



Results of the School Children Ocular Biometry and Refractive Error Study in South India

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Abstract

Objectives: Axial length (AL) is an important contributor to refraction, and growth curves are gaining importance in the prediction of myopia. This study aimed to profile the distribution of ocular biometry parameters and to identify correlates of spherical equivalent refraction (SE) among school children in South India.

Materials and Methods: The School Children Ocular Biometry and Refractive Error study was conducted as part of a school screening program in southern India. The enrolled children underwent tests that included vision check, refraction, binocular vision assessment, and biometry measurements.

Results: The study included 1382 children whose mean (standard deviation [SD]) age was 10.18 (2.88) years (range: 5-16 years). The sample was divided into 4 groups (grades 1-2, grades 3-5, grades 6-9, and grade 10) based on significant differences in right AL ($p < 0.001$). The mean (SD) AL (range: 20.33-27.27 mm) among the four groups was 22.50 (0.64) mm, 22.88 (0.69) mm, 23.30 (0.82) mm, and 23.58 (0.87) mm, respectively. The mean SE (range: +1.86 to -6.56 D) was 0.08 (0.65 D) in class 1 and decreased with increasing grade to -0.39 (1.20 D) in grade 10. There was a significant difference in all biometry parameters between boys and girls ($p < 0.001$). Age, AL, and mean corneal curvature were the main predictors of SE.

Conclusion: This study provides a profile of ocular biometry parameters among school children in South India for comparison against profiles from other regions across the country. The study data will form a reference for future studies assessing myopia in this ethnicity.

Keywords: Myopia, ocular biometry, school children

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Received: 12.01.2021 **Accepted:** 08.10.2021

Cite this article as: Gopalakrishnan A, Hussaindeen JR, Chaudhary R, Ramakrishnan B, Arunachalam S, Balakrishnan AC, J S SD, Sahoo M, S R, M V, S S, Narayanan A. Results of the School Children Ocular Biometry and Refractive Error Study in South India. Turk J Ophthalmol 2022;52:412-420

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Turkish Journal of Ophthalmology, published by Galenos Publishing House.

Introduction

Myopia is increasing in prevalence globally and is predicted to affect half the world's population by 2050.¹ Trends in myopia prevalence vary among different ethnicities and regions of the world, with East Asians being more susceptible.^{1,2,3,4,6,7}

In India, the prevalence of myopia among school children has shown a steady increase in the past decade from 4-8% to 14-21%.^{8,9,10,11,12} Accelerated eye growth is one of the key factors in the onset and progression of myopia. Hence, it is important to study the distribution of ocular biometry parameters among children to understand and predict myopia.^{13,14} It is also important to have baseline ocular biometry data for individual ethnicity and race to understand the regional prevalence and patterns of myopia and to be able to correlate and compare with other regions and ethnicities.

There are large data sets on refraction and biometry measures available from various studies among children of various ethnicities.^{5,6,7,15,16,17,18,19,20,21,22} In India, although ocular biometry data are available for adults, they are scarce for children.^{23,24,25} This may be related to limitations in measurement techniques, as previously biometry measurements were largely obtained through ultrasound contact biometry. With the advent of non-contact biometry, it is now possible to assess ocular biometry parameters even in younger children.

Therefore, the aim of the School Children Ocular Biometry and Refractive Error study was to examine the distribution of ocular biometry parameters, identify correlates of spherical equivalent refraction, and create a database for ocular biometry measures among children aged 5 to 15 in South India.

Materials and Methods

Study Design and Location

This cross-sectional study was conducted from July 2017 to December 2018 in three private schools (one rural and two in urban locations) as part of the school vision screening camps conducted in Chennai, Tamil Nadu, India.

Consent and Ethics Approval

A written informed consent form explaining the purpose and procedures of the screening was distributed to the parents prior to the school vision screening. Consent was obtained from both the school authorities and parents. Oral assent was also obtained from the children prior to performing additional procedures apart from the regular vision screening. The study was approved by the institutional review board and ethics committee of the vision research foundation (approval number: 639-2017-P) and followed the tenets of the Declaration of Helsinki.

Inclusion and Exclusion Criteria

Children between aged 5-15 years with best corrected visual acuity of 20/30 or better were included in this study. Children with previous ocular morbidities and surgeries and children with special needs (e.g., cerebral palsy, mental retardation, and autism spectrum disorders) were excluded.

Vision Screening Process

The screening comprised three phases.

Phase 1: All the children underwent vision screening using a validated pocket vision screener with a 6/9 visual acuity cut-off, penlight examination, and basic binocular vision testing (a minimum test battery to diagnose non-strabismic binocular vision anomalies) in Phase 1 of the testing.^{26,27} Children who passed Phase 1 were sent for objective refraction and axial length measurements.

Phase 2: If the children failed Phase 1 of testing, they were sent to Phase 2 for objective refraction, subjective refraction, and spectacle prescription. For children who were referred to Phase 2 and needed refractive correction or had a change in existing spectacle prescription, binocular vision assessment was done with subjective acceptance in trial frames followed by biometry.

Phase 3: Children whose visual acuity could not be improved with refraction were referred to Phase 3 for further assessment and referral. Children with ocular morbidities such as ptosis and strabismus were referred to the tertiary eye care center for further evaluation and management. These children were not included in the present study.

The school vision screening process is shown in Figure 1.

Definitions

Refractive errors were defined as follows based on refraction measurements obtained by open field autorefractor without cycloplegia:

- Myopia: Spherical equivalent refractive error of ≤ -0.75 diopters (D) in either eye²⁸
- Hyperopia: Spherical equivalent refractive error $\geq +2.00$ D in either eye²⁹
- Astigmatism: Cylindrical correction of ≤ -0.75 D in either eye
- Emmetropia: Spherical equivalent refraction of > -0.75 D to $< +2.00$ D

Refraction Measurements

Refraction measurements were obtained by open field autorefractor (WAM 5500™, Grand Seiko) without cycloplegia. Studies have found that open field autorefractors are reliable under non-cycloplegic conditions and have greater accuracy than closed field autorefractors because of the binocular open-field system.^{30,31} Therefore, this was used as the preferred autorefractor for measuring refraction among children.

The average of five readings was taken as the final refraction measurement for each eye. A Maltese cross target was used at 6 m for distance. The open field autorefractor was calibrated once a week in accordance with the manufacturer's recommendations. Refractive error was converted to spherical equivalent for the purpose of statistical analysis.

Biometry Measurements

Ocular biometry parameters were measured using a non-contact swept source optical coherence tomography-based biometer (ARGOS™, Movu Inc.).^{32,33} Measurements were done thrice and the average of the three readings was taken for

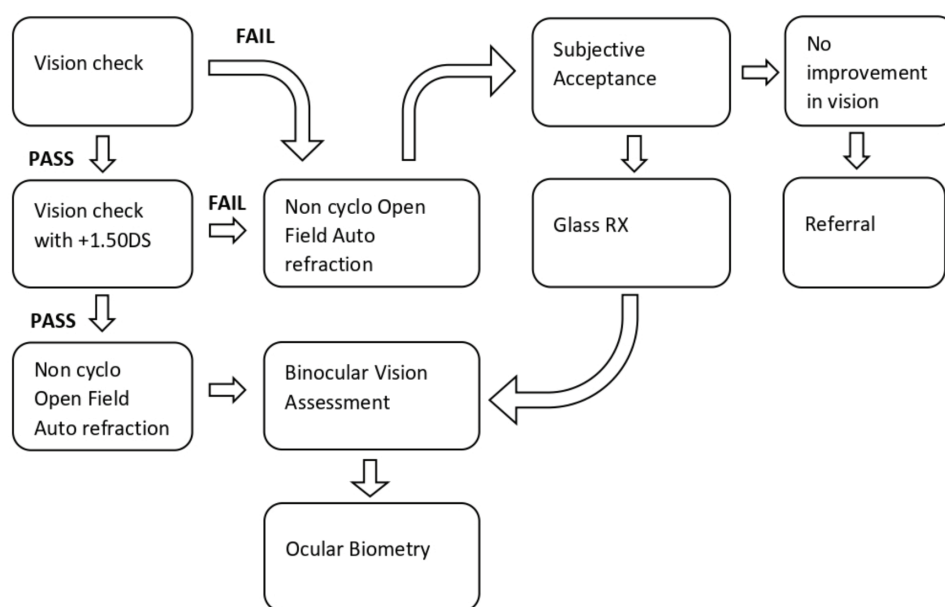


Figure 1. Flow chart of the school vision screening process

analysis. The outcome parameters of the ARGOS include axial length, anterior chamber depth, lens thickness, and corneal curvature along the flat and steep meridians.

All the tests were done at the schools by optometrists. One optometrist handled an instrument throughout the course of data collection. Calibration of the ARGOS is mandatory before beginning measurement and was performed by the optometrist as recommended by the manufacturer each day before use.

Data Entry and Data Quality Process

The data were entered by school and class into a Microsoft Excel spreadsheet. The entered data were re-checked twice by two of the investigators. The data were verified for completeness and scrutinized for errors.

Statistical Analysis and Outcome Measures

Statistical analysis was performed using SPSS Statistics for Windows, version 17.0 (SPSS Inc, Chicago, IL, USA). The mean, standard deviation, and 95% confidence intervals were obtained for all continuous measurements.

The primary outcome measures included spherical equivalent refraction and axial length measures. Other ocular biometry parameters, including anterior chamber depth, lens thickness, corneal curvature, and correlation between ocular biometry parameters and refraction, were considered as the secondary outcome measures.

There was no statistical difference between the two eyes in any refraction or biometry measures ($p > 0.05$ in paired t-test; Pearson's correlation coefficient range: 0.60-0.97, $p < 0.05$). Thus, only the right eye was taken for analysis. Spherical

equivalent refraction and ocular biometry parameters were tested for normality using the Shapiro-Wilk test. Independent t-test was used to study the differences in ocular biometry parameters between genders.

Pearson's correlation analysis was used to understand the correlation between spherical equivalent refraction and biometry parameters. Linear regression was used to identify predictors of spherical equivalent refraction.

Results

In total, there were 1382 children included in the study, out of which 700 children were boys. The mean age of the children was 10.2 (2.9) years (range: 5-15). In the sample, based on the definition of refractive status described, 877 children were emmetropic (63.5%), 390 children had astigmatism (28.2%), and 229 children (16.6%) had myopia. Of the children with myopia (≤ -0.75 D), 188 children had -0.75 D or less in both meridians whereas 41 children had -0.75 D or less in one of the meridians. Only 3 children (0.2%) had a hyperopic error greater than 2 D. Mean age, spherical equivalent, and ocular biometry parameters from grade 1 to grade 10 are summarized in Table 1.

There was a statistically significant difference across the grades for all ocular biometry measures (one-way ANOVA, $p < 0.001$). The sample was then divided into four groups based on post-hoc analysis using Bonferroni correction with a conservative p value. These four groups represent grades 1-2 (mean age: 6.20 [0.75] years), grades 3-5 (mean age: 9 [1.04] years), grades 6-9 (mean age: 12.17 [1.30] years), and grade 10 (mean age: 14.71 [0.50] years).

Distribution of Ocular Biometry Parameters

The distribution of ocular biometry measures across the four groups is depicted in Figure 2. The axial length (range: 20.33-27.27 mm) showed an increasing trend with higher grade, with

a corresponding increase in anterior chamber depth. There was progressive lens thinning with flattening of the corneal curvature across the four groups with age.

Table 1. Mean and standard deviation values of ocular biometry parameters, age, and spherical equivalent refraction in the right eyes of children from grades 1 to 10

| School grade | n | Age (years) | SE (D) | AL (mm) | ACD (mm) | LT (mm) | Flat K (D) | Steep K (D) |
|----------------|-------------|---------------------|---------------------|---------------------|--------------------|--------------------|---------------------|---------------------|
| 1 | 150 | 5.67 (0.47) | 0.11 (0.68) | 22.46 (0.65) | 3.32 (0.23) | 3.82 (0.20) | 43.71 (1.48) | 44.86 (1.50) |
| 2 | 126 | 6.84 (0.37) | 0.05 (0.61) | 22.55 (0.62) | 3.37 (0.23) | 3.75 (0.19) | 43.71 (1.33) | 44.74 (1.45) |
| 3 | 153 | 7.94 (0.24) | 0.07 (0.69) | 22.86 (0.66) | 3.45 (0.22) | 3.69 (0.20) | 43.45 (1.40) | 44.53 (1.54) |
| 4 | 149 | 9.02 (0.98) | 0.26 (0.66) | 22.90 (0.70) | 3.45 (0.24) | 3.67 (0.22) | 43.48 (1.49) | 44.40 (1.54) |
| 5 | 154 | 10.05 (0.21) | 0.21 (0.61) | 22.96 (0.76) | 3.50 (0.26) | 3.61 (0.25) | 43.66 (1.52) | 44.61 (1.59) |
| 6 | 138 | 10.70 (0.50) | 0.07 (1.05) | 23.27 (0.85) | 3.56 (0.24) | 3.60 (0.23) | 43.42 (1.41) | 44.44 (1.57) |
| 7 | 129 | 11.68 (0.54) | -0.05 (0.93) | 23.35 (0.79) | 3.53 (0.25) | 3.59 (0.21) | 43.15 (1.45) | 44.04 (1.55) |
| 8 | 128 | 12.64 (0.59) | -0.27 (1.24) | 23.39 (0.93) | 3.57 (0.28) | 3.62 (0.22) | 43.39 (1.38) | 44.41 (1.51) |
| 9 | 115 | 13.97 (0.28) | -0.32 (1.24) | 23.50 (0.89) | 3.59 (0.26) | 3.62 (0.21) | 43.52 (1.65) | 43.54 (1.60) |
| 10 | 140 | 14.71 (0.50) | -0.39 (1.20) | 23.58 (0.87) | 3.56 (0.29) | 3.60 (0.22) | 43.14 (1.50) | 44.15 (1.50) |
| Overall | 1382 | 10.19 (2.88) | -0.03 (0.93) | 23.07 (0.85) | 3.49 (0.26) | 3.66 (0.23) | 43.47 (1.47) | 44.46 (1.56) |

SE: Spherical equivalent, AL: Axial length, ACD: Anterior chamber depth, LT: Lens thickness, K: Corneal curvature

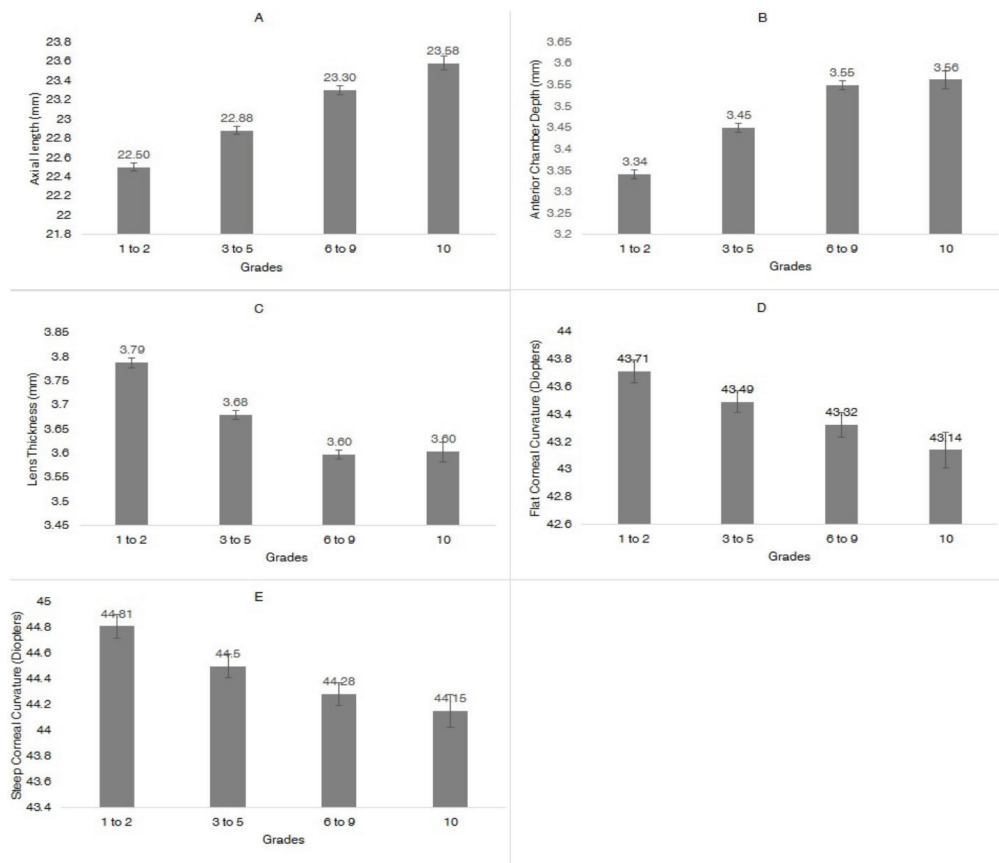


Figure 2. Ocular biometry distribution across the four groups from grades 1 to 10

Ocular Biometry and Spherical Equivalent Distribution by Sex

There were statistically significant differences in all biometry parameters between boys and girls (two sample t-test, $p < 0.001$). Boys had longer axial lengths, deeper anterior chambers, thinner lenses, and flatter corneal curvatures compared to girls. However, there was no statistically significant difference in mean spherical equivalent refraction between the two groups. The mean ocular biometry parameters for the right eyes of the two groups are presented in Table 2.

Correlation of Age and Refractive Error with Ocular Biometry Parameters

Axial length and anterior chamber depth increased with age ($r = 0.43$ and $r = 0.30$, respectively; $p < 0.001$), whereas lens thickness showed a decreasing trend with age ($r = 0.28$) (Figure 3).

Similarly, an increase in axial length and anterior chamber depth was noted with increased spherical equivalent; i.e., negative spherical equivalent refraction or myopia was associated with longer axial length and deeper anterior chamber ($r = 0.50$ and 0.22 , respectively; $p < 0.001$). A decreasing trend in lens thickness was noted with increased negative spherical equivalent refraction ($r = 0.15$; $p < 0.001$).

Multiple linear regression analysis was done to predict spherical equivalent refraction based on age and ocular biometry parameters ($R^2 = 0.32$; $F(5,1376) = 129.83$, $p < 0.001$). According to the model, axial length (β coefficient = -0.83 , $p < 0.001$), mean corneal curvature (β coefficient = -0.24 , $p < 0.001$), and age (β coefficient = 0.02 , $p = 0.003$) were significant predictors of spherical equivalent refraction.

Refractive Error Profile

The distributions of spherical equivalent refraction in the right eye across the four age groups are illustrated in Figure 4 (SE range: $+1.86$ to -6.56 D). The mean spherical equivalent showed

a leptokurtic distribution in grades 3-5, followed by a gradual skew towards negative refraction with increasing age/grade.

Discussion

The prevalence of myopia among Indian children has steadily increased in the past two decades. The present study reports a 16.6% prevalence, which is consistent with the recent Indian studies.^{11,12} This is the first study to analyze the distribution of ocular biometry components and their correlation with refractive error distribution among children in India. We observed a significant increase in axial length and anterior chamber depth and a decrease in lens thickness and corneal curvature with increasing age among Indian children, consistent with previous studies.^{5,6,7,13,14,15,16,17,18,19,20} A comparison of the findings of the present study with those of previous studies is shown in Table 3.

In recent years, growth percentile curves of axial length and refraction have gained importance for predicting the development of high myopia.^{20,34} Given the differences in the prevalence of myopia among different ethnicities, it is important to develop region-specific growth percentiles to better predict ocular development. In this sense, the present study will be a reference point to develop similar percentile curves across various regions of India. The present study data when combined with other regional data can be a valuable tool for clinicians in myopia management.

Ocular Biometry Distribution

In the present study, children in grades 1 and 2 (mean age: 6.2 years) had a mean axial length of 22.50 mm, which was comparable with Australian children in grade 1 (age range: 5.5-8.4 years).¹⁶ In a study of children in Singapore, the mean axial lengths at age 7, 8, and 9 years were 23.1, 23.4, and 23.8 mm, respectively, whereas in the present study the axial length was under 23 mm until the age of 9.¹⁵ In a study among European children, the mean axial length was 22.36 mm at the age of 6, which is slightly lower than in the present study.²⁰ Chinese

Table 2. Comparison of ocular biometry parameters and spherical equivalent refraction between genders

| Parameters | Sex | Mean ± SD | 95% CI | P value* |
|-------------|---------------|--------------|----------------|----------|
| AL (mm) | Boys (N=700) | 23.35 (0.81) | 23.29 to 23.41 | <0.0001 |
| | Girls (N=682) | 22.77 (0.80) | 22.71 to 22.84 | |
| ACD (mm) | Boys | 3.53 (0.26) | 3.51 to 3.55 | <0.001 |
| | Girls | 3.44 (0.26) | 3.42 to 3.46 | |
| LT (mm) | Boys | 3.64 (0.22) | 3.62 to 3.65 | <0.001 |
| | Girls | 3.68 (0.23) | 3.67 to 3.70 | |
| Flat K (D) | Boys | 43.09 (1.38) | 42.99 to 43.19 | <0.001 |
| | Girls | 43.86 (1.46) | 43.75 to 43.97 | |
| Steep K (D) | Boys | 44.08 (1.49) | 43.97 to 44.19 | <0.001 |
| | Girls | 44.86 (1.53) | 44.75 to 44.98 | |
| SE (D) | Boys | -0.06 (0.95) | -0.13 to 0.01 | 0.204 |
| | Girls | 0.004 (0.92) | -0.06 to 0.07 | |

*Independent t test; AL: Axial length, ACD: Anterior chamber depth, LT: Lens thickness, Flat K: Corneal curvature along the flatter meridian, Steep K: Corneal curvature along the steeper meridian, SE: Spherical equivalent

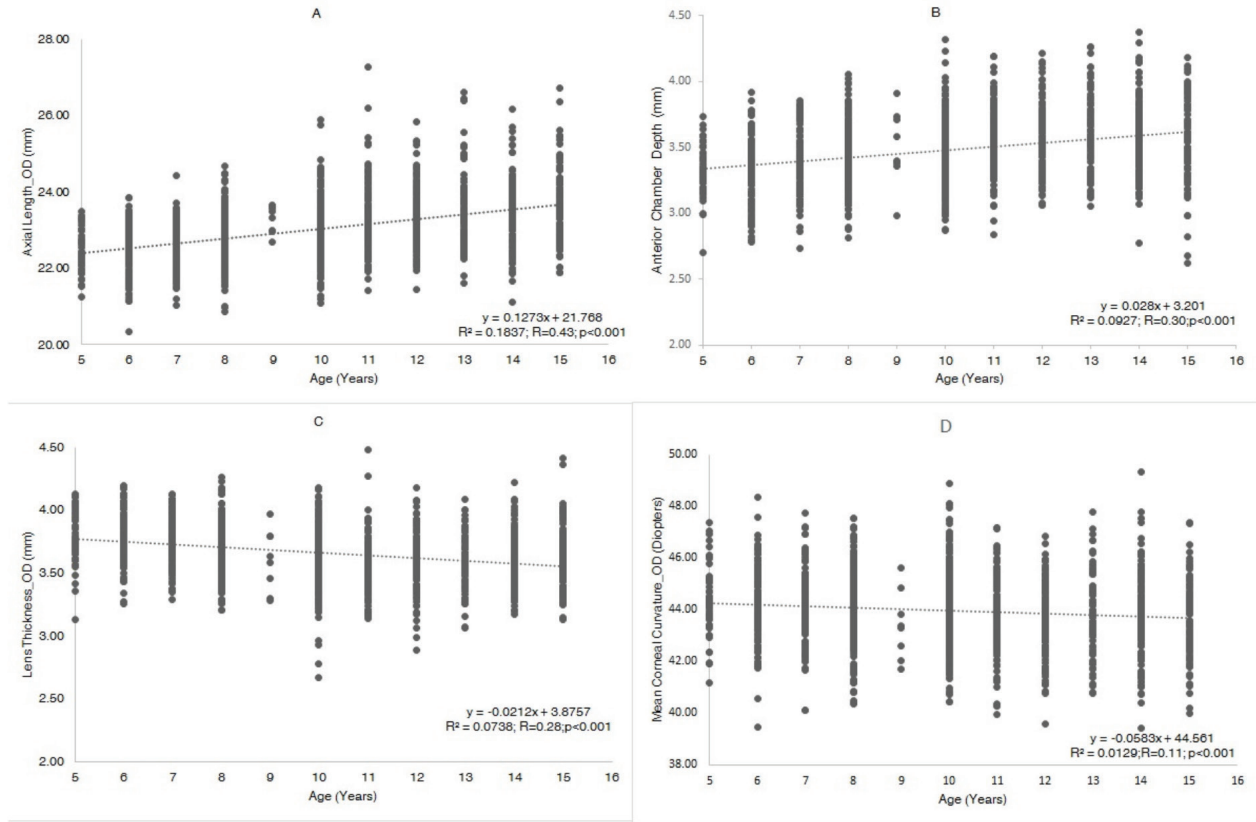


Figure 3. Correlation of ocular biometry parameters of the right eye with age. A) Age vs. axial length (in mm), B) Age vs. anterior chamber depth (in mm), C) Age vs. lens thickness (in mm), D) Age vs. mean corneal curvature (in diopters)

Table 3. Comparison of the present study findings with those in other ethnic groups

| Study, year of publication | Location | Age (years) | SE (D) | AL (mm) | ACD (mm) | LT (mm) | MEAN K (mm) |
|---------------------------------|-------------|-------------|--------------|--------------|-------------|-------------|-------------|
| Present study, 2019 | South India | 6.2 | 0.08 (0.65) | 22.50 (0.64) | 3.34 (0.23) | 3.79 (0.20) | 7.63 (0.24) |
| | | 9.0 | 0.15 (0.70) | 22.88 (0.69) | 3.45 (0.23) | 3.68 (0.20) | 7.68 (0.26) |
| | | 12.17 | -0.06 (0.99) | 23.30 (0.82) | 3.55 (0.25) | 3.60 (0.22) | 7.71 (0.26) |
| | | 14.71 | -0.39 (1.20) | 23.58 (0.87) | 3.56 (0.29) | 3.60 (0.22) | 7.74 (0.26) |
| Saw et al. ¹⁵ | Singapore | 7-9 | -0.5 (1.7) | 23.3 | 3.6 | 3.5 | 7.7 |
| Ojaimi et al. ¹⁶ | Australia | 6.7 | 1.26 (0.03) | 22.61 (0.02) | 3.34 (0.01) | - | - |
| Li et al. ¹⁷ | China | 7 | 0.95 | 22.72 | 2.89 | 3.61 | 7.89.7.70 |
| | | 14 | -2.06 | 24.39 | 3.18 | 3.42 | 7.89.7.71 |
| Hashemi et al. ¹⁸ | Iran | 6-18 | - | 23.13 | 3.01 | 3.58 | 7.77 |
| Lira et al. ¹⁹ | Brazil | 5-7 | 0.96 (0.95) | 22.5 (0.66) | 3.00 (0.26) | 3.50 (0.20) | - |
| | | 9-11 | 0.89 (1.07) | 23.0 (0.81) | 3.12 (0.28) | 3.42 (0.20) | |
| | | 13-15 | 0.57 (1.23) | 23.2 (0.78) | 3.16 (0.28) | 3.41 (0.20) | |
| Tideman et al. ²⁰ | Europe | 6 | - | 22.36 (0.75) | | | 7.77 |
| | | 9 | 0.74 (1.30) | 23.10 (0.84) | | | 7.78 |
| | | 15 | - | 23.67 (1.26) | | | |
| Harrington et al. ²¹ | Ireland | 6-7 | 1.44 (1.25) | 22.53 (0.79) | 3.40 (0.21) | | 7.81 (0.27) |
| | | 12-13 | 0.38 (1.61) | 23.50 (0.89) | 3.61 (0.25) | | 7.87 (0.26) |
| Yotsukura et al. ²² | Japan | 6-11 | -2.40 (2.23) | 24.09 (1.30) | 3.69 (0.27) | 3.41 (0.19) | |

SE: Spherical equivalent, D: Diopters, AL: Axial length, ACD: Anterior chamber depth, LT: Lens thickness, Mean K: Average corneal curvature (converted to mm to compare with other studies)

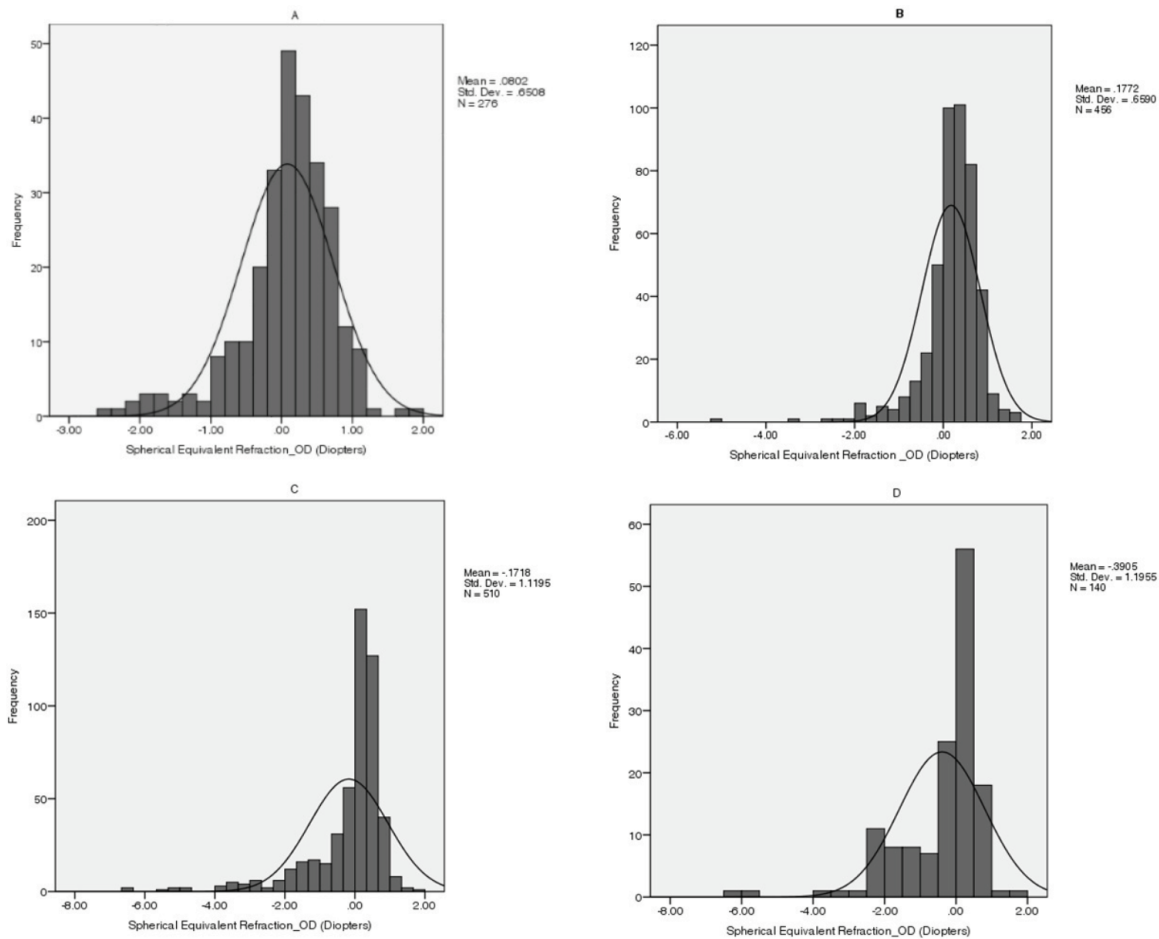


Figure 4. Distribution of spherical equivalent refraction across the four groups. A) Grades 1-2, B) Grades 3-5, C) Grades 6-9, D) Grade 10

children had a longer axial length at the age of 7 (22.72 mm) compared to Indian children in the present study (22.51 mm).¹⁷

Similarly, the mean anterior chamber depths of the children in the present study were comparable to children in Australia and Ireland.^{16,21} Chinese children had a shallower anterior chamber compared to Indian children.¹⁷ However, the data cannot be directly compared due to differences in measurement techniques, which ranged from ultrasound to partial coherence interferometry. The instrument used in the present study was comparable to and in agreement with the gold standard IOL master among children.⁵⁵

The trend of increasing axial length with age is consistent with all previous studies on ocular biometry among various ethnicities. The increasing axial length with increasing anterior chamber depth, thinning of the lens, and flattening of corneal curvature is observed in all ethnicities. In addition, the significant difference found in all biometry parameters between boys and girls is consistent across all ethnicities.^{5,7,16,17,18} Boys in the present study also had a significantly longer axial length, deeper anterior chamber depth, thinner lens, and flatter corneal curvature than girls. It is suggested that boys' taller stature

could be a reason for longer axial lengths.¹⁸ Although there was a difference in biometry parameters between genders, there was no significant difference in spherical equivalent refraction between the genders, indicating a compensatory mechanism of flattening of the corneal curvature with longer axial length among boys and vice versa among girls to keep the refraction in check.

Spherical Equivalent Refraction

The spherical equivalent refraction of children in the present study across all age groups was less myopic compared to children in Singapore and Japan.^{15,22} Six-year-old children of Australia, China, Brazil, and Ireland had a more hyperopic refraction compared to the present study population, and remained more hyperopic than Indian children at 14 years of age, except in China.^{16,17,19,21} Chinese children had a higher myopic refraction at 14 years (-2.06 D) compared to Indian children of the same age (-0.39 D).¹⁴ This difference could be attributable to differences in genetic predilection and environmental factors, such as academic and near visual demands, gadget use, and outdoor activities. Compared to the current global myopia prevalence, the prevalence of myopia is still low in India (16.6% in this study)

compared to the rates reported in other urban Asian countries.³⁶ Since the aim of our study was to understand the distribution of ocular biometry parameters and their correlation with spherical equivalent refraction, we did not separately analyze astigmatism in this cohort of children.

The present study has a few limitations. The findings of the study are cross-sectional in nature, and a longitudinal study is warranted to understand the trends and risk factors that could give rise to myopia. Another limitation is that the refractive error distribution was non-cycloplegic in nature, thus there could be bias in the estimation of myopia prevalence in this study group. The use of cycloplegic drops on school premises is restricted by the government, thus it was not possible to obtain cycloplegic refraction estimates. The open field autorefractor has good agreement with cycloplegic refraction for myopia and also has a binocular viewing system.^{7,30,31} Along with using an open field autorefractor, a higher cut-off for myopia (0.75 D or more) was used rather than 0.50 D as recommended by the International Myopia Institute (IMI).²⁸ However, the IMI also recommends using spherical equivalent refraction to identify myopia, thus the definition of myopia was based on SE refraction rather than sphere in both meridians.²⁸

Study Limitations

The strength of this study is that there are no prior normative data available for Indian children in this age group, and the results of the study give an overall pattern of ocular biometry distribution among children in India. The study results will form a baseline reference for future studies on refractive errors and their associated risk factors, especially myopia among school-aged children, which is now being explored in a longitudinal study by the same study group. Further studies are required across different regions of the country to establish age-based norms for ocular biometry.

Conclusion

In conclusion, the present study is a valuable contribution to the literature in terms of profiling and establishing a database of ocular biometry parameters among school children in India. The findings of this study could be applied in future studies aimed at understanding risk factors for myopia among Indian children.

Ethics

Ethics Committee Approval: The study was approved by the institutional review board and ethics committee of the vision research foundation (approval number: 639-2017-P) and followed the tenets of the Declaration of Helsinki.

Informed Consent: Written informed consent was obtained from the children's parents and oral assent was obtained from the children.

Peer-review: Externally peer reviewed.

Authorship Contributions

Concept: A.G., J.R.H., R.C., B.R., S.A., A.C.B., D.S.J.S., M.S., R.S., V.M., V.S., A.N., Design: A.G., J.R.H., R.C., B.R., S.A.,

A.C.B., D.S.J.S., M.S., R.S., V.M., V.S., A.N., Data Collection or Processing: A.G., J.R.H., R.C., B.R., S.A., A.C.B., D.S.J.S., M.S., R.S., V.M., V.S., A.N., Analysis or Interpretation: A.G., J.R.H., R.C., B.R., S.A., A.C.B., D.S.J.S., M.S., R.S., V.M., V.S., A.N., Literature Search: A.G., J.R.H., R.C., B.R., S.A., A.C.B., D.S.J.S., M.S., R.S., V.M., V.S., A.N., Writing: A.G., J.R.H., R.C., B.R., S.A., A.C.B., D.S.J.S., M.S., R.S., V.M., V.S., A.N.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support.

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