CHAPTER 5

DISCUSSION
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The current study aimed at development of a protocol for screening visual impairment in children aged 3 to 6 years. The objectives of the study were to develop a protocol and validate the visual acuity charts, stereo acuity charts and photo refractor for screening vision impairment in 3-6 year old children. 128 normal eyes and 126 visually impaired eyes were analyzed to address the aforementioned objectives.

The most vital feature of a screening battery is the equilibrium between sensitivity, specificity and time efficiency. More the test combinations, more the chair time required. There is ongoing debate on the preschool vision screening batteries across the globe and lack of consensus on the protocol used even within territories. Moreover, comparisons were not possible as the socioeconomic backgrounds and ethnicity of the sample were diverse.17

5.1 Development of a protocol for screening visual impairment

Our study developed a screening protocol in children aged 3 to 6 years based on extensive review of literature. The screening tests employed were Lea symbol, HOTV and E charts for recording visual acuity Frisby, Randot preschool and Titmus stereo fly test for stereo acuity measurement and Plusoptix A09 for refractive error assessment. It was followed by complete eye examination. Comprehensive eye examination was taken as the gold standard for final diagnosis.

Bloomberg et al proposed that the sensitivity for identifying amblyogenic risk factors could be enhanced by the integration of Plusoptix photo screener and cover or stereo test in children aged 0 to 5 years.148 Our study results do not support the findings
of Bloomberg et al. The reasons may be due to different age group and retrospective nature of the study.

Casas and co-workers developed an amblyopia screening protocol, using Lea symbols charts, ocular alignment, motility assessment and TNO random dot test in a kindergarten for 4- to 5-year-old children by qualified professionals. The sensitivity, specificity, PPV, NPV for the protocol were 89.3%, 93.1%, 83.3% and 97.5%. We cannot comment on the protocol as our diagnostic criteria, screening tests and population under study were varied.

Silbert and co-workers observed 98% negative predictive value for ocular anomalies including significant refractive errors if a normal Plusoptix result combined with normal ocular alignment tests and visual acuity was obtained for children above 3 years. We computed kappa for visual acuity, stereoacuity and Plusoptix combinations and found it to be below 0.5 with different combinations. Our study findings are inconsistent with the results of Silbert et al. It may be because of the difference in population demographics and diagnostic criteria.

5.2 Validation of the developed screening protocol

The sensitivity and specificity of visual acuity charts in this study were much superior to other screening tests. In the present study, sensitivity, specificity, PPV and NPV of Lea chart were 88.1%, 96.9%, 96.5% and 89.2% and for HOTV were 87.3%, 97.7%, 97.3% and 88.1% respectively for detecting visual impairment. E chart was taken as the reference chart as it was the most commonly used chart in developing nations. The presenting visual acuity of < 20/40 or 0.3 log MAR with E chart was used to categorize the study eye as visually impaired.
The following published studies have endorsed or raised objections to the findings of this study. Diana et al found the sensitivity, specificity, PPV and NPV of E chart to be 99%, 15%, 45% and 94% while the Lea symbol showed 93% sensitivity, 56% specificity, 59% PPV and 92% NPV for visual acuity \( \leq 0.2 \) log MAR. The screening was performed by an optometrist in a preschool of semi urban locality. Miller et al observed the sensitivity and specificity of Lea symbols at 20/40 as 92% and 56% in preschoolers with astigmatism. Busic and co-workers estimated the sensitivity, specificity, PPV and NPV of Lea distance chart as 96.4%, 11.7%, 9.4% and 97.1% for screening amblyopia. The screening was done by general ophthalmologists and residents. Omar et al found the sensitivity and specificity of Lea symbol chart to be 97.5 % and 57.1% and Sheridan Gardiner chart to be 75.1% and 92% respectively in preschoolers. The authors recommended Lea Symbols chart for its superior pick-up rate in the visual impairment screening programmes of Malaysia. All the testings were conducted by optometrists. Our study results showed lesser sensitivity and better specificity compared to the abovementioned studies. This might owe to the diagnostic criteria and settings of the studies reported compared to the current study.

According to Bertuzzi and colleagues, the sensitivity and specificity of Lea symbol chart was 78% and 93% in screening visual acuity deficiency. The authors suggested Lea symbol to be an economic, simple and rapid tool for massive vision screening in children aged 38-54 months. The present study supported the findings of Bertuzzi et al in better specificity compared to sensitivity of Lea visual acuity chart. The diagnostic condition was based on visual deficiency for both the studies.

For screening significant refractive errors, Lea symbol chart showed sensitivity, specificity, PPV and NPV of 87.8%, 75%, 62.6%, 92.8% while HOTV and E chart
displayed 90.2%, 77.3%, 65.5%, 93.8% and 90.2%, 69.8%, 58.7%, 93.8% respectively. The sensitivity and NPV values were almost equal for both the diagnostic criteria. The specificity and PPV for the visual acuity charts were higher for refractive error screening as compared to visual impairment detection.

Cyert et al determined the sensitivity of HOTV and Lea chart for 3, 4 and 5 year old children. They reported the sensitivities for detecting amblyopia, refractive error and strabismus (VIP targeted vision disorders) for Lea symbol chart in these age group to be 83%, 83% and 78%. HOTV test yielded sensitivity of 57%, 80% and 82% for 3, 4 and 5 year olds. The specificity was set close to 90% with both the charts in all age groups. No statistical significant differences were observed between 2 visual acuity charts in the different age groups.36

Our results were consistent with the study findings of Cyert et al in screening refractive errors. We had not categorized the participants into different age groups due to lesser sample size and the specificity was not set at a constant value in our study.

However, there is a wide range in sensitivity reported with preschool visual acuity charts. This may be due to the diversity in the diagnostic conditions, screening personnel and settings of the study. Further, comparison between 3 charts in the same participants group was not found in the literature.

The current study found 66.7% sensitivity, 63.6% specificity, 60% PPV and 70% NPV for Frisby stereo test in visual impairment detection and 82.1%, 52.4%, 45.1% and 86.0% for screening significant refractive errors. Titmus stereo fly test exhibited 88.5%, 40.0%, 54.1% and 81.2% validity for visual impairment identification and 91.9%, 35.8% 39.5% and 90.6% for significant refractive error screening. Randot preschool test
displayed a sensitivity, specificity, PPV and NPV of 74.1%, 56.1%, 58% and 72.5% for identifying visual impairment and 77.5%, 51.9%, 58% and 44.3% in screening significant refractive errors. All the stereo tests showed better sensitivity for refractive error screening in contrast to visual impairment detection.

In a study by Diana et al., the sensitivity, specificity, PPV and NPV of Titmus and Frisby were reported to be 75%, 13%, 8% and 85% and 75%, 27%, 9% and 92% for visual acuity <0.2 log MAR.38 These results showed higher sensitivity and less specificity than the current study for screening visual impairment which do not support our findings. It may be because of the differences in cut offs and the setting of the study.

Ancona and co-workers reported the sensitivity, specificity, PPV and NPV of Titmus stereo fly test in screening strabismus as 83.1%, 83.3%, 77.8% and 87.5% respectively.144 Farvardin and colleagues reported the sensitivity of TNO, Titmus and Randot tests to be 55.5%, 48.4% and 44.4% in a screening set up. He underscored the fact that stereo tests employed were diverse across studies.45 The sensitivities of Randot E, Titmus and TNO stereo test for picking up amblyopia were 36%, 38% and 46% according to Ohlsson et al.46 There is a wide variation in the sensitivities reported in published literature. This may be due to different diagnostic criteria and screening set ups.

The present study recorded a sensitivity, specificity, NPV and PPV of 56%, 52.3%, 54.8% and 53.5% for spherical and 62.6%, 64%, 64.8% and 61.8% for cylindrical values in identifying visual impairment with Plusoptix A09. For significant refractive error screening, the values procured were 52.5%, 48.3%, 33.3% and 67.4% for sphere and 62.1%, 56.3%, 40.9% and 75.3% for cylinder values. The sensitivity and specificity were better for cylindrical values compared to spherical.
These findings were inconsistent with a handful of the studies published. The Plusoptix A09 was found to have 89% sensitivity and 80% specificity for identifying ARF in a study by Silbert at al.\textsuperscript{52} Plusoptix A09 revealed 94%, 89%, 11% and 6% sensitivity, specificity, PPV and NPV for sensing ARF by lay screeners and hence suggested to have enormous implications in public eye health.\textsuperscript{53} Yan et al reported Plusoptix A09 to have a sensitivity of 86.7% for hyperopia >1.88 D, 85.7% for myopia >-3D, 85% for astigmatism >1.5 D for regular and >1 D for oblique astigmatism, 72.2% for anisometropia >1.25 D and specificity of 89.5%, 94.7%, 85.5% and 84.8% respectively for detecting refractive amblyopia risk factors in Chinese children aged 6.2±2.4 years who attended an eye clinic. The sensitivity and specificity of the Plusoptix A09 to pick up strabismus were 40.7% and 98.3%, detection of amblyopia and/or strabismus was reported to be 84.7% and 63.2%, respectively. Yan et al considered Plusoptix A09 suitable for large-scale refractive screening in children. On the other hand, it was not suggested for strabismus screening.\textsuperscript{54} Alley et al highlighted in her review that the shortcoming of all photo screeners was that it checked only the risk factors and not the actual disease.\textsuperscript{10} The reason for reduced sensitivity and specificity in the current study might owe to the ethnicity and age range variation as reported by Bharadwaj et al.\textsuperscript{149}

### 5.2 Intraclass Correlation Coefficient and agreement between different screening methods

A good correlation was observed between the 3 charts in the current study. (ICC = 0.990) Bland Altman analysis showed very good agreement between Lea and HOTV, Lea and E and HOTV and E charts having 95% of the values within Mean ± 2SD. Hence, Lea chart, HOTV and E charts could be used interchangeably for PVS. The acuity difference was least between Lea and HOTV (0.1 log MAR) in contrast to Lea and E and HOTV and E (0.24 log MAR).
Diana et al reported good agreement with Lea, HOTV and E vision charts in a preschool set up. Lea and HOTV showed minimum acuity difference. The current study findings were consistent with their results. Sankar and colleagues observed Tumbling E chart to be as good as Lea in assessing visual acuity of preschoolers, especially in 5 to 6 year olds. ICC value was also high between the charts which fall in line with our study results.

VIP study group reported fair agreement between HOTV and Lea charts. The present study observed very good agreement between the charts. Cyert et al found better visual acuity scores with Lea in 3-5 year olds compared to HOTV. A study conducted by Osaiyuwu found Lea symbol to be more dependable than Sheridan Gardiner for vision assessment, especially in 3 year olds. This was inconsistent with our findings and might be because the current study results were applicable in the age group 3 to 6 years. A study by Cyert et al in 3 to 3.5 year children found crowded HOTV to be 0.25 log MAR better than Lea symbol which was not in agreement with our findings. Our study showed only 0.1 log MAR difference between Lea and HOTV charts in 3 to 6 year age group.

Becker et al compared Lea 15 line folding chart with Landolt C acuity and there was a difference of 1.5 lines (0.16 log MAR) between the charts in children aged 21 months to 7 years while in our study it was 0.24 log MAR between Lea and E chart even though the age range was varied.

The current study had not categorized the age group as 3, 4, 5 and 6 years to find out agreement. Hence it is not possible to comment on the superiority of any one of the charts for a specific age.
The correlation between stereo acuity charts was very poor in this study (ICC = 0.198). Ancona and colleagues reported low agreement among stereo tests, mostly if associated with a binocular vision anomaly. The authors highlighted the fact that the stereo test could not be used interchangeably in young adults. From a practical standpoint, the Frisby test needed no simulated means for stereo acuity measurement. Randot and Titmus depended on polarized glasses to produce binocular incongruence, which might result in incomplete dissociation or bring about retinal conflict. It was difficult to comment which test is better for clinical practice and the need of an improved design was suggested by Ancona et al. The tests for stereo acuity assessment differed in pattern and extent of disparity, shape and size of figures, testing distances and use of different glasses for simulating stereo acuity. This was the reason put forth by the author for lesser agreement between the stereo tests. The results of the current study fall in line with the agreement of stereo charts in the published literature.

The correlation between Plusoptix A09 and cyclorefraction was very poor in the current study. (ICC = 0.074) The distribution of values were scattered for the spherical and cylindrical values obtained with cyclorefraction and photo refraction (Plusoptix A09).

The literature reported varied views regarding Plusoptix photo screeners. According to Won et al, Pearson’s correlations between the Plusoptix S09 and cycloplegic auto refractometer for spherical power, cylinder power, and spherical equivalent were 0.748, 0.893, and 0.782, respectively. There was statistical difference between the Plusoptix S09 and cycloplegic auto refractometer for the spherical power and spherical equivalent in hyperopia of ≥+3.0 D. The authors had excluded eccentric fixation, media opacities and considered refractive errors of range -7.00 to +5.00 D and pupil size from 3 to 8mm for the study. In the current study, we had not excluded any
of the mentioned conditions and so had poor correlation between Plusoptix A09 and cyclorefraction compared to the study by Won et al.

The study conducted by Noor and colleagues reported the sensitivity of 19% in screening hypermetropia >+3.00 D and 50% for anisometropia > 1.00 D in Plusoptix Vision Screener. It was perceived that the strabismus cases with refractive error could not be attained with the instrument. Lack of consensus was noticed between photo refraction and cyclorefraction in a hospital based pediatric eye care services. The authors deterred from using Plusoptix Vision Screener as a sole basis for identifying amblyogenic risk factors in children aged 5.5±1.5 years. They proposed the requirement of a distance fixation target to curtail the errors. Our study results were consistent with the findings of Noor et al. It may be because both were done in a hospital based population.

Singman et al recommended the need to formulate their own referral criteria for better accuracy while screening with Plusoptix photo screeners. It was pointed out that photo refraction might underestimate hyperopia and overestimate myopia in cases of normal accommodation.

The diverse reports might be due to the values obtained in the instrument being determined by the illuminance profile and its conversion to dioptries. Hence, it may be influenced by ethnicity and the diagnostic condition employed. Intra and inter subject variability in measurements observed by Bharadwaj et al could also contribute to the differences observed. The age range of subjects were also different across studies.
5.3 Clinical characteristics of visual impairment

The major causes of visual impairment in the current study were amblyopia (42.1%) and refractive errors (41.3%). 83% of the amblyopia eyes had refractive error associated with it. These findings were supported by previous studies in literature.28,61,67

On doing kappa statistics, poor agreement was observed between plusoptix A09 and cyclorefraction both for spherical (κ = -0.13) and cylindrical refractive errors (κ =0.348) in screening refractive ARF. Cylindrical errors showed better agreement than spherical errors. Our study findings are contrary to the findings by Yan et al where plusoptix was recommended for mass refractive screening and detection of ARF.54 It may be due to wide refractive range obtained in the participants which was beyond the manufacturer recommendation.

Kappa statistics to find the agreement between different combinations of vision charts, stereo charts and Plusoptix A09 revealed that the visual acuity chart combinations (HOTV and Lea) had good agreement (κ = 0.850) over the other test combinations for screening visual impairment. E visual acuity chart was used as gold standard as it was used for categorizing VI. We also did the analysis by taking Lea and HOTV as gold standard and similar results were obtained. HOTV and E combination displayed a kappa value of 0.858 and Lea and E combination exhibited a kappa value of 0.851 which inferred to the use of any two visual acuity chart combinations for screening a visually impaired eye. The combination of tests rather than a single test was recommended by Langreze at al as PPV of any single test used in VIP study was low.26 Donahue et al warranted future research on the combinations of vision screening tests for preschool screenings.22
These studies supported our findings on the combination of screening tests rather than a single test for PVS.

5.4 Association of study variables with visual impairment

The participants were 49.2% boys and 51.5% girls. There was no association between age ($\chi^2= 2.0, p=0.571$) and gender ($\chi^2= 2.12, p=0.345$) with visual impairment screening in the current study.

MEPDES group reported age to be associated with visual acuity while neither gender nor ethnicity showed association. MEPDES and BPEDS found that girls often completed vision test compared to the boys of the same age which was inconsistent with the current study results. There was no relation between gender and vision, but ethnicity and socioeconomic status had impact on visual acuity according to Ying and co-workers. This was similar to the findings studied by us.

Ying et al observed direct correlation between preschool attendance and response to visual acuity testing. The reason cited was the behavioural development rather than physiological growth of the visual system. Lai et al found high testability in 3 to 6 year old children and all study subjects were preschool students. In the present study, all children had attended preschools or anganwadis and hence the response to vision assessment and other screening tests were good which was consistent with the results reported by Ying et al and Lai et al.

In this study, 60.9% children were residing in rural and 39.1% in urban locality. No statistical significant differences were observed between the rural and urban subjects for the visual acuity charts employed viz. Lea ($\chi^2=1.09, p=0.296$), HOTV ($\chi^2=0.287, p=0.59$) and E ($\chi^2=0.204, p=0.65$) and Randot preschool stereo test ($\chi^2= 0.699, p=0.403$)
on performing chi square test. As it is was a hospital based study, it is felt that it needs to be reinforced by doing a population based study.

Colmain et al reported that the odds ratio of children from a better socioeconomic strata testable to vision screening was 1.4 times greater than preschool children from a poor socioeconomic status and geographical access. The authors reported ARF to be more common in underprivileged children. This result showed the need for public health intervention in screening and resource management. These findings were contrary to our study results. It may be due to the retrospective nature of the data and racial variation which was reported as a limitation by Colmain and colleagues. Moreover, the sample in the present study was not adequate to determine the usability of the charts in rural and urban participants.

As per the objectives, we have developed and validated the vision screening protocol for children aged 3 to 6 years which needs pilot testing.

5.5 Strengths of the study

1. Various screening tests performed on the same study participants.

2. Comprehensive eye examination including dilated fundus evaluation and cycloplegic refraction for all study subjects.

3. We have developed a validated vision screening tool for children aged 3 to 6 years.
5.6 Limitations

1. The IQ of the all participants enrolled for the study was not assessed. Some children with mild neurodeficit may have been included in the study.

2. The sample size was inadequate to conclude the usability of the visual acuity and stereo acuity charts across children residing in rural and urban areas.

5.7 Recommendations for future research

1. In India, there is no validated vision screening tool for children aged 3 to 6 years at present. The protocol has to be pilot tested for further implementation.

2. The screening protocol could be used in designing population based studies to detect visual impairment of 3 to 6 year old children in our population.