• Clinical Research •

Development and external validation of a prediction model for suboptimal orthokeratology control in adolescents

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Abstract

● **AIM:** To develop and externally validate a risk prediction model for adolescents wearing orthokeratology (OK) lenses to predict the probability of suboptimal control effects.

● **METHODS:** A retrospective analysis of myopic children who used OK lenses consistently for at least 18mo between January 2021 and March 2023 were conducted. Various ophthalmic examinations and recorded baseline parameters were performed. A risk prediction model was developed using multifactorial logistic regression analysis, and the model's discrimination and calibration were assessed using the area under the receiver operating characteristic curve (AUC) and Brier score.

● **RESULTS:** The modeling group included 228 eyes (mean age, 10.46±1.99y; 55.7% males), with 120 right eyes (52.6%) and 108 left eyes (47.4%), and the validation group included 100 eyes. Anisometropia was absent in 174 eyes (76.3%) and present in 54 eyes (23.7%). The risk prediction model identified age, anisometropia, and corneal diameter as independent predictors for the control effect of OK lenses. The model showed good discrimination [AUC 0.781, 95% confidence interval (CI) 0.721–0.841] and acceptable calibration in derivation (Brier score 0.186) in the validation group.

● **CONCLUSION:** The study constructs a risk prediction model to forecast the likelihood that myopic adolescents will not achieve the ideal control effect after wearing OK lenses, offering proactive and effective guidance for frontline clinical practitioners in devising diagnostic and therapeutic strategies.

● **KEYWORDS:** myopia; orthokeratology; risk prediction model; adolescents; axial length

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INTRODUCTION

In recent years, the global prevalence of myopia has increased significantly compared to the past, with the myopia prevalence rate among children and adolescents in East Asia (60%–73%) being much higher than in North America (42%), Europe (40%), South America, and Africa (both<10%), and other economically less developed regions[1]. It is anticipated that the global incidence of myopia will exceed 740 million cases by 2050[2], and according to four national surveys on students' physical fitness and health conducted in 2005, 2010, 2014, and 2019, the myopia rate among Han students aged 7–18 has been rising year by year[3]. High myopia can cause cataracts, glaucoma, staphyloma, retinal detachment, macular degeneration, and other complications that threaten vision[4-6], severely affecting the quality of life of patients and posing a huge challenge to global medical public health. For adolescent myopia, we should discover early, intervene early, and treat early, which will help to delay further decline in vision, reduce the incidence rate of high myopia, and significantly improve the quality of life of patients. We developed and externally validated a simple clinical model to predict which adolescents wearing orthokeratology (OK) lenses are unlikely to achieve adequate myopia control.

According to the latest expert consensus on myopia prevention and control[7], for low to moderate myopia, there are two

methods of myopia control: pharmacological and optical. Among them, OK lenses are a specially designed type of corneal contact lens, the unique reverse-geometry design of OK lenses induces peripheral defocus, thereby exerting control over axial elongation and myopia progression[8-9]. A large number of clinical studies have found[10-12] that the effective control of myopia by OK lenses can reach 50%–80%, and it is currently recognized as one of the most effective ways to reduce the increase in axial length (AL) and slow down the progression of myopia. However, the control effect of OK lenses on the progression of myopia is also affected by many factors. Wang *et al*[13] conducted a study and analysis on 249 adolescent right eyes using OK lenses and found that the increase in AL was related to the wearing time of OK lenses, baseline equivalent sphere degree, and follow-up time. Chen *et al*[14] analyzed 137 myopic children's right eyes and found that the child's age, equivalent sphere degree, pupil area, and decentration distance after stable wearing have a greater impact on the control effect of myopic eyes after wearing OK lenses. The influencing factors of OK lenses on the progression of myopia are of great significance for personalized and precise myopia prevention and control. This study plans to use multifactorial logistic regression analysis using an 18-month axial elongation ≥0.3 mm as the outcome to select variables to draw a nomogram and construct a risk prediction model to predict the probability of adolescents with myopia not achieving the ideal control effect after wearing OK lenses, providing positive and effective guidance for clinical frontline workers to formulate treatment strategies.

PARTICIPANTS AND METHODS

Ethical Approval Retrospective review approved by the Ethics Committee of The Second Affiliated Hospital of Chongqing Medical University (Ref: 2024IIT079). The requirement for informed consent was waived owing to the retrospective design. Research Registry UIN: researchregistry12345.

Study Participants A total of 228 eyes from 132 myopic children (using OK lenses and persisting in wearing for at least 18mo) from the Ophthalmic Optometry Center of the Second Affiliated Hospital of Chongqing Medical University from January 2021 to June 2022 were included in the modeling group. A total of 100 eyes from 58 myopic children (using OK lenses and persisting in wearing for at least 18mo) from the Ophthalmic Optometry Center of the Second Affiliated Hospital of Chongqing Medical University from July 2022 to March 2023 were included in the validation group. Inclusion criteria: 1) age ≥8y; 2) best-corrected visual acuity (BCVA) ≥1.0 in both eyes; 3) visual acuity ≥0.8 in a single eye during the follow-up period; 4) the lens is not worn out; 5) persist in wearing OK lenses for at least 18mo; 6) no history of eye diseases, trauma, or systemic diseases; 7) no history of using myopia control drugs, no complications such as keratitis.

Research Methods All patients completed regular fitting and persisted in wearing for at least 18mo. The following related examinations were completed and relevant information was recorded before wearing the lenses: 1) uncorrected visual acuity (UCVA) and right (*oculus dextrus*; OD) or left eye (*oculus sinister*; OS); 2) intraocular pressure (IOP): measured using a non-contact tonometer, the effective value obtained after 3 measurements was taken as the average; 3) AL: measured using an optical biometer IOL Master 500 (Carl Zeiss Meditec, Jena, Germany); 4) slit-lamp examination: detailed anterior and posterior segment examination by an ophthalmologist using a slit-lamp biomicroscope; 5) small pupil and dilated refraction: if the difference in sphere power between the two eyes is ≥1.50 D or the difference in cylinder power is ≥1.00 D, it is recorded as existing anisometropia; 6) pentacam anterior segment analysis (Pentacam HR; Oculus of Germany) examination: measurements obtained using Pentacam HR for corneal diameter, flat axis corneal curvature (flat keratometry; Kf), steep axis corneal curvature (steep keratometry; Ks), mean corneal curvature (mean keratometry; Km), corneal eccentricity (e-value), corneal thickness (CT), anterior chamber depth (ACD), pupil size (PS) were recorded. Both eyes were measured to obtain at least 2 qualified images; 7) corneal endothelial microscopy examination (TOPCON CORPORATION SP-3000P, Topcon corporation, Tokyo, Japan): recording of endothelial cell count (corneal endothelium cell density).

After completing the fitting and wearing of the lenses, routine examinations of UCVA and anterior segment slit-lamp examination were conducted 1d, 7d, 1mo, and then every 2 or 3mo. After wearing the lenses for at least 18mo, the AL was measured and recorded. Previous studies have reported that OK-lens wearers exhibited a mean axial elongation of 0.39±0.27 mm after 24mo, and each 1 mm increase in AL corresponds to roughly -3.00 D of spherical equivalent refractive error[15], so an increase in AL ≥0.3 mm at 18mo was recorded as excessive growth (suboptimal control effect).

Predictors associated with axial elongation on univariable analysis (P<0.10) entered multivariable logistic regression. We assessed discrimination [area under the aurve (AUC)] and calibration (calibration plot, Brier score) and performed external validation in a temporally separate cohort.

Statistical Analysis The data obtained were processed and analyzed using IBM SPSS Statistics 27.0 and R language (R4.2.3) software. First, we used Spearman's correlation analysis for various baseline parameters with the change in AL after 18mo of lens wear and excessive AL growth (increase ≥0.3 mm) after 18mo of lens wear. Candidate variables

(P<0.10) entered multivariable models. To reduce overfitting, we recommend bootstrap validation and, if needed, penalized regression.

The training group was used to construct the model, and the receiver operating characteristic curve (ROC) was plotted using R language to calculate the AUC of the model in the training and validation groups. An AUC>0.7 indicates that the model has good discrimination. The calibration of the model was evaluated by plotting a calibration curve and Brier score (ranging from 0 to 0.25), with a score closer to 0 indicating higher calibration of the model. A nomogram was plotted using variables selected by multifactorial logistic regression to predict the probability of excessive AL growth. The value of each variable corresponds to the corresponding score on the scale above, and the total score is the sum of the scores for each variable. The total score corresponds to the risk of excessive AL growth below, with a higher total score indicating a higher risk of excessive AL growth after wearing OK lenses.

RESULTS

Basic Information Before Lens Wear in the Modeling Group As a retrospective study, all included cases had complete relevant data. A total of 228 eyes were included in the modeling group, with 120 right eyes (52.6%) and 108 left eyes (47.4%). Anisometropia was absent in 174 eyes (76.3%) and present in 54 eyes (23.7%). The baseline characteristics of the remaining patients' eyes are shown in Table 1.

Table 1 Initial basic information of the modeling group

Parameters	Sample (%), mean±SD
OD	120 (52.6)
OS	108 (47.4)
Anisometropia	
No	174 (76.3)
Yes	54 (23.7)
Age (y)	10.46±1.99
Sex	
Male	127 (55.7)
Female	101 (44.3)
UCVA	0.36±0.18
IOP (mm Hg)	15.44±2.53
DS (D)	-2.27±1.14
DC (D)	-0.54±0.69
SE (D)	-2.54±1.26
Baseline AL (mm)	24.63±0.87
CD (mm)	11.89±0.39
Kf (D)	42.33±1.21
Ks (D)	43.63±1.39
Km (D)	42.97±1.26
Eccentricity	0.57±0.11
CECD (cells/mm²)	3161.09±264.04
CT (μm)	544.41±43.08
ACD (mm)	3.32±0.25
PS (mm)	3.17±0.67

OD: *Oculus dextrus*; OS: *Oculus sinister*; UCVA: Uncorrected visual acuity; IOP: Intraocular pressure; DS: Diopters sphere; DC: Diopters cylinder; SE: Spherical equivalent; AL: Axial length; CD: Corneal diameter; Kf: Flat keratometry; Ks: Steep keratometry; Km: Mean keratometry; CECD: Corneal endothelium cell density; CT: Corneal thickness; ACD: Anterior chamber depth; PS: Pupil size; SD: Standard deviation. Anisometropia: The difference in sphere power between the two eyes is ≥1.50 D or the difference in cylinder power is ≥1.0 D.

Correlation Analysis of AL Change Spearman's correlation analysis results showed that the change in AL after 18mo of lens wear was positively correlated with spherical lens power (r=0.156, P=0.018), equivalent sphere power (r=0.156, P=0.018), e-value (r=0.192, P=0.004), and corneal endothelial cell count (r=0.181, P=0.006). It was negatively correlated with anisometropia (r=-0.263, P<0.001), age (r=-0.474, P<0.001), IOP (r=-0.131, P=0.048), baseline AL (r=-0.245, P<0.001), corneal diameter (r=-0.151, P=0.023), and ACD (r=-0.198, P=0.003). There was no correlation with gender, UCVA, cylindrical lens power, corneal curvature, CT, or PS (P>0.1). Excessive AL increase (change in AL≥0.3 mm after 18mo of lens wear) was positively correlated with the e-value (r=0.215, P=0.001) and corneal endothelial cell count (r=0.191, P=0.004), and negatively correlated with anisometropia (r=-0.266, P<0.001), age (r=-0.437, P<0.01), baseline AL (r=-0.153, P=0.021), corneal diameter (r=-0.128, P=0.054), and ACD (r=-0.153, P=0.021). There was no correlation with gender, IOP, UCVA, spherical lens power, cylindrical lens power, equivalent sphere power, corneal curvature, CT, or PS (P>0.1; Figure 1).

Stepwise Linear Regression Analysis Stepwise linear regression analysis of baseline variables that were correlated with the change in AL revealed that baseline age (B=-0.055, P<0.001), anisometropia (B=-0.088, P=0.017), and corneal diameter (B=-0.118, P=0.003) were negatively correlated with AL increase after 18mo of lens wear. Spherical lens power (B=0.035, P=0.008) was positively correlated with AL increase after 18mo of lens wear (Table 2).

Binary Logistic Regression Analysis Binary logistic regression analysis of baseline variables that were correlated with excessive AL increase showed that age [odds ratio (OR)=0.612; 95% confidence interval (CI): 0.501–0.748; P<0.001], corneal diameter (OR=0.367; 95%CI: 0.137–0.985; P=0.047), and anisometropia (OR=0.410; 95%CI: 0.178–0.942; P=0.036) emerged as independent protective factors against excessive axial elongation (Table 3).

Establishment and External Validation of the Risk Prediction Model Based on the multifactorial logistic

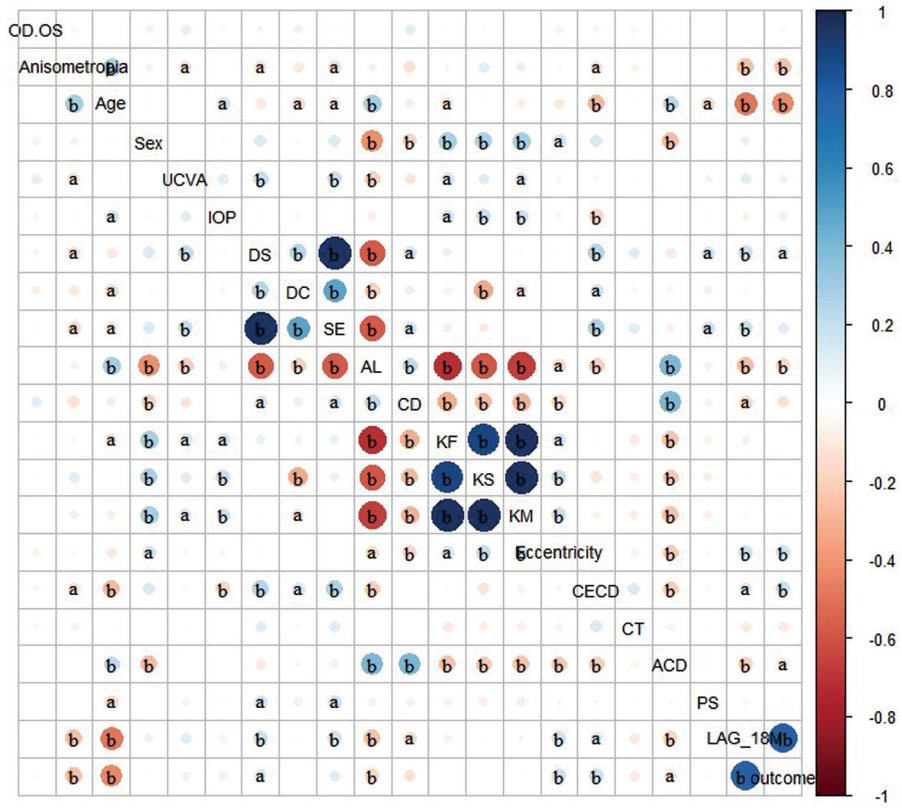


Figure 1 Correlation analysis between AL increase and the risk factors at the initial time of lens wear OD: *Oculus dexter*; OS: *Oculus sinister*; UCVA: Uncorrected visual acuity; IOP: Intraocular pressure; DS: Diopters sphere; DC: Diopters cylinder; SE: Spherical equivalent; AL: Axial length; CD: Corneal diameter; Kf: Flat keratometry; Ks: Steep keratometry; Km: Mean keratometry; CECD: Corneal epithelial cell density; CT: Corneal thickness; ACD: Anterior chamber depth; PS: Pupil size; LAG_18M: 18-month axial length growth. [a]*P*<0.05, [b]*P*<0.01.

Table 2 Results of multiple linear regression models

Parameters	*B*	SE	*β*	*t*	*P*	95%CI	VIF
Constant	2.311	0.462		5	<0.001		
Age (y)	-0.055	0.008	-0.414	-6.963	<0.001	-0.070 to -0.039	1.113
DS (D)	0.035	0.013	0.153	2.661	0.008	0.009 to 0.062	1.046
CD (mm)	-0.118	0.039	-0.176	-3.045	0.003	-0.194 to -0.042	1.049
Anisometropia	-0.088	0.037	-0.143	-2.402	0.017	-0.161 to -0.016	1.122
R^2	0.285						
F	23.437						
P	<0.001						

DS: Diopters sphere; CD: Corneal diameter; SE: Standard error; CI: Confidence interval; VIF: Variance inflation factor.

Table 3 Binary logistic regression model results

Parameters	SE	Wald	Degrees of freedom	*P*	Exp (*B*)	95%CI	VIF
Age (y)	0.102	23.046	1	<0.001	0.612	0.501–0.748	1.272
Anisometropia	0.425	4.409	1	0.036	0.410	0.178–0.942	1.130
Baseline AL (mm)	0.272	0.119	1	0.730	1.098	0.644–1.872	2.053
CD (mm)	0.504	3.961	1	0.047	0.367	0.137–0.985	1.342
Eccentricity	1.433	3.028	1	0.082	12.112	0.730–201.087	1.073
CECD (cells/mm^2)	0.001	0.515	1	0.473	1.000	0.999–1.002	1.174
ACD (mm)	0.803	0.191	1	0.662	1.421	0.294–6.856	1.455
DS (D)	0.192	2.067	1	0.150	1.318	0.905–1.919	1.787
Constant	7.480	2.153	1	0.142	58482.616		

AL: Axial length; CD: Corneal diameter; CECD: Corneal endothelium cell density; ACD: Anterior chamber depth; DS: Diopters sphere; SE: Standard error; CI: Confidence interval; VIF: Variance inflation factor.

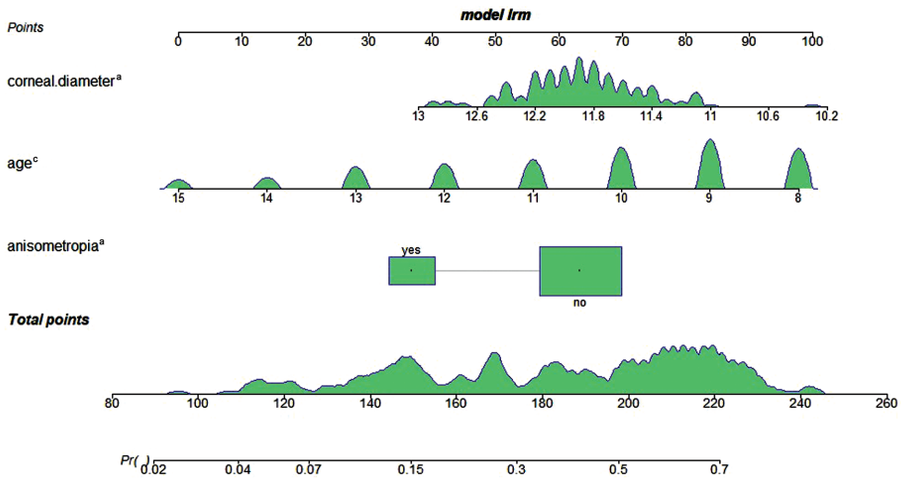


Figure 2 Nomogram for predicting the risk of excessive axial length increase after wearing orthokeratology (OK) lenses [a]*P*<0.05, [c]*P*<0.001.

regression analysis, age, anisometropia, and corneal diameter were identified as independent predictors for excessive AL increase after wearing OK lenses. A risk prediction model was established and a nomogram was plotted (Figure 2). The logistic regression model prediction formula: Logit (*P*)=14.848-0.503×age-0.955×anisometropia-0.829×corneal diameter. The final model (age, corneal diameter, anisometropia) achieved an AUC of 0.781 in derivation and 0.810 in external validation, with reasonable calibration.

In the ROC curve analysis, the AUC of the prediction model for the modeling group in this study was 0.781 (95%CI: 0.721–0.841; Figure 3), indicating good discrimination of the model. The AUC value of the ROC curve for external validation was 0.810 (95%CI: 0.723–0.897; Figure 4), indicating that the model in this study has good predictive value for the length of AL increase after wearing OK lenses. The Brier score of the modeling group was 0.186 (95%CI: 0.161–0.211), and the calibration curve showed good calibration of the model (Figures 5 and 6). Using a probability threshold of 0.531, specificity was 0.788 and sensitivity was 0.670 (Figure 7). A risk score >0.531 predicts that the patient will have an AL increase ≥0.3 mm after wearing OK lenses. For example, a 10-year-old adolescent with anisometropia and a corneal diameter of 12 mm receives an age score of 70, an anisometropia score of 37, and a corneal-diameter score of 60, summing to 167 points. This total corresponds to a predicted probability of approximately 0.20 for excessive axial elongation after 18mo of OK treatment, which is below the cutoff of 0.531. Therefore, it is predicted that this adolescent will not experience excessive axial elongation with OK lenses alone.

Clinical utility was evaluated by decision curve analysis (DCA; Figure 8). The net benefit is calculated as: Net Benefit=TP/N-FP/N×threshold/(1–threshold). Within the threshold range of 0.05–0.705, the model's net benefit consistently exceeds that of both the "treat-none" and "treat-all" strategies.

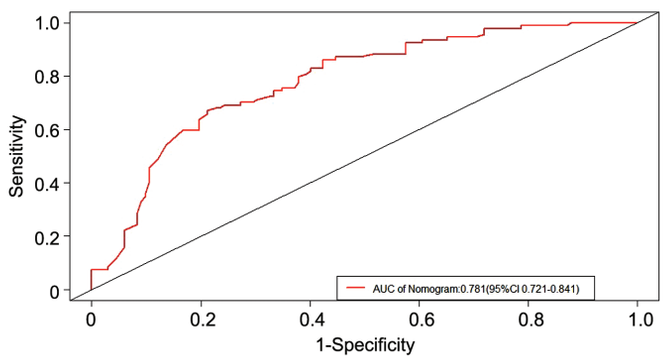


Figure 3 ROC curves for the modeling group ROC: Receiver operating characteristic; AUC: The area under the curve; CI: Confidence interval.

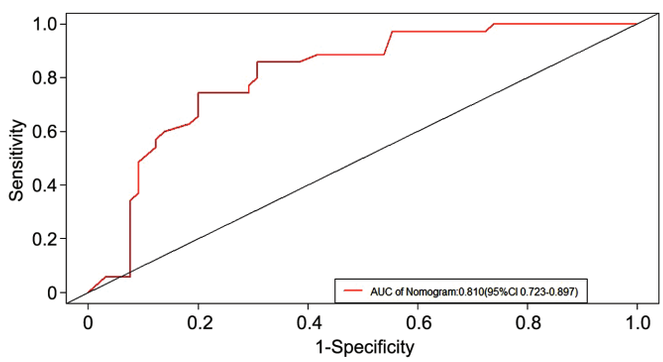


Figure 4 ROC curves for the validation group ROC: Receiver operating characteristic; AUC: The area under the curve; CI: Confidence interval.

DISCUSSION

OK lenses are widely recognized for their role in myopia progression, but there is a phenomenon of varying sensitivity to this treatment method among different patients. Therefore, exploring the factors affecting the effectiveness of OK lenses in controlling myopia has important clinical significance.

In this study, an axial elongation ≥0.30 mm over 18mo was used to define "inadequate myopia control" in children

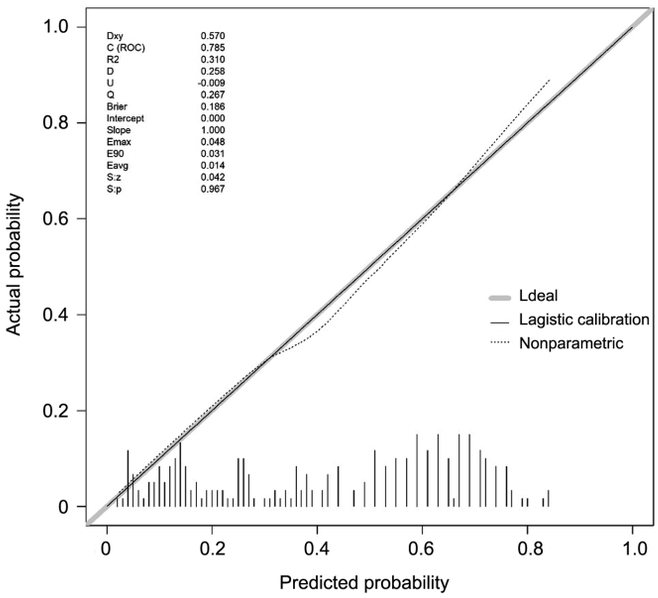


Figure 5 The calibration plot for the modeling group ROC: Receiver operating characteristic.

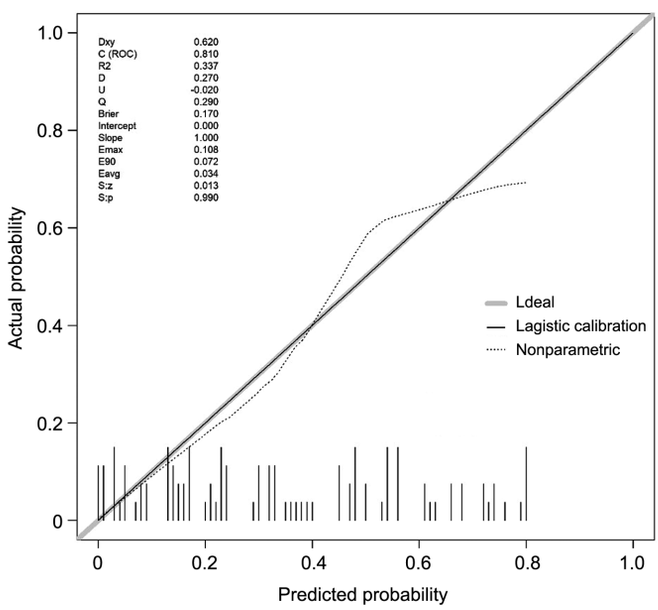


Figure 6 The calibration plot for the validation group ROC: Receiver operating characteristic.

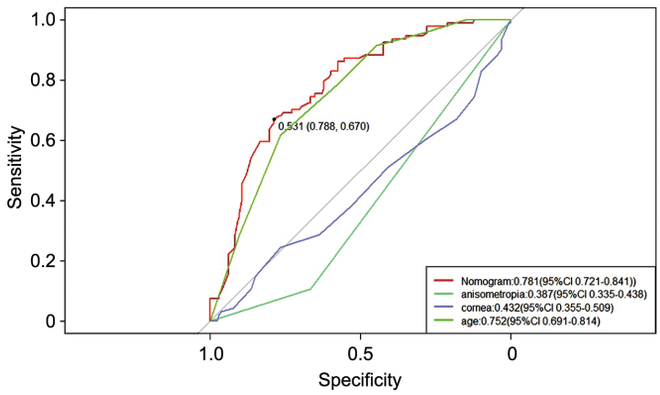


Figure 7 The black dot indicates the cutoff value for this model CI: Confidence interval.

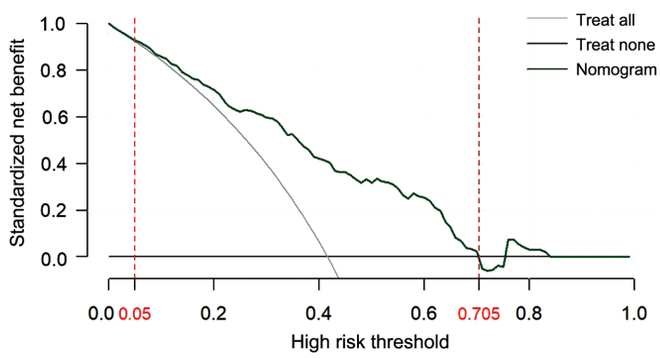


Figure 8 Decision curve analysis of predictive models.

wearing OK lenses. In 2011, Kakita *et al*[15] reported that OK-lens wearers exhibited a mean axial elongation of 0.39±0.27 mm after 24mo, whereas spectacle wearers showed 0.61±0.24 mm. Because approximately 95% of human myopia is axial, each 1 mm increase in AL corresponds to roughly -3.00 D of spherical equivalent refractive error. A 2025 living systematic review and network Meta-analysis of 104 randomized controlled trials by Lawrenson *et al*[16] corroborated this relationship. More recently, Ji *et al*[17] followed 246 children (492 eyes, aged 8–18y) and demonstrated a negative correlation between AL and spherical equivalent: every 0.81 mm increase in AL was associated with a -1.00 D change in refraction. Based on the Chinese expert consensus that an annual AL increase ≤0.20 mm indicates acceptable myopia control, we adopted an 18-month AL increase ≥0.30 mm as the binary outcome for "unsatisfactory control" in the present investigation.

This study found through bivariate correlation analysis that age, spherical lens power, anisometropia, and corneal diameter are related to the control of AL increase by OK lenses. The results of the binary logistic regression analysis showed that younger age, absence of anisometropia, and smaller corneal diameter are independent risk factors for excessive AL increase after wearing OK lenses.

Our study found that age is related to the speed of AL control by OK lenses, with older patients having better control of AL increase. In 2017, Tarutta and Verzhanskaya[18] studied 84 cases (168 eyes) of adolescents wearing OK lenses and found that the older the age, the better the control effect on myopia progression. Zhou *et al*[19] in 2017 also reached the same conclusion, which is consistent with our study results. The reason may be related to the gradual slowing down of the progression speed of myopia as age increases.

The smaller the spherical lens power, the deeper the myopia degree, and the slower the AL increase after wearing OK lenses. In 2024, Wu *et al*[20] conducted a multiple linear regression analysis on 126 myopic children wearing OK lenses and found that spherical lens power was significantly related to the effect of OK lenses on controlling AL increase. Previous studies by Wang *et al*[13] and Zheng *et al*[21] also reached the

same conclusion, consistent with our analysis results this time. Higher myopia degrees generally show longer AL, which are related to the formation of more peripheral defocusing effects. Anisometropia was associated with lower risk in multivariable analysis; we interpret this as smaller susceptibility to suboptimal control. In 2020, Lu and Jin[22] selected 108 myopic astigmatic children aged 8–16 who wore OK lenses in both eyes and followed up for 1y, finding that during the follow-up period, the level of anisometropia in both eyes and the AL of both eyes decreased, concluding that OK lenses are suitable for myopic children with anisometropia. Zhang *et al*[23] and Lyu *et al*[24] also believe that wearing OK lenses can effectively delay the AL increase and reduce the anisometropia in children and adolescents with anisometropia.

In this study, we found that corneal diameter affects the control effect of OK lenses, with a larger corneal diameter resulting in slower AL increase. Santodomingo-Rubido *et al*[25] in 2013 and Fang *et al*[26] in 2022 also reached similar conclusions. This may be related to the larger reversal area of OK lenses with larger corneal diameters. The larger the reversal area, the more peripheral defocusing may be produced on the retina, resulting in slower AL increase. However, the specific mechanism of action still needs further research in the future.

Early prediction of the rate of AL increase in patients is of great significance for controlling the progression of myopia and preventing the occurrence of high myopia. In recent years, domestic and foreign scholars have conducted various studies and drawn conclusions on the factors affecting the effectiveness of OK lenses[13-15,18-26], but few scholars have studied the prediction model for AL increase after wearing OK lenses. Compared with previous prediction model studies, this study has the advantages of a large sample size, multiple collected variables, and is convenient for use and promotion in clinical work. Moreover, the model has undergone external validation, making it more persuasive in clinical use. However, the study still has limitations. First, this study is a retrospective analysis, which may have retrospective bias. Second, it is well recognized that visual habits, outdoor activity, daily OK lens-wearing time, and sleep duration also modulate the myopia-controlling efficacy of OK lenses[27]. Owing to the retrospective design of the present study, we attempted to collect these variables by questionnaire and telephone follow-up; however, parental participation was poor and the data obtained were too sparse to be incorporated. Consequently, our model does not account for the potential influence of these factors on myopia control. Third, due to the large sample size required for robust model construction, we included data from both eyes in the present study. This approach, however, violates the independence assumption of conventional statistical tests, leading to underestimated standard errors and overly optimistic *P*-values, thereby inflating the risk of type I errors. Last, stepwise selection without internal validation may inflate performance and that the validation is temporal but single-center.

In future work, we will expand the sample size and incorporate additional potential confounders to improve the predictive performance and accuracy of the model. Furthermore, prospective and multicenter validation studies are warranted to enhance the robustness and generalizability of the predictive model. Nevertheless, the proposed risk-prediction model provides clinicians with an easily applicable tool to identify high-risk patients at an early stage, permitting timely modification of treatment—such as adjunctive low-dose atropine—to enhance therapeutic outcomes.

In conclusion, older age, larger corneal diameter and anisometropia lowered risk. This nomogram may help identify patients who need earlier adjuncts (*e.g.*, low-dose atropine).

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Data Availability Statement: De-identified participant data and the full statistical code will be made available upon reasonable request to the corresponding author 1y after publication.

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Conflicts of Interest: Wang LX, None; **Xiang BY,** None; **Liu SH,** None; **Zhang L,** None.

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