

# Evaluation of The Plusoptix S08 in Dedection of Refractive Amblyogenic Risk Factors

## Refraktif Ambliyopinin Risk Faktörlerinin Tespitinde Plusoptix S08'in Değerlendirilmesi

Faruk Kaya<sup>1</sup>, İbrahim Koçak<sup>1</sup>, Ali Aydın<sup>1</sup>, Hakan Baybora<sup>1</sup>,  
Hacı Koç<sup>2</sup>, Salih Bozkurt<sup>2</sup>

<sup>1</sup> İstanbul Medipol Üniversitesi; Tıp Fakültesi; Göz Kliniği; İstanbul

<sup>2</sup> İnci Göz Hastanesi, Sakarya

### Abstract

- Purpose:** To evaluate the plusoptix S08in dedection of refractive amblyogenic risk factors.
- Methods:** Our prospective comperative study included 97 children aged between 2 and 12 years old. Student- t correlation test was used to compare the differences between Plusoptix S08 and Topcon autorefractometer regarding ; sensitivity, specificity, positive predictive value, negative predictive value, false negative results and false positive results. Statistically significant difference was described as  $p<0.05$ . The differences between refractive outcomes obtained from the Plusoptix and Topcon autorefractometer were evaluated for overall patients, patients aged 2-5 and 5-12 years old.
- Results:** 25 of the total patients ( % 26 ) were determined to have refractive error that could cause amblyopia on the comprehensive ophthalmologic examination. The Plusoptix was concluded to have sensitivity of 64 % , specificity of 93 % , positive predictive value of 76 % and negative predictive value of 88 % in determining amblyogenic risk factors. There were 9 % false negative results and 5 % false positive results. There were statistically significant differences between Plusoptix S08 and Topcon autorefractometer device for spheric ( $p=0.0001$ ) and cylindrical ( $p=0.005$ ) values, but there was no statistacally signficiant difference for spherical equivalent ( $p=1.6$ ).
- Conclusions:** The Plusoptix S08 is user friendly, rapidly and has acceptable sensitivity and specificity; particularly in preschool children's refractive error screenings.
- Keywords:** The Plusoptix S08, refractive amblyopia.

### Özet

- Amaç:** Plusoptix S08 cihazının, refraktif ambliyopiye yol açabilecek, risk faktörlerinin tespiti açısından değerlendirmek.
- Gereç ve Yöntem:** Prospektif karşılaştırmalı çalışmamıza 2 ve 12 yaşları arasındaki 97 çocuk hastamızı dahil ettik. Plusoptix S08 ve Topcon otorefraktometre cihazları arasındaki farklar, sensitivite, spesivite, pozitif prediktif değer, negatif prediktif değer, yanlış negatif sonuç, yanlış pozitif sonuç açısından; student-t korelasyon testi kullanılarak karşılaştırıldı.  $P<0.05$  bulunduğu fark istatistiksel olarak anlamlı kabul edildi. Plusoptix S08 ve Topcon otorefraktometreden elde edilen refraktif sonuçlar; bütün hastalar, 2-5 yaş aralığı ve 5-12 yaş aralığındaki hastalar açısından değerlendirildi.
- Bulgular:** Yapılan tam oftalmolojik muayene sonucunda 25 hastada (%26) ambliyopiye sebep olabilecek refraktif kusur tespit edildi. Plusoptix cihazının; ambliyopiye yol açan refraktif risk faktörlerini tespit etmede sensitivitesi %64, spesivitesi %93, pozitif prediktif değeri %76, negatif prediktif değeri %88 olarak tespit edildi. Yanlış negatif sonuç %9, yanlış pozitif sonuç %5 olarak bulundu. Sferik ( $p=0,0001$ ) ve silindirik ( $P=0,005$ ) değerleri açısından plusoptix S08 ve Topcon otorefraktometre arasında istatistiksel olarak anlamlı fark tespit edilirken; sferik ekivalan açısından istatistiksel olarak anlamlı fark tespit edilmedi ( $p=1.6$ ).
- Sonuç:** Plusoptix S08 kolay kullanılan, hızlı ve özellikle okul öncesi çocuklarda refraktif kusur tespitinde iyi spesivite ve sensitiviteye sahip bir cihazdır.
- Anahtar Kelimeler:** Plusoptix S08, refraktif ambliyopi

## INTRODUCTION

Early diagnosis of amblyopia is important for a successful treatment<sup>1,2</sup>. Early pediatric visual acuity screening is recommended but the best way of screening is not definite<sup>3</sup>. Among first four years of life, eye chart acuity screening isn't so effective<sup>4</sup>. Photoscreening can be a good option and some studies showed that it had higher sensitivity and predictive value and needed less time than visual acuity testing<sup>5,6,7</sup>. The plusoptix S08 Photoscreener ( Plusoptix GmbH; Nuremberg, Germany) is a newly available device for screening children. It is a fourth generation photoscreening device that can provide refractive error, angle between fixating eyes and a photo of pupillary centers. It performs refraction at a distance of 1 meter under non cycloplegic conditions.

In this study our purpose was to explore the accuracy of plusoptix S08 in screening children aged 2 to 12 years for detecting amblyopia and amblyopia risk factors by using AAPOS referral criteria. We compared the device with gold standart cycloplegic examinations on the basis of 2003 AAPOS referral criteria<sup>8</sup>.

## MATERIALS and METHODS

At the beginning of this study local ethic committee approval was attained. Written informed consent was attained from all patients. Our study was appropriate to the tenets of the Helsinki Declaration. This study is a prospective comparative study and all children aged 2 to 12 years who had a cycloplegic refraction and plusoptix S08 during 3 months study period were included in this study. The plusoptix photoscreening was performed by one of our experienced physicians at Nisa Hospital, İstanbul, Turkey. 3 consecutive non cycloplegic measurements were taken with plusoptix S08 and 1 non cycloplegic, 1 cycloplegic measurement was taken with autorefractometer (Topcon KR 8800, Tokyo, Japan). The other parts of routine examination ( slit-lamp examination, cover test, prism alternate and cover test, fundus examination) were performed.

Non cycloplegic measurements from the Plusoptix and cycloplegic datas from autorefractometer were compared and patients were evaluated to have amblyopia or amblyopia risk factors on the basis of the AAPOS referral criteria guidelines (table 1). In this study; myopia, hyperopia, astigmatizm, ani-

sometropia were evaluated as referral criteria. Sensitivity, specificity, positive and negative predictive values of the plusoptix S08 were assessed. We examined also the patients as two groups; patients aged 2-5 years old as group 1 and patients aged 5-12 years old as group 2.

Gold standart examination	Parameter
anisometropia	>1.5 D
hyperopia	>3.5 D
astigmatism	>1.50 D axial, >1.00 D oblique
Myopia	>3.00

Also datas from the plusoptix were compared with cycloplegic outcomes from autorefractometer. The Student-t test was used to evaluate differences between two devices. Statistical analysis was performed with the Statistical Package for Social Sciences (SPSS) version 12.0(SPSS Inc, Chicago, Illinois, USA). Results were considered statistically significant if  $p < 0.05$ .

## RESULTS

97 children aged from 2 to 12 years old ( mean age  $6,13 \pm 2,56$  years old ) were included. 46 of patients were 5 years old and less; as 51 of them were over 5 years old. 25 of the total patients ( % 26 ) were determined to have refractive error that could cause amblyopia on the comprehensive ophthalmologic examination.

A total of 21 patients were referred by the plusoptix photoscreener. The plusoptix was concluded to have sensitivity of 64 %, specificity of 93 %, positive predictive value of 76 % and negative predictive value of 88 % in determining amblyogenic risk factors. There were 9 % false negative results, children didn't referred on plusoptix but who were evaluated to have amblyogenic risk factors with autorefractometer. There were 5 % false positive results, children referred on plusoptix but who were not evaluated to have amblyogenic risk factors with autorefractometer ( table 2 ).

At children aged 2 to 5 years old (  $n=46$  ), the plusoptix was found to have sensitivity of 70 %, specificity of 96 %, positive predictive value of 93 % and negative predictive value of 80 % in determining amblyogenic risk factors. There were 6

(13%) false negative results, and 1 (2%) false positive results (table 2).

At children aged 6 to 12 years old (n=51), the plusoptix was found to have sensitivity of 42%, specificity of 89%, positive predictive value of 37% and negative predictive value of 91% in determining amblyogenic risk factors. There were 4 (7%) false negative results, and 5 (9%) false positive results (table 2).

The difference between outcomes from the plusoptix and autorefractometer was evaluated by using student-t test. There were statistically significant differences between two device for spherical (p=0.0001) and cylindrical (p=0.005) values, but there was no statistically significant difference for spherical equivalent (p=1.6) when outcomes obtained from total of patients compared. For patients aged under 5 years old: there were statistically significant differences between two device for spherical (p=0.003) and spherical equivalent (p=0.004) values, but there was no statistically significant difference for cylindrical values (p=0.36). For patients aged over 5 years old; there were statistically significant differences between two device for spherical (p=0.02), cylindrical (p=0.002) and spherical equivalent (p=0.001) values. Data gained from the Plusoptix S08 and autorefractometer are shown on table 3

and total statistical results for comparing data from two devices are shown on table 4.

Table 4. Statistical difference between data from plusoptix S08 and autorefractometer

Age Group	P value for spheric data	P value for cylindrical data	P value for spheric equivalent
All patients (n=97)	P<0.05 (p=0.0001)	P<0.05 (p=0.005)	P>0.05 (p=1.6)
Age 2-5 (n=46)	P<0.05 (P=0.003)	P>0.05 (p=0.36)	P<0.05 (p=0.004)
Age 6-12 (n=51)	P<0.05 (p=0.02)	P<0.05 (p=0.002)	P<0.05 (p=0.001)

**DISCUSSION**

All of studies proved that early vision screenings with an appropriate treatment decrease the prevalence and severity of amblyopia<sup>9,10,13,14</sup>. Preschool vision screening is suggested as a universal policy by many of pediatric ophthalmologists<sup>11</sup>. But it must be proved that these methods give sufficient sensitivity and specificity when compared with a detailed cycloplegic ophthalmic examination. The plusoptix and full pediatric ophthalmic examination were found to have similar results for detecting amblyopic risk factors; but screening method found to be a lower cost method<sup>12</sup>.

Table 2. Screening results of the plusoptix S08

Age Group	Sensitivity(%)	Specificity(%)	PPV (%)	NPV (%)	FPR (%)	FNR (%)
All patients(n=97)	64	93	76	88	5	9
Age 2-5 (n=46)	70	96	93	80	2	13
Age 6-12 (n=51)	42	89	37	91	9	7

PPV: positive predictive value; NPV: negative predictive value; FPR: false positive rate; FNR: false negative rate

Table 3. Data gained from plusoptix S08 and autorefractometer

Age group (n)		The Plusoptix			Topcon autorefractometer		
		Spheric value	Cylindrical value	Spheric equivalent	Spheric value	Cylindrical value	Spheric equivalent
All patients (n=97)	Mean	0.63±1.66	-0.73±0.79	0.29±1.60	1.09±2.1	-0.63±0.82	0.85±2.03
	Range	-3.50-4.75	-3.00-0	-3.25-4.50	-2.25-6.25	-3.00-0	-2.25-6.00
Age 2-5 (n=46)	Mean	1.36±1.4	-0.91±0.95	0.96±1.3	1.96±1.88	-0.86±0.95	1.55±1.92
	Range	-1.50-4.25	-3.25-0	-1.75-4.25	-2.50-6.50	-2.75-0	-2.75-6.25
Age 6-12 (n=51)	Mean	0.01±1.61	-0.58±0.60	-0.29±1.59	0.34±2	-0.44±0.62	-0.25±1.95
	Range	-3.00-4.25	-3.25-0	-1.75-4.25	-2.50-6.50	-2.75-0	-2.75-6.25

The Plusoptix A08 was found to have sensitivity (86.85%) and specificity (88%) those could be compared favorably with sensitivities of HOTV (54%) and Lea chart (61%) visual acuity testing<sup>15,16</sup>. Bloomberg et al. reached satisfactory results for sensitivity, specificity, positive and negative predictive value of 87%, 88%, 93%, 78% respectively with plusoptix A0816. In our study the device offered a low sensitivity (42%) and positive predictive value (37%) but high specificity (89%), and negative predictive value (91%) for children aged over 6 years old. Positive refractive value (PPV) indicates patients who was evaluated by the Plusoptix as having amblyopia, but not having amblyopia actually. In our study the reason of low PPV may be accommodative insufficiency. Arnold et al pointed to that; the device was recording relative hyperopia at near because of insufficient accommodation<sup>20</sup>. On the other hand in group who aged under 5 years old, Plusoptix S08 provided more satisfactory sensitivity, specificity, positive and negative predictive values in our study. (70,96,93,80% respectively).

A caution for the Plusoptix is; adjusting referral criteria for small sample size can cause important changes in sensitivity and specificity<sup>12</sup>. Bloomberg and Simons cautioned that Plusoptix A08 had low sensitivity for detection of exotropia and esotropia of magnitude  $\leq 10^\circ$ <sup>16,19</sup>. In our study negative predictive value of Plusoptix was 88%. This means about 1 child of 10 children the device says normal is actually has amblyopia or strabismus. In this study we did not researched the success of device for detection of strabismus. We caution against the use of the Plusoptix S08 in population with high prevalence of strabismus like Bloomberg and Simons et al<sup>16,19</sup>.

Also it was said that population differences can explain the disparity seen in predictive values between the studies. Moghaddam found a positive predictive value of 19%, in which the children were chosen from city population those had low amblyopia risk factors<sup>17</sup>. On the other hand Bloomberg and Matta reported positive predictive value of 93% and 97% respectively in children from populations with high prevalence of amblyopia<sup>16,18</sup>.

There are some other studies evaluating Plusoptix photoscreening's success in detection of refractive error in children. Matta et al reported Plusoptix offered sensitivity of

99%, specificity of 82%<sup>21</sup>, sensitivity of 98% and specificity of 88% in their another study<sup>12</sup>. Arnold reported sensitivity and specificity of 74% and 88% in preschool children and of 67%, 100% in delays, respectively<sup>22</sup>. McCurry et al found sensitivity and specificity of 94% and 48% respectively in Plusoptix A08<sup>23</sup>. Dahlmann-Noor reported sensitivity and specificity of 44% and 100% respectively with Plusoptix photoscreener<sup>24</sup>. Based on this study and previous studies, we can say that; the Plusoptix S08 is reliable, user friendly, rapidly and has acceptable sensitivity and specificity; particularly in preschool children's refractive error screenings.



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