

An Analysis of Objective Vision Screening Technologies

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During the preschool age period (up to 6 years), the most common ocular conditions are strabismus, anisometropia, and high bilateral uncorrected refractive error such as hypermetropia and astigmatism. All of these, if untreated, can produce amblyopia. Traditional techniques for preschool screening involve optotype-based evaluation of visual acuity and a cover test for strabismus. However, such screening is difficult in the pediatrician's office and is therefore often not performed until at least 3.5 years of age, if at all. Thus, prior to this age a child is at risk for the development of amblyopia and cannot be detected. While some studies have demonstrated the ability of traditional acuity screening to detect amblyopia in 3 year old children, most do not show good success rates until at least age 4.

Recent developments in technology and the desire to detect abnormalities before they cause amblyopia have led to the development of new instruments for preschool vision screening. Primarily, these instruments involve either automated retinoscopy or photoscreening. There are several instruments which are commercially available and which have various levels of validation. The purpose of this paper is to review the current validation data regarding these instruments recognizing that this is a rapidly evolving field.

A major difference between traditional acuity screening and the newer methodologies for vision screening is that the former detects decreases in acuity directly, while the latter detects problems that may lead to decreased visual acuity. These problems have been termed "amblyopia risk factors" and include high uncorrected refractive error (hypermetropia & astigmatism), high myopia, and anisometropia. The detection of amblyopia risk factors rather than direct detection of decreased acuity is a limitation of these newer technologies; the natural history of amblyopia is

unknown and as a result, these technologies over-refer children since some children who are at risk for amblyopia may never in fact develop it.

A consensus regarding the magnitude for each amblyopic risk factor has been established recently. The Vision Screening Committee of the American Association of Pediatric Ophthalmology and Strabismus (AAPOS) has published a policy statement that mandates those refractive errors that should be detected with preschool vision screening. The factors listed in the table below represent an initial attempt at consensus by pediatric ophthalmologists and optometrists for those amblyopia-producing conditions that should be detected with preschool vision screening instruments. However, it should be noted that further revisions that take into account child's age, family history, and other factors need to occur in the future.

Table 1 Amblyopia risk factors to be detected by screening

- **Anisometropia (spherical or cylindrical) ≥ 1.5 D**
- **Any manifest strabismus**
- **Hyperopia > 3.50 D in any meridian**
- **Any media opacity > 1 mm in size**
- **Astigmatism > 1.5 D at 90 or 180° > 1.0 in oblique axis (more than 10° eccentric to 90 or 180°)**
- **Ptosis ≤ 1 mm margin-reflex distance***
- **Visual acuity; per AAP (age-appropriate standards)**

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

This policy statement also allows studies of these instruments to report results uniformly allowing for direct comparison of sensitivity and specificity data for these new techniques. Details of the studies supporting these levels for detection are provided in the policy statement.

Photo refraction screening utilizes a flash of light and the observation of the reflection of that light from the blur circle of the fundus to detect ocular misalignment and refractive blur. Of the commercially available photoscreening instruments available, the most prominent are the MTI Photoscreener, the iScreen Photoscreener and the Plus OptixSO8 Photoscreener. The MTI Photoscreener and the iScreen Photoscreener require manual interpretation of the flash reflections and difficulties with interpretation currently limit the acceptance of photoscreening technology for widespread screening. The MTI Photoscreener is perhaps the most well evaluated automated visual screening instrument. It is an off-axis photoscreener that utilizes two photographs taken with an eccentric flash unit that rotates 90° for each pair of images. These two images are captured on Polaroid film for interpretation by trained personnel. The instrument is easy to use, portable, and although it has a dated analog output, the Polaroid film is available for immediate interpretation. Other limitation of this instrument include high costs ranging from \$6-7 per child, lack of support for current instruments (old cameras need to be retrofitted to handle currently available film), and the lack of a company providing support or new investment (the company is no longer in business). Despite these limitations, there have been several large validation studies.

Field studies generally report positive predictive value (since normal children are not referred) while clinic-based studies report sensitivity and specificity (since predictive value depends upon disease prevalence). One large field-based vision screening program using the MTI Photoscreener began in Tennessee. Referred children were evaluated by local optometrists and ophthalmologists and the results are collected centrally. Over 200,000 children were screened using the MTI

Phoscreener with a referral rate of 4%, a screenability rate of 96% and a positive predictive value of over 75%. This program has been expanded by the Lions' Club International Foundation to include multiple other states and foreign countries. The results from the 17 programs that have screened over 400,000 preschool children show similar overall results with a referral rate averaging 5%, a screenability rate of 97% and a positive predictive value averaging 80%.

The VIP (Vision in Preschool) studies evaluated phoscreening with the MTI Phoscreener as one methodology in a prospective trial of over 1000 children with an enriched proportion of ocular pathology. In that study, phoscreening had a lower sensitivity than autorefraction (see below) when specificity was fixed retrospectively at 94% reporting an overall sensitivity of 37% and a 63% sensitivity for amblyopia. However, the relatively high sensitivity for the autorefraction was likely a result of a retrospective reanalysis of the data using a revised set of referral criteria for the autorefractors (but not for the phoscreeners) that was determined by re-evaluating the study results. Other issues with respect to the methodology of the VIP study which biased against phoscreening technology have been discussed extensively in the literature.

Plus Optix has introduced a phoscreening instrument that allows detection of ocular misalignment in addition to an automated calculation of refractive error. It is a handheld video/photorefractor that binocularly measures refractive error in 8 meridians and measures eye alignment. Although field evaluation of this instrument has only recently begun, there are many advantages to the Power Refractor including automated interpretation and the ability to alter the referral criteria.

An earlier version of the Plus Optix instrument (Power Refractor) was tested in the VIP studies. The purpose of the VIP study was to compare 11 preschool vision screening tests administered by

licensed eye care professionals. Sensitivity for detecting children with one or more targeted conditions (amblyopia, strabismus, significant refractive error, and unexplained visual acuity) at selected levels of specificity was the primary outcome measure. The Power Refractor had a higher sensitivity than other photoscreening devices but was statistically significantly lower than the Retinomax autorefractor. The study reported a screenability rate of 98.5%, a positive predictive value ranging from 50-60%, and a sensitivity of 54% when specificity was set to 90%.

Dahlmann-Noor recently published one of the first studies evaluating the Plus Optix as a screening tool to detect risk factors for amblyopia by comparing it with gold standard orthoptic vision screening in children. Results from a community-based screening of 288 children aged 4-7 reported a referral rate of 5.6% for the Plus Optix compared to a 12.5% referral rate from orthoptic screening.ⁱ However, the Plus Optix underestimated visually significant refractive errors and also indicated only moderate sensitivity (44%; 95% CI 27.9 to 61.9%) but a high specificity (100%; 95% CI 98.5 to 100%) to detect factors associated with amblyopia.ⁱⁱ The authors of the study concluded that the using a single screening test in young children may miss a significant number of children with amblyopia or amblyogenic risk factors.

In another study published in 2008 by Matta, Singman, and Silbert the Plus Optix vision screener referred 67% of the 58 patients found to have amblyopia or amblyopia risk factors based on AAPOS referral criteria. Matta and colleagues found the Plus Optix to also have a sensitivity of 98%, specificity of 69%, and false-negative rates of 1.4%.ⁱⁱⁱ For practical purposes, Arnold and Clausen pointed out in a separate study that estimated sensitivity, positive predictive value, and speed of objective photoscreeners exceeded that of visual acuity testing.^{iv}

iScreen is a company which uses digital photography and a high quality photograph with off axis photo screening to detect amblyopia risk factors. Their marketing plan typically places the screening device in the primary care doctor's office with remote image transfer to a centralized location for interpretation. Referral criteria are proprietary and have not been published. Kennedy and Thomas demonstrated high sensitivity and specificity of the iScreen visual screening instrument when tested in the pediatric ophthalmologists' office. Results reported a sensitivity of 92.4% at a specificity of 89.1% when a total of 449 consecutive patients (median age 7 years) from a private pediatric ophthalmology practice underwent screening with the iScreen photoscreener.^v In the VIP study, the iScreen device had nearly identical sensitivity as MTI Photoscreening with a screenability rate of 99.9%. When failure criteria was set to obtain 94% specificity, the iScreen sensitivity for all of the targeted conditions was statistically significantly below the values of noncycloplegic retinoscopy, the Retinomax Autorefractor, the SureSight, and LEA Symbols Visual Acuity test.

An important advance in the interpretation of automated vision screening devices into primary care offices is a new CPT code for vision screening, 99174, which became effective January 1, 2008. Its RVU value (0.68) recognizes photoscreening as a useful adjunct in the primary care office. A statement encouraging the use of photoscreening for preschool vision screening has also been published by the American Academy of Pediatrics and is currently being updated.

Automated refraction is another method of vision screening preschool children. The most widely available autorefractors include the Welch Allyn SureSight and the Nikon Retinomax both which were formally validated by the VIP study. The autorefractors utilize ultrasonic measurements of the wavefront to estimate refractive error, which can then be used to predict the actual refractive error in screened children. However, these instruments cannot control accommodation and therefore their estimates do not correlate well with refractive error determined under cycloplegic conditions.

Condonnier and Kallay have used the handheld Retinomax autorefractor to detect refractive errors in 12,012 children in Brussels, Belgium. They found this device to have a sensitivity ranging from 37-87% and a positive predictive value from 19-69% depending on the type of pathology observed. The VIP study found more definitive results reporting a positive predictive value ranging from 50-60%, a 85% sensitivity to detect amblyopia and a 63% overall sensitivity to detect all targeted conditions (amblyopia, strabismus, significant refractive error, and unexplained reduced VA) all at a specificity of 90%. The VIP study found the Retinomax and SureSight to have similar high sensitivities for all targeted conditions which exceeded those of all other tested methodologies.

The handheld SureSight measures and indicates abnormal readings without provider interpretation. The SureSight has been much more extensively studied than the Retinomax, likely due to its lower cost, high marketability, and high visibility. Multiple referral criteria have been proposed for the SureSight device. The criteria proposed by the manufacturer have the highest sensitivity but the highest referral rate and the lowest positive predictive value. The VIP study demonstrated the SureSight to have a sensitivity of over 90% to detect high magnitude refractive error when the manufacturer's criteria were used, but experience from the Vanderbilt group in field studies is that this set of criteria yields substantial over-referrals with a positive predictive value under 10%. When specificity was set to 90%, the results of the VIP study indicated that in the hands of eye care professionals, the SureSight is as accurate as the LEA Symbols test, the Retinomax Autorefractor, and noncycloplegic retinoscopy in detecting children who had one or more of the targeted conditions (amblyopia, strabismus, significant refractive error, and unexplained reduced VA).^{vi}

The VIP study proposed a second set of referral criteria in an attempt to increase specificity for the SureSight. These criteria had a post-hoc specificity of 94% in increasing the predictive value to

50% but decreased the referral rate substantially. Unfortunately, more specific referral criteria are not currently commercially available and it is unclear whether further modification of criteria can produce corresponding increases in referral rate and predictive value without substantially jeopardizing sensitivity.^{vii}

Establishing proper referral criteria may prove to be the biggest challenge facing these new autorefractors. Various referral criteria may be appropriate, depending on the screening situation specifically for the suspected prevalence of the disease in the population, the availability and cost of subspecialty providers for referred patients, and the net direct and indirect costs of over-referrals. Areas of the country that have low access to providers and referral subspecialists and high direct and indirect costs of obtaining care need to balance a low sensitivity with extremely high specificity and low referral rates. Conversely, areas with high population density and adequate primary pediatric eye care capacity may seek a high specificity with less regard for over-referrals. Further evaluation of autorefraction and adjustment of referral criteria in the future in order to maximize both sensitivity and specificity will likely continue to increase acceptance of this technology.

Name of Device	Type of Device	Energy Source	Cost	Analysis: Manual/Automated
Diopsys ENFANT II	Vision Evoked Potentials	EEG recording	Lease/Purchase arrangement	Automated
iScreen	Phoscreener	Digital Photography	Lease arrangement	Manual
MTI Phoscreener	Phoscreener	Polaroid Photography	\$5000	Manual
Nikon Retinomax	Autorefractor	Wavefront Technology	\$9600	Automated
Plus Optix PediaVision SO8*	Autorefractor	Infrared/Wavefront Technology	\$10,500	Automated
Welch Allyn SureSight	Autorefractor	Wavefront Technology		Automated

* Same device

** Screening personnel can alter referral criteria

*** Must specify referral criteria at purchase (see text)

Name of Device	Method to Manipulate	Specificity	Sensitivity in first year	Positive Predictive Value Number*	Reimbursement
Diopsys ENFANT II	Manufacturer's Criteria	81%	97%	71%	95930
iScreen	Manufacturer's Criteria	91%	62%		99174
MTI Photoscreener	Vanderbilt's Criteria	94%	63%	80%	99174
Nikon Retinomax	Manufacturer's Criteria	90%	85%	50-60%	92015
Plus Optix PediaVision SO8	Ability to alter Referral Criteria	69%	98%		99174
Welch Allyn SureSight	VIP's Criteria	90%	89%	<10%	92015

* PPV varies; depends upon population disease prevalence.

Name of Device	Advantages	Disadvantages
Diopsys ENFANT II	<ul style="list-style-type: none"> • No dilation or sedation for maximum patient safety • Tests pre-verbal children as young as 6 months of age • Portable • Immediate analysis 	<ul style="list-style-type: none"> • Cumbersome process of attaching and standardizing electrodes • Time required for testing • Monotonous stimuli • Complexity of the generated waveforms
iScreen	<ul style="list-style-type: none"> • Fast (less than 5 seconds) • High quality photograph 	<ul style="list-style-type: none"> • Remote image analysis
MTI Photoscreener	<ul style="list-style-type: none"> • Portable • Polaroid output that is available for immediate interpretation 	<ul style="list-style-type: none"> • Analog output • Lack of support for current instruments • Lack of a financially solvent company • Requires trained personnel for image analysis
Nikon Retinomax	<ul style="list-style-type: none"> • Handheld, easy to use • Can see on the screen the image of the child's eye, the different refractive measurements with time and the relaxation of accommodation, which is not possible with the SureSight 	<ul style="list-style-type: none"> • Shorter working distance than the SureSight, children may be more alarmed by having autorefractor closer to face • Cannot detect strabismus
Plus Optix PediaVision S08	<ul style="list-style-type: none"> • Allows user-chosen, age-related, referral criteria • Fast (takes less than 5 seconds) • Infrared • Tests pre-verbal children as young as 6 months of age • Binocular, simultaneous measurements 	<ul style="list-style-type: none"> • Lack of validation studies comparing SO4 to other instruments • Validation of strabismus detection poor
Welch Allyn SureSight	<ul style="list-style-type: none"> • Fast (less than 5 seconds) • No provider interpretation required • Minimal cooperation is necessary 	<ul style="list-style-type: none"> • Only two referral criteria available • Poor PPV with manufacturer's criteria • Cannot detect strabismus

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- ⁱ Dahlmann-Noor, AH. Vision Screening in children by Plus Optix Vision Screener compared with gold-standard orthoptic assessment. *British Journal of Ophthalmology* 2009; 93; 342-345.
- ⁱⁱ Dahlmann-Noor, AH. Vision Screening in children by Plus Optix Vision Screener compared with gold-standard orthoptic assessment. *British Journal of Ophthalmology* 2009; 93; 342-345.
- ⁱⁱⁱ Matta, NS, Singman, EL, and Silbert, DL. Performance of the Plus Optix vision screener for the detection of amblyopia risk factors in children. *Journal of the American Association for Pediatric Ophthalmology and Strabismus* 2008; 5; 490-92.
- ^{iv} Arnold, RW and Clause, MM. Pediatric eye/vision screening: Referral criteria for the PediaVision Plus Optix s04 photoscreener compared to visual acuity and digital photoscreening. *Binocular Vision Strabismus Quarterly* 2007; 22; 83-89.
- ^v Kennedy, RA and Thomas, DE. Evaluation of the iScreen digital screening system for amblyopia risk factors. *Canadian Journal of Ophthalmology* 2000; 35; 256-62.
- ^{vi} Comparison of Preschool Vision Screening Tests as Administered by Lincensed Eye Care Professional in the Vision in Preschoolers Study. *Ophthalmology* 2004; 111; 637-650.
- ^{vii} Silverstein, E, Lorenz, S, et al. Limits on improving the positive predictive value of the Welch Allyn SureSight for preschool vision screening. *Journal of the American Association of Pediatric Ophthalmology and Strabismus* 2009; 13; 45-50.