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# Comparison between the PlusoptiX and IScreen Photoscreeners in Detecting Amblyopic Risk Factors in Children

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## ABSTRACT

**Purpose:** To compare the accuracy of plusoptiX A08 photoscreener (PPS) and iScreen 3000 photoscreener (IPS) in objectively screening for amblyopic risk factors in children age 5 months to 13 years old. **Methods:** Cross-sectional study of 148 children who received photoscreenings via PPS and IPS and a comprehensive pediatric ophthalmic examination in our office. Patients were considered to have amblyogenic risk factors based on the AAPOS referral criteria guidelines. **Results:** 45 percent of patients undergoing a pediatric ophthalmology examination were found to have amblyopia or amblyogenic risk factors. In this study, PPS demonstrated an overall sensitivity of 75.4%, specificity of 68.0%, positive predictive value (PPV) of 67.1%, and negative predictive value (NPV) of 76.1%. However, IPS photoscreener had an overall sensitivity of 66.2%, specificity of 87.6%, PPV of 81.8%, and NPV of 75.5%. **Discussion:** The accuracy of PPS and IPS was compared in different age groups. The sensitivity and specificity were analyzed according to varied amblyogenic risk factors. The statistic results of this study were compared to those of previous studies, including Vision in Preschoolers (VIP) Study and the Iowa PhotoScreening Program. **Conclusion:** PPS and IPS proved to be useful tools in the objective vision screening in children. PPS was found to have a higher sensitivity, and IPS showed a higher specificity and PPV in detecting amblyopic risk factors. In conclusion, one device may be more beneficial over the other, depending on the patient population and office settings.

**Keywords:** Amblyogenic Risk Factors; Photoscreeners

## 1. Introduction

Amblyopia is a major cause of visual problems in the developed world [1-3] and the leading cause of blindness in the 20 to 70 year age group [4], affecting 2% to 5% of the population [5]. Several studies, including the Prospective Amblyopia Treatment Study, have demonstrated that amblyopia treatment is highly effective when detected and treated in young children [6-12]. Early detection is critical, because there is a window for successful treatment [6,7,10]. US Preventive Services Task Force recommends preschool vision screening, beginning at age 3, which is consistent with the American Academy of Pediatrics "Recommendations for Preventive Pediatric Health Care," and *Bright Futures Guidelines for Health Supervision of Infants Children and Adolescents* [13-15].

Traditional vision screening methods have a relative low compliance due to high over-referral rates, low sensitivity and low specificity [16]. Newer screening methods, including photoscreeners and autorefractors, have been proposed as potential replacements or supplements to traditional screening methods [17-25]. Potential advantages are reduced testing time, increased objectivity of screening, and enhance testability rates in younger children, who may be poorly cooperative with traditional tests. Potential disadvantages are the high initial costs associated with the instruments, and the need with some photoscreeners for external interpretation of screening results [15].

The purpose of this study is to compare the accuracy of plusoptiX A08 photoscreeners (PPS) (plusoptiX Inc., Hillsboro, Beach, FL) and iScreen 3000 photoscreeners (IPS) (iScreen Vision, Cordova, TN) in objectively screening for amblyopic risk factors in children age 5 months to 13 years old.

## 2. Methods

We evaluated the PPS and IPS for detecting amblyopia and amblyogenic risk factors in a pediatric ophthalmolo-

 

gy practice in Central Iowa on children age 5 months to 13 years. This is a cross-sectional study of one hundred forty-eight subjects. Before starting this research we received Clinical Research Board approval in West Des Moines, IA. We received a waiver of consent owing to the low risk nature of this research and followed appropriate Health Insurance Portability and Accountability Act of 1996 guidelines.

After retrospective chart review during a 2 months period, all children ages 5 months to 13 years who had a cycloplegic refraction and photoscreening with PPS and IPS devices within 6 months were included. One hundred and forty-eight children were examined consecutively in our office. Each patient had photoscreenings via PPS and IPS and a comprehensive pediatric ophthalmic examination (gold-standard eye examination) during the same visit. The photoscreening was performed by either a certified orthoptist or an ophthalmic technician prior to the patient's examination.

PPS performs refraction at a 1 meter distance under non-cycloplegic conditions. The AAPOS criteria apply to cycloplegic retinoscopy only and therefore should not be directly imported into the device. PPS results were interpreted by the incorporated software. Referral criteria for the PPS were provided by the manufacturer [26] (**Table 1**). The software allows for customized criteria on the basis of the patient's age. Our study used categories of 5 to 12 months, 12 to 18 months, 18 to 30 months, 30 to 54 months, and 54 to 72 months. For each group there are referral criteria for 5 distinct measurements, including anisometropia, astigmatism, myopia, hyperopia, and anisocoria. Patients were automatically referred from the PPS photoscreening if any of these measurements exceeded our preset values, if both round pupils could not be seen (such as with crying, thrashing, or visually significant ptosis), if the gaze of one eye is eccentric by more than 10 degrees (suggesting a tropia), or if a reading could not be obtained after two attempts.

IPS takes image at a 1 meter distance under non-cycloplegic conditions. Images and information are sent via an Ethernet connection to iScreen Vision Central Analysis for an independent clinical review by a trained technician. A full patient report is returned to the physician by email in less than 24 hours.

**Table 1. Referral criteria for the plusoptiX A08.**

| Age, mo | Anisometropia, D | Astigmatism, D | Myopia, D | Hyperopia, D | Anisocoria, mm |
|---|---|---|---|---|---|
| 5 - 12 | >1.25 | >2.00 | >2.00 | >3.25 | ≥1 |
| 12 - 18 | >1.00 | >1.50 | >1.50 | >2.00 | ≥1 |
| 18 - 30 | >1.00 | >1.00 | >1.25 | >2.00 | ≥1 |
| 30 - 54 | >1.00 | >1.00 | >1.00 | >2.00 | ≥1 |
| 54 - 240 | >0.75 | >0.75 | >1.00 | >2.00 | ≥1 |

The results from both screening methods were compared with comprehensive gold-standard examination findings. Patients were considered to have amblyopia or amblyogenic risk factors in the comprehensive examination on the basis of the American Association of Pediatric Ophthalmology and Strabismus (AAPOS) referral criteria guidelines (**Table 2**). The complete examination consisted of manual cycloplegic retinoscopy using cyclopentolate hydrochloride 1%, slit lamp examination, cover test, Krimsky test, alternate prism cover test, sensory testing using Titmus Stereogram, and fixation pattern assessment. A cycloplegic refraction was performed that same day or within 6 months. Sensitivity, specificity, positive predictive value and negative predictive value of the instruments were defined for different age groups.

## 3. Results

One hundred and forty-eight patients were included in this study. Each patient had photoscreenings via PPS and IPS and a comprehensive pediatric ophthalmology examination (gold-standard eye examination). 67 patients out of a total of 148 patients (45%) were found to have amblyopia or amblyogenic risk factors according to AAPOS guidelines (**Table 2**). Amblyogenic risk factors detected in the gold-standard eye examination are shown in **Figure 1**. 20 patients failed the gold-standard exam due to manifest strabismus alone, including 16 esotropia, 2 exotropia and 2 hypertropia. 23 patients failed the exam due to refractive error alone, including 16 hyperopia, 1 myopia and 6 astigmatism. 21 patients failed the exam due to a combination of 2 risk factors; 15 patients have hyperopia and strabismus, 1 patient hyperopia and astigmatism, 3 patients astigmatism and strabismus and 1 patient myopia and strabismus. 3 patients failed the exam due to ptosis.

In this study, PPS demonstrated an overall sensitivity of 75.4%, specificity of 68.0%, positive predictive value (PPV) of 67.1%, and negative predictive value (NPV) of 76.1%. IPS had an overall sensitivity of 66.2%, specificity of 87.6%, PPV of 81.8%, and NPV of 75.5% (**Tables 3** and **4**). The comparison of the present study to previous studies was listed in **Table 5**.

**Table 2. Amblyogenic risk factors (AAPOS criteria).**

| |
|---|
| Anisometropia (spherical or cylindrical) > 1.50 |
| Any manifest strabismus |
| Hyperopia > 3.5 D in any meridian |
| Myopia > 3.0 D in any meridian |
| Any media opacity > 1 mm in size |
| Astigmatism > 1.5 D at 90˚ or 180˚ or >1.0 D in oblique axis (>10˚ eccentric to 90˚ or 180˚) |
| Ptosis ≤ 1 mm margin reflex distance |
| Visual acuity per age-appropriate standards |

 

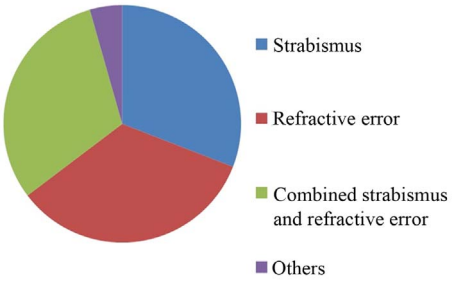


**Figure 1. Amblyogenic risk factors detected in gold-standard eye examination.**

**Table 3. Screening results using plusoptiX A08 and iScreen 3000.**

| | Results from the gold-standard eye exam | |
|---|---|---|
| Screening test results | + for amblyogenic risk | − for amblyogenic risk |
| plusoptiX A08 All patients | | |
| Fail | 49 | 24 |
| pass | 16 | 51 |
| Age 0-3 | | |
| Fail | 24 | 16 |
| pass | 10 | 37 |
| Age ≥ 4 | | |
| Fail | 25 | 8 |
| pass | 6 | 14 |
| iScreen 3000 All patients | | |
| Fail | 45 | 10 |
| pass | 23 | 71 |
| Age 0-3 | | |
| Fail | 19 | 7 |
| pass | 15 | 47 |
| Age ≥ 4 | | |
| Fail | 26 | 3 |
| pass | 8 | 24 |

**Table 4. Statistic analysis of screening results.**

| Screening test | Patient population | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) |
|---|---|---|---|---|---|
| plusoptiX | overall | 75.4 (75.9) | 68.0 (69.1) | 67.1 (67.7) | 76.1 (77) |
| | age 0 - 3 | 70.5 (70.4) | 69.8 (71.7) | 60.0 (59.4) | 78.7 (80.5) |
| | age ≥ 4 | 80.6 | 63.6 | 75.8 | 70.0 |
| iScreen | overall | 66.2 (70.5) | 87.6 (87.8) | 81.8 (82.7) | 75.5 (78.3) |
| | age 0 - 3 | 55.9 (63) | 87.0 (87.2) | 73.1 (73.9) | 75.8 (80.4) |
| | age ≥ 4 | 76.5 | 88.9 | 90.0 | 75.0 |

(Excluding subjects who are younger than 1 yr).

**Table 5. Comparison of the present study to previous studies.**

| Screening test | Study, year | Sensitivity (%) | Specificity (%) | PPV (%) | NPV (%) |
|---|---|---|---|---|---|
| plusoptiX A08 | present study, 2011 | 75.4 | 68.0 | 67.1 | 76.1 |
| Power refractor | VIP, 2004 | 54 | 90 | 70 | 79 |
| plusoptiX S04 | Matta *et al.*, 2009 | 98.9 | 96.1 | 97.9 | |
| iScreen 3000 | present study, 2011 | 37 | 94 | 71 | 79 |
| iScreen | VIP, 2004 | 37 | 94 | 71 | 79 |
| MTI | Matta *et al.*, 2009 | 83.6 | 90.5 | 94.2 | |

(Note: Power refractor is a previous model of plusoptiX, and MTI is a previous model of iScreen.)

The accuracy of PPS and IPS was also compared in different age groups. Both screening methods showed a better sensitivity in children age 4 years or older compared to 0 - 3 years (80.6% vs. 70.5% with plusoptiX, and 76.5% vs. 55.9% with iScreen). The specificity for both screening tests is similar among different age groups (**Table 4**). If patients younger than 1 year old were excluded, the overall sensitivity of IPS improved from 66.2% to 70.2%, and the sensitivity for younger than 3 year old improved from 55.9% to 63% (**Table 4**).

Data was further stratified according to different amblyogenic risk factors (**Table 6**). PPS demonstrated a sensitivity of 40.0% to detect a single condition of manifest strabismus, and a sensitivity of 81.8% to detect a single condition of refractive error. With IPS, the sensitivity to detect a single condition of manifest strabismus or refractive error is 66.7% and 43.5%, respectively. The sensitivity is 100% for PPS and 90.5% for IPS when combined conditions exist.

False positive rates were compared in selected milder conditions (**Table 7**). Among all the 81 patients who passed the gold-standard eye exam, 12 patients have intermittent strabismus or heterophoria, 15 have mild hyperopia, 6 have mild astigmatism and 13 have multiple conditions. False positive rate for each condition with PPS and IPS were listed in **Table 7**.

## 4. Discussion

We believe that this study is the first report with comparison of PPS and IPS. We conducted a retrospective chart review of 148 patients who received photo- screenings via PPS and IPS and a comprehensive pediatric ophthalmic examination during the same visit. Forty five percent were found to have amblyopia or amblyogenic risk factors according to AAPOS guidelines. Among the amblyogenic risk factors detected in our examination,

 

**Table 6. Comparison of sensitivity for different amblyogenic risk factors (interpretation for FN results).**

| Amblyogenic risk factors (# of patient) | PlusoptiX | iScreen |
|---|---|---|
| Manifest strabismus (21) | 40.0% | 66.7% |
| Refractive error (23) | 81.8% | 43.5% |
| Combined condition (21) | 100% | 90.5% |
| Overall | 75.4% | 66.2% |

**Table 7. Comparison of false positive rate for selected conditions (interpretation for FP result and the specificity).**

| Selected condition (# of patient) | PlusoptiX | iScreen |
|---|---|---|
| Intermittent strabismus or heterophoria (12) | 16.7% | 8.3% |
| Mild hyperopia (15) | 23.1% | 13.3% |
| Mild astigmatism (6) | 80.0% | 16.7% |
| Combined condition (13) | 66.7% | 30.8% |
| Overall | 32.4% | 12.5% |

(Definition: mild hyperopia ≥ 2.0 D, mild astigmatism ≥ 1.0 at 90˚ or 180˚ or ≥ 0.75 at oblique axis).

hyperopia, esotropia or a combination of both are the most frequently encountered amblyopic risk factors.

31 studies evaluated the diagnostic accuracy of various preschool vision screening tests [15]. The Vision in Preschoolers (VIP) study is the largest study so far to directly compare the diagnostic accuracy of different individual screening test, including Power Refractor (previous model of plusoptiX) and iScreen [24,25]. The statistical analysis result was shown in **Table 5**. Iowa Photoscreening Program reported a study with the largest number of participants (147,809) using MTI PhotoScreener over a 9-year period [19]. The sensitivity and specificity of the MTI PhotoScreener was not evaluated in this study, but was predetermined to have a sensitivity of 81.8% and a specificity of 90.6% in a previous study [27]. The overall PPV is 94.2% for the MTI Photo- Screener over the 9 years of the program. Differences between studies in the patient populations, prevalence of target diseases, model of the devices, and screening thresholds applied make it difficult to reach strong conclusions about how they compare with one another.

In the present study, PPS was found to have a higher sensitivity, and IPS showed a higher specificity and PPV in detecting amblyopic risk factors (**Tables 4** and **5**). The difference in sensitivity and specificity may be explained by the differences in the mechanism of these 2 devices. The IPS consists of an off-axis photorefractor connected to a laptop computer that binocularly measures refractive error in one meridian and measures eye alignment. The refractive error was determined based on the red reflex images of the eyes. PPS is a binocular autorefractor which can detect refractive error down to 0.25 D and significant strabismus.

Evidence on the comparative accuracy of preschool vision tests in different age groups among children ages 1 to 5 years is limited. Four studies found no clear differences in the diagnostic accuracy of various screening tests in preschool-aged children stratified according to age [15]. In this study, the accuracy of PPS and IPS photoscreeners was compared in age 0 - 3 years vs. 4 years or older (**Table 4**). Both screening methods showed a better sensitivity in children age 4 years or older, with more dramatic difference in IPS results. The specificity is similar in different age groups. This result demonstrated a higher false negative rate in the 0 - 3 years old age group, which may be explained by less cooperativeness in younger patients during the tests. When patients younger than 1 year old were excluded, the sensitivity of IPS was improved 7.1% in 0 - 3 year old age group. Statistical analysis for PPS was not affected by this exclusion. The results from our study suggest that PPS is a more sensitive test in comparison to IPS in detecting amblyogenic risk factors, with more superiority in patients age 0 - 3 years.

In order to answer the question of why false negative results exist, we further stratified the data according to different amblyogenic risk factors (**Table 6**). PPS demonstrated a lower sensitivity to detect manifest strabismus, with a sensitivity of 40.0% compared to 66.7% in IPS results. However, PPS has a higher sensitivity to detect refractive error, with a sensitivity of 81.8% compared to 43.5% in IPS results. The sensitivity increased significantly when combined conditions exist, 100% for PPS and 90.5% for IPS.

To explain why machines failed some patients who have milder disease that do not meet the AAPOS referral criteria, "mild conditions" was defined in **Table 7**. PPS had a highest false positive rate (80%) when mild astigmatism exists. Coexistence of 2 or more mild conditions causes high false positive rate, 66.7% with PPS and 30.8% with IPS. False positive rate is in a reversed relationship to specificity. This result suggests that PPS has a lowest specificity when mild astigmatism or combined mild conditions exist. Further study with a larger patient number is needed to confirm the above statement.

## 5. Conclusion

The PPS and IPS photoscreeners proved to be useful tools in the objective vision screening in children. PPS was found to have a higher sensitivity, and IPS showed a higher specificity and PPV in detecting amblyopic risk factors. PPS demonstrated a lower sensitivity in detecting manifest strabismus, and an excellent sensitivity in detecting refractive error. On the contrary, IPS had a higher

 

sensitivity in detecting manifest strabismus than refractive error. With mild astigmatism or coexistence of 2 or more mild conditions, PPS showed a higher false positive rate, *i.e.*, lower specificity. In conclusion, one device may be more beneficial over the other, depending on the patient population and office settings. Despite each device has its own strengths and weaknesses, they both are found to be very useful tools in the objective vision screening in children.

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