Artigo Original

The performance of Plusoptix A09 in detection of Refractive Amblyopia Risk Factors

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RESUMO

Objetivo: Avaliar a eficácia da fotorrefração com o Plusoptix A09 na deteção de fatores de risco refrativos para ambliopia (FRRA) em crianças e determinar pontos de corte.
Métodos: Este estudo incluiu 402 crianças observadas em consulta de Oftalmologia Pediátrica entre Junho e Dezembro de 2014. Foram inicialmente submetidas a uma fotorrefração usando o Plusoptix A09 seguida por esquiascopia sob cicloplegia (durante um exame oftalmológico completo). As crianças foram consideradas como tendo FRRA usando os critérios de risco de ambliopia das *guidelines* de 2013 da Associação Americana de Oftalmologia Pediátrica e Estrabismo. Usando a esquiascopia como *gold standard*, calcularam-se os parâmetros de eficácia da fotorrefração na deteção de FRRA.
Resultados: FRRA foram encontrados em 148 (36.8%) e 151 (37.6%) casos por esquiascopia e fotorrefração, respectivamente. O Plusoptix demonstrou uma sensibilidade global de 85.1%, especificidade de 90%, valor preditivo positivo de 83.4% e valor preditivo negativo de 91.2% para a deteção de FRRA. O Plusoptix apresentou boa especificidade na deteção de todos os tipos específicos de FRRA (entre 93.0 e 98.1%) e boa sensibilidade na miopia (96.6%) e astigmatismo (91.0%), contudo, a sua sensibilidade para a deteção de hipermetropia como FRRA foi apenas 48.9%. Usando um ponto de corte de +1.5D na hipermetropia em vez de +3.5D (em crianças > 48 meses), a sensibilidade pode ser melhorada para 88.6%.
Conclusões: O Plusoptix A09 é um instrumento útil, portátil e eficaz na deteção de FRRA em populações pediátricas. Porém, para a deteção de hipermetropia como FRRA um valor de corte alternativo deve ser utilizado.

Palavras-chave
Ambliopia; Oftalmologia Pediátrica; Rastreio Visual; Fotorefração; Esquiascopia sob cicloplegia.

ABSTRACT

Purpose: To assess the accuracy of the Plusoptix A09 noncycloplegic photorefraction for detection of refractive amblyopia risk factors (RARFs) in children and determine cutoff points.
Methods: This study included 402 children observed in Pediatric Ophthalmology Clinic between June and December 2014. All children underwent initially photorefraction using Plusoptix A09 followed by cycloplegic retinoscopy (obtained during a complete ophthalmologic examination). Patients were considered to have RARFs based on American Association for Pediatric Ophthalmology and Strabismus 2013 guidelines. Considering cycloplegic retinoscopy as the gold standard, accuracy parameters of noncycloplegic photorefraction were calculated for detection of RARFs.

Results: RARFs were found in 148 (36.8%) and 151 (37.6%) cases by cycloplegic retinoscopy and photorefraction, respectively. Plusoptix showed an overall 85.1% sensitivity for 90% specificity, 83.4% positive predictive value and 91.2% negative predictive value for detection of RARFs. Plusoptix had good specificity for detection of all specific types of RARFs (between 93.0 and 98.1%), and good sensitivity for detection of myopia (96.6%) and astigmatism (91.0%), however its sensitivity for detecting hyperopia RARFs was only 48.9%. Using a cutoff point of +1,5D for hyperopia instead of +3.5D (in children > 48 months), sensitivity can be improved to 88.6% in this group.
Conclusions: The Plusoptix A09 is a useful, portable and accurate tool for the detection of RARFs in pediatric populations. However, in hyperopic RARFs an alternative cutoff value should be used.

Key-words
Amblyopia; Pediatric Ophthalmology; Vision Screening; Photorefraction; Cycloplegic retinoscopy.

INTRODUCTION

Amblyopia is an important public health problem because it is the most common cause of decreased vision in children with an estimated worldwide prevalence of 1.0-5.3%.[5,13,14] Significant refractive errors are one of the most important causes of amblyopia.[21,29] Previous studies have indicated that timely treatment of amblyopia improves visual acuity and binocularity,[25,26] which can have a substantial impact on quality of life[4,12] and it is also cost-effective.[15]

Due to the importance of early diagnosis and treatment, several methods of amblyopia screening were assessed.[17] Some of these methods detect amblyopia by measuring visual acuity directly while others do so indirectly by evaluating refractive errors and ocular deviation.[8] The gold standard in the evaluation of refractive errors in children is cycloplegic retinoscopy (CR),[29] however it is time consuming, requires an experienced examiner and the use of cycloplegic drops that may predispose the child to untoward side effects.[11,30]

The Plusoptix photoscreener® (PlusoptiX GmbH, Nuremberg, Germany) is a handheld, user-friendly, binocular pediatric vision screening photorefractor. It measures refractive errors, pupil size, interpupillary distance and gaze deviation in real time, requiring only few seconds of attention by the patient and without administration of cycloplegic drops.

This screening approach was based on the evidence that noncycloplegic photorefraction (NCP) had acceptable accuracy and advantages of speed and portability when compared to CR.[7,33] On the contrary, others regarded photorefraction without cycloplegia as unreliable because of poor accuracy and limited range of refractive errors.[6,35] In addition, although there are some reports of the sensitivity and specificity of the Plusoptix S04 or S08 for detecting amblyopia risk factors,[1-3,19,22,24,27] data from the newest version, the Plusoptix A09, are still scarce and with small sample sizes.[38] This instrument has not been widely used in the pediatric ophthalmology practice of Portuguese hospitals.

The purpose of this study was to evaluate the performance of the Plusoptix A09 for detecting refractive amblyopia risk factors (RARFs) in a large sample of our pediatric ophthalmology practice. The results of our study may also provide valuable practical cutoff points for defining RARFs when Plusoptix A09 is employed for screening in Portuguese children.

METHODS

Patients

The present retrospective study followed the tenets of the Declaration of Helsinki and all procedures were done in accordance with the ethical standards of the institutional research committee. All consecutive patients examined by one of 2 pediatric ophthalmologists (IR or AM) at the Pediatric Ophthalmology Consult of our Hospital, between June and December 2014 were included in the study. Plusoptix A09 is already used in our daily routine consult for all children since 2011. All medical records were retrospectively reviewed for collection of relevant data. Cases with impaired fixation, ptosis, significant media opacities and strabismus were excluded.

A total of 402 children were analyzed, with ages between 2 and 16 years. All children were submitted to NCP using Plusoptix A09 and to full ophthalmologic examination.

Examination

Both eyes of all children were examined with the Plusoptix A09 photoscreener by trained orthoptists, with Plusoptix placed at a distance of 1 meter in front of the patient in a darkroom. This device contains a screen with a picture and a light point that captures child attention toward it. In case of out-of-range measurements, as shown on the Plusoptix printout, the uppermost limits of the photorefractor (-7 or +5 diopters (D)) were considered for analysis.

In the CR step, cycloplegia was obtained (depending on the case) with instillation of 1 eye drop of atropine 1.0% every 12 hours, starting 3-5 days before the visit; or with instillation of cyclopentolate 1.0%, following the approved protocol in our department: 3 drops in each eye, with 10-minute interval, followed by retinoscopy after 30 minutes. All retinoscopy with atropine were scheduled in a 1-month period after first visit. All CR were done by a masked and experienced pediatric ophthalmologist (IR or AM).

Based on the results of CR (gold standard), we used the diagnostic criteria of amblyopia risk factors of the American Association of Pediatric Ophthalmology and Strabismus (AAPOS) guidelines reviewed in 2013 to compare the two methods employed in this study (Table 1).[9] These diagnostic criteria were set as cutoff for defining significant refractive errors with risk of refractive amblyopia (isometropic or anisometropic). Astigmatism was recorded and transformed in minus cylinder notations for comparison between the two methods.

Data Analysis

Binocular measurements were obtained for all patients. The only parameter used for this study was refractive errors of right eyes to avoid enantiomorphism bias (except in subjects diagnosed with anisometropia by either method, where left eyes data were also considered).[28]

Descriptive data were presented as mean, standard deviation, frequency and percentages. To describe the agreement of measurements between the two methods we employed Pearson correlation. Sphere and cylinder powers obtained by the Plusoptix and retinoscopy were compared by paired t test to evaluate differences between the two methods. Specificity, sensitivity, positive and negative predictive values of the device were defined in comparison with retinoscopy. We analyze the performance of Plusoptix in age-stratified groups (considering the few number of children in 12-30 months group - only 4, subgroup analysis was not done in this age group): 31-48 months, 49-72 months and > 72 months. Finally, in order to assess the best cutoff points for the Plusoptix instrument examination, the receiver operating characteristic (ROC) curve was used for the 3 refractive errors (myopia, hyperopia and astigmatism). Considering the few number of children with RARFs in the age groups 12-30 months and 31-48 months, we only constructed ROC curves for patients with > 48 months. In all evaluations, CR was considered as the gold standard. All statistical analyses were performed using IBM SPSS® (version 20.0, IBM-SPSS, Chicago, Illinois, USA). A p-value <0.05 was considered as statistically significant.

RESULTS

The study included 217 male (54.0%) and 185 female (46.0%) subjects with mean age of 6.6 ± 2.6 years (range 2 to 16 years, 12-30 months: 4 patients; 31-48 months, 37 patients; 49-72 months: 109 patients; >72 months: 252 patients). Cyclopentolate was used for CR in 313 patients and atropine in 89 patients. The range of refractive errors (spherical equivalent) measured via CR was from -6.0 to +6.63D. Hyperopia was found in 217 eyes (54.0%), myopia in 70 eyes (17.4%) and emmetropia (-0,5D to +1,0D) was found in 115 eyes (28.6%). The upper or lower limit of the photorefractor was considered for analysis in 7 eyes (1.7%), which had an out-of-range response. Of these, 1 was myopic and 6 were hyperopic.

Table 1 | Refractive amblyopia risk factors targeted with automated preschool vision screening (Guidelines AAPOS 2013).

	Astigmatism	Hyperopia	Myopia	Anisometropia
12-30 months	>2.0 D	>+4.5 D	>-3.5 D	>2.5 D
31-48 months	>2.0 D	>+4.0 D	>-3.0 D	>2.0 D
>48 months	>1.5 D	>+3.5 D	>-1.5 D	>1.5 D

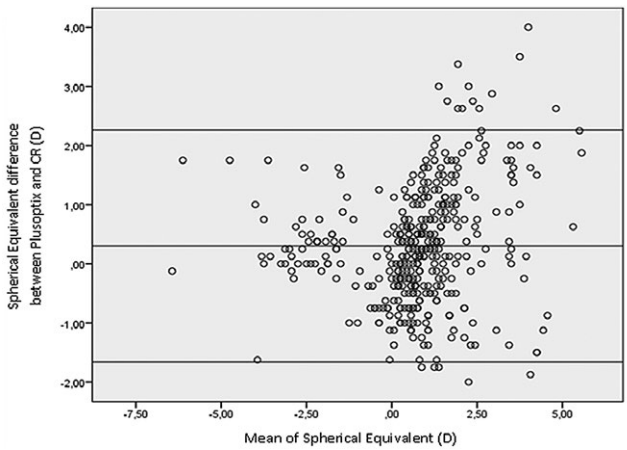

Fig. 1 | Bland-Altman plot showing agreement between the Plusoptix A09 and cycloplegic retinoscopy for spherical equivalent.

Comparison between the Plusoptix A09 and cycloplegic retinoscopy

The mean ± standard deviations for spherical power, cylindrical power and spherical equivalent measured by NCP (+1.15 ± 1.78, -1.11 ± 1.03, +0.59 ± 1.69 D, respectively) were significantly correlated with those measured by CR (+1.38 ± 1.92, -0.95 ± 1.01, +0.90 ± 1.87 D, respectively). The corresponding Pearson correlations were 0.85, 0.90 and 0.85, respectively (p<0.0001 for all comparisons). A Bland-Altman plot was used to assess the pairwise agreement of NCP and CR (Fig. 1).

The paired t test was done in order to compare the sphere, cylinder and spherical equivalent measures of the Plusoptix with the CR. The average differences of the sphere, cylinder and spherical equivalent were -0.22 ± 1.04, -0.15 ± 0.45 and -0.30 ± 1.00D, respectively. Therefore, the Plusoptix A09 found more myopia than the CR for sphere, cylinder and spherical equivalent, and the differences were statistically significant (p <0.0001 for all comparisons).

Sensitivity and specificity for detecting refractive amblyopia risk factors

Overall, at least one RARF was present in 151 (37.6%) and 148 (36.8%) of patients as determined by NCP and CR, respectively, with an 88.3% agreement. RARFs were detected using NCP and CR in 35 (8.7%) and 29 (7.2%) patients in myopic range, 35 (8.7%) and 47 (11.7%) patients in hyperopic range, 103 (25.6%) and 89 (22.1%) patients in astigmatic range, as well as 38 (9.5%) and 27 (6.7%) patients with anisometropia, respectively. Some patients presented more than 1 RARF.

The Plusoptix A09 presented 85.1% sensitivity, 90.1% specificity, 83.4% positive predictive value (PPV) and 91.2% negative predictive value (NPV) in detecting all RARFs (Table 2).

There were 22 false-negative results: 18 had amblyogenic hyperopia and 5 had amblyogenic astigmatism (1 case with simultaneously amblyogenic hyperopia and astigmatism) not detected by the Plusoptix, based on AAPOS criteria.

There were 25 false-positive results, children who presented RARFs on Plusoptix A09 but who were found to have no RARFs by CR. Of these, 17 were because an overestimation of astigmatism, 4 were because of an overestimation of hyperopia, 5 were because of an overestimation of myopia and 4 because an overestimation of anisometropia (5 cases with more than 1 cause).

Table 2 | **Screening results with Plusoptix A09.**

	N	Mean age (years)	RARFs PO, n	RARFs CR, n	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
All patients	402	6.6 ± 2.6	151	148	85.1	90.1	83.4	91.2
31-48 months	37	2.6 ± 0.5	9	7	71.4	86.7	55.6	92.9
49-72 months	108	4.7 ± 0.5	38	38	78.9	88.6	78.9	88.6
>72 months	253	8.0 ± 2.1	104	103	88.3	91.3	87.5	91.9
73-96 months	137	6.46 ± 0.6	48	49	81.6	90.9	83.3	89.9
> 96 months	116	9.78 ± 1.9	56	54	94.4	91.9	91.1	95.0

Legend: RARFs – refractive amblyopia risk factors; PO – Plusoptix; CR – cycloplegic retinoscopy; PPV – positive predictive value; NPV – negative predictive value.

Analysing the results by age group, in children aged 31-48 months, the instrument presented 71.4% sensitivity, 86.7% specificity, 55.6% PPV and 92.9% NPV in detecting all RARFs. In the group 49-72 months, the instrument showed 78.9% sensitivity, 88.6% specificity, 78.9% PPV and 88.6% NPV in detecting all RARFs. In the children with

Table 3 | Agreement coefficient values for noncycloplegic photorefraction compared to standard cycloplegic retinoscopy (all patients).

	Hyperopia	Myopia	Astigmatism	Anisometropia	Any refractive amblyopia risk factor
Frequency, n	47	29	89	27	148
Sensitivity (%)	48.9	96.6	91.0	88.9	85.1
Specificity (%)	96.6	98.1	93.0	96.3	90.1
Positive predictive value (%)	65.7	80.0	78.6	63.2	83.4
Negative predictive value (%)	93.4	99.7	97.3	99.2	91.2
True positive, n	23	28	81	24	126
True negative, n	343	366	291	361	229
False positive, n	12	7	22	14	25
False negative, n	24	1	8	3	22
Overall agreement (%)	91.0	98.0	92.5	95.8	88.3
Prevalence (%)	11.7	7.2	22.1	6.7	36.8

Table 4 | Agreement coefficient values for noncycloplegic photorefraction compared to standard cycloplegic retinoscopy together with calculated cutoff points based on ROC curve analysis (only patients with > 48 months, n=361).

	Hyperopia	Myopia	Astigmatism	Anisometropia	Any refractive amblyopia risk factor
Frequency, n	44	29	85	26	141
Sensitivity (%)	47.7	96.5	91.8	88.5	85.8
Specificity (%)	96.2	98.2	93.1	95.8	90.5
PPV (%)	63.6	82.4	80.4	62.2	85.2
NPV (%)	93.0	99.7	97.3	99.1	90.9
True positive, n	21	28	78	23	121
True negative, n	305	326	257	321	199
False positive, n	12	6	19	14	21
False negative, n	23	1	7	3	20
Overall agreement (%)	90.3	98.1	92.8	95.3	88.6
Prevalence (%)	12.2	8.0	23.5	7.2	39.1
Cutoff points (Diopters)	+1.5	-1,25	±1,75		----
Area under the curve (AUC)	0.877	0.996	0.970		----
Sensitivity for cutoff point (%)	88.6	100.0	92.9		95.7
Specificity for cutoff point (%)	73.2	96.1	93.5		77.2
PPV for cutoff point (%)	31.5	69.0	81.4		73.0
NPV for cutoff point (%)	97.9	100.0	97.7		96.6

Legend: PPV – positive predictive value; NPV – negative predictive value.

more than 72 months, Plusoptix A09 presented an overall 88.3% sensitivity, 91.3% specificity, 87.5% PPV and 91.9% NPV in detecting all RARFs. If we divide this group in 2 subgroups, we can see that the results were better in older children (>96 months) with all values over 90% (Table 2).

Considering the CR as the gold standard, all accuracy parameters of NCP were calculated in the various ranges of refractive errors used for amblyopia screening (Table 3). NCP had good specificity for detecting all types of refractive errors (93.0 to 98.1%) and good sensitivity for anisometropia, astigmatism and myopia (88.9, 91.0 and 96.6% respectively); however, its sensitivity for detecting hyperopia risk factor (>4.5D 12-30 months; >4.0D 31-48 months; and >3.5D above 48 months) was only 48.9%. Accordingly, overall agreement between the two methods was slightly better for myopia (98.0%) and anisometropia (95.8%), than astigmatism (92.5%) and hyperopia (91.0%).

In order to find the best cutoff points for NCP in amblyopia screening, ROC curve analysis was applied in patients with more than 48 months (Table 4); In this age group, this showed that for astigmatism, the appropriate cutoff for NCP was 1,75 D for detection of errors > 1.5D as determined by CR; for myopia, the appropriate cutoff for NCP was -1,25 D for detection of errors > - 1.5D as determined by CR; for hyperopia, the appropriate cutoff for NCP was +1.5 D for detection of errors >+3.5D as determined by CR; Using this new cutoff points, we can improve the overall sensitivity of NCP (for detection of presence of any RARF in patients with >48 months) to 95.7%, but with a decrease in specificity (77.2%) (Table 4).

Using this modified criteria (Table 5), we can improve the overall sensitivity of NCP (for detection of any RARF in all patients) to 94.6%, but with a decrease in specificity (78.7%). The NPV was of 96.2% and PPV was of 72.2%.

Table 5 | Modified refractive amblyopia risk factors.

	Astigmatism	Hyperopia	Myopia	Anisometropia
12-30 months	>2,0 D	>+4,5 D	>-3,5 D	>2,5 D
31-48 months	>2,0 D	>+4,0 D	>-3,0 D	>2,0 D
>48 months	>1,75 D	>+1,5 D	>-1,25 D	>1,5 D

DISCUSSION

The value of a diagnostic test is determined by its ability to distinguish a diseased from a normal, non-diseased state. Although an ideal test would have 100% specificity (the ability to ignore all non-targeted disease), 100% sensitivity (the ability to detect all targeted disease) and 100% PPV, there are no vision screening tests with this level of accuracy.[16] There is a recognizable inverse relationship between sensitivity and specificity illustrated by the ROC curve.

Early screening for amblyopia and amblyogenic risk factors, followed by adequate treatment, can significantly reduce the prevalence and severity of amblyopia in children.[10,36,37] Although CR remains the gold standard for detecting refractive errors,[29] it is time consuming, uses cycloplegic eye drops and requires experienced medical staff, so it is not an optimal approach for amblyopia risk factor screening.

NCP has been introduced as a method for screening RARFs in infants and children.[11,29] Comparing to conventional CR, the Plusoptix A09 has indispensable merits for the vision screening, namely: it is a portable instrument without connection to a laptop computer, has faster data acquisition and it is patient-friendly using a smile face with flashing lights as the fixation target.[31]

Our study provides additional information regarding the performance of the Plusoptix A09 in children. We compared the Plusoptix A09 with the gold standard ophthalmology examination in children observed in our pediatric ophthalmology practice for the detection of RARFs.

In the present study, the Plusoptix A09 revealed to have a general trend towards myopic values, underestimating hyperopia and overestimating myopia. The mean difference in spherical equivalent measured by the Plusoptix and CR was -0.30 ± 1.00D. This agrees with previous studies of Erdurmus *et al* and Schimitzek *et al* that reported a myopic shift of 0.7 D and 0.96D, respectively.[11,30] These findings show the possibility of uncontrolled accommodation in patients who were examined by the Plusoptix. The discordant amounts of myopic shift between studies may be due to different methodology, models of photoscreeners, patient age and range of hyperopia.

Significant and strong correlations were observed in our study between NCP and CR for spherical, cylindrical and spherical equivalent refractive errors (0.85,0.90 and 0.85, respectively). Comparable correlation coefficients

(0.76, 0.86 and 0.76, respectively) were reported by Rajavi *et al*.[27]

In our study, RARFs were detected in 148 (36.8%) and 151 (37.6%) of studied children as determined by CR and NCP, respectively. Previous studies by Rajavi *et al*[27] reported 30.8% and 28.1% and the study of Matta *et al*[20] reported 67% and 53%, respectively. Our study and those studies were done with children chosen form a patient population. As one might expect, the percentage of children seen in a pediatric ophthalmology practice with RARFs was greater (36.8%) than would be expected in a general pediatric population. Differently, the study of Moghaddam *et al*[23] included children that were chosen from the city population and the prevalence of amblyopia risk factors was 15.2%. The agreement between the two methods for detecting RARFs was 88.3% in our study, which is comparable to those obtained with other studies (between 84 and 89.7%).[27]

Results of our study showed that the sensitivity and specificity of the Plusoptix in detecting refractive amblyopia risk factors varied with the selected referral criteria, as shown in previous studies.[20,23,27] It is essential to optimize the referral criteria for the Plusoptix A09 before using it as a screening device for RARFs. Singman *et al*[32] evaluated the sensitivity and specificity of the Plusoptix on the same cohort of children using seven different referral criteria. They suggested that vision screening programs should adjust referral criteria according to the local conditions. Considering the potential severity of amblyopia and the cost of screening examinations, we prefer an approach with the ability to detect all amblyopic patients and so adjusting the referral criteria with a higher sensitivity without sacrificing too much specificity. We found that the measurements obtained by Plusoptix A09 for myopic and astigmatic errors are reliable, however in the hyperopic range lower values of spherical power measured by NCP should be set as a cutoff point for screenings purposes. Applying a modified cutoff value (+1.50D) as suggested by ROC curve analysis in our study (> 48 months), increases the sensitivity of NCP from 47.7% to 88.6% for detecting hyperopia in this age group, hence making it suitable for detecting all types of refractive error in children. This is comparable to findings reported by previous studies.[27]

In the present study, using the revised criteria for Plusoptix A09 (Table 5), we obtained excellent overall sensitivity results for screening all RARFs without losing too much specificity (94.6% sensitivity, 78.7% specificity, 96.2% NPV and 72.2% PPV).

Our study used the revised 2013 guidelines of AAPOS for the detection of RARFs. To our knowledge, this is only the second study that evaluated the detection of RARFs using this updated guidelines[32] (previous studies used the guidelines AAPOS 2003). Other strength of our study is the large sample of children that allowed us to subdivide the sample by age groups. We can see that there was a gradual increase in sensitivity and specificity for detecting RARFs with Plusoptix with the increase of children's age, with the children with >96 months presenting the best results (with sensitivity, specificity, PPV and NPV all over 90%). This result probably can be explained by the effect of uncontrolled accommodation in small children, as previously described.[11]

Unfortunately, considering the few number of children in the group 12-30 months (only 4) we were unable to analyse the performance of Plusoptix in this age group or to construct ROC curves in this group or in the 31-48 months group (only 37 patients and only 7 with RARFs in CR). Additional studies with larger samples of these age groups are needed.

The present study has some limitations. The Plusoptix A09 detects risk factors for amblyopia but does not detect the condition directly, as does, for example, the Pediatric Vision Scanner.[18] Therefore, sensitivity and specificity for the direct detection of amblyopia cannot be measured by the Plusoptix.

Other limitation of our study is that the comparison is based on the prevalence levels of amblyogenic factores and the prevalence data are not of a population-based study. The levels of prevalence of amblyogenic factors are much higher than those previously reported for the population (3-5%) and so the accompanying sensitivity and specificity levels may be reduced with a lower prevalence and an increase in false negatives and positives (spectrum bias).[34] Further studies with a population based large-scale photorefraction in a healthy child population are needed.

In conclusion, based in our results, Plusoptix A09 is an appropriate method for amblyopia screening in children and for detection of risk factors for refractive amblyopia. However, the optimal cutoff value for hyperopia should be different from that used in cycloplegic retinoscopy. Our findings need to be confirmed in future studies with a larger sample focusing on age-stratified groups.

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