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Effect of the plus power ring zone area on myopia control with orthokeratology lenses

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配戴角膜塑形镜后离焦环面积的大小对近视防控的影响

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摘要

目的:观察离焦环总面积(PPRZ)的大小和分布对近视进展的影响。

方法:本回顾性研究于2019至2021年在太原爱尔眼科医院招募137名8-12岁青少年。受试者因屈光不正首次配戴角膜塑形镜,并进行为期1 a的随访观察。为明确入瞳离焦环面积(PPROPZ)和离焦环总面积(PPRZ),根据PPROPZ与PPRZ比值对受试者进行分组:实验组103眼的PPROPZ与PPRZ比值≥0.2,对照组103眼的比值<0.2。受试者球镜度数介于-6.00 D至-0.75 D之间,逆规散光小于1.00 D,顺规散光小于1.50 D,角膜曲率范围为39.00 D至46.00 D。配戴角膜塑形镜(Ortho-K)时,其最佳矫正视力稳定在0.10 LogMAR(20/25)或更高水平。使用Image J软件测量PPRZ和PPROPZ参数;通过角膜地形图评估角膜相关指标,并采用光学生物测量仪检测配戴前后1 a的眼轴长度变化。

结果:当PPRZ($P<0.01$)或PPROPZ($P<0.001$)显著增加时,眼轴增长呈下降趋势。对照组的眼轴增长更快,增长量为(0.37±0.2)mm,而实验组的增长量为(0.21±0.11)mm。此外,水平可见虹膜直径(HVID)越大,眼轴增长速度越慢。相比之下,眼轴增长与角膜表面规则指数(SRI)、角膜表面非对称指数(SAI)、平坦角膜曲率值(K_f)及陡峭角膜曲率值(K_s)均无相关性。

结论:对于具有较大PPROPZ与PPRZ比值的角膜塑形镜配戴者通常眼轴增长减缓。PPRZ和PPROPZ与眼轴增长呈负相关。研究结果为通过角膜塑形镜研究近视控制机制提供了建议和方法。

关键词:角膜塑形镜;近视防控;离焦环总面积(PPRZ);入瞳离焦环面积(PPROPZ)

Abstract

• AIM: To observe the effect of the plus power ring zone (PPRZ) area and distribution on myopia progression.

• METHODS: This retrospective study enrolled 137 pre-teens aged 8-12 at Taiyuan Aier Eye Hospital between 2019 and 2021. They were fitted with Ortho-K lenses for the first time due to refractive error, with a one-year follow-up period. To indicate the peripheral plus ring zone overlapping with the pupil zone (PPROPZ) accompanying PPRZ, participants were divided based on the PPROPZ to PPRZ ratio. The experimental group had 103 eyes with a PPROPZ to PPRZ ratio of ≥0.2, and the control group had 103 eyes with a ratio of <0.2. Participants had a spherical diopter in the range of -6.00 D to -0.75 D, against-the-rule astigmatism less than 1.00 D, with-the-rule astigmatism less than 1.50 D, and corneal curvatures of 39.00 D to 46.00 D. They had a stable best corrected visual acuity of 0.10 LogMAR (20/25) or better when wearing orthokeratology (Ortho-K) lenses. PPRZ and PPROPZ were measured using ImageJ; corneal topography assessed corneal-related parameters, and an optical biometer measured the axial length of the eyes pre and post-one years of lens wear.

• RESULTS: Changes in axial length elongation were found to decrease when either the PPRZ ($P<0.01$) or PPROPZ ($P<0.001$) was increased significantly. The axial length growth was faster in the control group (0.37±0.2 mm) than in the experimental group (0.21±0.11 mm). Furthermore, we found that a larger horizontal visible iris diameter (HVID) corresponded to slower axial growth of the eye. In contrast, axial length growth showed no correlation with surface regularity index (SRI), surface asymmetry index (SAI), flat keratometry value (K_f), steep keratometry value (K_s).

• CONCLUSION: For orthokeratology, wearers with larger PPROPZ to PPRZ ratio usually experiences a reduction in axial length growth. The PPRZ and PPROPZ are negatively correlated with the axial length. Our findings provide a recommendation and methods for studying the myopia

control mechanism through Ortho-K lenses.

• KEYWORDS: orthokeratology; myopia prevention and control; plus power ring zone (PPRZ); peripheral plus ring zone overlapping with the pupil zone (PPROPZ)
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INTRODUCTION

Myopia usually begins in children at the developmental stage and is one of the most common causes of visual impairment. According to the World Health Organization's World Vision Report 2019, there are approximately 2.5 billion myopic patients in the world, and China accounts for nearly a quarter of them, with the prevalence of myopia among teenagers as high as 67% and a trend towards younger age groups[1-2]. The continuous progression of myopia can cause various pathological consequences, including posterior scleral staphyloma, macular degeneration, retinal detachment, and vitreous liquefaction[3-4]. Currently, there are many non-surgical methods to control myopia. Orthokeratology (OK) lenses are one of the most effective ways to control myopic progression. It uses a rigid corneal contact lens made of a highly oxygen-permeable, breathable material to flatten the centre of the cornea and reduce the myopia-inducing effect of hyperopic defocus in the peripheral retina, thereby reducing myopia and astigmatism and improving naked eye vision. Up to 30%-60% inhibition of axial length (AL) elongation has been reported compared to other optical interventions[5-7]. Many factors can influence the myopic control effect of OK lenses, including the amount of peripheral retinal defocus, eccentricity, optical zone design, and pupil diameter. Previous studies have shown that reducing the diameter of the basal arc zone will induce a smaller optical zone, producing more myopic defocus into the pupil and thus slowing down myopia's progression. Within a certain eccentricity range in OK lenses, the larger treatment zone decentration, the control efficiency is higher[8-9]. A larger pupil diameter is more conducive to delaying the AL elongation of myopia[10]. The greater the refractive error, the greater the defocus produced and the better the myopic control. However, not all of them form a larger plus power ring zone (PPRZ) area, so it is unknown whether the PPRZ area can affect myopic control. This study is the first to explore the effect of the change in the PPRZ area using ImageJ software on the AL elongation within 1 a. The results of this study may enhance the understanding of corneal topography after shaping and provide clues and a basis for revealing the principle and mechanism of controlling myopia development by OK.

SUBJECTS AND METHODS

Subjects All data of children who met the clinical conditions and consecutively wore OK lenses for 1 a between 2019 and 2021 were selected from the first hospital visit. The inclusion criteria included: 1) Aged from 8 to 12 years old and free from any other ocular disorder; 2) Had diopter limited to 6.00 D, with-the-rule astigmatism less than 1.50 D, against-the-rule astigmatism less than 1.00 D, and had an apical corneal refractive power between 39.00 D to 46.00 D; 3) No history of surgery, contact lenses, long-term allergy, myopic control, *etc*.; 4) Had a stable best corrected visual acuity of 0.10 LogMAR (20/25) or better. Written informed consent was obtained from all patients and their parents after the procedure. This study was approved by Taiyuan Aier Eye Hospital (No.EYETYYY-20221104-02).

Grouping Using ImageJ software to measure the PPRZ and the peripheral plus ring zone overlapping with the pupil zone (PPROPZ) area after being treated with OK lens for 3, 6, 9, and 12 mo (Figure 1). Grouping was conducted under the ratio of the PPROPZ area to the PPRZ area after 3 mo. A ratio below 0.2 was classified into the control group while above 0.2 was the experiment group. There were 103 eyes in the experiment group, with 54 males and 49 females, and 103 patients, with 52 males and 51 females in the control group. AL was performed 1 year later after the experiment started.

Optometry Visual acuity was tested by a standard logarithmic visual chart at a distance of 5 m. A slit lamp (Topcon, SL-2G) was used to examine the health of the ocular surface. A Fluorescein Sodium Ophthalmic Strip evaluated the break-up time of the tear film. Comprehensive optometry (TOPCON, CV.5000, Japan) was used to exclude high myopia and irregular astigmatism. The corneal topography (TOMEY, 22C-200S-2A5) was used to detect the morphology of the overall cornea. A Laser scanning ophthalmoscope (Optimal ® plus) was used to detect oculi diseases.

Lenses Protocol OK lenses were worn for 8-10 h daily and removed 10 min after waking in the morning. It was performed according to the lens manufacturer's fitting guidelines and as described before. In short, the lens size covered 95% of the horizontal visible iris diameter (HVID); fluorescein accumulation was in a reverse curve and kept circular; the range of lens movement was from 1.0 to 2.0 mm. All participants were fitted with Alpha OK lenses. The specifications of the lenses (Alpha OK lenses; Japan) are listed in Table 1.

Indexes Corneal topographic PPRZ and PPROPZ were quantitatively analyzed using ImageJ software (1.52e; National Institutes of Health, Bethesda, MD). Briefly, raw topographic images were imported into ImageJ and split into individual RGB channels *via* the Split Channels function. The red-channel image was selected for analysis due to its optimal contrast for identifying PPRZ.

A standardized thresholding protocol was applied to binarize the image, with manual corrections performed using the Brush

Table 1　Lens specifications of Menicon Z Night lens

Parameters	Description
Material name	BOSTON EM (Fluorosilicone-oxyalkylene polymer)
Dk (IOS)	104×10^{-11}
Design	Multi-curve design (Spherical/toric lens)
Back optic zone diameter (mm)	6.0
Lens diameter (mm)	9.60-11.6
Reverse curve width	For a 10.6 mm lens, it is 0.6 mm
Alignment curve width	For a 10.6 mm lens, it is 1.3 mm
Peripheral curve width	For a 10.6 mm lens, it is 0.4 mm
Central thickness (mm)	0.22

Tool when necessary to ensure accurate delineation of defocus boundaries. Spatial calibration was performed using a reference scale of 48.6 mm to ensure consistent pixel-to-millimeter conversion across all measurements.

Regions of interest (ROIs) corresponding to PPRZ and PPROPZ were manually outlined using the Polygon Selection Tool, and their areas were computed *via* the Measure function (Analyze > Measure). All measurements were performed in triplicate by a masked investigator to minimize intraobserver variability.

Measurements of the PPRZ area were as follows. According to the compartmentation of corneal topography, the refractive power values change the defocus zone within 5 D. The defocus zone was limited to less than 4 kinds of colours in the relative scale and kept the PPRZ area circular in instantaneous corneal topography. Subsequently, an AL examination (TOMEY OA-2000 IOL col.OPT) was recorded after wearing OK lenses for 1 a.

Statistical Analysis　SPSS 20.0 (Shanghai Cabit, China) was used for the statistical analyses and GraphPad Prism v.8.0.1 (Shenzhen SOFTHEAD, China) to generate figures. All data are represented as the mean ± SD. We analyzed differences between the test groups using a two-tailed paired Student's *t*-test, considering differences statistically significant at $P<0.05$. The data description of PPRZ area and PPROPZ area between different months were statistically analyzed using one-way analysis of variance (AVONA), and tested for significant ($P<0.05$) treatment differences using Tukey's test. The multiple regression analysis method may be used to identify the relationship between AL growth and multiple factors.

RESULTS

Demographic Characteristics　Between 2019 and 2021, 137 patients were enrolled in the study. Based on the ratio of the PPROPZ to the PPRZ area, there were 103 eyes in the control group and 103 in the experimental group. The average age of the patients in the control group was (9.81±1.44) years and (10.04±1.30) years in the experimental group. The mean SER at baseline in the control group was (-2.85±1.19) D, while (-2.75±1.18) D in the experimental group. Baseline AL ranged from 23.82 to 25.34 mm for the control eyes and

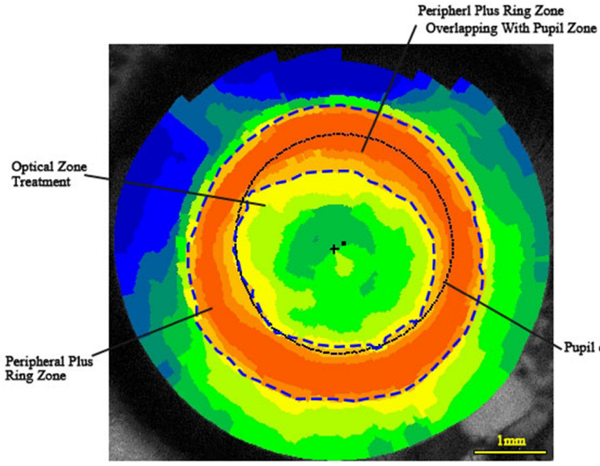

Figure 1　A tangential topographic map showing the plus power ring zone and the zone of peripheral plus ring overlap with the pupil zone analyzed in this study.

24.11 mm to 25.41 mm for the experimental eyes. All baseline characteristics were balanced, with no statistically significant differences between treatment groups, as shown in Table 1. AL increased significantly in the control group throughout the observed 1 year compared to the experiment group (Table 2).

PPRZ Area, PPROPZ Area, the Ratio of PPROPZ Area to PPRZ Area and AL　The results align with previous studies[10]. We found no statistical difference between the PPRZ area of OK lenses and the PPROPZ area at 3, 6, 9, and 12 mo (Figure 2). During the 12 mo, the axial elongation, PPRZ area, PPROPZ area, and a PPROPZ:PPRZ ratio was observed, respectively. We used line regression analysis to evaluate whether the PPRZ area interacted with AL, and our results indicated that axial elongation change was significantly decreased when increasing the PPRZ area ($r=-0.206$, $P<0.01$, Figure 3A). Consistently with previous studies[11], we found that the PPROPZ area was negatively correlated to axial elongation ($r=-0.413$, $P<0.001$, Figure 3B). Interestingly, the ratio of the PPROPZ to PPRZ area, especially above 0.2, appeared to significantly affect axial elongation ($r=-0.374$, $P<0.001$, Figure 3C).

Table 2　Summary of the baseline demographic characteristics and axial length changes from baseline to the 12 months across two groups $\bar{x}\pm s$

Baseline parameters	Ratio<0.2 (n=103)	Ratio≥0.2 (n=103)	P
Baseline age (years)	9.81±1.44	10.04±1.30	0.284
Baseline spherical equivalent(diopter)	−2.85±1.19	−2.75±1.18	0.550
Baseline axial length (mm)	24.58±0.76	24.76±0.65	0.068
12-month-baseline axial length (mm)	0.37±0.20	0.21±0.11	<0.001[a]

Ratio: Ratio of peripheral plus ring zone overlapping with the pupil zone area to plus power ring zone area; [a]Paired sample t-test.

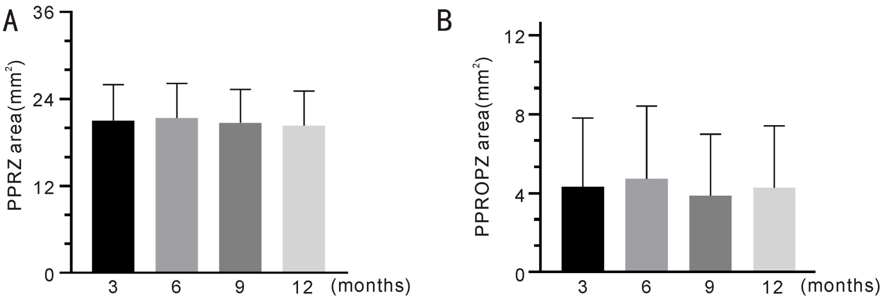

Figure 2　Distribution of subjects with plus power ring zone (A) and peripheral plus ring zone overlapping with the pupil zone (B) in 3, 6, 9, and 12 months in relation to axial length change annually. PPRZ: Plus power ring zone; PPROPZ: Peripheral plus ring zone overlapping with the pupil zone.

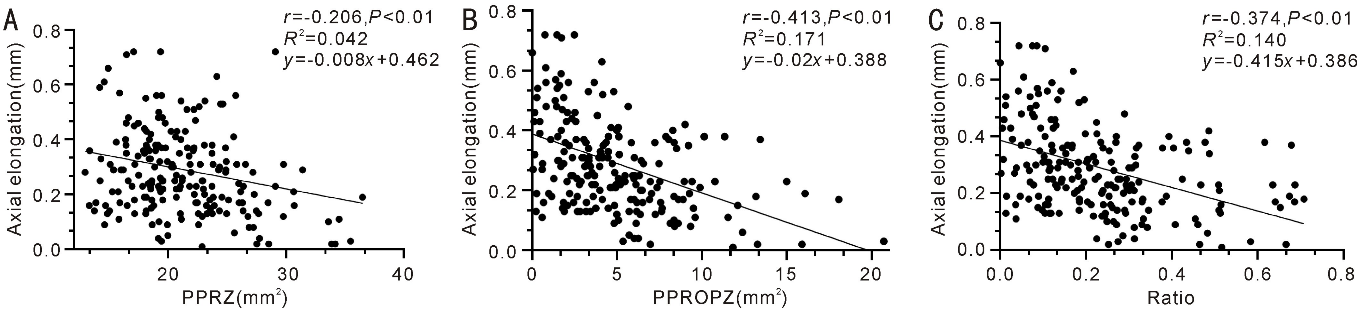

Figure 3　The correlation between axial elongation and the plus power ring zone (A) of Ortho-K lenses (n=206). And the spots are represented by the mean values. The association between axial elongation and the PPRZ area (A), the PPROPZ area (B), the ratio of PPROPZ area to PPRZ area (C) of Ortho-K lenses. PPRZ: Plus power ring zone; PPROPZ: Peripheral plus ring zone overlapping with the pupil zone.

Axial elongation was significantly associated with the PPRZ area (A), the PPROPZ area (B), the ratio of PPROPZ area to PPRZ area (C) of OK lenses. (Figure 3).

Horizontal Visible Iris Diameter and Axial Length To explore the association of axial elongation with related parameter of corneal topography, a multiple regression analysis was applied in a stepwise manner. The correlation analysis between parameter of corneal topography and axial elongation showed no significant correlation between the SRI, SAI, K_f, K_s with axial elongation (Table 3). Multiple regression showed that HVID was significantly associated with axial elongation (Table 4).

DISCUSSION

After birth, the eye grows gradually, influenced by many factors, including visual stimulation and nutrition, especially during the first year. At that time, the basic optical capacity is built. In the following years, AL elongates in response to the normal hyperopia of the infant's eye, known as emmetropisation. This normal process continues for several years until full maturity in the late teens. If the AL grows longer than the need for emmetropia, then myopia develops. The specific pathophysiological mechanisms of emmetropisation and myopisation have not been illuminated. Digging into the relevant factors of axial change will be helpful to uncover the mechanism[11]. In recent years, with the development of optical coherence tomography and histomorphological, researchers have discovered that axial elongation in myopia was associated with the equatorial zone containing a thinning of posterior sclera, choroid and retinal, a decreasing cell density of retinal pigment epithelium. Surprisingly, they found the retina's and choroid chorionic thickness and retinal pigment epithelial cell density in the macular were independent of axial extension. Other researchers also considered that the over-expansion of Bruch's membrane may cause hyperopic defocus of the peripheral retina, possibly one of the mechanisms leading to the abnormal

Table 3 A matrix of correlations between axial elongation and topographic map parameters (n=50)

Parameters	ALC	HVID	SRI	SAI	K_s	K_f
ALC	1	0.287	-0.050	0.169	-0.141	-0.082
	.	0.020	0.365	0.118	0.162	0.284
HVID	0.287	1	0.019	-0.297	-0.347	-0.294
	0.020	.	0.447	0.017	0.006	0.018
SRI	-0.050	0.019	1	0.527	0.077	0.020
	0.365	0.447	.	0	0.295	0.444
SAI	0.169	-0.297	0.527	1	0.039	0.063
	0.118	0.017	0	.	0.392	0.329
K_s	-0.141	-0.347	0.077	0.039	1	0.931
	0.162	0.006	0.295	0.392	.	0
K_f	-0.082	-0.294	0.020	0.063	0.931	1
	0.284	0.018	0.444	0.329	0	.

ALC: Axial length change; HVID: Horizontal visible iris diameter; SRI: Surface regularity index; SAI: Surface asymmetry index; K_s: Steep keratometry value; K_f: Flat keratometry value.

Table 4 Multivariable regression analysis showing the association between axial elongation and HVID, SRI, SAI, K_s, K_f in corneal topography

Predictors	B	β	t	P	95%CI	F	Adjust RSquare
HVID	0.173	0.428	2.754	0.008	0.047 to 0.300	2.464	0.047
SRI	-0.341	-0.290	-1.745	0.088	-0.735 to 0.053		
SAI	0.613	0.447	2.582	0.013	0.135 to 1.092		
K_s	-0.006	-0.057	-0.147	0.883	-0.081 to 0.070		
K_f	0.008	0.075	0.199	0.843	-0.076 to 0.092		

HVID: Horizontal visible iris diameter; SRI: Surface regularity index; SAI: Surface asymmetry index; K_s: Steep keratometry value; K_f: Flat keratometry value.

optical axis elongation[12-15].

With careful animal experiments and clinical observation, low-dose atropine, OK, low-intensity laser therapy and defocus incorporated multiple segments spectacle lenses are effective and acceptable for preventing AL change in children. Previous studies have reported that axial elongation in children treated with these are reduced by approximately 30%-80%[16]. OK is based on gas-permeable contact lenses that temporarily reshape the corneal surface to control myopia progression[17]. Research involving laboratory animals has proved that near-periphery myopia defocus can also influence AL[18-19]. Peripheral hyperopic defocus is associated with eye growth, resulting in central axial growth and refractive development myopia. OK flattens the central cornea temporarily and corrects central myopic refraction using mechanical pressure of the OK lenses surface and negative pressure shaping created by tears, but it also changes the peripheral refractive state from relative hyperopic defocus to relative myopic defocus, which prompts interest in the use of the OK lenses as a tool to control myopia progression[20]. Pauné *et al*[21] observed that by modifying the corneal parameters' design and reducing the visual zone diameter, myopia progression and AL elongation could be reduced. A study by Zhong *et al*[22] showed that the greater the refractive, inducing greater amount of relative myopic defocus on the peripheral retina which have a better myopia control. A 2020 study by Professor Pauline's team demonstrated that an increased compression factor of 1 D, compared with the default of 0.75 D, resulted in a rapid change of refraction and stability[23]. According to the research conducted by Li *et al*[24], the axial growth after being fitted with 6.2 mm or 5.0 mm back optical zone diameters OK lenses for 1 a showed that the two groups were different in the size of the optical zone, and the axial growth of the patients wearing the 5.0 mm OK lenses was 0.15 mm less than that of the patients wearing the 6.0 mm. In a paper published by Jiang *et al*[25], the pupil size and spatial distribution of the relative corneal refractive power shift were studied, and the patients were divided into the OK lenses group and the multifocal soft contact lens group with peripheral defocus design. A large number of analyses were made through the corneal topographic map, and the research showed that when the pupil diameter was larger than the plus power ring, the myopia control effect was better. This suggests that the zone of plus power ring overlapping the pupil is closely related to the AL.

Many OK lenses studies, mostly focusing on the "treatment zone", have documented that a significant AL changes with a larger treatment zone[26]. The plus ring zone induces central corneal epithelial flattening, resulting in mid-peripheral epithelial thickening. This structural change produces myopic defocus, which may contribute to the optical control of myopia progression, known as the key to controlling the axial elongation. So, we wonder if there is a relationship between the area of the mid-peripheral zone and AL. We measured the area of the plus ring zone to observe the axial change in the following year. In this study, we used the ImageJ software for the first time to measure the area of PPRZ. According to the compartmentation of corneal topography, while the plus ring zone was limited to less than 4 kinds of colours in the relative scale and the keratometry value changes within 5 diopters, the whole area can be covered. The size of the two groups was the same when the classification standard was set by 0.2 (the ratio of PPROPZ area to PPRZ area). It also exhibited a significant change in axial growth. Additionally, we found that the area of the PPRZ showed no statistical difference in the following time, as shown in Figure 2. Meanwhile, the results have shown that the larger the area of the PPRZ, the slower growth of the axis, especially in the experiment group, which may be due to the fact that the larger PPRZ area into the pupil, forming a smaller "optical zone", which can effectively prevent the progress of myopia (Figures 3). This reminded us that a large PPRZ area will further decrease the axial change. Interestingly, we found that the axial growth was associated with HVID, as shown in Table 4 and we speculate that the reason may be the smaller HVID will cooperate with a smaller volume of the eyeball.

The observed inverse correlation between horizontal iris diameter and OK efficacy in controlling axial elongation may be explained through anatomical and optical considerations: In eyes with larger irises, the OK lens treatment zone may become relatively insufficient to maintain an effective myopic defocus ring. As the iris diameter increases, the peripheral defocus signals become more dispersed across a wider retinal area, potentially reducing their inhibitory effect on ocular growth. Larger irises are often associated with flatter corneal geometries. This anatomical relationship may predispose to lens decentration, as flatter corneas provide less optimal fitting stability. Decentration can cause asymmetric defocus patterns, with nasal-temporal imbalance reducing overall myopia control efficacy[27].While not directly measured in this study, larger irises frequently correlate with lower baseline pupil constriction ability. Under mesopic conditions, this may lead to excessive peripheral light focus behind the retina, potentially stimulating axial elongation - a phenomenon observed in recent aberrometry studies[28].

Subfoveal choroidal is anatomically adjacent to the retina, and some studies have demonstrated a thickening of the choroid associated with ocular growth of myopia[29]. In short, it is longer in AL and the choroid's thinning. Li *et al*[30], followed up with myopic children for one year and found that OK treatment has increased the subfoveal choroid for up to 20 μm and slowed down the axial elongation significantly. Previous studies with atropine have proved that different doses induce varying increases in choroid thickness[31]. Xiong *et al*[32] has found that the mean choroid thickness increased by about 35 μm in children treated with repeated low-intensity laser therapy for 6 mo. In the future, we will monitor the choroid thickness and blood flow in the posterior pole of the two groups by optical coherence tomography angiography to elucidate the relationship between the PPRZ area and the choroid. Or using MRT to observe the difference in peripheral retinal refraction between the two groups, to determine the correlation between the amount of peripheral retinal defocus and peripheral retinal refraction, and further uncover the mechanism of prevention and control of myopia by OK lenses to provide a theoretical basis for the optimisation of OK lens design.

The limitation of the current study lies in the small sample size of baseline HIVD and AL. Further studies are needed to assess whether there is a correlation between baseline HIVD and AL. In addition, we did not consider the influence of medication and withdrawal of medication on this study due to his occasional allergy and corneal spot staining. In addition, as a retrospective study, this analysis lacks an age-matched untreated control group. Next, we will further collect additional data to complement the findings.

In conclusion, our study provides evidence consistent with the notion that a larger PPROPZ area facilitates OK lenses' effect to slow axial growth in myopia.

Conflicts of Interests: Hao WW, None; Wang YR, None; Jia D, None.

Authors' contributions: Hao WW, Wang YR and Jia D conceptualized the manuscript; Hao WW and Wang YR prepared original draft; Hao WW and Wang YR reviewed and edited the manuscript; Jia D did the supervision. All authors have read and agreed to the published version of the manuscript.

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