A calculator proposal for estimating refractive error after 3 years using the onset biometric values in primary school children: a cohort study

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Abstract

Aim To evaluate consecutive measurements of the biometric parameters, age, and refraction error in a Turkish population at primary school age. Materials and Methods A total of 197 children aged between 7-12 years were included. The data of three consecutive measurements of children, who were examined at least once a year for three years using both cycloplegic auto-refractometry and optical biometry, were used in this retrospective study. Spherical equivalent <-0.50D was considered to be myopic; >+0.75D was considered to be hypermetropic. Age, gender, body mass index, spherical equivalent, axial length, anterior chamber depth, central corneal thickness, keratometry, and lens thickness were analyzed. The onset data obtained in 2013 whereas, the final data were from 2015. Logistic and Cox regression analyses were performed ($p<0.05$). Results The mean of the onset and the final spherical equivalents were 0.19D (0.56), and 0.08D (0.80), respectively. The myopia prevalence was increased among refractive errors in observation periods (univariable analysis $p=0.029$; multivariable analysis $p=0.017$). The onset axial length (HR:4.55, 95%CI:2.87-7.24, $p<0.001$), keratometry (HR:2.04, 95%CI:1.55-2.67, $p<0.001$) and age (HR:0.73, 95%CI: 0.57-0.92, $p=0.009$) correlated myopia progression. To calculate the estimated spherical equivalent, the onset data were included in the logistic regression model. The onset data of spherical equivalent ($\beta=0.916$, $p<0.001$), axial length ($\beta=-0.451$, $p<0.001$), anterior chamber depth ($\beta=0.430$, $p=0.005$) and keratometry ($\beta=-0.172$, $p<0.001$) were found to be significantly associated with the mean SE at the final data. Conclusions To calculate the estimated spherical equivalent following three years, an equation was proposed. The estimated refractive error of children can be calculated by using the proposed equation with the associated onset optical parameters.

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ABSTRACT

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were analyzed. The onset data obtained in 2013 whereas, the final data were from 2015. Logistic and *Cox* regression analyses were performed ($p<0.05$).

Results

The mean of the onset and the final spherical equivalents were 0.19D (0.56), and 0.08D (0.80), respectively. The myopia prevalence was increased among refractive errors in observation periods (univariable analysis $p=0.029$; multivariable analysis $p=0.017$). The onset axial length (HR:4.55, 95%CI:2.87-7.24, $p<0.001$), keratometry (HR:2.04, 95%CI:1.55-2.67, $p<0.001$) and age (HR:0.73, 95%CI: 0.57-0.92, $p=0.009$) correlated myopia progression. To calculate the estimated spherical equivalent, the onset data were included in the logistic regression model. The onset data of spherical equivalent ($\beta=0.916$, $p<0.001$), axial length ($\beta=-0.451$, $p<0.001$), anterior chamber depth ($\beta=0.430$, $p=0.005$) and keratometry ($\beta=-0.172$, $p<0.001$) were found to be significantly associated with the mean SE at the final data.

Conclusions

To calculate the estimated spherical equivalent following three years, an equation was proposed. The estimated refractive error of children can be calculated by using the proposed equation with the associated onset optical parameters.

Key words: Axial length; Biometry; Biometric Calculator; Myopia; Refractive error; Spherical equivalent

What is already known about this topic?

Children at 5-15 age considered as primary school age are accepted as the onset age of myopia.

Ocular biometric parameters are known as significant variables to onset myopia and its progression.

What does this article add?

In school-age children, spherical equivalent, axial length, anterior chamber depth, and keratometry are significant parameters that can clinically help determine children to be estimated refractive errors after 3 years.

Introduction

Uncorrected refractive errors and especially myopia are the leading disorders that cause vision loss in the world.[1]Recently, it has been reported that over 157 million people suffer from vision loss related to mid or severe refractive disorders globally.[1] The estimated cost of this burden to the global economy has been reported that to be over US $ 269 billion annually.[2] Accordingly, refractive defects present a major public health problem in the world.

The most common refractive error type is hypermetropia in the postnatal term.[3] The post-natal hyperopic state regresses over time due to physiological emmetropization mechanisms associated with alters in the axial length of the eyeball, lens, and corneal refractive power. If the emmetropization mechanism fails or delays during this period due to environmental or hereditary reasons, refractive errors occur.[4-6] Although underlying risk factors and onset mechanisms are known, the underlying mechanisms of refractive errors is not fully understood yet.

Epidemiological indicators have shown that there has been a significant increase in the prevalence of myopia in the last decade. Clinically, early diagnosis of myopia initial and progression is crucial to control this refractive error. Eventually, uncorrected myopia may have a risk of complications related to detachment or neovascularization of the retina, early cataracts, and glaucoma.[7] These complications not only related to the high socio-economic treatment costs but also may arise irreversible conditions for patients, such as blindness.

Clinical studies are essential to analyze the refractive errors and ocular biometric changes of the populations in the onset age ranges of myopia.[8] Such information is also necessary due to understanding the progressive nature of refractive errors. Rozema*et al.* [9] have reported that monitoring the progression of ocular biometric parameters on school-age children up to adolescence was an ideal method for interpreting biometric changes

related to the initiation of myopia. However, the above-mentioned epidemiologic data of 7-12-year-old children are not available for Turkish population in the literature.

Wolffsohn *et al.* [10] have reported that potential myopia calculators could be beneficial tools to reflect the average potential outcome based on research data. Authors have emphasized that the data should be collected based on carefully selected cases examined for between 2 and 5 years only. To the best of our knowledge, no methods have been prescribed yet to calculate the amount of refractive error onset in school-age children. Also, it has been reported that such optic calculators could be employed as a guide to estimate the risk of developing myopia. Possibly, such optic calculators might be employed as a guide to estimate the risk of developing myopia.[11]

With this motivation, the current study aims to correlate the repetitive measurements, their onset biometric parameters that may indicate progressions, such as refractive errors. More specifically, we aimed at evaluating consecutive measurements of the biometric parameters, age, and refraction error in a Turkish population at primary school age. The null hypothesis of this cohort study assumes that there was no correlation or regression amongst the consecutive measurements.

Methods

Ethical Statement

The study protocol adhered to the tenets of the declaration of Helsinki. The study protocol was approved by the human subject office, office of non-invasive research compliance – Eskisehir Osmangazi University (Study #:45, issue date: 27.02.2018, Eskisehir, Turkey). In this study, the patient records between 2013-2015 were obtained from the database of the department of ophthalmology, Eskisehir Osmangazi University, Eskisehir, Turkey.

Inclusion criteria

Children aged 7-12 years who existed the records in the pediatric ophthalmology unit of the department of ophthalmology for routine ocular examination between January 2013 – January 2015 were consecutively selected for this study. The data of three measurements of children aged 7-12 years who were examined at least once a year for three years using both cycloplegic auto-refractometry (RM-A7000B; Topcon Medical Systems, Inc., Oakland, NJ) and optical biometry (Lenstar LS900; Haag-Streit Diagnostics AG, Koeniz, Switzerland), were included as the cohort data for this study. Only the right-eye data were included for each subject.

The main inclusion criteria of subjects were no additional ocular problems except refractive errors. Furthermore, subjects who had no refractive error at the start of the three years were also included. For this purpose, ptosis, pterygium, dry eye, corneal disease, cataracts, retinal disease, strabismus, contact lens usage history, previous ophthalmic surgery in any eye, or uncooperative children were not included in the study. The common inclusion criteria were (1) children with no systemically compromised and (2) having fully achievable records with auto-refractometry and optical biometry instruments in all observation periods.

Patients who had an anamnesis as previous ocular surgery, ocular trauma, wearing hard contact lenses were not included in the study. Besides, patients with corneal scarring or edema on biomicroscopic examination were also excluded from the study.

Ocular examination

All examinations were performed by ophthalmologists with 2-4 years of clinical experience using both instruments registered in the unit per the manufacturers' instructions. Spherical equivalents were calculated by adding the sum of the sphere power with half of the cylinder power obtained by the Topcon RM-A7000B instrument. The spherical equivalents were as follows: Emmetropia was between -0.50 D to + 0.50 D; myopia was $<$ - 0.50 D; Hyperopia was $>$ + 0.75 D. Axial length, anterior chamber depth, central corneal thickness, keratometry, and lens thickness were measured by Lenstar LS 900 instrument. K_{mean} shows the arithmetic mean of K1 and K2 values.

Baseline parameters of age, gender, height, body mass index (BMI), spherical equivalents (SE), axial length (AL), anterior chamber depth (ACD), central corneal thickness (CCT), keratometry (K_{mean}), and lens thickness (LT) were analyzed and were compared both annually including the final data. The baseline data belonged from 2013-year and the final data belonged from 2015-year. In this study, the "onset datum" was defined as the corresponding parameter when children came first to time to the hospital. Accordingly, the onset age was defined as the age when children came first to time to the hospital.

Statistical analysis

Statistical analyses were conducted utilizing statistical package software (IBM SPSS Statistics for Windows, v21.0. IBM Corp., Armonk, NY). The normality of data was examined using the Shapiro-Wilk normality test. In normally distributed data, independent t-test and one-way ANOVA tests were performed for comparisons. In non-normally distributed data, Mann-Whitney U and Kruskal-Wallis tests were performed for comparisons. Logistic regression and Cox regression analyses were performed to identify the association of risk factors. Statistical significance was assumed at $p< 0.05$.

Results

A total of 671 records of school-age children were scanned. Amongst them, 474 subjects were excluded from the study due to not having consecutive follow-up visits or not having the inclusion criteria. One hundred and ninety-seven eyes were included in the study according to the inclusion criteria. Out of the subjects, 48.7% (n = 96) were females and 51.3% (n = 101) were males. At the onset age, the cohort aged 9.58 ± 1.56 years. Amongst the prevalence of onset refractive errors of emmetropia, hypermetropia, and myopia were 74.1% (n=146), 14.2% (n=28), and 11.6% (n=23), respectively.

Mean and standard deviations of onset and final biometric measurements by age are given in **Table 1** . There were significant differences between onset age and biometric parameters. Accordingly, the increased onset age was caused to significant increase ACD (p = 0.002) and CCT (p = 0.044) whilst it was caused to significant decrease in LT (p = 0.011). The AL progression by onset age was not significant (p = 0.092). In comparisons of the biometric measurements by consecutive follow-up visits, there were significant differences in AL (p = 0.045), ACD (p <0.001) and LT (p = 0.026). In younger onset age, the progression rate of AL and ACD were higher than older onset age whereas, the regression rate LT was lower. In final visits, these significant differences among biometric measurements and final age were lost (p>0.05).

Progression of myopia

Mean and standard deviations of the onset and final biometric measurements by refractive error type are given in **Table 2** . The myopia prevalence was increased among refractive errors in observation periods (In the univariable analysis p = 0.029; in the multivariable analysis p= 0.017). The mean of the onset and the final SE were 0.19D (0.56), and 0.08D (0.80), respectively.

In the comparison of the onset biometric measurements between myopic and non-myopic children, AL was longer (p<0.001), ACD was deeper (p=0.001), LT was thinner (p=0.021) in myopic subjects. In myopic patients, the mean SE decreased by 0.69 D (0.41) in 3 years (p<0.001), while the mean AL increased by 0.49 mm (0.29) (p<0.001). In non-myopic patients, the mean SE increased by 0.04 D (0.30), and the mean AL 0.25 mm (0.33) in 3 years (p<0.001).

Factors associating the final SE of 41 children with myopia progression were evaluated by Cox regression analysis including the onset biometric parameters are given in **Table 3** . SE was significantly correlated by age (HR:0.73, 95% CI: 0.57-0.92, β = -0.32, p = 0.009), AL (HR: 4.55, 95% CI:2.87-7.24, β = 1.52, p < 0.001), and K_{mean} (HR: 2.04, 95% CI:1.55-2.67, β = 0.71, p < 0.001). (Hazard ratio=HR)

Calculation of estimated refractive error

Factors correlating the average SE at the end of three years were evaluated by logistic regression. Logistic regression analysis of factors correlating mean SE is given in **Table 4** . For this purpose, the onset biometric and demographic (age, gender, weight, and height) data were included in the logistic regression model. The

onset data of SE (β = 0.916, p < 0.001), AL (β = -0.451, p < 0.001), ACD (β = 0.430, p = 0.005), and Kmean (β = -0.172, p < 0.001) were found to be significantly associated with the mean SE at the final data. However, demographic onset data were not significantly correlated with the mean SE at the final data (p>0.05). The coefficient of determination (R^2) of regression was set at 0.761 for these variables. To calculate the estimated SE following three years,**equation 1** was established *via* the logistic model.

$$SE_3 = [16.46 + \ (0.916\ x\ \mathrm{SE}) + \ (0.430\ x\ ACD)] - \ [(0.451\ x\ AL) + (0.172\ x\ K_{\mathrm{mean}})\ ] (1)$$

SE_3 shows the estimated spherical equivalent following three years; SE shows the onset spherical equivalent; ACD shows the onset anterior chamber depth; AL shows the onset axial length;K_{mean} shows the onset arithmetic mean of keratometry.

Lastly, reliability and validity checks of the estimation model were carried out deductively using our onset dataset created by MS Excel.

Discussion

We analyzed the refractive errors and ocular biometric changes over time in a Turkish population at the onset age ranges of myopia over time. Regarding onset ages of cohort, there were significant differences between onset biometric parameters and age. Accordingly, the increased onset age was caused to significant increase ACD (p = 0.002) and CCT (p = 0.044) whilst it was caused to significant decrease in LT (p = 0.011). Regarding consecutive follow-ups, there were significant differences in AL (p = 0.045), ACD (p <0.001) and LT (p = 0.026). In younger onset age, the progression rate of AL and ACD were higher than older onset age whereas, the regression rate LT was lower. Interestingly, these significant differences among biometric measurements and final age were lost at final visits (p>0.05). It was noted that only myopia prevalence was increased in observation time periods. Regarding the Cox regression results, myopic SE was significantly correlated by age (HR: 0.73, 95% CI: 0.57-0.92, β = -0.32, p = 0.009), AL (HR: 4.55, 95% CI:2.87-7.24, β= 1.52, p<0.001), and K_{mean} (HR: 2.04, 95% CI:1.55-2.67, β = 0.71, p < 0.001). In the cohort study, factors correlating the average SE at the end of three years were evaluated by logistic regression. The onset data of SE (β=0.916, p<0.001), AL (β = -0.451, p < 0.001), ACD (β = 0.430, p = 0.005), and Kmean (β = -0.172, p<0.001) were found to be significantly associated with the mean SE at the final data and therefore, the null hypothesis was rejected.

As an output of the statistical analyses of this study, an equation was proposed using the logistic regression model for calculating the estimated SE following three years. The proposed equation or calculator uses the onset SE, ACD, AL, and K_{mean} parameters as input to calculate estimated SE following three years. Regarding the proposed equation, the output is positively (increasingly) impacted by the onset SE and ACD, while it is negatively (decreasingly) impacted by the onset AL and K_{mean}.

Physiologically, biometric parameters such as AL, ACD, LT, and corneal power could affect the steadily refractive condition of the eye.[12] Correspondingly, the onset of myopia or its progression could be seen during the enlargement of AL which is not able to be tolerated naturally.[4-6] More specifically, 5-15 aged children are considered as the onset age of myopia.[13,14] It has been reported that observing the changeover of optic biometric values on school-age children up to adolescence is an ideal method for interpreting the initiation of myopia.[9] Besides, it has been reported that the increasing onset age of young patients could be one of the significant variables correlating clinical outcomes in a previous report.[13] Hence, the proposed equation in this study should be considered as specific for the children between the ages of 7-12. When it is employed to younger ages or older ages than the cohort, the progression cannot estimate via the proposed calculator due to unique developmental mechanisms.[15,16]

In a previous report, it has been reported that potential myopia calculators could be beneficial tools to reflect the average potential outcome.[10] In addition, it has been reported that such tool built-on the data should be collected from cases examined for between 2 and 5 years.[10] In agreement with the previous report, the underlying data of the proposed calculator were collected from cases examined for 3 years. For the first time, the logistic regression was employed to propose an SE calculator in 7-12 aged children. Regarding

the proposed calculator, associated biometric variables were identified as the onset values of SE, ACD, AL, and K_{mean}. The input parameters consisted of the department database records collected from registered instruments (Topcon RM-A7000B and Lenstar LS900). Hence, data variability might be possible when the proposed calculator is validated with different optical biometry instruments due to the incompatibility phenomenon. The rationale of this phenomenon, the low in agreement status in interchangeably used biometry instruments has been also reported in a previous study.[17]

The environmental factors regarding the onset of myopia in children are the outcomes of close-up physical activities.[18,19]However, this retrospective study cannot standardize individual environmental factors. The retrospective design of this study was considered a limitation of the study. As the nature of a retrospective study, selection bias could occur unintentionally among the patients. The present study described the calculation of estimated refractive error after 3 years using baseline biometric values in primary school children. Only patients with consecutive measurements for three years were included. Consequently, we found that the 3-year estimation of the refractive error correlated regularly with initial parameters in 7-12 aged children. Regarding the proposed logistic model, it could be used for patients with developing or progressing myopia as scheduling follow-ups and treatment planning purposes. Also, in patients with an estimation of fewer refractive error, the follow-ups could be made less often those. With this motivation, further prospective studies are needed to validate the proposed logistic regression equation in follow-up patients.

In this cohort study, data from Eskisehir-city and surroundings were analyzed therefore, the outcomes might not reflect the general Turkish population or other nations. However, the primary purpose of this study was not to conduct a demographic study.

It has been reported normative values for the axial length can be used to monitor eye growth in European children at both 6 and 9 years of age (N = 6934) in a previous study.[20] Similarly, Sanz Diez et al.[21] have reported a clinical model for the prediction of myopia development based on the creation of percentile curves of axial length in school-aged children from Wuhan in central China (N=12,554). Very recently, Truckenbrod et al.[22]have reported correlation curves for axial length by spherical equivalent, age, or gender in German children between 2-18 years of age (N=1965). In addition, the authors have concluded that the percentile curves of axial length can be used as a predictive measure for the likelihood of developing as well as the progression of myopia.[22] In agreement with the previous reports, the axial length was one of the biometric variables in our generated model in the present study. Sanz Diez *et al* .[21] have used the successive measurements of 226 children to verify the predictive power of the axial length growth percentile curves. In agreement with the previous report, data validation was performed on the dataset of included children (N=197, 100%) in this study. The equation or the calculation model was firstly generated in this study. Though less sample size was used relatively from the previous reports, the model was validated with our data set.

Within the limitation of this cohort study, we can conclude as follows:

- The proposed equation with this study can provide a foresight about refractive errors three years after in school-age children aged 7-12 years based on identified optical biometric measurements. Knowing about the level of refractive errors might act as guidance to assist for this process management and creating a prevention strategy. - This study assessed the onset of myopia and its progression correlated by optical biometric measurements in 7-12 aged children. This information and the model may as a reference for future comparative studies to control myopia progression.

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