obtained from vision screening, and weight of the instrument. We excluded instruments without publications testing their utility in screening for amblyopia risk factors in clinical settings. Lastly, we conducted searches on MEDLINE and OVID to extract literature published on each instrument and report sensitivities (SN), specificities (SP), positive predictive values (PPVs), and negative predictive values (NPVs) of each instrument (ranges) based on different referral criteria.

RESULTS

The risk factors for the development of amblyopia as outlined by AAPOS in the years 2003 and 2013 are reported in Figure 1 [7,8]. After excluding instruments without published testing or utility in clinical settings, seven portable vision-screening instruments were left. These include the Spot Vision Screener (Welch Allyn, Skaneateles Falls, NY), 2WIN (Adaptica, Padova, Italy), the S12C/R Mobile Vision Screener autorefractor (Plusoptix, Nuremberg, Germany), the iScreen 3000 photo screener (iScreen Vision Inc, Cordova, TN), the OPTEC 5500 vision screener (Stereo Optical Co., Inc., Chicago, IL), the GoCheck Kids smartphone photo screening application (Goquity Mobile Health, Scottsdale, AZ) on the iPhone (Apple Inc, Cupertino, CA), and the Pediatric Vision Scanner or “blinq” (Rebion, Boston, MA).

The cost of each instrument, conditions screened, and clinically relevant information is reported in Table 1. Although all the instruments screen for refractive errors and strabismus, only the Plusoptix and iScreen instruments detect cataracts. The Optec instrument measures visual acuity (VA) and is suitable for children that can cooperate with VA testing. The Goquity and Plusoptix (S12 C) instruments are currently the only members of this group that can interface with the electrical medical record (EMR), although some other companies are working on interfaces in subsequent models. All but the iScreen and Goquity instruments automatically analyze tests. With the iScreen and Goquity, trained personnel conduct re-

Table 1. Comparison of seven portable vision screening instruments outlining the cost, amblyopia risk factor screened, and clinically useful characteristics.

Company		Welch Allyn	Adaptica	Plusoptix	iScreen	Optec	Goquity	Rebion
Instrument		Spot Vision Screener	2WIN	S12C/R	3000	5500P	GoCheck Kids#	Blinq
Place of Manufacture		Skaneateles Falls, NY, USA	Padova, Italy	Nuremberg, Germany	Cordova, TN, USA	Chicago, IL, USA	Scottsdale, AZ, USA	Boston, MA, USA
Cost (US\$)		6750-8436	5000-6850	5495-8898	5000	3545-4716	169*	7495-8995
Amblyopia Risk Factors (ARFs)	Refractive Errors	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Strabismus	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Cataracts (media opacity)	No	No	Yes	Yes	No	No	No
EMR friendly interface§		No	No	Yes	No	No	Yes	No~
Battery Life (minutes)§		240 *	240	180/variable**	480	-	360-480	360
PHI Transmission§		No	Yes	No	Yes	No	Yes	Yes
Remote analysis§		No	No	No	Yes	No	Yes	No
Weight (pounds)§		2.55	1.88	1.76-2.20	4.35	15.50	0.30-0.46	4.00

Currently only on the iPhone, * only monthly finance available, § Clinically useful characteristics, ~ EMR (electronic medical record) interface is currently being developed, ** Based on the rechargeable AA battery used.

Spot Vision Screener (Welch Allyn, Skaneateles Falls, NY), 2WIN (Adaptica, Padova, Italy), the S12C/R Mobile Vision Screener autorefractor (Plusoptix, Nuremberg, Germany), the iScreen 3000 photo screener (iScreen Vision Inc, Cordova, TN), the OPTEC 5500 vision screener (Stereo Optical Co., Inc., Chicago, IL), the GoCheck Kids smartphone photo screening application (Goquity Mobile Health, Scottsdale, AZ) on the iPhone (Apple Inc, Cupertino, CA), and the Pediatric Vision Scanner or “blinq” (Rebion, Boston, MA).

*** Device cannot be used while charging / batteries cannot be changed during the screening; RRR Plusoptix 4/13/2021**

mote analyses of tests.

With regards to referral criteria, the Spot Vision Screener has unique referral criteria that are updated as newer models of the instrument are released, with the option for the user to enter a different set of criteria (eg, AAPOS 2013), if desired. Similarly, in addition to the option of entering user-specific criteria, Plusoptix instruments have five different referral criteria. These criteria were implemented based on studies [9-16] and are different combinations of SN-SP values, allowing the provider to choose the desired sensitivity or specificity. Several instruments have adopted the 2013 AAPOS criteria including the Adaptica with a slight revision to children > 48mo, as well as the iScreen and Goquity instruments. These are guidelines stating limits of hyperopia, myopia, astigmatism, anisometropia, strabismus, or media opacity above which the patients are referred for a criterion standard exam since these patients are at risk for developing amblyopia (Figure 1). The Optec and Rebion instruments are slightly different from the rest. Optec 5500P differs from other instruments as its measurements of visual acuity and phoria require output from the child while the others objectively assess refraction, alignment, fixation, and media clarity based on a child's ability to fixate on a target. The Rebion instrument is designed to detect amblyopia and strabismus through disrupted bi-foveation, and signals to refer if abnormalities are found. In Table 2, we include the manufacturer and AAPOS referral criteria. Unless otherwise stated, the studies compare instrument referral criteria to criterion standard confirmatory examinations by ophthalmologists.

DISCUSSION

Portable vision screening instruments are gaining popularity in the United States and the world, especially in developing countries where access to sophisticated and expensive vision screening instruments is limited [17,18]. The portability, affordability, and user-friendly nature of these instruments enable primary care providers and trained personnel to conduct vision screening, effectively expanding access to eye care. In May 2020, at least 6,500 US pediatricians had incorporated the new GoCheck Kids app into their practice [17]. Owing to decades of prospective studies showing the efficacy of instruments like the Spot Vision Screener, Plusoptix, 2WIN, and iScreen (Table 2), these instruments have since been adopted as part of routine eye screening by many primary care practices. These instruments could significantly expand access to vision screening on a global scale, providing frontline providers with an objective way of identifying children that need to be triaged to obtain a criterion standard ophthalmologic exam and amblyopia treatment. Thus, primary care providers and health administrators should

be equipped with information to ensure that they select instruments that best serve their patient populations.

Sensitivity and specificity are traditionally used to determine the utility of a screening test but in pediatric vision screening, these values depend on a predetermined set of referral criteria. Referral criteria are thresholds beyond which an instrument recommends that a child be triaged for a criterion standard uniform exam by a specialist or treatment. Instrument manufacturers can recommend referral criteria that optimize SN and SP values either as detailed in the user manual or as a pre-programmed mode on the device. When available, receiver operating characteristic (ROC) curve analyses are also helpful as the area under those curves (AUC) provides a summary of the general performance of the instrument and allows for comparison of different referral criteria.

AAPOS and the American Academy of Ophthalmology (AAO) established guidelines in 2003 [7], which were later revised in 2013 [8] (Figure 1) to present a standard for comparing screening instruments, and to recognize that an instrument may detect amblyopia directly, instead of relying on ARFs. Despite the presence of guidelines, AAPOS recommends that with instrumental screening, providers can rely on the manufacturer-determined criteria if those criteria yield a more accurate test result for the instrument of interest. These manufacturer-specific criteria are available either on their respective websites or in the instrument manuals. A 2014 study comparing SN and SP values of different versions (v.1.1.51 and 2.0.16) of the Spot Vision Screener, each with unique manufacturer-recommended criteria reported higher values for sensitivity and specificity for the manufacturer's criteria compared to the 2013 AAPOS criteria [19]. The manufacturer's criteria had less stringent cutoffs for anisometropia, myopia, and hyperopia and also screened children from 6 to 12 months (AAPOS recommends screening from 12 months due to limited evidence supporting the benefit of screening before that age [8]).

SN and SP values depend on referral criteria as well as the age group being studied. While testing the Spot Vision Screener for ARFs using the 2013 AAPOS referral criteria, Forcina et al. found that children aged 6 to 11 months had a sensitivity of 100% (95% CI; 29.2-100) compared to those aged 12 to 23 months with a sensitivity of 82.4% (95% CI; 56.6-96.2) [20]. On the other hand, PPV was highest in children between 24 and 35 months at 64.3 (95% CI; 50.4-76.6) and lowest in the 6 to 11-month age group at 30 (95% CI; 6.7-65.3). A test with a higher PPV in conjunction with high sensitivity is preferred as it can identify children at risk of developing amblyopia while reducing over-referrals. For pre-school age children, a test with high specificity may reduce over-referrals, and also lead to finding those children before amblyopia is entrenched [8]. Thus, providers need to

Table 2. Statistical Measures of Vision screening instruments stratified by referral criteria.

Company	Instrument	Referral Criteria	Sensitivity, % (Median)	Specificity, % (Median)	PPV, % (Median)	NPV, % Median
Welch Allyn	Spot Vision Screener	Manufacturer (v. 1.03) [22]	80	74	88	61
		Manufacturer (v.1.151) [19]	88.1	71.9	79.3	83.1
		Manufacturer (v.2.0.16) [19]	87.7	75.9	81.7	83.4
		2003 AAPOS [23]	77	87		
		2013 AAPOS [19,20,22,24-26]	60-92.6 (87)	70.4-93 (84.5)	58.1-86 (77.1)	75-98.9 (89.3)
Adaptica	2WIN	Manufacturer [27]	71	67		
		2003 AAPOS* [28,29]	68-91 (79.5)	68-84 (76)	84	
		2013 AAPOS [30]	67.4	83.7	87.9	59.4
Plusoptix	S12C/R	Manufacturer ROC [27]	85	73		
		Manufacturer ROC3 [31]	86	84		
		Manufacturer ROC5 [32]			69-83 (76)	
		2013 AAPOS [25,33,34]	64-100 (90.2)	61-93 (88)	65-76 (65)	87-100 (98.5)
iScreen	3000	Manufacturer [35]	77.2	94.1		
		2003 AAPOS [23,36-38]	66.2-90.7 (78)	42.9-92 (81.8)	81.8	75.5
Optec	5500	2013 AAPOS [39]	77.4-81 (79.2)	87-100 (93.5)	91.9-100 (96.0)	50-71.4 (60.7)
Goquity	Gocheck kids	2003 AAPOS [40]	81	91	92	
		2013 AAPOS [41-45]	65-90.5 (81)	67.2-85 (68.1)	50-76 (56.9)	80-94 (88.5)
Rebion	blinq. (pediatric vision scanner)	Manufacturer [25,28,46-50]	41-98 (96.5)	75-96 (87)	38-82 (47)	78-100 (89)
		2003 AAPOS [28]	75	68	81	

* slightly modified version as outlined in Arnold, 2020 [28].

be aware of the ramifications of differences in SN, PPV, and SP in vision screening instruments for children of different ages.

Interestingly, we obtained a wide range of SN and SP values for instruments with several studies published. This could be due to the presence of user-specific differences in screening, highlighting the need for understanding the operating principles of the selected instrument as well as the proper training of screening personnel. Each manufacturer provides a unique set of instructions that are available either online or included upon purchase of the instrument. Sometimes, provisions are made for representatives to provide guidance and/or troubleshoot issues that may arise. Providers should make use of these resources when needed to achieve suitable SN and SPs values in their respective clinics.

These findings indicate that there are a variety of vision screening instruments that are effective for screening children with amblyopia. Most are based on identifying ARFs, although the Pediatric Vision Scanner identifies patients with amblyopia and strabismus directly. Moreover, these instruments are compact, user-friendly, require minimal participation by children, and are reimbursable by several private insurers and Medicaid in some states in the US (CPT codes 99177 and 99174). Given that the traditional letter and symbol charts have varying efficacy [21], these instruments provide an objective method for early detection and subsequent treatment of amblyopia in this population. Pediatricians can use these findings to determine which instrument they find suitable to incorporate into their practice.

Our report has several limitations. First, different studies sometimes used different models of instruments, so we decided to group instruments by referral criteria or version, when available. Secondly, we report ranges of reported sensitivities and specificities by instrument based on studies identified in a literature search, some of which are wide. Due to the wide range reported, we also include the median values in Table 2. We have attached a supplement that contains all of the studies included in this report with sensitivities and specificities broken down for individual review (Appendix A).

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Appendix A. List of studies that test the sensitivities and specificities of pediatric vision screening instruments compared to the criterion standard confirmatory examination.

Last name of first author	Location	Year	Journal	Comparison	Age of Children	Referral Criteria
Yakar	Brazil	2020	Arq. Bras. Oftalmol.	spot vs standard autorefractor	3-10 yrs	AAPOS 2013
Forcina	US	2017	AJO	spot	6-35mo	AAPOS 2013
Petersheim	US	2014	JAAPOS	spot	11-221	AAPOS 2013, v.1...., v.2.0.16
Srinivasan	US	2019	JAAPOS	spot	6-36 mo	AAPOS 2013 (also study specific)
Silbert	US	2014	JAAPOS	spot	1-6y	AAPOS 2013, version1.03
Mendez	Costa Rica	2015	JAAPOS	spot	20-119	AAPOS 2013
Nishimura	Canada	2019	BMC	spot vs Plusoptix vs PVS	3-6y	AAPOS 2013
Arnold	US	2013	JAAPOS	iScreen vs Plusoptix vs spot vs icheckkids	6-130mo	AAPOS 2003
Zhang	China	2019	OPO	spot vs Plusoptix	<7	AAPOS 2013
Arnold	US	2020	Clic ophth	2WIN vs blinq	median 6.5y	2003 AAPOS
Racano	US	2019	JAAPOS	2WIN vs Plusoptix	mean 37.9m	2013 AAPOS
Arnold	US	2019	AJO	2WIN	median 6y	2003 AAPOS
Kirk	US	2014	JPOS	2WIN vs Plusoptix vs SPOT	1-10y	2WIN
Kirk	US	2014	JPOS	2WIN vs Plusoptix vs SPOT	1-10y	
Nishimura	Canada	2019	BMC	Plusoptix vs spot		AAPOS 2013
Kinori	US	2018	Curr Eye Research	Plusoptix vs retinomax	3-5y	ROC3
Crescioni	US	2015	JAAPOS	Plusoptix vs spot	3-6 grade	AAPOS 2013
Ugurbas	Turkey	2019	BMC	Plusoptix	36mo-11yrs	ROC5
Zhang	China	2019	OPO	Plusoptix vs spot	<7	AAPOS 2013
Silbert	US	2013	JAAPOS	iScreen vs MTI	6mo-17y	AAPOS 2003
Arnold	US	2013	Binocular Vision and Strabology	iScreen vs Plusoptix vs spot		AAPOS 2003
Arnold	US	2013	JAAPOS abstract	iScreen vs Plusoptix vs spot vs icheckkids	6-130mo	AAPOS 2003
Wang	US	2012	JAAPOS abstract	iScreen vs Plusoptix	5mo-13y	AAPOS 2003
Kerr	US	2011	AOJ	iScreen	2-5y	
Omran	US	2011	Abstract	iScreen		AAPOS 2003
Haschke	US	2018	JPOS	Optec		AAPOS 2013
Law	US	2020	JAAPOS	gocheck	3-48mo	2013 AAPOS, 2017 AAO
Walker	US	2020	JAAPOS	gocheck	6mo-6y	2013 AAPOS
Petersiem	US	2018	AJO	gocheck	6mo-6y	2013 AAPOS
Arnold	US	2020	JPOS	gocheck		2013 AAPOS
Arnold	US	2018	Clinical Ophthalmology	gocheck	1-6y	2013 AAPOS
Arnold	US	2014	JPOS	gocheck vs spot vs Plusoptix vs iScreen	1-12y	2003 AAPOS
Arnold	US	2020	Clic ophth	2WIN vs blinq	median 6.5	2003 AAPOS
Nishimura	Canada	2019	BMC	PVS vs Plusoptix vs PVS	3-6y	manufacturer
Yanni	US	2013	ARVO Abstract	PVS vs SureSight vs Randot	2-6y	manufacturer
Jost	US	2014	JAMA Ophtho	PVS vs SureSight	2-6y	manufacturer
Beauchamp	US	2013	JAAPOS Abstract	PVS vs SureSight	2-6y	manufacturer
Kane	US	2012	JAAPOS	PVS	3-8y	manufacturer
Loudon	US	2011	IOVS	PVS	2-18y	manufacturer