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A Comparison of the PlusoptiX S04 and A09 Photoscreeners

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Abstract

Purpose—We compare the plusoptiX S04 and A09 photoscreeners on a single cohort of children.

Methods—One hundred and thirteen children were evaluated on both the plusoptiX S04 and A09 photoscreener. A lay screener performed all of the testing prior to a pediatric ophthalmology examination. The order was alternated so that the S04 was performed first on one patient then second on the next to minimize fatigue bias.

Results—Utilizing our modified criteria previously published, the plusoptiX S04 was found to have a sensitivity of 85%, specificity of 94%, false positive rate of 15%, and false negative rate of 6% in detecting American Association for Pediatric Ophthalmology and Strabismus-defined amblyopia factors. The plusoptiX A09 was found to have a sensitivity of 92%, specificity of 88%, false positive rate of 11%, and false negative rate of 8%.

Conclusion—The plusoptiX S04 and A09 photoscreeners perform similarly when used by a lay screener to evaluate the same population of children.

Keywords

Pediatric; screening and infant vision development; strabismus; strabismus screening; vision screening; vision screening/diagnosis

INTRODUCTION

The plusoptiX S04 photoscreener is an FDA-approved handheld, user-friendly, binocular, infrared photoscreener that screens for amblyopia risk factors. The device obtains an undilated autorefractor reading, and will refer patients with significant myopia, hyperopia, anisometropia, or astigmatism based on preset criteria. It is designed to obtain a reading on a child when 2 round pupils can be seen at once, and thus will frequently refer children with conditions such as visually significant ptosis, coloboma, or strabismus that causes the eye to deviate by more than 10 degrees. It provides the operator with a simple score, either “pass” or “refer,” to guide the next step in a patient’s care.

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DECLARATION OF INTEREST

The authors report no conflict of interest.

We have used this device successfully for screening children in underserved areas, such as inner city schools and on mission trips.¹ Recently, an updated version, model A09 and the similar S09, has been released. The A09 and S09 are mechanically the same device with the A09 marketed to ophthalmologists, while the S09 is marketed to pediatricians and vision screening programs. While the devices are engineered identically, the printouts provide slightly different information. The plusoptiX A09 version uses the same infrared detector as the S04 but no longer needs to be connected to a Windows® laptop computer with a USB Firewire and audio cables. Instead, it is self-contained and uses Linux-based software connected to a standard monitor with a VGA cable. Data acquisition time of the new model is faster than the older model as well (0.8 seconds versus 1.5 seconds).

On all plusoptiX photoscreeners there is a sound emanating from the device to attract the child's attention. In addition, there is a fixation target for the subject to view during testing, which is performed at 1 meter. The fixation target on the new devices is a smiley face in addition to the flashing lights. Though the manufacturer has assumed that the S04 and A09/S09 work similarly, there is some concern that the smiley face on the A09/S09 may stimulate less accommodation than the attention lights presented by the S04. One could suggest that this might lead the A09/S09 to underestimate hypermetropic refractive errors and the criteria employed by the A09/S09 to pass or refer a patient would need adjustment. There is also a new referral criteria added to the newer model in which corneal reflexes are compared as a way of detecting strabismus. One might suggest that this application would improve the ability of the A09/S09 to detect strabismus and therefore would permit this device to not only be more sensitive than the older model but also provide more "refer" scores.

In this study, we sought to determine whether the referral pattern of the A09 was consistent with that of the S04 using the same preprogrammed referral criteria. The two devices were compared head to head, and also against the results of a gold-standard comprehensive pediatric ophthalmic examination.

METHODS

Before starting this research, we received Institutional Review Board approval from Lancaster General Hospital. We received a waiver of consent because of the low risk of this research and followed appropriate Health Insurance Portability and Accountability Act of 1996 guidelines.

We provided a lay screener in our office with both devices (AB). She was given basic training in using the devices and consecutively examined children who were undilated and presenting for a pediatric ophthalmology examination. If a reading could not be obtained (such as might occur if a child were to cover his or her eyes during screening) the lay screener repeated the test once. If the second test also could not obtain a reading the child was considered a "refer." She alternated which device was used first on each child. When she completed the screening the child was seen by one pediatric ophthalmologist (DS). All children had a comprehensive exam including an assessment of their alignment and a cycloplegic refraction. The refraction was performed either on the same day as the screening or within the 6 months prior. Children were determined to have amblyopia risk factors based on the current American Association for Pediatric Ophthalmology and Strabismus (AAPOS) referral criteria²:

- Anisometropia (spherical or cylindrical) >1.5 D
- Any manifest strabismus
- Hyperopia >3.5 D in any meridian

- Myopia magnitude >3.0 D in any meridian
- Any media opacity >1 mm in size
- Astigmatism >1.5 D at 90 degrees or 180 degrees; >1.0 D in oblique axis (more than 10 degrees from 90 degrees or 180 degrees)
- Ptosis 1 mm margin reflex distance

RESULTS

We evaluated 113 children, ages <1 to 11 years (average age 5 years), using both the plusoptiX S04 and A09 photoscreeners. We compared the pass/refer pattern of responses from the two machines using the Chi-square method. In addition, we calculated the specificity, sensitivity, false positive rate, and false negative rate of the two machines, using the comprehensive pediatric ophthalmic examination as our standard. We compared these metrics for statistically significant differences using the McNemar test.

There was no significant difference in the “pass/refer” pattern of results for the A09 compared to the S04. In fact, the correlation between the results was 0.8345. In addition, there was no significant difference in sensitivity, specificity, false positive rate, or false negative rate between the two devices (see Table 1).

CONCLUSION

The ability to obtain rapid, reliable results is the crux of effective vision screening programs. The plusoptiX system has been compared to other screening tools,^{3–6} however our study is the first to compare two models of the same device against each other.

The A09/S09 has the distinct advantage over the S04 in that it does not need to be connected to a laptop to generate responses or record data. This makes it more portable and less dependent on information technology specialists. This relieves manpower requirements when screening teams are required travel to remote areas such as on medical missions. In these circumstances, the less equipment and the less training needed by the screening teams, the more likely it will be that teams will be able to obtain more complete and accurate data for larger numbers of people.

The A09/S09 is a Linux-based infrared photoscreener. Our study shows that it performs equivalently to the Windows-based S04. Referral criteria designed and validated on the S04 should be equally effective when used on the A09/S09. We believe that the plusoptiX S04 and A09/S09 photoscreeners are both validated and useful tools for vision screening programs.

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TABLE 1

Reliability of referral, S04 versus S09. Comparison of the results for the plusoptiX S04 and A09 photoscreeners.

	Sensitivity	Specificity	False Positive Rate	False Negative Rate
PlusoptiX S04	85%	94%	15%	6%
PlusoptiX A09	88%	92%	17%	5%
<i>p</i> value	0.7055	0.3173	0.6818	0.7416