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Effect of the defocus ring area after orthokeratology lens wear on the progression of adolescent myopia Running title: The defocus ring area after OK lens wear and myopia control

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Abstract

Objective

Orthokeratology (OK) lenses are one of the most effective optical treatments for myopia control. Herein, this study investigated the effect of the defocus ring area after OK lens wear on the progression of myopia in adolescents.

Methods

A total of 180 myopic adolescents were randomized into control (wearing frame glasses) and OK lens groups (90 cases per group). The diopter, ocular axial length, and visual quality of participants were recorded. The Spearman's correlation, multivariate logistic regression, and ROC analyses were performed to assess effect of the defocus ring area on the progression of myopia (growth of the ocular axis and diopter) and its predictive value for the progression of myopia.

Results

The increase in the growth of ocular axial length and diopter was significantly slowed after 1 year of lens wear. Additionally, the visual quality was not affected after 1 year of OK lens wear. The defocus ring area was positively correlated with the growth of the ocular axis and the diopter after 1 year of OK lens wear. The increased defocus ring area after OK lens wear was an independent risk factor for poor myopia control. The defocus ring area could aid in predicting myopia progression in adolescents (cutoff value, 22.05) with high AUC, sensitivity, and specificity.

Conclusion

The defocus ring area after OK lens wear is an independent risk factor for myopia progression in adolescents and can assist in predicting myopia progression after 1 year of lens wear.

Introduction

Myopia, the most frequent refractive error, is a chief cause of reversible visual impairment and blindness globally [1]. The prevalence of myopia is on the rise in recent years, particularly in East Asia, where 80 – 90% of adolescents aged 18 years suffer from myopia and 10 – 20% suffer from high myopia [2, 3], suggesting the high prevalence of adolescent myopia. High myopia progresses more quickly and can also jeopardize visual health by provoking severe complications such as retinal detachment, macular degeneration, glaucoma, and cataract [4, 5]. Currently, a range of myopia management and control strategies are available, including optical interventions, pharmacological interventions, and surgical

treatment [6]. Among these interventions, Orthokeratology (OK) lenses have gained increasing recognition among clinicians and optometrists in recent years [7].

Orthokeratology (OK) lenses are rigid contact lenses with a reverse geometry on the posterior surface, which can reshape the cornea to control ocular axial growth, thus achieving the purpose of prevention and control of myopia [8]. Recently, OK has been reported as one of the most effective optical treatments for myopia control, with similar efficacy to atropine [9]. Overnight OK lens wear has been globally approved as a promising strategy for temporary reduction of myopia [10]. Several studies have demonstrated that OK lenses are effective in controlling the progression of myopia in adolescents [11, 12]. Several studies have unveiled that the pupil diameter and the area of the defocus ring formed after lens wear may affect the effect of OK lenses on ocular axial growth in individuals [13, 14]. Treatment zone decentration after lens wear changes the relative position of the defocus ring and the pupil, which affects the myopic defocus formed by effective defocused light entering the eyes in the periphery of the retina, thus affecting the effectiveness of OK lenses on myopia control [15, 16]. OK lenses can alter corneal epithelial morphology, flatten central corneal curvature, and steepen mid-peripheral corneal curvature [17], which increases myopic retinal defocus [18]. A recent study reported that the design of OK lens parameters and the degree of myopia may affect the defocus ring area after lens wear [19]. Therefore, adjusting the parameters of OK lenses according to the defocus ring area after lens wear and the biomechanical properties of the cornea is of great clinical significance to improve the prevention and control of myopia.

Current studies related to the key factor of OK lenses effective in myopia control mostly focus on the effect of the lenses on the cornea but rarely on the influence of the defocus ring area on the effectiveness of OK lenses in myopia control. Accordingly, this study analyzed the effect of the defocus ring area after OK lens wear on the progression of myopia in adolescents.

Materials and methods

Participants

A total of 241 adolescents with myopia admitted to the Beijing TongRen Hospital, between January 2020 and February 2023 were selected, from which 186 cases were screened according to the inclusion and exclusion criteria. Furthermore, there were 6 cases excluded due to refusal of participation but no study dropouts. Finally, 180 cases were included, and their guardians had signed an informed consent form before the study. These participants were randomly allocated into control (frame glasses) and OK lens (OK lenses) groups (90 cases per group) with the random number table method based on the randomization principle. The study was reviewed and approved by the Ethics Committee of Beijing TongRen Hospital, and complied with the *Declaration of Helsinki*.

Inclusion and exclusion criteria

Inclusion criteria for participants were as follows: 1) individuals without a history of ocular diseases and trauma; 2) their age was between 8 and 15 years; 3) adolescents and guardians were informed of the experimental protocol and procedures, and their guardians signed the informed consent form; 4) the degree of myopia was between − 6.00 and − 0.50D; 5) astigmatism ≤ 1.50D; 6) participants in the OK lens group and their parents voluntarily agreed to receive OK lens treatment for more than 12 months as well as 1-year follow-up, and these participants had relevant indications; 7) clinical and follow-up data were complete.

Exclusion criteria for participants were as follows: 1) individuals with a history of myopia control treatments, such as bifocal or multifocal spectacles, atropine eye drops, and soft or rigid contact lenses; 2) individuals with strabismus or amblyopia; 3) individuals with systemic conditions that potentially affect refractive development, such as rheumatoid arthritis and diabetes, or ocular conditions that possibly affect refractive error, including ptosis and cataract; 4) individuals with a history of ocular inflammation, infection, or corneal dystrophy.

Method procedures

All enrolled patients sequentially underwent detailed history inquiry, examination of uncorrected visual acuity (UCVA) with the utilization of a TOPCON computer optometer (RM-800; Topcon Optical Technology Co., Ltd., Dongguan, China) and a TOPCON Compu-Vision (CV-5000; Topcon, Tokyo, Japan), subjective refraction, cover-uncover test for esotropia (qualitative) measurement, heterophoria measurement with a comprehensive optometer combined with a Maddox rod (quantitative), measurement of accommodative lag with a fused cross-cylinder, intraocular pressure (IOP) measurement (the non-contact tonometer [TX-20P, Canon, Tokyo, Japan]), and anterior segment examination with a slit lamp microscope (SL-D701; Topcon). Subsequent to enrollment, the type of the lens wear was chosen as per the will of patients and guardians.

Spectacle fitting

For participants in the control group, glasses were conventionally fitted. After routine ophthalmologic examinations, these participants were given frame glasses for correction according to the results of the subjective refraction after mydriasis with Compound Tropicamide Eye Drops (Shenyang Xingqi Pharmaceutical Co., Ltd.; National Medical Products Administration Approval No. H20055546).

For participants in the OK lens group, OK lenses were fitted. 1) Pre-fitting examination: the medical history was consulted and recorded to understand the purpose of fitting of participants in detail. The optician truthfully and objectively informed participants and their parents about the performance, effects, and possible adverse reactions and side effects of OK lenses and carefully introduced the fitting process and precautions. The optician created a proprietary medical record for the eye and general condition of participants in detail, mainly including history of present illness, history of past illness,

family history, and allergy history, and their refractive status, visual acuity changes, and refractive correction methods and time. The optician completed all necessary ophthalmologic and optometric examinations for participants to determine the suitability of OK lenses and select the appropriate material, design, and method based on the examination data. Contraindications to OK lens wear were ruled out through detailed ophthalmologic examinations, including slit-lamp microscopy, corneal topography, measurements of ocular axis, IOP, ocular position, tear quality, corneal diameter, and pupil diameter, and fundus examinations. Special eye examinations were conducted to measure corneal thickness. For refractive examinations, standardized optometry was performed to assess the refractive status of participants. 2) Selection of try-on lenses: first, according to the design program and lens selection principles provided by each manufacturer, the try-on lenses were selected after the measured refractive degree, corneal curvature, and corneal diameter, as well as corneal topography values, were input into the computer design software or using the calculation method. The main parameters selected included the base curve of the lens, the optical zone diameter of the lens, the degree of the lens, and the total diameter of the lens. Second, the base curve of the lens was selected after flat keratometry value, steep keratometry value, and mean keratometry value of the cornea were determined, and corneal curvature measurements were obtained through corneal topography. Then, the degree of myopia to be reduced was determined and adjusted appropriately to meet the needs of individuals after the degree of myopia and astigmatism was accurately measured in one or both eyes at distance and near vision through a medical optometry procedure. If corneal astigmatism degree exceeded − 1.25D, the spherical equivalent was calculated. If myopia degree was over − 4.00D, the spherical equivalent was converted according to the vertex distance effect. Third, the optical zone diameter of the lens was selected. Generally, the optical zone diameter was determined by the manufacturer's lens design and was usually 6.0 to 6.5 mm. Fourth, the refractive power of the lens was chosen. The refractive power of the lens was mostly designed as + 0.75D or + 0.50D when the reduced degree of myopia was not more than 5.00D and mostly designed as + 0.50D or + 0.25D when the reduced degree was ≥ 5.00D but ≤ 6.00D. When high myopia exceeded 6.00D, different negative refractive power was designed for daily wear according to the additional correction on the lens of the best visual acuity. Conversion based on the vertex distance effect was also performed when the additional correction exceeded − 4.00D. Fifth, the total diameter of the lens was chosen based on the corneal diameter. The horizontal visible iris diameter (HVID) is commonly used to represent the size of the cornea in clinical practice since the boundary of the corneal limbus is relatively difficult to determine with semi-transparent corneoscleral limbus to be the demarcation line between the cornea and the sclera. The total diameter of the OK lenses is generally chosen to be 1.00 to 1.50 mm less than the HVID. 3) Evaluation of lens fitting and adjustment of parameters: usually, after 30–40 min of glass try-on, the wearers could open eyes naturally, and meanwhile, there was no obvious irritation symptoms, with relatively stable tear. Therefore, the fitting state of the lenses could be observed under the slit-lamp microscope through fluorescein staining. In the presence of good lens fit, the values of the parameters of the lenses could be determined. In the presence of poor lens fitting, the parameters of the try-on lenses were adjusted according to the manufacturer's specific requirements. 4) Additional correction to determine the degree of the lens: optometry was conducted when participants wore the try-on lenses with the determined parameters. For

optometry, only spherical power was augmented after fog vision to obtain the maximal positive degrees of the optimal visual acuity, namely the degree of optometry. The degree of the customized OK lenses was the sum of the degree of optometry and the degree of the try-on lenses, which should be generally + 0.50 to + 1.00D. 5) Lenses were customized and distributed, followed by education for participants.

Observation indicators

The ocular axial length, diopter, and visual quality of the participants were recorded before and after spectacle fitting. The ocular axial length was measured with SUOER Ophthalmic Optical Biometer (SW-9000; Suoer, Tianjin, China; BJ0443GA3A), and each eye was measured three times or more, with the average value obtained. The diopter of the participants was also independently tested three times by objective computer optometry in combination with subjective refraction, and the results of three measurements were averaged. Visual quality was assessed with the objective scatter index (OSI) and modulation transfer function (MTF) analyzed on the objective optical quality analysis system (Visiometrics, Castelldefels, Spain). OSI reflected the degree of intraocular scatter, and an OSI value of < 2 was considered normal. The limit of normal MTF was 35 – 45, and the higher value denoted the higher visual quality.

Detection of the defocus ring area

a corneal topographer was used for the measurements of the defocus ring area, and measurements for each ear were repeated at least three times. The corneal topography was printed and saved to record the mean radius of the corneal curvature. The center of the defocus ring was marked on the corneal topographer, and the instrument was utilized to automatically calculate the distance between the center of the defocus ring and the center of the pupil. The data were recorded as the decentration of the OK lenses, while the pupil region was calculated based on the pupil diameter measured by the corneal topographer. The corneal topography was exported to Adobe Photoshop software (Adobe Systems Incorporated, San Jose, CA, USA) to calculate the defocus ring area.

Follow-up and review

Participants were examined monthly for the first 3 months after overnight lens wear and regularly every 1 to 2 months thereafter. We recorded the mode of lens wear, the duration of lens wear, the presence or absence of discomforts, the stabilization of visual acuity, UCVA, corrected visual acuity, refractive error, corneal curvature, corneal topography result, slit-lamp microscopic results, tear examination results, lens fitness, and lens parameters. In addition, the lenses damage, lenses contamination, and deposits on lenses were observed. The evaluation of lens fitness at the early stage of wear was important. Particularly, in the case of poor stability and lack of certainty, lens fitness was assessed based on repeated observations with fluorescein staining under the slit-lamp microscope after 1 day, 1 week, 2 weeks, and 3 to 4 weeks of lens wear, along with corneal topographic changes, and visual improvement.

If necessary, the lens design was changed or lens polishing was performed to achieve the optimal fitting status. Ocular axial length, corneal thickness, and parameters related to visual quality and visual function were testified every 3 months. Lenses with visible scratches, deposits, or damage were stopped to wear immediately, and new lenses were fitted. Lens cases and other accessories were replaced every 3 months.

Statistical analysis

Statistical analysis and graphing were performed with SPSS 27.0 statistical software (IBM, Armonk, NY, USA) and GraphPad Prism 9.5 software (GraphPad Software Inc., San Diego, CA, USA). The Kolmogorov-Smirnov test was conducted to evaluate normal distribution. The measurement data conforming to normal distribution were presented as mean ± standard deviation, and comparisons between two groups were carried out with the independent samples *t*-test. Measurement data with skewed distribution were described as the median (minimum, maximum), and comparisons between two groups were performed with the Mann-Whitney U test. Enumeration data were displayed as the number of cases (percentage), and the chi-square test was utilized for comparisons between two groups. Spearman's linear correlation was utilized to analyze the correlations of the defocus ring area with the growth of the ocular axis and the diopter after 1 year of OK lens wear. Multivariate logistic regression was utilized to assess the effect of the defocus ring area on the progression of myopia. Receiver-operating characteristic (ROC) curves were plotted and the cut-off value and the area under the ROC curve (AUC) were obtained to determine the predictive value of the defocus ring area for the progression of myopia in participants after 1 year of OK lens wear. *P* values were obtained from two-sided tests, and differences were considered statistically significant at $P < 0.05$.

Results

Comparisons of baseline data between the two groups

This study eventually included 180 juvenile participants with myopia, who were randomized into control (wearing frame glasses) and OK lens groups (90 cases per group). There were no significant differences between the two groups regarding gender, age, body mass index (BMI), diopter, anterior chamber depth, pupil diameter, age of onset of myopia, radius of curvature before lens wear, IOP, and central corneal thickness (all $P > 0.05$) (Table 1).

Table 1
Clinical baseline characteristics in the two groups

Items	Control group (N = 90)	OK lens group (N = 90)	*P*
Gender (Male/female)	49/41	52/38	0.652
Age (years)	11 (8, 15)	11 (8, 15)	0.807
BMI (kg/m2)	16.81 ± 2.15	17.26 ± 1.72	0.125
Diopter (D)	-3.00 (-6.00, -0.50)	-3.00 (-6.00, -0.50)	0.498
Anterior chamber depth (mm)	3.13 ± 0.21	3.08 ± 0.24	0.119
Pupil diameter (mm)	5.6 (4.4, 6.8)	5.7 (4.5, 6.7)	0.225
Age of onset of myopia (years)	8 (6, 14)	8 (6, 14)	0.746
Radius of curvature before lens wear (mm)	7.86 ± 0.29	7.85 ± 0.24	0.767
IOP (mmHg)	14 (11, 20)	14 (11, 21)	0.713
Central corneal thickness (μm)	547.97 ± 25.13	551.49 ± 17.15	0.274
Eccentricity (mm)	-	0.80 ± 0.17	-
Defocus ring area (mm^2)	-	21.68 ± 1.59	-

Note: BMI, body mass index; IOP, intraocular pressure. Enumeration data were displayed as the number of cases (percentage), and the chi-square test was utilized for comparisons between two groups. The measurement data conforming to normal distribution were presented as mean ± standard deviation, and comparisons between two groups were carried out with the independent samples *t*-test. Measurement data with skewed distribution were described as the median (minimum, maximum), and comparisons between two groups were performed with the Mann-Whitney U test.

OK lens wear effectively controls the progression of myopia in participants

Changes in ocular axial length and diopter of participants before and 1 year after lens wear were compared between the control and OK lens groups. The results displayed no statistically significant differences in ocular axial length and diopter between the two groups before lens wear (all $P > 0.05$). All of the included participants showed increases in ocular axial length and diopter after 1 year of lens wear, with the increases markedly lower in the OK lens group than that in the control group ($P < 0.001$, Table 2).

Table 2
Comparison of visual acuity-related indicators between the two groups

Groups	Ocular axis length (mm)			Diopter (D)		
	Before lens wear	After 1 year of lens wear	P_a	Before lens wear	After 1 year of lens wear	P_a
Control group (N = 90)	24.91 ± 0.53	25.58 ± 0.48	< 0.001	-3.20 ± 1.36	-4.03 ± 1.30	< 0.001
OK lens group (N = 90)	25.05 ± 0.48	25.24 ± 0.45	0.008	-3.08 ± 1.38	-3.41 ± 1.33	0.099
P_b	0.062	< 0.001		0.560	0.002	

Note: The measurement data conforming to normal distribution were presented as mean ± standard deviation, and comparisons between two groups were carried out with the independent samples *t*-test. Measurement data with skewed distribution were described as the median (minimum, maximum), and comparisons between two groups were performed with the Mann-Whitney U test. P_a indicates the *P* value for the comparison of the indicators within groups before and 1 year after lens wear. P_b indicates the *P* value for the comparison of the indicators between the two groups before or 1 year after lens wear.

OK lens wear does not affect the visual quality of participants

Subsequently, the visual quality (OSI and MTF) of participants was assessed. No statistically marked differences were observed in OSI and MTF between the two groups either before or 1 year after OK lens wear (all $P > 0.05$, Fig. 1).

The defocus ring area is positively correlated with myopia progression after 1 year of OK lens wear

The study next clarified the significance of the defocus ring area of OK lenses in myopia prevention and control. The findings of the Spearman's analysis demonstrated that the defocus ring area shared a positive correlation with the growth of the ocular axis ($r = 0.756$, $P < 0.001$, Fig. 2A) and diopter ($r = 0.616$, $P < 0.001$, Fig. 2B) in participants after 1 year of OK lens wear.

The defocus ring area affects myopia progression in participants after 1 year of OK lens wear

To accurately evaluate the effect of the defocus ring area on the progression of myopia in participants after 1 year of OK lens wear, we performed the multivariate logistic regression analysis with the ocular axial change of participants 1 year after lens wear (0 = good control, 1 = bad control) as the dependent variable and baseline characteristics (gender, age, BMI, diopter, anterior chamber depth, pupil diameter, age of onset of myopia, radius of curvature before lens wear, IOP, central corneal thickness, decentration, and the defocus ring area) as independent variables. The assessment criteria for myopia control referred to previous studies [20, 21]. The results exhibited that the increased defocus ring area after OK lens wear was an independent risk factor for poor myopia control in participants, while the progression of myopia

was more effectively controlled with a smaller increase in the ocular axis in the younger patients and those with elevated decentration of the defocus ring was small (all $P < 0.05$, Table 3).

Table 3
Analysis of factors affecting myopia progression in participants after 1 year of lens wear

Factors	*P*	OR	95%CI
Age	0.008	0.427	0.228 – 0.802
Age of onset of myopia	0.071	1.990	0.942 – 4.202
Gender	0.929	1.063	0.274 – 4.131
BMI	0.897	0.975	0.668 – 1.424
Diopter	0.111	1.534	0.906 – 2.597
Anterior chamber depth	0.090	0.073	0.003 – 1.509
Pupil diameter	0.520	0.695	0.229 – 2.108
Radius of curvature before lens wear	0.781	0.638	0.027 – 15.203
IOP	0.190	0.805	0.582 – 1.114
Central corneal thickness	0.563	1.014	0.968 – 1.062
Eccentricity	0.049	0.008	0.001 – 0.980
Defocus ring area	< 0.001	3.143	1.789 – 5.522

Note: OR, odds ratio; 95%CI, 95% confidence intervals; BMI, body mass index; IOP, intraocular pressure.

The defocus ring area assists in predicting myopia progression in participants after 1 year of OK lens wear

Eventually, this study investigated the value of the defocus ring area of OK lenses in the assessment of myopia progression in adolescents. The results of the ROC curves revealed that the AUC of the defocus ring area for assisting in the prediction of myopia progression in adolescents was 0.829 (95%CI: 0.763 to 0.901), with a cutoff value of 22.05, a sensitivity of 78.12%, and a specificity of 77.59% (Fig. 3).

Discussion

The incidence of myopia in children is on the rise in East Asia [22]. OK lenses have been prescribed to temporarily decrease or eliminate refractive error, and the progression of myopia in myopic children can be notably slowed after OK lens wear [23]. Herein, this study mainly assessed the effect of the defocus ring area after OK lens wear on myopia progression in adolescents. The results unraveled that the defocus ring area after OK lens wear was an independent risk factor for myopia progression in adolescents and that adolescents with smaller defocus ring areas exhibited better myopia control and

slower ocular axial growth. In addition, further results highlighted that the defocus ring area could assist in predicting myopia progression in adolescents after 1 year of OK lens wear.

Accelerated ocular axial growth is one of the essential causes of myopia [24]. An earlier study, which included 60 adult eyes with high myopia (ocular axis length ≥ 26.00 mm), disclosed that the ocular axis of myopic eyes was elongated consistently over 4 years [25]. Therefore, at present, an important goal of myopia prevention and control is to control ocular axial growth in myopic patients, thereby reducing the risk of a series of blinding complications such as retinal detachment and myopic macular degeneration [26]. Of note, many studies have revealed that OK lens wear is effective in controlling ocular axial growth. For instance, a meta-analysis involving 14 randomized controlled trials revealed that ocular axial growth was reduced after 1 and 2 years of OK lens wear, which contributed to delaying the progression of myopia [27]. Another study demonstrated a significant corrective and preventive/control effect of 2-year OK lens wear with significantly slowed increases in the axial length (OK *vs*. Control: 0.29 ± 0.27 mm *vs*. 0.54 ± 0.27 mm) [28]. Chen et al. also observed that after 24 months, the mean axial elongation in the OK group (0.31 ± 0.27 mm) was 52% slower than that in the control group (0.64 ± 0.31 mm) [29]. Of note, similar results were observed in the present study: after 1 year of OK lens wear, increases in the ocular axis were substantially lower in the OK lens group than in the control group. In addition, an increase of diopter is vital for the development of myopia [30]. A prior study further exhibited that 1-year and 2-years OK lens wear diminished the changes in diopter of children with myopia [27]. Consistently, our study showed that 1 year of OK lens wear reduced the diopter increase of adolescents with myopia. Furthermore, MTF and OSI, which are two important optical quality parameters [31], were also detected in our study. The statistically insignificant differences in OSI and MTF between the two groups before and 1 year after OK lens wear suggested that OK lens wear did not affect patients' visual quality. Overall, 1 year of OK lens wear effectively controlled the progression of myopia in adolescents, without affecting visual quality.

OK lenses flatten the cornea *via* back optic zone diameters (BOZD), generating an optical treatment zone on the cornea, which produces a gap occupied by tears between the reverse curve of the lens and the front corneal surface. As a consequence, gradient pressure is generated, with positive pressure at the corneal center and negative pressure in the surrounding areas. Correspondingly, epithelial cells migrate from the central cornea towards the peripheral steepening zone, commonly referred to the defocus ring [14]. A prior study elucidated that ocular axial length changes in subjects wearing OK lenses with smaller BOZDs were smaller than those in subjected with larger diameters, accompanied by smaller plus power ring diameters [32]. According to these results, it can be hypothesized that a smaller defocus ring may offer better myopia control. However, there are no studies on the effect of the defocus ring area after OK lens wear on myopia progression. Accordingly, a series of experiments were conducted in the present study to further illustrate this potential effect. Spearman's analysis results elaborated that the defocus ring area was positively correlated with the growth of the ocular axis and diopter in adolescents with myopia after 1 year of OK lens wear. Subsequent multivariate logistic regression analysis showed that an elevation in the defocus ring area after OK lens wear was an independent risk factor for poor myopia control in adolescents. Finally, ROC curves revealed that the AUC of the defocus ring area for predicting

myopia progression in adolescents was 0.829 (cutoff value, 22.05; sensitivity, 78.12%; specificity, 77.59%), illustrating that the defocus ring area had a good predictive value for myopia progression in adolescents after 1 year of OK lens wear. As for this result, it is hypothesized that the defocus ring with a smaller diameter can provide better myopic control because the ring is closer to the pupil region. In addition, our study found that the effect of the defocus ring area on axial growth was also related to peripheral myopic defocus and that the smaller defocus ring area was associated with increases in effective defocus light entering the eye, myopic defocus received by the central cornea receives, and efficacy of OK lenses in controlling axial growth. Similar conclusions were yielded by Guo et al. [33]. Another possibility is that the smaller defocusing ring area results in a greater variation of the central high-order aberration. It has been reported that higher-order aberrations in the eye, especially spherical aberrations, may be a possible mechanism for slowing the elongation of the ocular axis after OK treatment [34, 35]. Hence, decreasing the optical zone diameter and the defocus ring area can lead a greater change in the central higher-order aberration, thereby slowing the growth of the ocular axis. It has also been demonstrated that the size of the intersection area between the pupil and the defocus ring can influence retinal defocus and axial growth after OK lens wear. A prior study revealed that a larger intersection area between the pupil and the defocus ring contributed to a greater amount of myopic defocus at 30–53° from the fovea and that a larger intersection area may be more effective in controlling axial growth [14]. In addition, corneal biomechanical properties may explain the variability in the defocus ring area between individuals. Lam et al. found that the corneal tangent modulus was significantly higher in subjects with good responses to OK lenses than in those with poor responses and that greater baseline corneal stiffness was associated with greater reductions in myopia [36]. Moreover, another study displayed that corneal deformation is related to intraocular pressure (IOP) and that corneal stiffness was lower and corneal deformation was larger in patients with lower IOP [37]. OK lenses can temporarily correct refractive error by deforming the anterior surface of the cornea and then reshaping the corneal morphology. We hypothesized that the inconsistency in the defocus ring area among patients with OK lens treatment may be related to the biomechanics of the cornea itself. Therefore, further studies are warranted to analyze the relationship between the defocus ring area and the biomechanics of the cornea.

Despite these findings, this study had several limitations. First of all, the participants in this study were fitted with different brands of OK lenses, and slight differences in the design of each brand might lead to different myopia control effects. Secondly, 1-year follow-up period was relatively short. Therefore, although it was confirmed that OK lenses were effective in controlling the development of myopia in adolescents, the long-term myopia control effect of OK lens wear was still unknown, and also the optimal age of OK lens wear for myopia control was not identified. In addition, this study did not analyze other influencing factors for myopia progression, including outdoor activity time and dietary intake. Longer follow-up can allow the identification of the optimal age and the duration of lens wear to reach a plateau in myopia control. As a result, multi-center studies with long-term follow-up and large sample sizes were warranted to increase reliability of our results.

Nevertheless, our results confirmed that OK lens wear effectively controlled myopia progression in adolescents, without affecting visual quality. Innovatively, our study also disclosed that the defocus ring area after OK lens wear was an independent risk factor for myopia progression in adolescents and could assist in predicting myopia progression in adolescents after 1 year of lens wear. Our findings hold certain significance for its clinical application in myopia management.

Declarations

Ethics approval and consent to participate

The study was reviewed and approved by the Ethics Committee of Beijing TongRen Hospital and complied with the *Declaration of Helsinki*.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated during and analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

JH is the guarantors of integrity of the entire study and contributed to the study design; XWL contributed to the the study concepts, definition of intellectual content; HCY contributed to the literature research, statistical analysis; JXL contributed to the clinical studies, data acquisition, data analysis; MYX contributed to the manuscript preparation, editing and review; All authors read and approved the final manuscript.

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Figures

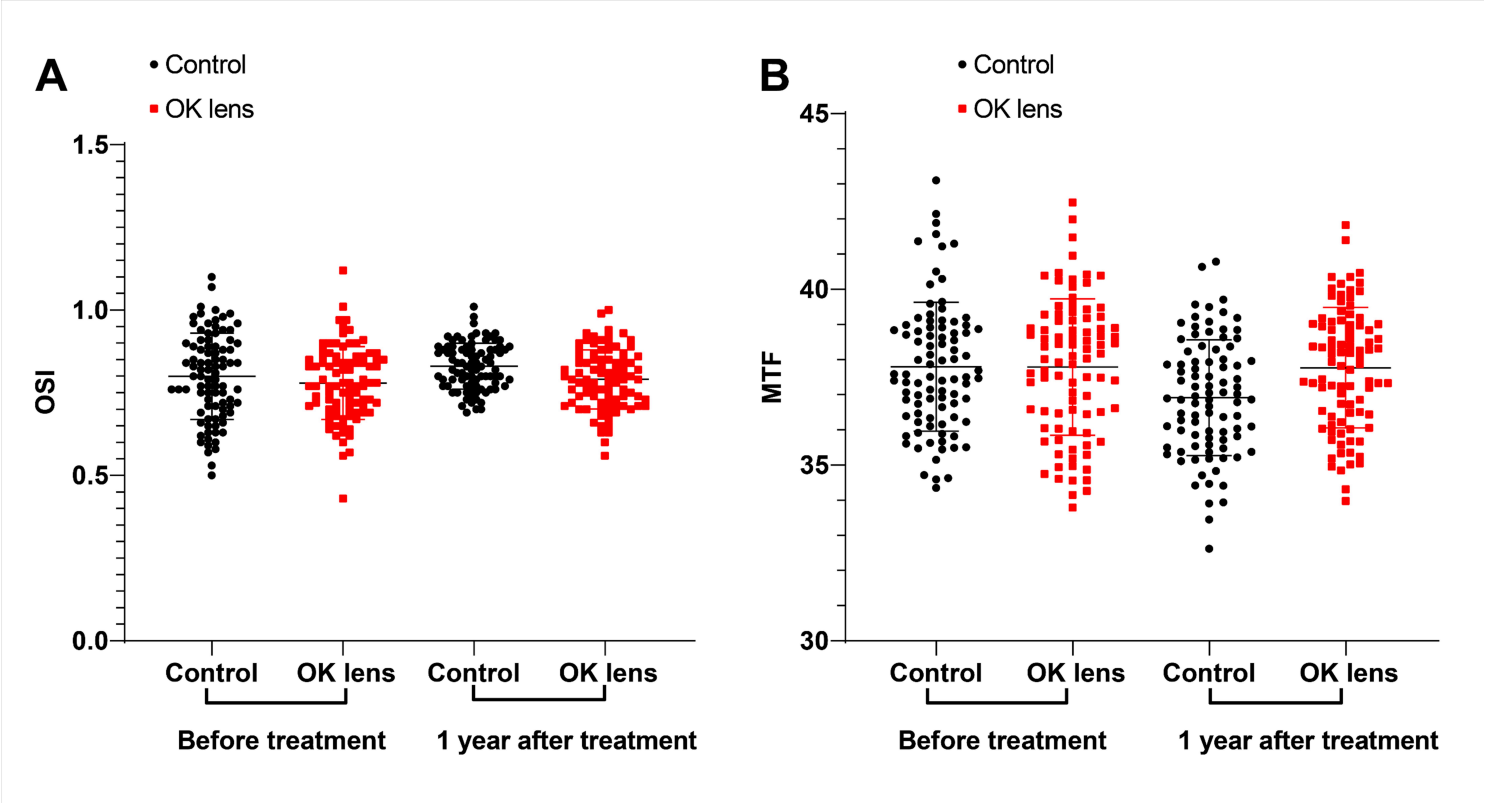

Figure 1

Comparison of visual quality of adolescents between the two groups. A, OSI; B, MTF. Data were expressed as mean ± standard deviation and compared with the two groups with the independent samples *t*-test.

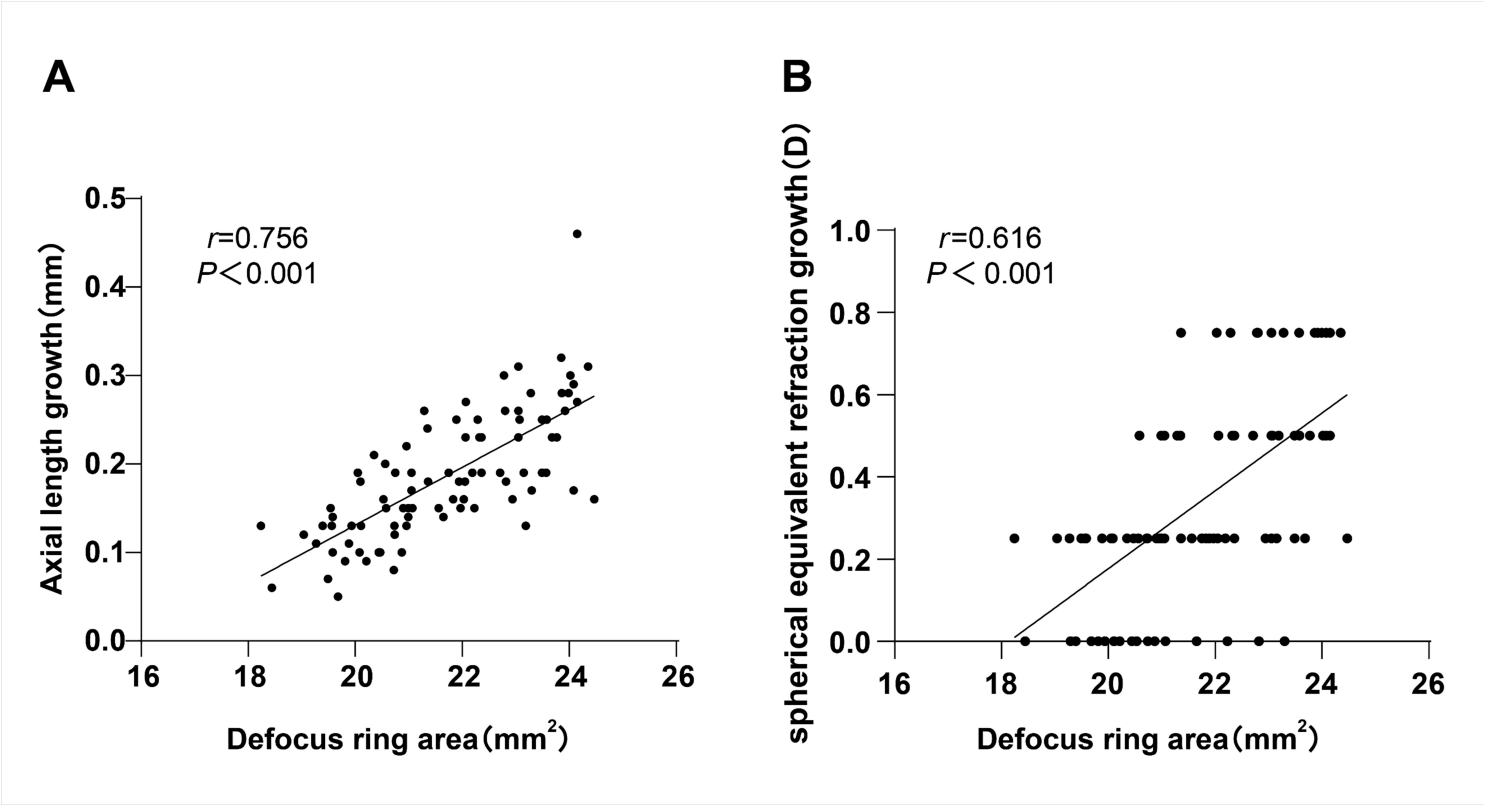

Figure 2

The defocus ring area is positively correlated with the growth of the ocular axis and diopter in participants after 1 year of OK lens wear. A-B, Spearman's analysis of the correlation between the defocus ring area and the growth of the ocular axis (A) and the diopter (B). *r* represents the correlation coefficient.

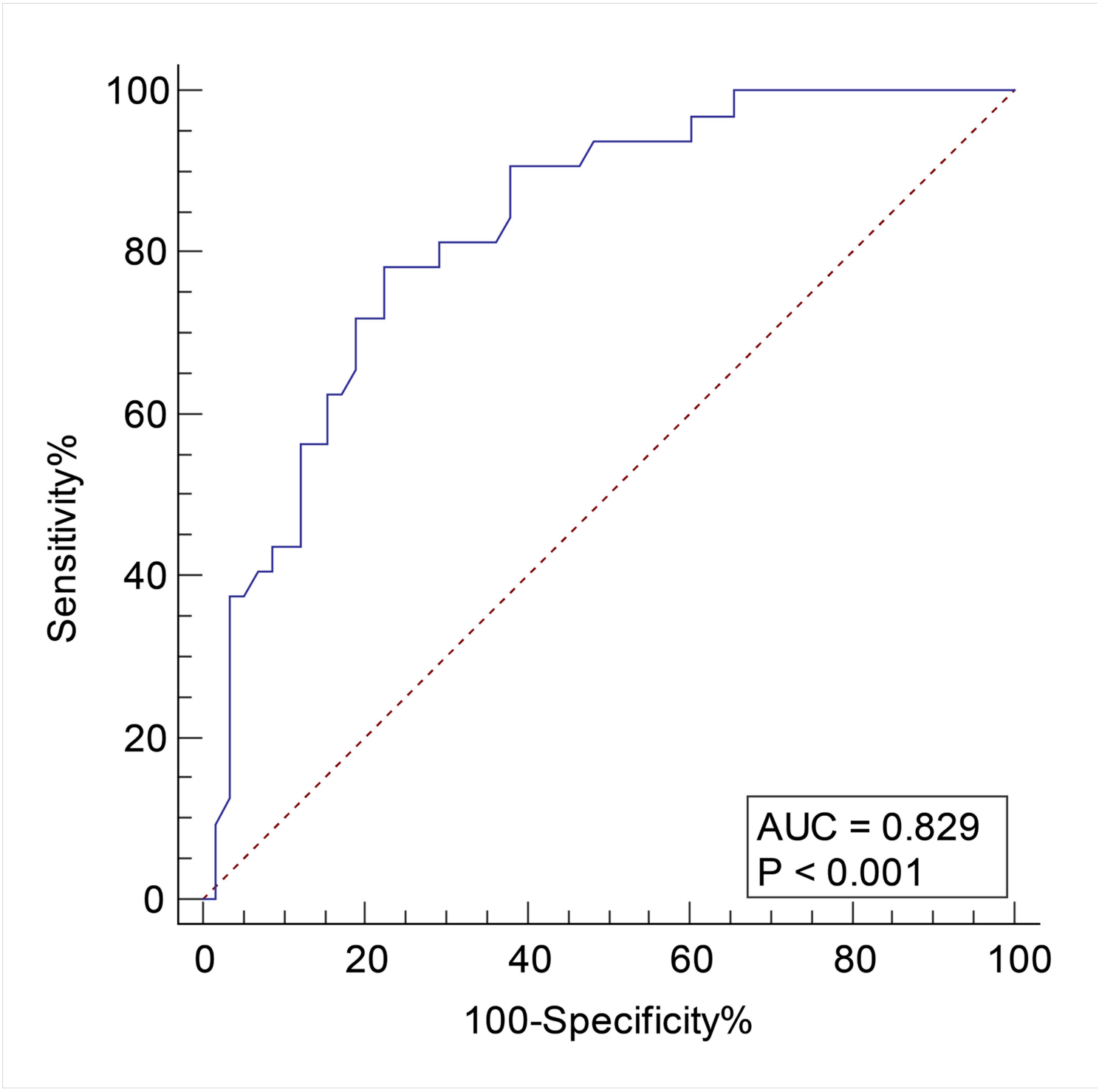

Figure 3

ROC curve analysis of the predictive value of the defocus ring area for myopia progression in adolescents.