

To assess the accuracy of Plusoptix S12-C photoscreener in detecting amblyogenic risk factors in children aged 6 months to 6 years in remote areas of South India

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Purpose: To assess the screening accuracy of a novel fourth generation, handheld Plusoptix S12 C photo screener in detecting amblyogenic risk factors in children aged 6 months to 6 years in remote areas of South India. **Methods:** In this cross sectional study, 381 children aged 6 months to 6 years were screened by a trained fieldworker in Anganwadis and schools using the Plusoptix photoscreener. This was followed by complete ophthalmic evaluation including retinoscopy, subjective refraction, and strabismus evaluation by an optometrist and an orthoptist. All children further underwent complete ocular examination by the senior pediatric ophthalmologist for validation of the results. **Results:** A total of 367 children were included in the study. The sensitivity and specificity of the photo screener were found to be 86.76% and 82.27%, respectively. Positive Predictive Value, Negative Predictive Value, and Receiver Operative Characteristics were 52.67%, 96.47%, and 83.11%, respectively. In subgroup younger than 3 years, sensitivity and specificity was 89.19% and 81.18%, respectively. Myopic astigmatism was the most common amblyogenic risk factor in our study group. **Conclusion:** In India, with a lack of adequate healthcare professionals and poor health-seeking behavior; photo screeners can play an important role. We recommend the use of photo screeners for screening children as young as 6 months, especially in remote low-resource settings. This will help in expanding reliable eye care services to previously underserved areas.

Key words: Amblyogenic factors, mass screening, pediatric, photo screener, plusoptix

Amblyopia is the most common cause of decreased vision in children. Schmucker *et al.* showed that early diagnosis, timely referrals for further evaluation, and early interventions lead to better visual outcomes.^[1] The American Academy of Pediatrics, the American Association of Pediatric Ophthalmology and Strabismus (AAPOS), and the U.S. Preventive Services Task Force guidelines have also recommended early vision screening for children.^[2]

The barriers to vision screening among Indian children include lack of awareness, relatively lower accessibility to eye care specialists, and limited healthcare providers. Thus, a large proportion of children rely on vision screening performed at schools or vision screening camps organized by local eye hospitals. However in these camps, preschool children - the most vulnerable age group is neglected due to lack of awareness about the need for screening at this age and also lack of experience in examining these children among ophthalmologists. Thus, there is a strong urge for a cost-effective and reliable screening tool for screening this age group in mass numbers. The screening tool should be easy to

use and handle, portable, fast, cost effective and should run on rechargeable batteries so that it can be used in rural areas with no electricity.

In younger children, it is quite cumbersome to reliably determine visual acuity (VA) using vision charts. This makes traditional vision screening inappropriate for screening large numbers. One alternative to this can be use of photo screeners. Photo screener is a device that captures two "red reflex" images of a patient's eyes. In this study, we have used the fourth generation Plusoptix S12-C photo screener, which is a portable handheld vision screener. It screens both eyes simultaneously (binocular) in 0.5 seconds at a distance of 1 meter (3.3 feet). Therefore, children as young as 6 months, with a short attention span can also be screened. This instrument assists in measuring refractive error, pupil diameter, and interpupillary distance. It automatically compares refractive error with preprogrammed referral criteria, which can be modified based on the population being screened to affect the specificity and sensitivity of the screening.^[3] This model can be connected to EMR (electronic medical record) and thus

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allows easy data storage. We screened 6 months to 6 years old children, considering limited data available on the use of photo screeners especially the preverbal age group.^[4-8]

Various photo screeners such as the iScreen, Medical Technology and Innovations (MTI), Plusoptix,^[4] Welch Allyn Spot vision screener,^[9] Sure sight autorefractor,^[10] Pediavision, and 2WIN (Alaska Blind Child Discovery; Adaptica, Padova, Italy)^[9] have been studied and found to be accurate relative to traditional eye examination techniques in detecting amblyogenic risk factors (high refractive errors, anisometropia, strabismus, cataracts involving visual axis). Ganekal S *et al.* reported ametropia (50%), anisometropia (40.9%), strabismus (6.8%), visual deprivation (4.5%), and combined causes (2.2%) as the various amblyogenic causes in their study from Southern India.^[11]

On a thorough literature search using PubMed, Cochrane database, Google Scholar and ePUB; we found lack of convincing evidence about the use of photo screeners among children in South India. The purpose of our study was to analyze whether the photoscreeners like Plusoptix with tested efficacy can be reliably used for mass screening of the pediatric population, by a nonmedical personnel. Once proven beneficial, these can be used by health policymakers to improve the scale of pediatric vision screening with accuracy, especially the large underserved rural population.

Methods

A cross-sectional study was conducted over 2 years from July 2015 to June 2017, wherein a total of 381 children, aged 6 months to 6 years were screened. The study was done through outreach endeavors conducted at Integrated Child Developmental centers (ICDS), primary healthcare centers (PHCs), and primary schools. Children with non-vision threatening conditions such as conjunctivitis, hordeolum, and allergic conditions were excluded. The study was conducted following the Declaration of Helsinki and received Institutional Review Board approval from Aravind Eye Hospital, Pondicherry, India. Informed consent was obtained from the parents/guardian of all study participants.

Several meetings were conducted and the pertinent authorities at Anganwadis, PHCs, and primary schools were explained in detail about the study. The consent forms and an information sheet regarding common ocular problems of childhood were distributed 3–4 days preceding each outreach endeavor. Children for whom consent forms were duly signed by parents/legal guardians were included in the study.

For each subject screened, age, gender, the place at which the screening was performed were recorded. Photo screening with the Plusoptix S12-C was performed by a trained technician for each subject and device-generated either a pass, refer, or inconclusive status which was based on age-related criteria selected for screening. We used preprogrammed screening criteria for the Plusoptix as detailed in Table 1.

Whenever feasible the uncorrected VA was recorded following which cycloplegic retinoscopy/refraction was performed for all children. This was followed by strabismus evaluation; if necessary and complete anterior segment, and dilated fundus examination by the ophthalmic team. Retinoscopy and refraction

were performed using HOTV charts for children aged 3 years or more whereas only retinoscopy values were used for children under 3 years of age or children who were unable to perform HOTV matching. Pediatric ophthalmologist determined the final diagnoses and management.

Statistical analysis

The results of the Plusoptix photo screening were compared with the complete ophthalmic examinations. Characteristics of the study population, such as age and gender, were presented as percentages. Statistical parameters of sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were determined and presented as percentages with 95% confidence intervals. All analyses were considered significant at $P < 0.05$. Statistical analysis was done using IBM SPSS version 23.0 and OpenEpi version 3.01.

Results

A total of 381 children underwent screening with the Plusoptix S12-C photo screener. As per our exclusion criteria, 14 children were not considered for evaluation either due to lack of signed consent, or who needed management for non vision threatening conditions like hordeolum, acute conjunctivitis, or allergic conjunctivitis. Thus, the results from 367 children (96% of children screened) were considered for evaluation. The baseline demographic characteristics of the subjects are shown in Table 2. The average age among the cohort was 4.17 years with the distribution in age ranging from 6 months to 6 years.

The screening results with Plusoptix and ophthalmologist have been summarized in Table 3.

Of the 255 subjects who were given a “Pass” by the photo screener, 96.5% were also found to have a normal examination by the pediatric ophthalmologist. However, 3.5% subjects labelled “Pass” by the photoscreener were found to have an underlying ocular pathology when examined by the pediatric ophthalmologist. Of the 112 subjects who were given a “Fail” by the photo screener, 52.7% were found to have an underlying amblyogenic risk factor, while 47.3% were found to be normal by the ophthalmologist.

The sensitivity and specificity of the photo screener for all ages were found to be 86.76% and 82.27%, respectively. PPV, NPV, and Accuracy Receiver Operator Characteristics (aROC) were 52.67%, 96.47%, and 83.11%, respectively. In the subgroup of subjects 3 years of age or younger, the sensitivity and specificity of the photo screener were 89.19% and 81.18%, respectively. The area under the ROC was 83.6% for the younger age group.

Of the subjects who were found to have an abnormality by the pediatric ophthalmologist, the most common amblyogenic risk factor was refractive error which included astigmatism in 23 subjects (38.9%), followed by hypermetropia in 7 subjects (11.9%), and myopia in 6 subjects (10.2%). Other conditions diagnosed included squint in 9 subjects (15.2%), Brown syndrome in 1 subject (1.7%), cataract in 2 subjects (3.4%), and significant ptosis in 1 subject (1.7%). Ten infants with history of prematurity (16.9%) were referred to base hospital for detailed evaluation, of whom 2 had history of retinal laser.

Table 1: Preprogrammed, age-based screening criteria of the Plusoptix S12-C photo screener using ROC 1 (Receiver Operator Characteristics)

Age (months)	Difference in Sphere (Δ SE) or Cylinder (Δ Cyl) between two eyes	Cylinder (D)	Myopia (D)	Hypermetropia (D)	$\Delta\theta$	Asymmetry
5-9	1.50	3.00	2.00	3.25	1.00	5.00
9-13	1.25	2.25	2.00	3.25	1.00	5.00
13-19	1.00	1.50	1.50	2.00	1.00	5.00
19-30	1.00	1.00	1.25	1.25	1.00	5.00
30-50	1.00	1.00	1.00	1.00	1.00	5.00
50-300	0.75	0.75	1.00	1.00	1.00	5.00

Table 2: Baseline demographic characteristics of the study population

Age	Gender		Total
	Male	Female	
≤ 3 Years	62 (50.8%)	60 (49.2%)	122 (33.3%)
> 3 Years	130 (53.1%)	115 (46.9%)	245 (66.7%)
Total	192 (52.3%)	175 (47.7%)	367 (100%)

Table 3: Screening results with Plusoptix photo screener and a pediatric ophthalmologist

Plusoptix photo screener	Pediatric ophthalmologist		
	Pass	Refer	Total
Pass	246 (96.5%)	9 (3.5%)	255 (100%)
Refer	53 (47.3%)	59 (52.7%)	112 (100%)
Total	299 (81.5%)	68 (18.5%)	367 (100%)

Discussion

In developing countries like India, there is a large targeted population that needs to be screened. It seems like almost an impossible task to screen the entire population especially the children, in whom early diagnoses and treatment of amblyogenic factors would yield a maximum number of productive life years. Photo screening offers an option for screening the unscreened age group without being dependant on traditional vision charts. In the United States, the American Academy of Pediatrics (AAP), American Association of Certified Orthoptists (AAO), AAPOS, and American Academy of Ophthalmology (AAO) issued a joint statement advocating instrument-based vision screening for children between the ages of 6 months to 3 years.^[12] In India and similar countries with poor access to vision care and no policy for early vision screening, photo screening tools can play a vital role in detecting amblyogenic risk factors. Many photoscreeners such as iScreen, MTL, Plusoptix, Welch Allyn Spot and 2WIN have been developed to screen amblyogenic degrees of refractive error in children.^[13,14] However, due to nonvalidation none of these seems to have widely replaced the screening practices or have been able to find space in the pediatrician's office.

The Plusoptix S12 C is among the first handheld portable model that is lightweight, compact, less time consuming, easy to handle, and transport. The Plusoptix S12-C, an updated version of the Plus photo screeners, has indispensable merits for the large-scale vision screening e.g., it is a portable instrument

without connection to a laptop/ desktop, has faster data acquisition, allows easy data storage, runs on rechargeable batteries, and is patient-friendly using a smiling face with flashing lights as the fixation target.^[15] Plusoptix models have inbuilt referral criteria based on AAPOS guidelines, which was used in our study as described in Table 1. The traditional screening methods include retinoscopy which is time-consuming, requires co-operation from a child, and additionally demands well-trained optometrists and orthoptists, making it practically an impossible solution for mass screening.

The present study evaluates the performance of the Plusoptix S12-C photo screener among 367 south Indian children from the age group of 6 months to 6 years, compared with the gold standard complete ophthalmic examination. We found early screening for amblyopia and amblyogenic risk factors, followed by appropriate treatment, can significantly reduce the prevalence and severity of amblyopia in children. This was similar to earlier statements given by various authors.^[16-18]

Silbert DI *et al* evaluated the efficacy of Plusoptix A 09 in Honduras and found a sensitivity of 89% and specificity of 80%.^[19] Similarly, Plusoptix A 08 tested in central Iowa by Bloomberg JD and Suh DW calculated sensitivity of 87% and specificity of 88%.^[20] Our results were consistent with the above studies. Kirk *et al.* screened sequential pediatric eye patients with high prescreening prevalence of amblyopia risk factors with Plusoptix S12, SPOT, and TWIN photo screeners. Values for sensitivity, specificity, and inconclusive results for Plusoptix, SPOT and 2WIN were 91%, 78%, 71%; 71%, 59%, 67%; 10%, 13%, and 5%, respectively.^[9]

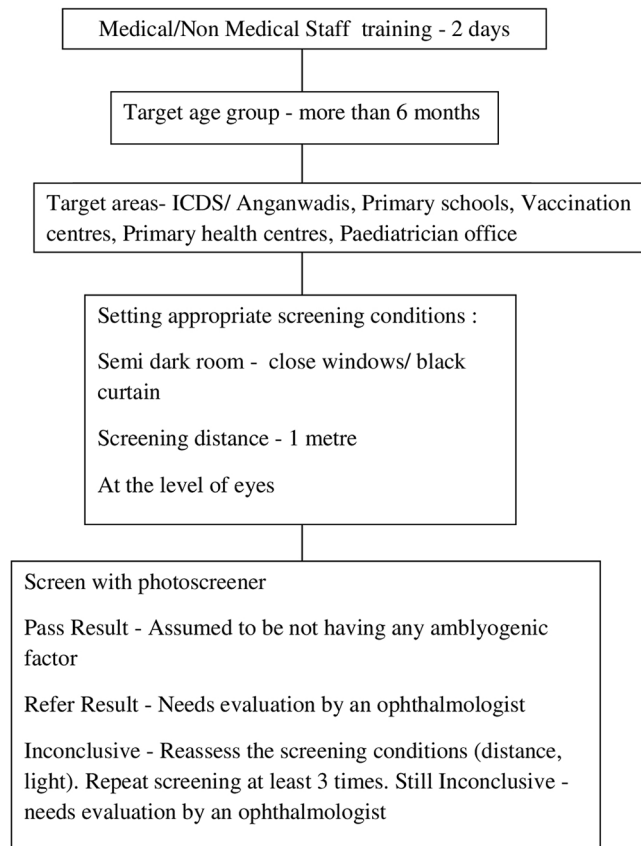
The strengths of our study include a population-based design, the use of the latest handheld portable Plusoptix model, its focus on South Asian population where the accuracy of photo screeners has not been much studied, and the inclusion of most vulnerable and sensitive age group which is left out in all regular screening protocols. To our knowledge, this is the first population-based study for determining the accuracy of the Plusoptix S12-C in amblyopia screening among the South Indian population.

Our study has few limitations as atropine refraction was not done, thus potentially decreasing the accuracy of the gold standard examination in detecting refractive amblyopia risk factors. The study sample was heterogeneous as there were more subjects in the > 3 years old group than in the < 3 years old group.

Conclusion

Thus, Plusoptix S12-C photoscreener can be used reliably to screen children as young as 6 months old for amblyogenic risk

Outline for Mass Screening



Flowchart 1: Proposed algorithm for mass screening with photoscreeners in underserved areas

factors. The use of such photo screeners is particularly beneficial in rural areas of developing countries, where children are more medically underserved. Employing photo screeners can amplify the number of children who can be screened, and at an earlier age than others methods of screening, thus resulting in greater and earlier detection of children with risk factors for amblyopia. Screening efforts by traditional methods (i.e., transporting a high number of skilled personnel to eye camps with large amounts of equipment) pose a logistical and financial challenge. With the photoscreener, these barriers can be lifted, all without much sacrifice to the accuracy of the screening results.

Future work should focus on establishing optimal referral criteria for photo screeners based on our population. There is also a need to determine the cost-effectiveness of instrument-based screening on a large scale basis. Since early detection of treatable eye disorders has significant benefits for vision and well-being, establishing policies for early vision screening should be considered in India. Photo screeners with tested efficacy needs to be promoted for mass screening. The authors hope that this study will help policymakers in achieving the dream of preventing needless blindness. A brief outline has been proposed about the use of photo screeners for mass screening [Flowchart 1].

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Conflicts of interest

There are no conflicts of interest.

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