

Comparison of Plusoptix S12R photoscreener with cycloplegic retinoscopy and autorefractometry in pediatric age group

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Purpose: To compare refractive measurements of noncycloplegic photoscreener Plusoptix S12R with cycloplegic retinoscopy, noncycloplegic autorefractor, and cycloplegic autorefractor in children. **Methods:** The study population (200 eyes of 100 children) was divided into two groups: Group 1 (age 3–7 years) and Group 2 (age 8–15 years). In Group 1, Plusoptix was compared with cycloplegic retinoscopy. In Group 2, Plusoptix was compared with cycloplegic retinoscopy and autorefractometry. The second group was made because the younger group was found to be uncooperative for autorefractometry. Paired *t*-test and Pearson's correlation were used for statistical analysis. **Results:** The mean difference in sphere (DS), spherical equivalent (DSE), and cylinder (DC) between cycloplegic retinoscopy and Plusoptix in Group 1 was 0.68 ± 0.55 ($P < 0.001$), 0.77 ± 0.61 ($P < 0.001$), and 0.18 ± 0.28 ($P < 0.001$), respectively. In Group 2, DS, DSE, and DC between cycloplegic retinoscopy and Plusoptix were 0.86 ± 0.49 ($P < 0.001$), 0.97 ± 0.51 ($P < 0.001$), and 0.23 ± 0.28 ($P < 0.001$); between cycloplegic autorefractor and Plusoptix were 0.69 ± 0.47 ($P < 0.001$), 0.74 ± 0.49 ($P < 0.001$), and 0.10 ± 0.31 ($P = 0.002$); and between noncycloplegic autorefractor and Plusoptix were -0.25 ± 0.39 ($P < 0.001$), -0.19 ± 0.41 ($P < 0.001$), and 0.11 ± 0.31 ($P < 0.001$), respectively. Pearson's correlation coefficients of S, SE, and C between Plusoptix and cycloplegic retinoscopy were 0.948, 0.938, and 0.924 in Group 1 and 0.972, 0.972, and 0.946 in Group 2, and these values were statistically significant. Bland–Altman plots showed good agreement between cycloplegic retinoscopy and Plusoptix in both groups. Plusoptix gave axis values within 10° of cycloplegic retinoscopy in 81.56% of eyes in Group 1 and in 71.44% of eyes in Group 2. **Conclusion:** Plusoptix photoscreener can be used for prescription of axis of cylinder in children; however, other refractive measurements must be refined by cycloplegic retinoscopy.

Key words: Amblyopia, photoscreener, refractive errors

Refractive errors are the most common cause of visual impairment in the world and the second most common cause of treatable blindness in the world.^[1] Unless diagnosed and corrected early, they can lead to an irreversible diminution of vision despite optimal refractive correction – a condition known as amblyopia. Amblyopia affects 1.6%–3.6% of the population.^[2] Early diagnosis and prompt treatment is the best way to counter amblyopia. The American Academy of Pediatrics and the American Association of Pediatric Ophthalmology and Strabismus as well as the European Strabismological Association and Societies advocate early pediatric vision screening to diagnose and prevent amblyopia.^[3,4] The various methods of vision screening are direct measurement of visual acuity using optotype-based eye charts and instrument-based screening, which includes retinoscopy, autorefractors, photoscreeners/photorefractors, and electrophysiological testing by visual evoked potential.

Retinoscopy or skiascopy is an objective method of finding out the refractive error using the technique of neutralization of light reflex. Cycloplegic retinoscopy is considered the gold

standard for refraction in children due to the high degree of accommodation in them.^[5] Retinoscopy has some drawbacks because it is time-consuming, necessitates advanced training, and is subject to interobserver variability.^[6] Autorefractors are devices which perform automated retinoscopy on each eye separately. They are easy to operate, are quicker, and have more repeatability than other techniques of objective refraction such as retinoscopy. The disadvantage is pseudomyopia caused by accommodation and inadequate autofocusing mechanisms.^[7] Moreover, they are table-mounted devices and difficult to use in pediatric age group because of non-cooperation.

Photoscreeners use an infrared camera that captures and analyzes images of the red reflex of undilated pupil to assess the alignment of both eyes and estimate the refractive error.^[8] Plusoptix S12R is the newest photoscreener marketed as a screening tool to rule out amblyogenic risk factors (high refractive error, anisometropia, strabismus) in children.

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Approved by the US Food and Drug Administration, Plusoptix S12R is a method of remotely measuring refractive data, pupil size, pupil distance, and gaze deviation in real-time. Due to the large working distance of 1 m, photoscreeners are suitable for examining children and disabled patients. Photoscreeners allow simultaneous examination of both eyes without cycloplegia, thereby accelerating the measurement procedure.^[9]

The purpose of this study was to compare refractive measurements made in children using noncycloplegic photoscreener Plusoptix S12R (Plusoptix GmbH, Nurnberg, Germany), with noncycloplegic autorefractor (Potec PRK-6000; Potec Co., Ltd., Daejeon, Korea), cycloplegic autorefractor, and cycloplegic retinoscopy (Heine Beta-200 streak retinoscope; Heine Optotechnik, Herrsching, Germany).

Methods

A prospective, observational, and comparative study was conducted at Pediatric Ophthalmology Services (redacted for review) between November 2015 and December 2016 to compare noncycloplegic Plusoptix photoscreening with noncycloplegic autorefraction (NCAR), cycloplegic autorefraction (CAR), and cycloplegic retinoscopy in the pediatric population. The study was reviewed and approved by the institute's ethics committee. The conduct of the study was in accordance with the Declaration of Helsinki.

Erdurmus *et al.*^[10] compared Plusoptix vision photoscreeners with cycloplegic retinoscopy in terms of refractive error. Taking their results as reference values, the minimum required sample size at 5% level of significance and 95% power was computed to be 73 eyes. Due to availability of time, a sample of 200 eyes was taken: 100 eyes in age group 3–7 years (Group 1) and 100 eyes in age group 8–15 years (Group 2). The second group was taken because subjects in the first group were found to be uncooperative for autorefraction. The subjects comprised consecutive patients in each age group in the 1-year period. They were taken up for study after obtaining written and informed consent from the parents. Exclusion criteria were active eye pathology, dense cataracts preventing fixation, previous ophthalmic surgery, corneal opacities, dry eyes, history of contact lens wear, glaucoma, retinal disease, inability to open eyes widely, poor ocular fixation, and nystagmus. Refractive errors exceeding spherical range of -7.00 to $+5.00$ diopters (D) and a cylindrical range of -7.00 to $+5.00$ D were also excluded as they were out of the measurement range of Plusoptix.

In group 1, noncycloplegic photoscreening was performed. Then, cycloplegia was attained using four drops of homatropine 2% instilled at intervals of 15 min and cycloplegic retinoscopy was done after 1 h of putting the first drop. Autorefraction was not done in this group because of noncooperation of small children for table-mounted devices. In Group 2, noncycloplegic photoscreening and NCAR were performed. Then, cycloplegia was attained using homatropine 2% and CAR and cycloplegic retinoscopy was done. Sphere (S), cylinder (C), spherical equivalent (SE), and axis were calculated using each method. The average of three readings was taken for each value of Plusoptix and autorefraction. The person performing retinoscopy was blinded to the results of plusoptix and autorefraction.

Statistical analysis

The comparison of refraction measurements by the different instruments was done using the following well-established criteria. The difference between average spherical powers [difference in sphere (DS)] was formulated as $DS = S_c - S_t$. The subscripts "t" (test) and "c" (control) represent the instrument being tested (Plusoptix) and the control technique (cycloplegic retinoscopy) for comparison. The difference in the average SE refractive error (DSE) was calculated as $DSE = (S_c + 0.5 \times C_c) - (S_t + 0.5 \times C_t)$. The difference between the cylindrical powers (DC) was calculated as $DC = C_c - C_t$. All the cylinder powers were taken as negative values for the ease of comparison. Positive cylinder powers were converted to negative values using transposition.

Descriptive statistics included measurements of means and standard deviations. Comparisons between measurements were performed using paired two-tailed *t*-tests. Correlations were measured using Pearson's correlation coefficient. Bland-Altman plots were studied to know the agreement between Plusoptix and cycloplegic retinoscopy in the two groups. Statistical analyses were performed using Statistical Package for Social Sciences (SPSS) version 24. Statistical significance was defined as $P < 0.05$.

Results

Plusoptix, NCAR, CAR, and cycloplegic retinoscopy measurements of 200 eyes of 100 children in age group 3–15 years were conducted.

In Group 1, the mean S, SE, C, and axis values measured by cycloplegic retinoscopy were 1.84 ± 1.70 D, 1.50 ± 1.73 D, -0.71 ± 0.73 D, and $174.00 \pm 17.88^\circ$ and those measured by Plusoptix were 1.15 ± 1.50 D, 0.72 ± 1.52 D, -0.89 ± 0.66 D, and $134.61 \pm 65.44^\circ$, respectively [Fig. 1]. The DS, DSE, and DC values between cycloplegic retinoscopy and Plusoptix are given in Table 1. S (Pearson's correlation coefficient, $r = 0.948$, $P < 0.001$), C ($r = 0.924$, $P < 0.001$), and SE ($r = 0.938$, $P < 0.001$) values measured by cycloplegic retinoscopy correlated strongly with Plusoptix.

In Group 2, the mean S, SE, C, and axis values measured using cycloplegic retinoscopy were 1.74 ± 1.93 D, 1.26 ± 2.00 D, -0.97 ± 0.86 D, and $156.76 \pm 43.31^\circ$; using Plusoptix were 0.88 ± 1.71 D, 0.28 ± 1.75 D, -1.20 ± 0.80 D, and $121.39 \pm 67.29^\circ$; using CAR were 1.57 ± 1.88 D, 1.02 ± 1.94 D, -1.10 ± 0.74 D, and $134.87 \pm 61.55^\circ$; and using NCAR were 0.63 ± 1.69 D, 0.09 ± 1.77 D, -1.08 ± 0.78 D, and $132.09 \pm 63.84^\circ$, respectively [Fig. 2]. The DS, DSE, and DC values between cycloplegic retinoscopy and Plusoptix, CAR and Plusoptix, and NCAR and Plusoptix are given in Table 2.

Table 1: Comparison between cycloplegic retinoscopy and Plusoptix in Group 1

	Cycloplegic retinoscopy vs Plusoptix		
	Mean±SD	P*	95% CI
DS (D)	0.68±0.55	<0.001	0.58-0.79
DSE (D)	0.77±0.61	<0.001	0.65-0.89
DC (D)	0.18±0.28	<0.001	0.12-0.24

SD=Standard deviation; CI=Confidence interval; DS=Difference in sphere, DSE=Difference in spherical equivalent, DC=Difference in cylinder, D=Diopter. *Paired t-test significant at $P < 0.05$

Table 2: Comparison between cycloplegic retinoscopy, Plusoptix, CAR, and NCAR in Group 2

	Cycloplegic retinoscopy vs. Plusoptix			CAR vs. Plusoptix			NCAR vs. Plusoptix		
	Mean±SD	P*	95% CI	Mean±SD	P	95% CI	Mean±SD	P	95% CI
DS (D)	0.86±0.49	<0.001	0.76-0.95	0.69±0.47	<0.001	0.59-0.78	-0.25±0.39	<0.001	-0.32--0.17
DSE (D)	0.97±0.51	<0.001	0.87-1.07	0.74±0.49	<0.001	0.64-0.84	-0.19±0.41	<0.001	-0.27--0.11
DC (D)	0.23±0.28	<0.001	0.17-0.28	0.10±0.31	0.002	0.03-0.16	0.11±0.31	<0.001	0.05-0.17

CAR=Cycloplegic autorefraction, NCAR=Noncycloplegic autorefraction, CI=Confidence interval, DS=Difference in sphere, DSE=Difference in spherical equivalent, DC=Difference in cylinder, D=Diopter. *Paired *t*-test significant at $P<0.05$

S ($r = 0.972$, $P < 0.001$), C ($r = 0.946$, $P < 0.001$), and SE ($r = 0.972$, $P < 0.001$) values measured by cycloplegic retinoscopy correlated strongly with Plusoptix. S ($r = 0.970$, $P < 0.001$), C ($r = 0.920$, $P < 0.001$), and SE ($r = 0.970$, $P < 0.001$) values measured by CAR correlated strongly with Plusoptix. S ($r = 0.973$, $P < 0.001$), C ($r = 0.921$, $P < 0.001$), and SE ($r = 0.972$, $P < 0.001$) values measured by NCAR correlated strongly with Plusoptix.

Bland–Altman plots depicting the agreement between sphere, SE, and cylinder values measured by Plusoptix and cycloplegic retinoscopy are given in Figs. 3 and 4. Plusoptix gave axis values within 10° of axis values of cycloplegic retinoscopy in 81.56% of eyes in which cylindrical refractive error was measured by both modalities in Group 1 and in 71.44% of such eyes in Group 2. The sensitivities and specificities of Plusoptix for diagnosis of cylindrical power ≤ 0.75 D were 96.2% and 88.9%, respectively.

Discussion

The primary purpose of vision screening is for early identification of amblyopia and early intervention to reduce the burden of disease. Photoscreening/photorefraction is an easy and rapid method of measuring refractive values of both eyes simultaneously without cycloplegia. It works on the principle of analyzing the vergence of reflected light rays returning to a camera after illuminating a point on the retina. Plusoptix S12R is the newest photoscreener designed specifically for children and disabled persons. It is marketed as a pediatric vision screener to be used by lay persons for detection of amblyogenic risk factors in general population. It is capable of measuring refractive data (sphere, SE, cylinder, axis), pupil size, pupil distance, and gaze deviation in real-time. Using prestored referral criteria, it decides whether to refer the subject to a pediatric ophthalmologist or not. Refractive status is determined by assessing the distribution of the reflected light across the pupil. The measurement range is -7.0 to $+5.0$ D in steps of 0.25 D for spheres and cylinders, and 4.0–8.0 mm in steps of 0.1 mm for pupil diameter. The acquisition time is 0.8 s.

Previous studies have shown the efficacy of Plusoptix as a screening tool. Plusoptix A 09 was found to have a sensitivity of 44.4% and specificity of 97.7% for hyperopia detection; sensitivity of 85.7% and specificity of 94.7% for myopia; and sensitivity of 40.7% and specificity of 98.3% for strabismus.^[11] In a study by Demirci *et al.*, the sensitivities and specificities of Plusoptix S08 for diagnosis of cylindrical power ≤ 0.75 D were 97.1 and 83.3%, respectively. The sensitivity and specificity of Plusoptix CR03 for the diagnosis of cylindrical power 0.75 D were 98 and 71%, respectively.^[12]

This study was undertaken to compare the refractive values of plusoptix S12R with cycloplegic retinoscopy, CAR, and NCAR and assess the possibility of use of plusoptix photoscreener for prescribing spectacles, especially in uncooperative children. To our knowledge, this was the first study comparing Plusoptix S12R with cycloplegic retinoscopy, autorefraction, and CAR, and also the first of its kind on Indian population. In our study, Plusoptix S12R underestimated hypermetropia and overestimated myopia when sphere and SE values of Plusoptix were compared with cycloplegic retinoscopy and CAR.

Previous studies on Plusoptix photoscreener have also yielded similar results. Demirci *et al.*^[12] found DS and DSE between cycloplegic retinoscopy and plusoptix S08 to be 0.46 ± 0.34 D ($P = 0.006$) and 0.46 ± 0.35 D ($P = 0.007$), respectively. Erdurmus *et al.*^[10] found DS and DSE between cycloplegic retinoscopy and Plusoptix CR03 to be 0.70 ± 0.62 D ($P < 0.001$) and 0.64 ± 0.61 D ($P < 0.001$), respectively. Paff *et al.*^[13] found DSE between and cycloplegic retinoscopy and Plusoptix S08 to be 1.13 ± 1.25 Mirzajani *et al.*^[14] found DS and DSE between and cycloplegic retinoscopy and plusoptix S08 to be 0.16 ± 0.75 D and 0.22 ± 0.75 D, respectively. These results indicate that Plusoptix underestimates hyperopia and overestimates myopia when compared with cycloplegic retinoscopy. This considerable myopic shift has been attributed to uncontrolled accommodation in children. This highlights the importance of retinoscopy under cycloplegia to determine the accurate refractive error in children.

The refractive values of the two modalities had a strong positive Pearson's correlation showing that a change in one variable (S, C, or SE) as measured by cycloplegic retinoscopy will lead to a proportional change in that variable as measured by Plusoptix. A previous study has suggested that Plusoptix A09 may eliminate the need for cycloplegia in early detection of refractive errors in children. However, the authors concluded that further studies with a larger population having extreme ametropic eyes may be needed to confirm this study result.^[15] The axis values measured by Plusoptix correlated well with cycloplegic retinoscopy. These results are similar to previous studies that concluded that plusoptix is very useful in determining the axis and magnitude of cylinder. This attribute of Plusoptix S 12R can be used to measure the axis of cylinder in cases of young and uncooperative children in which other methods like retinoscopy are difficult to use. Bland–Altman plots show good agreement between cycloplegic retinoscopy and Plusoptix in both groups.

Newer photoscreening technology can quickly identify strabismus, refractive errors, and in some cases media opacity, thus potentially eliminating the need of a dilated fundus examination in most patients. A study by Silbert *et al.*^[16]

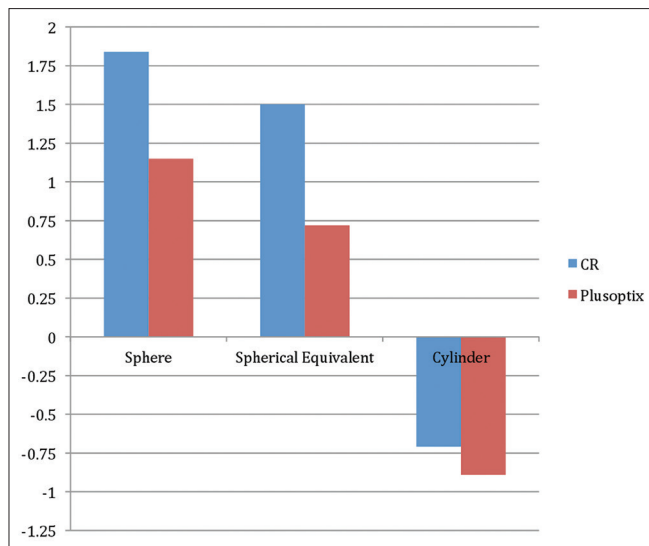


Figure 1: Comparison between mean sphere (S), spherical equivalent (SE), and cylinder (C) values of cycloplegic retinoscopy (CR) and Plusoptix in Group 1

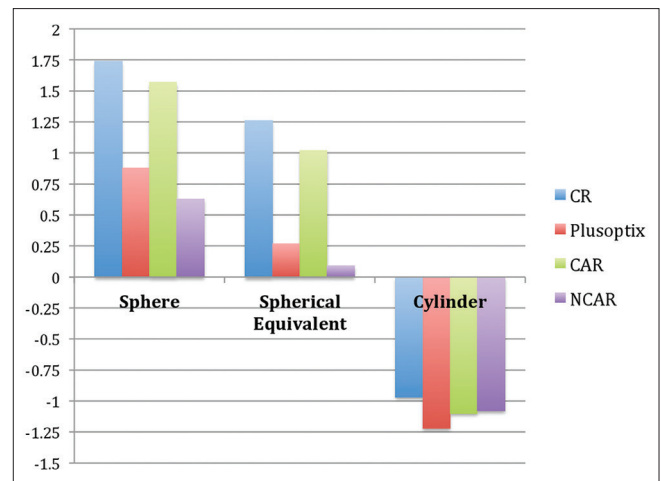


Figure 2: Comparison between mean sphere (S), spherical equivalent (SE), and cylinder (C) values of cycloplegic retinoscopy (CR), Plusoptix, cycloplegic autorefraction (CAR), and noncycloplegic autorefraction (NCAR) in Group 2

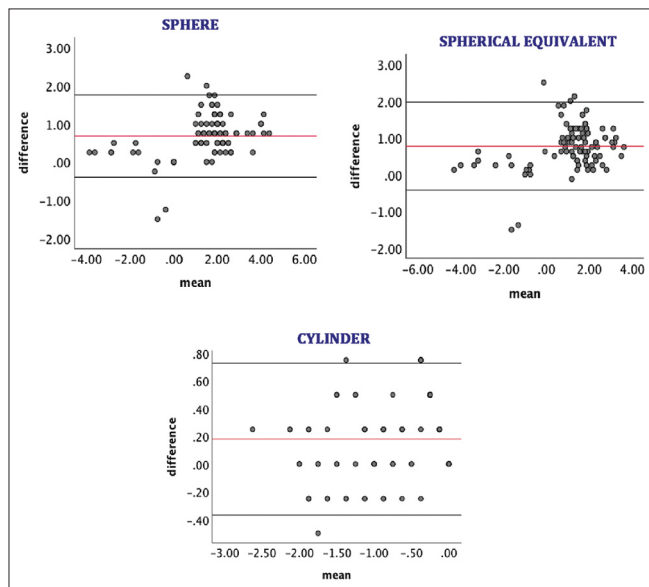


Figure 3: Bland–Altman plots for S (sphere), SE (spherical equivalent), and C (cylinder) measurements by cycloplegic retinoscopy versus Plusoptix in Group 1

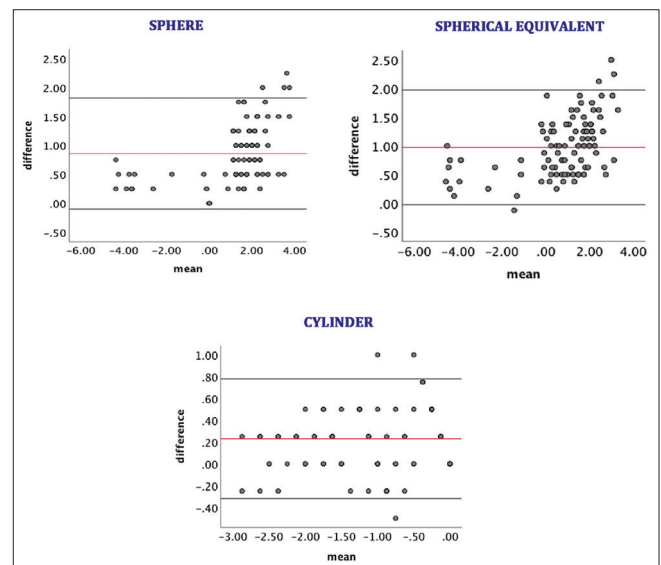


Figure 4: Bland–Altman plots for S (sphere), SE (spherical equivalent), and C (cylinder) measurements by cycloplegic retinoscopy versus Plusoptix in Group 2

showed that only 1% of verbal children with a normal Plusoptix photoscreener result, normal visual acuity, and alignment had additional pathology seen by dilated fundus examination. It concluded that screening with Plusoptix in combination with visual acuity and ocular alignment results can curtail the necessity for a dilated fundus examination, thereby saving time and resources.

Conclusion

In conclusion, Plusoptix S12 R has a strong positive correlation with cycloplegic retinoscopy and autorefraction in children. Plusoptix can be used to prescribe the axis of cylinder in children. The S, SE, and C measured by Plusoptix must

be refined by cycloplegic retinoscopy. Technology such as photorefractors can be used in the pediatric ophthalmology practice to hasten the screening of routine issues such as refractive errors and amblyopia, thereby increasing the efficiency of the overburdened healthcare system, especially in developing countries.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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