Comparison between Plusoptix A09 and gold standard cycloplegic refraction in preschool children and agreement to detect refractive amblyogenic risk factors

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Abstract:

BACKGROUND: The preschool children hardly complain about their vision problems. It is of paramount importance to screen them with an objective tool and compare with the gold standard technique.

AIM: To compare the values obtained with Plusoptix A09 and cycloplegic refraction in 3–6 years children and agreement to detect refractive amblyogenic risk factors.

SUBJECTS AND METHODS: A cross-sectional study was conducted in the Outpatient Department of Ophthalmology in a tertiary care hospital. Informed consent from parents and verbal assent from children were obtained. Each subject had monocular vision assessment with Lea symbol chart, stereo acuity measurement with Frisby, refractive screening with Plusoptix A09, squint assessment, and anterior segment evaluation before administering Homatropine hydrobromide (homide) 2% eye drops. Cycloplegic refraction and posterior segment evaluation were performed for final diagnosis.

STATISTICAL ANALYSIS: Descriptive statistics were used to summarize the data. Spearman correlation coefficient and kappa statistics were also employed.

RESULTS: In total, data of 94 children were analyzed. The correlation values obtained between plusoptix and cyclorefraction values for spherical, cylindrical, spherical equivalent were 0.508 (P < 0.0001), 0.779 (P < 0.0001), and 0.407 (P < 0.0001), respectively. Refractive errors were seen in 32% and amblyopia in 17% of eyes. Kappa value was κ = 0.974 in detecting refractive amblyogenic risk factors.

CONCLUSION: Good correlation was found between the plusoptix and cyclorefraction values. Cylindrical values showed a better correlation. Refractive errors and amblyopia were the major ocular disorders observed. There was significant agreement between the refractive techniques in detecting amblyogenic risk factors.

Keywords: Amblyogenic risk factors, cycloplegic refraction, plusoptix, preschool

Introduction

Preschool children rarely complain about their visual difficulties either because they cannot understand their symptoms or are unable to communicate it.[1] The widely used tests like visual acuity (VA) and stereo acuity are subjective and vary with the complexity of charts, concentration, cognitive ability of the child and experience of the screening personnel.[2,3]

Amblyopia is reported to be the most common reason for monocular visual...
impairment in children, refractive errors being the main cause. Hence, the precise measurement of refractive errors would facilitate the eradication of amblyopia. Amblyopia has a projected prevalence of 2%–5% and meets the World Health Organization criteria for a screening program.\(^4\) Undiagnosed visual deficit distresses the overall well-being of a child, primarily the educational potential. Literature accentuated early screening for better visual outcome.\(^5\) Cycloplegic refraction is considered the gold standard for refractive error measurement in children. Nevertheless, it causes discomfort for the child and consumes enormous time.\(^6\)

Photo screening is reported as an objective and cost-effective assessment that can be run quickly by a nonophthalmic personnel. Sensitivity and predictive values of photorefraction are stated to be much higher than VA measurements and can substitute for screening amblyogenic risk factors.\(^4,7\) Plusoptix photo screener is a portable, binocular pediatric vision screener approved by the US Food and Drug Administration.\(^3,8\) The screening tactic is based on the indication that noncycloplegic photo refraction has satisfactory precision, swiftness and repeatability.\(^9,10\)

The use of Plusoptix photo screeners and its studies in the eye care practices of developing nations like India are scarce, especially for the preschool age.\(^11,12\) Childhood vision loss could impose a heavy socioeconomic burden on individuals, societies and nations.\(^13\) There is a dire need to use screening tools like a photo refractor for early detection and intervention of the anomaly. With differing population demographics, variations in refractive measurements are foreseen, and hence, the tool needs to be compared against the gold standard across ethnicities.\(^2\)

The purpose of the current study was to compare Plusoptix A09 and cycloplegic refraction in preschool children to explore whether the objective tool could replace the gold standard cycloplegic refraction for the vision screening at a faster pace.

Subjects and Methods

The approval for the study protocol was obtained from the Institution Ethics Committee of Kasturba Hospital, Southern India and it adhered to the tenets of Declaration of Helsinki. It was a prospective study conducted at the Outpatient Department of Ophthalmology from November 2013 to December 2014. The children of age 3–6 years with normal developmental milestones were enrolled for the study. The objectives of the study and the examination protocol were explained. Written informed consent from parents and verbal assent from the subjects were obtained.

Each participant had unaided monocular vision assessment with Lea symbol chart (Good-Lite, Ellgin, Illinois, USA) and stereo acuity measurement with Frisby stereo test (Richmond Products Inc.). Plusoptix A09 was used to measure the refractive status of eyes. Dry refraction and acceptance were attempted for co-operative children. In patients with strabismus, Krimsky test was performed and the measurements recorded. Slit-lamp biomicroscope was used for the anterior segment evaluation. Dilatation was done using homatropine hydrobromide 2% eye drops. The drug was administered in each eye, one drop each after 10 minutes (twice) to warrant maximum cycloplegic effect. One more drop was instilled after 30 min if pupillary light reflex was present. Cycloplegic refraction and retinal examination followed. The diagnosis and management of each eye were recorded. The participants were excluded from the study if there was any missing data.

A single investigator recruited the participants and did all the assessments up to anterior segment examination. Cycloplegic refraction was done by another experienced optometrist with the streak retinoscope. Ophthalmologists specialized in pediatric eye care evaluated the retina. The gold standard for the refractive measurement was cycloplegic refraction. Comprehensive eye examination was considered as the gold standard for final diagnosis.

Measurement with Plusoptix A09

Plusoptix A09 was placed at a distance of 1.20 m (3.3 feet) from the child at eye level in dim illumination. The instrument was moved forward until green circles were spotted around the pupil, and a warble sound was heard. Binocular measurements were taken at this distance. When the refractive power was outside the range, “Hyperopia” or “Myopia” was displayed. If the screen showed as “measurement aborted,” the testing distance was rechecked, the room illumination reduced and the pupil brightness verified for any media opacities. If binocular values were not obtained, uniocular measurements were tried. The participant was excluded from the study if readings were still not obtained. Plusoptix measurements were done prior to the instillation of dilating eye drops.

Definitions

Refractive error was defined as hyperopia $\geq +2.00\text{D},$ myopia $\leq -0.50\text{D},$ astigmatism $\geq 0.75\text{D}.$

Strabismus was defined as asymmetric alignment or abnormal cover test results in addition to stereopsis $<120 \text{s of arc.}^{[14]}$ Unilateral amblyopia was defined as $\geq 2$ lines difference in best-corrected interocular VA.\(^{[15]}\) For detecting refractive amblyopic risk factors (RARF), American Academy of Pediatric Ophthalmology and
Strabismus (AAPOS) criteria was adopted. It was hyperopia >3.50D, myopia >−3.00D and astigmatism >1.50D.[12]

Data analysis
Statistical Package for the Social Sciences (SPSS Inc., Chicago, Illinois, USA) version 20 was used for tabulation and analysis. Normality of data was checked. Mean or median was reported based on the data distribution. Spearman correlation coefficient was determined to find the association between Plusoptix A09 and cycloplegic refraction. Kappa statistics was done to find the agreement between the refractive methods in screening RARF. A $P < 0.05$ was considered to be statistically significant.

Results
Two hundred children in the specified age group were considered for the study. Delayed milestones were seen in 35, 17 had eye infections and 20 declined from the study. One hundred and twenty-eight participants were recruited for the study. Plusoptix values were not obtained in 34 subjects. In total, 94 preschool children were included in the present study. Only the right eye of the participants was incorporated for analysis.

The normality of the data was checked using Q-Q plots and it was positively skewed. The median age of the participants was 67 (53, 72) months. There were 47 girls and 47 boys. Median presenting VA with Lea symbol was 0.20 (0.1, 0.6) log MAR. Frisby stereo test showed a median value of 150 (55, 340) seconds of arc. Median values of spherical, cylindrical and spherical equivalent (SE) obtained with both techniques are given in Table 1. Plus Optix showed more plus in spherical (1.5D) compared to cycloplegic values (0.75D) while the cylindrical errors were closer (−1.8 and −2.25D). Median difference (Q1, Q3) for spherical and cylindrical values between the two methods was 0.75D (0.12, 1.50) and 0.50 D (−0.75, −0.12).

Figures 1-3 depict the relation between spherical, cylindrical and SE values for plusoptix A09 and cyclorefraction. Spearman correlation coefficient was $r = 0.508$, $P < 0.0001$ for spherical, $r = 0.779$, $P < 0.001$ for cylindrical errors and $r = 0.407$, $P < 0.001$ for SE values. In the current study, cylindrical values showed better correlation compared to spherical and SE values.

Table 2 displays ocular diagnosis of the participants. Refractive errors were the most common. About 91% (27 eyes) had myopic astigmatism. The causes of amblyopia were refractive (13), mixed (1) and vision deprivation (2). Vision deprivation was due to developmental cataracts. Infantile esotropia was present in 2 eyes and 10 had anterior and posterior segment anomalies.

Kappa statistics was performed to find the agreement between the refractive measurements in detecting RARF. As 95% of the children with RARF were astigmats, kappa was run only for cylindrical values. It showed excellent agreement between plusoptix and cyclorefraction values ($k = 0.974$, $P < 0.0001$).

In the participants where measurements were not obtained, 18 had high refractive errors, 8 had amblyopia, 2 had strabismus, 2 had anterior segment pathologies and other 4 were normal eyes, considering right eye alone.

Discussion
In the present study, Plusoptix A09 showed comparable results with gold standard cycloplegic refraction in preschool children. It was designed to screen spherical and cylindrical range of −7.0 to +5.0D in increments of 0.25D according to the manufacturer.[13] There are varied views regarding Plusoptix as a screening device in younger children. The reliability of the device with cycloplegic refraction was agreed upon by some of the researchers while others had differed opinion.[4,16-18]

In this study, plusoptix readings were not obtained in 34 subjects. Most of the eyes in which plusoptix values were not obtained had ocular abnormalities. Hence, it may be safer to refer the child for further ophthalmic evaluation if the measurements are not attained.

According to Schimitzek and Lagrèze, the mean difference between photo refraction and cycloplegic autorefraction values was 0.73.[19] Schimitzek, Erdurmus and Dahlmann-Noor et al. observed underestimation in SE values with plusoptix.[19-21] Dahlmann-Noor et al. reported a myopic shift of 1.9D with the screener.[21] Accuracy was reported to be higher in myopia compared to hyperopia in the literature.[12,22] According to Lemos et al. and Singman et al., photorefraction might underestimate hyperopia and overestimate myopia in cases of normal accommodation.[11,23]
Won et al. found significant Pearson’s correlations between the Plusoptix S09 and cycloplegic auto refractometer for spherical power, cylinder power, and SE (0.748, 0.893, and 0.782 respectively). Similar results were obtained by Rajavi et al. (0.76, 0.86 and 0.76), Erdurmus et al. (0.63, 0.70, and 0.63), Lemos et al. (0.85, 0.90 and 0.85), Saini et al. (0.94, 0.92, 0.93). Good correlation was reported between Plusoptix screener and cycloplegic refraction by Payerols et al. The authors highlighted the need for large scale population-based studies to corroborate the findings. The current study results were consistent with the aforementioned reports, especially for the cylindrical values. Most of the previous reports had excluded refractive errors beyond the recommendation range and so the correlation was better.

Noor et al. discouraged using Plusoptix Vision Screener as a sole basis for identifying amblyogenic risk factors in children due to the lack of consensus with cycloplegic refraction. The findings of the current study were inconsistent with the results by Noor et al. Payerols et al. and Demirel et al. reported that cycloplegic refraction was indispensable for the first glasses. Bharadwaj et al. emphasized that fundal reflectance was less in darker eyes with the photo refractor. Intra- and inter-subject variability in measurements might be yet another contributing factor. Added research is warranted to know the basis of these differences among people residing in various geographical locations. Alley reported that photo screeners could only check the risk factors and not the actual disease. Cotter et al. emphasized the need to modify manufacturer’s pass/fail criteria of the plusoptix screeners in-field testing to improve the specificity for refractive error referral criteria.

The main causes of ocular disorders in this study were refractive errors and amblyopia. This corroborates with several previous reports. In this study, kappa ($\kappa = 0.974$) was found to be significant between plusoptix and cycloplegic refraction for detecting cylindrical RARF. Rajavi et al. observed an overall agreement between Plusoptix S04 and cyclorefraction in identifying refractive errors. Kappa was found to be superior for myopia (0.906) and astigmatism (0.762) as compared to hyperopia (0.492). For any RARF, it was reported to be

### Table 2: Distribution of ocular diagnosis in study eyes

| Diagnosis            | Number of eyes (%) |
|----------------------|--------------------|
| Emmetropia           | 37 (39.3)          |
| Refractive errors    | 30 (31.9)          |
| Amblyopia            | 16 (17.0)          |
| Strabismus           | 2 (2.1)            |
| Ocular pathologies   | 10 (10.6)          |
| Total                | 94 (100)           |

Figure 1: Scatter plot between cycloplegic refraction and plusoptix for spherical values

Figure 2: Scatter plot between cycloplegic refraction and plusoptix for cylindrical values

Figure 3: Scatter plot between cycloplegic refraction and plusoptix for spherical equivalent
The power of the study was 95%, with 5% level of significance when correlation value between photorefraction and cyclorefraction values was set at 0.5 based on the previous studies, thus justifying the sample size.

The current study has a good distribution of children with and without ocular anomalies which is its strength. The sample being hospital based might not be generalizable. Moreover, photorefraction measurement was instrument based while the cycloglepic refraction was individual based, which might be a potential source of error. Epidemiological studies in this area may be valuable for further deployment of this information with added confidence. This aspect needs to be further explored.

**Conclusion**

Plusoptix A09 showed good correlation with cycloglepic refraction, especially for cylindrical errors. However, high refractive errors could not be detected justifying the need for cycloglepic refraction. Hence, Plusoptix A09 might be a useful tool for vision screening of preschoolers where experienced human resource is unavailable.

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**Conflicts of interest**

There are no conflicts of interest.

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