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Article

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Abstract

Purpose: To investigate the influence of treatment zone size and decentration on myopia progression and anisometropia changes in monocularly myopic children fitted with orthokeratology (OK) lenses.

Methods: This retrospective study included 78 monocularly myopic children (aged 8–16 years) fitted with OK lenses. Spherical equivalent refraction (SE) ranged from –4.00 D to –0.75 D in myopic eyes and –0.50 D to +0.75 D in fellow eyes. Corneal topography at 3 months quantified treatment zone (TZ) area and decentration. Participants were dichotomised by mean TZ area into Small TZ ($\leq 9.82 \text{ mm}^2$, $n = 40$) and Large TZ ($> 9.82 \text{ mm}^2$, $n = 38$) groups. Axial length (AL) changes and interocular AL difference were compared over 12 months using independent-samples t-tests and linear regression.

Results: At 1 year, the Small TZ group showed less myopic AL elongation than the Large TZ group (0.07 ± 0.15 vs. 0.19 ± 0.20 mm/year, $t = -3.002$, $P = .004$), with no intergroup difference in fellow eye AL elongation (0.39 ± 0.27 vs. 0.37 ± 0.19 mm/year, $P = .715$). The reduction in interocular AL difference was greater in the Small TZ group (-0.32 ± 0.25 vs. -0.19 ± 0.18 mm/year, $t = -2.746$, $P = .008$). Regression analysis showed that myopic AL elongation (Y_1) correlated with TZ area ($Y_1 = 0.025X_1 - 0.112$, $R^2 = 0.077$, $P = .014$), but not with decentration. The change in interocular AL difference (Y_2) correlated with TZ area ($Y_2 = 0.040X_1 - 0.644$, $R^2 = 0.127$, $P < .001$) and myopic pupil diameter ($Y_2 = -0.11X_2 + 0.333$, $R^2 = 0.211$, $P < .001$).

Conclusions: OK lens wear effectively reduces anisometropia in monocularly myopic children. Smaller TZ area and larger pupil diameter are associated with greater anisometropia reduction.

Keywords: myopia; anisometropia; orthokeratology; treatment zone; pupil

1. Introduction

Anisometropia, defined as an interocular difference in spherical equivalent refraction (SE) of ≥ 1.00 D, has a reported prevalence of 5.3% to 7.0% among Chinese children aged 3 to 15 years¹. Among adolescents presenting to optometry clinics, unilateral myopic anisometropia accounts for approximately 2.9% of cases^{2,3}. Evidence indicates that both the prevalence and severity of anisometropia increase with the magnitude of myopia^{4,5}. Without timely intervention, the interocular refractive disparity tends to progress throughout the school-age years, irrespective of the initial degree of anisometropia. Higher degrees of anisometropia are associated with a range of binocular vision dysfunctions, including asthenopia, strabismus, and impaired fine motor tasks, all of which can compromise visual function and quality of life^{6,7}. Early correction of anisometropia and arrest of its progression are therefore clinically imperative.

Current therapeutic options for myopic anisometropia in school-aged children include spectacles, orthokeratology (OK) lenses, and atropine eye drops⁸⁻¹¹. Spectacles, however, may be less well tolerated in patients with significant anisometropia due to prismatic effects and aniseikonia. Atropine has not been widely adopted for this indication, as its efficacy specifically in reducing interocular refractive disparity remains inconclusive^{8,10}. In recent years, multiple studies have identified OK lenses as a promising modality for children with unilateral myopia. Following OK lens wear, the axial elongation rate in the

treated eye is significantly slower than that in the untreated fellow eye, thereby effectively reducing the magnitude of anisometropia, which may in turn contribute to improvements in binocular vision and stereopsis^{9,12,13}. To date, few studies have investigated the factors influencing the change in anisometropia following OK lens wear. Huang et al.¹⁴ reported that children with greater baseline anisometropia exhibited more pronounced anisometropia reduction after OK lens treatment. However, whether other factors modulate the degree of anisometropia improvement remains unclear.

Orthokeratology employs reverse-geometry rigid gas-permeable contact lenses that are worn overnight to flatten the central cornea and steepen the mid-periphery, thereby providing unaided functional vision during daytime. Although the precise mechanism underlying this effect remains incompletely elucidated, growing interest in the field has identified several factors—including age, baseline refractive error, and pupil diameter—as significant correlates of myopia progression in OK wearers¹⁵⁻¹⁷. More recently, the characteristics of the post-OK treatment zone have emerged as a critical determinant. Several studies have reported that a smaller treatment zone area is associated with less axial elongation^{18,19}. Decentration of the treatment zone has also been proposed as a potential modifier of myopia control efficacy¹⁹.

Against this background, the present study was designed to investigate whether treatment zone characteristics and pupil diameter influence myopia progression and the magnitude of anisometropia change in monocularly myopic children fitted with OK lenses.

2. Methods

2.1 Study Participants

This retrospective study included 78 monocularly myopic children of Han ethnicity who were fitted with OK lenses at the Eye Care Center of Xi'an No.1 hospital between 2022 and 2025. The inclusion criteria were: (1) aged 8 to 16 years; (2) spherical equivalent refraction (SE) of -4.00 D to -0.75 D in the myopic eye and -0.50 D to $+0.75$ D in the fellow eye; (3) interocular SE difference ≥ 1.00 D; and (4) cylinder ≤ 1.50 D; (5) best-corrected visual acuity ≥ 1.0 in the myopic eye and uncorrected visual acuity ≥ 0.8 in the fellow eye. The exclusion criteria were: (1) history of ocular trauma or surgery; (2) moderate-to-severe dry eye disease or elevated intraocular pressure; (3) corneal curvature abnormalities (e.g., excessively flat or steep corneas); and (4) any systemic or ocular condition that could contraindicate contact lens wear.

Sample size was estimated based on a previous study¹⁸ that reported a between-group difference in axial length (AL) elongation of 0.13 ± 0.14 mm

over 1 year in children wearing OK lenses with different optical zone designs. To achieve 80% power at a significance level of 0.05, and accounting for an approximate 10% loss to follow-up, a minimum total sample size of 42 participants was required.

2.2 Examination Procedures

All participants underwent comprehensive ophthalmic examinations at the initial visit. Cycloplegia was induced using 0.5% compound tropicamide eye drops (Santen Pharmaceutical Co., Japan), and cycloplegic refraction was measured using an automated keratorefractometer (KR 800, Topcon, Japan). Axial length (AL) and pupil diameter under photopic conditions were measured using an optical biometer (IOL Master 700, Zeiss, Germany), with each eye measured at least five times and the mean value recorded. Anterior corneal surface topography was assessed using a corneal topographer (TMS-4N, Tomey, Japan), and the flat meridian keratometry (K1) and steep meridian keratometry (K2) were recorded. All examinations were performed by trained and certified optometrists and ophthalmologists following standardised clinical protocols.

2.3 Orthokeratology Fitting

Children were fitted with spherical four-zone OK lenses (Euclid Systems Corporation, Herndon, USA) manufactured from oprifocon A (Boston EQUALENS II), with an oxygen permeability (Dk) of 127×10^{-11} (cm²/s)(mLO₂/mL·mmHg). The total lens diameter ranged from 10.2 to 11.0 mm. Following the exclusion of contraindications, all lenses were fitted by a single experienced ophthalmologist in accordance with standardised OK lens fitting protocols. Trial lenses were selected based on baseline ocular measurements, and the final lens parameters were determined after assessing lens alignment and movement using slit-lamp biomicroscopy, with over-refraction confirming the final prescription. All children were instructed to wear their lenses overnight and to adhere to a strict lens care regimen. Follow-up visits were scheduled at 1 day, 1 week, and 1 month after lens dispensing, and every 3 months thereafter.

2.4 Measurement of Treatment Zone Size and Decentration

Corneal topography was performed at the 3-month follow-up visit, and only maps with an accuracy >95% were included for analysis. To delineate the central treatment zone, a tangential curvature difference map was generated by subtracting the post-fitting tangential curvature map from the baseline map.

On the tangential difference map, the boundary of the treatment zone was defined by the innermost contour of the mid-peripheral steepening ring. Sixteen points with zero power change (0.00 D) were sampled along this boundary at 22.5° intervals (Figure 1). The polar radius of each point from the

corneal vertex was recorded. A custom MATLAB program (MathWorks, Inc., USA) was used to convert polar coordinates to Cartesian coordinates with the corneal vertex D (0, 0) set as the origin. An ellipse was fitted to the 16 sampled points, yielding the focal points F_1 and F_2 , the treatment zone centre C (x_c , y_c), and the semi-major axis (a) and semi-minor axis (b) of the ellipse (Figure 2). The intra-observer and inter-observer repeatability of the measurement method were assessed in 20 randomly selected maps, with intraclass correlation coefficients >0.95 .

The treatment zone area was calculated using the ellipse area formula:

$$S = \pi ab$$

The treatment zone decentration was defined as the distance from the corneal vertex to the treatment zone centre:

$$d = \sqrt{(x_c^2 + y_c^2)}$$

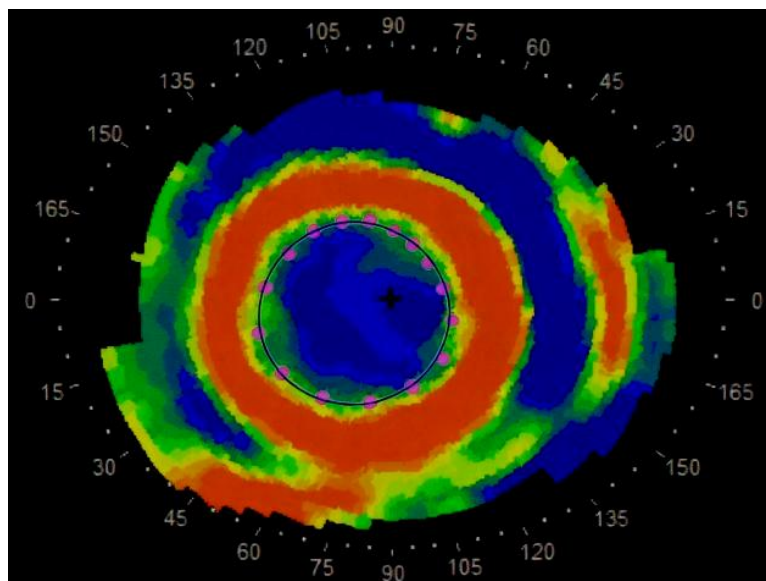


Figure 1. Tangential curvature difference map at 3 months post-fitting, illustrating the sampling points along the treatment zone boundary.

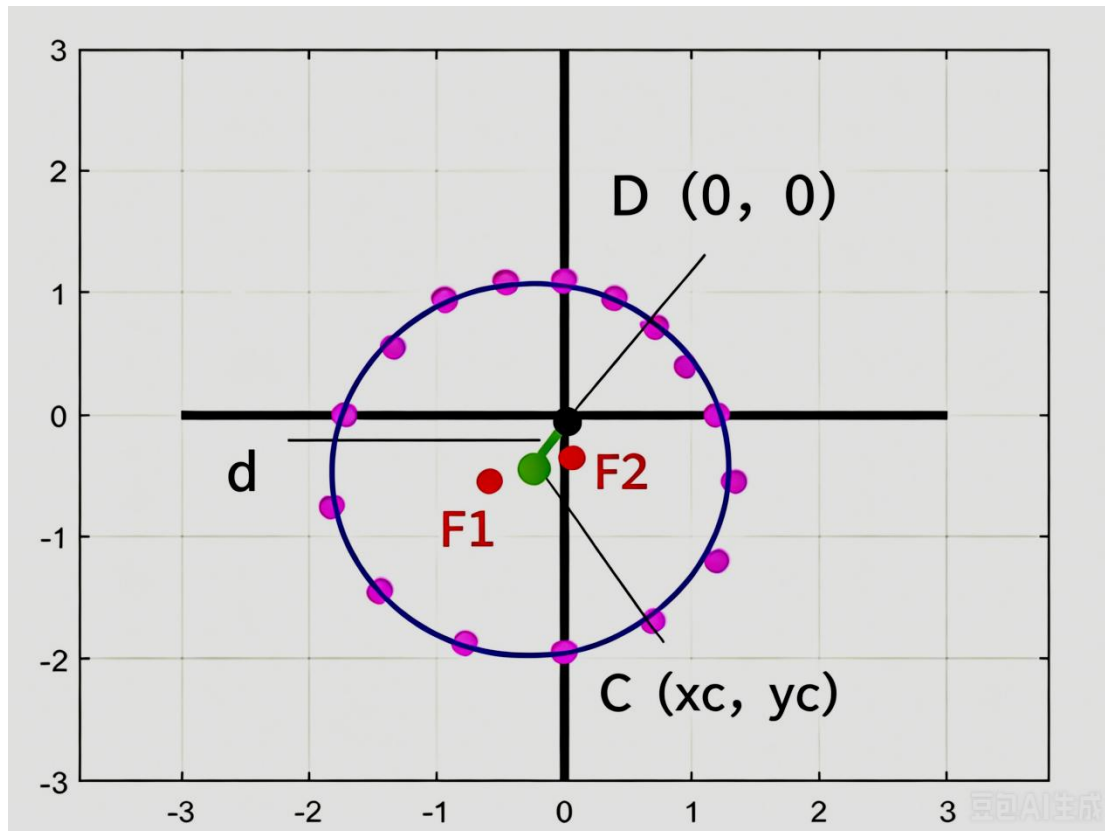


Figure 2. Fitted ellipse used to determine treatment zone size and decentration. F_1 and F_2 represent the two foci of the fitted ellipse; D denotes the corneal vertex; C represents the treatment zone centre; d indicates the decentration distance.

2.5 Statistical Analysis

Statistical analyses were performed using SPSS version 26.0 (IBM Corp., USA). Continuous data are presented as mean $\pm$ standard deviation (SD). Normality was assessed using the Shapiro–Wilk test, and all parameters were found to be normally or approximately normally distributed. Intergroup comparisons were conducted using independent-samples t-tests. Linear regression analysis was used to examine the relationships between variables. A P-value $< .05$ was considered statistically significant.

3. Results

3.1 Baseline Characteristics

A total of 78 children were included in this study, with a mean age of 11.27 ± 2.09 years. At baseline, the mean anisometropia (interocular SE difference) was -2.37 ± 1.14 D, and the mean interocular AL difference was 1.05 ± 0.53 mm. The mean pupil diameter was 5.37 ± 0.97 mm in the myopic eyes and 5.29 ± 1.02 mm in the fellow eyes. The mean treatment zone area was 9.68 ± 2.05 mm² (range: 5.57 to 13.99 mm²), and the mean treatment zone decentration was 0.56 ± 0.21 mm (range: 0.09 to 0.90 mm).

At 6 months, AL elongation in the myopic eyes was 0.05 ± 0.13 mm, compared with 0.19 ± 0.12 mm in the fellow eyes, corresponding to a reduction in interocular AL difference of -0.14 ± 0.14 mm. At 12 months, AL elongation in the myopic eyes was 0.13 ± 0.18 mm, compared with 0.38 ± 0.23 mm in the fellow eyes, with a corresponding reduction in interocular AL difference of -0.26 ± 0.23 mm.

3.2 Correlations with Axial Length Elongation and Interocular AL Difference Change

Linear regression analysis was performed to identify factors associated with myopic AL elongation and changes in interocular AL difference.

For myopic AL elongation (Y_1), a significant correlation was found with treatment zone area (X_1): $Y_1 = 0.025X_1 - 0.112$ ($R^2 = 0.077$, $P = .014$). No significant association was observed with treatment zone decentration ($P > .05$).

For the change in interocular AL difference (Y_2), which reflects the reduction in anisometropia, significant correlations were identified with treatment zone area (X_1), pupil diameter in the myopic eye (X_2), and baseline anisometropia (X_3):

$$Y_2 = 0.040X_1 - 0.644 \quad (R^2 = 0.127, P = .001)$$

$$Y_2 = -0.11X_2 + 0.333 \quad (R^2 = 0.211, P < .001)$$

$$Y_2 = 0.057X_3 - 0.12 \quad (R^2 = 0.080, P = .012)$$

No significant association was found between Y_2 and treatment zone decentration ($P > .05$). Collectively, these results indicate that a smaller treatment zone area, a larger pupil diameter, and a smaller baseline anisometropia are associated with a greater reduction in interocular AL difference (Figure 3).

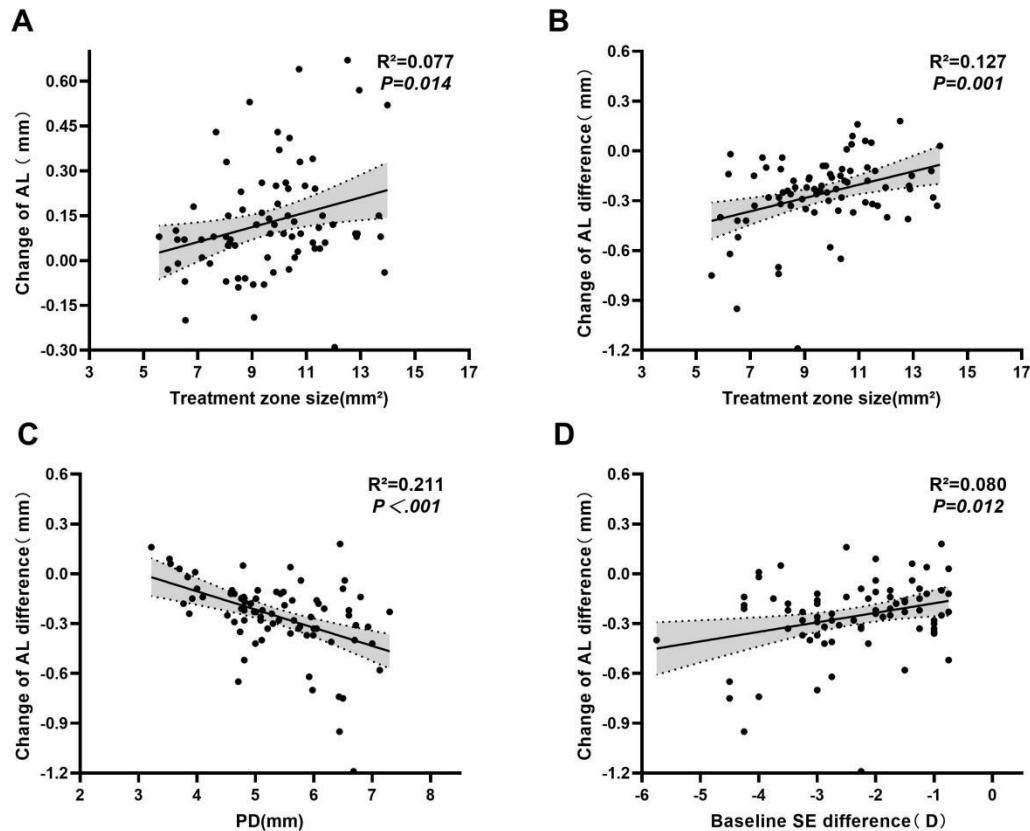


Figure 3. Scatter plots demonstrating the linear correlations identified by regression analysis. (A) Myopic AL elongation versus treatment zone area; (B) Change in interocular AL difference versus treatment zone area; (C) Change in interocular AL difference versus pupil diameter in the myopic eye; (D) Change in interocular AL difference versus baseline anisometropia.

3.3 Group Comparisons by Treatment Zone Size

Participants were dichotomised by the mean treatment zone area into a Small TZ group ($\leq 9.82 \text{ mm}^2$; $n = 40$) and a Large TZ group ($> 9.82 \text{ mm}^2$; $n = 38$). The Small TZ group had a mean age of 11.30 ± 2.10 years (male:female = 22:18), while the Large TZ group had a mean age of 11.24 ± 2.11 years (male:female = 15:23). The baseline anisometropia was $-2.42 \pm 1.02 \text{ D}$ in the Small TZ group and $-2.31 \pm 1.26 \text{ D}$ in the Large TZ group, and the baseline interocular AL difference was $1.04 \pm 0.46 \text{ mm}$ and $1.07 \pm 0.60 \text{ mm}$, respectively. No significant between-group differences were observed in any baseline parameters (all $P > .05$; Table 1).

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277

Table 1. Baseline characteristics of participants in the Small TZ and Large TZ groups

Groups	eyes	More myopic eye				Less myopic eye			
		Initial SE (D)	Initial AL (mm)	Initial K1 (D)	Initial K2 (D)	Initial SE (D)	Initial AL (mm)	Initial K1 (D)	Initial K2 (D)
Small TZ	40	-2.28±0.98	24.75±0.82	42.31±1.20	43.50±1.44	-0.13±0.60	23.71±0.68	42.30±1.32	43.56±1.37
Large TZ	38	-2.13±1.07	24.65±0.82	42.33±1.18	43.45±1.28	-0.18±0.58	23.58±0.63	42.42±1.09	43.70±1.26
t		-0.660	0.559	-0.057	0.158	-0.354	0.855	-0.434	-0.450
P		0.511	0.578	0.955	0.875	0.725	0.395	0.666	0.654

Data were expressed as means + standard deviations.

278

279 At 6 months, AL elongation in the myopic eyes was significantly less in the
 280 Small TZ group than in the Large TZ group (0.02 ± 0.12 mm vs. 0.09 ± 0.13
 281 mm; $t = -2.236$, $P = .029$). In contrast, no significant intergroup difference was
 282 observed in AL elongation of the fellow eyes (0.19 ± 0.12 mm vs. 0.20 ± 0.12
 283 mm; $t = -0.538$, $P = .592$). The reduction in interocular AL difference did not
 284 differ significantly between the two groups at 6 months (-0.17 ± 0.14 mm vs. $-$
 285 0.11 ± 0.14 mm; $t = -1.518$, $P = .134$).

286

287 At 12 months, the Small TZ group continued to demonstrate significantly less
 288 AL elongation in the myopic eyes compared with the Large TZ group (0.07 ±
 289 0.15 mm vs. 0.19 ± 0.20 mm; $t = -3.002$, $P = .004$). Again, no significant
 290 intergroup difference was found in AL elongation of the fellow eyes (0.39 ±
 291 0.27 mm vs. 0.37 ± 0.19 mm; $t = 0.367$, $P = .715$). Notably, the reduction in
 292 interocular AL difference was significantly greater in the Small TZ group than in
 293 the Large TZ group (-0.32 ± 0.25 mm vs. -0.19 ± 0.18 mm; $t = -2.746$, P
 294 $= .008$) (Table 2).

295

Table 2. Changes in AL and aniso-AL of Small TZ and Large TZ group (mm)

	Small TZ group	Large TZ group	t	P value
6 months				
AL change in MME	0.02±0.12	0.09±0.13	-2.236	0.029
AL change in LME	0.19±0.12	0.20±0.12	-0.538	0.592
Aniso-AL change	-0.17±0.14	-0.11±0.14	-1.518	0.134
12 months				
AL change in MME	0.07±0.15	0.19±0.20	-3.002	0.004
AL change in LME	0.39±0.27	0.37±0.19	0.367	0.715
Aniso-AL change	-0.32±0.25	-0.19±0.18	-2.746	0.008

aniso-AL, interocular difference of AL; MME, the more myopic eyes, LME, the less myopic eyes.

Data were mean+standard deviation.

3. Discussion

The present study investigated the influence of treatment zone characteristics on myopia control efficacy in monocularly myopic children fitted with OK lenses. The principal finding was that a smaller treatment zone area and a larger pupil diameter were associated with a greater reduction in interocular AL difference, primarily driven by slower AL elongation in the myopic eye. These results suggest that treatment zone size, rather than decentration, is a key determinant of anisometropia improvement in this population.

Consistent with previous reports, this study demonstrated that OK lens wear effectively reduced anisometropia in children with unilateral myopia. Over the 12-month follow-up period, AL elongation in the myopic eyes was 0.13 ± 0.18 mm, compared with 0.38 ± 0.23 mm in the fellow eyes, resulting in a reduction in interocular AL difference of -0.26 ± 0.23 mm. These values are broadly comparable with those reported in earlier studies, in which myopic eye AL elongation ranged from 0.05 to 0.14 mm, fellow eye elongation from 0.30 to 0.54 mm, and interocular AL difference reduction of approximately 0.30 mm^{9,12,13}. Collectively, these findings support the conclusion that OK lens wear not only retards myopia progression in the affected eye but also attenuates the progressive interocular disparity that characterises unilateral myopic anisometropia.

Beyond confirming the overall efficacy of OK lenses in this population, The current investigation specifically examined the role of treatment zone parameters. Linear regression analysis revealed a significant positive correlation between myopic AL elongation and treatment zone area, indicating that a smaller treatment zone was associated with less axial elongation. This finding is in agreement with the work of Guo et al.¹⁸, who reported that children fitted with lenses incorporating a smaller back optic zone diameter exhibited smaller treatment zones and slower AL elongation. Similarly, Lin et al.¹⁹ reached comparable conclusions. Notably, this study further demonstrated that a smaller treatment zone area was associated with a greater reduction in interocular AL difference. This effect can be attributed to the fact that treatment zone size influenced AL elongation only in the myopic eye, with no significant intergroup difference observed in the fellow non-myopic eyes. This observation is consistent with the findings of Long et al.²⁰, who reported that OK lens wear did not affect myopia progression in the fellow eyes of children with unilateral myopia.

The precise mechanism by which OK lenses control myopia progression remains incompletely understood. However, the peripheral defocus

theory—which posits that OK lenses induce peripheral myopic defocus at the retina—has gained broad acceptance^{21,22}. Cho et al.²³ hypothesised that greater corneal reshaping effects produce stronger peripheral myopic defocus signals, thereby enhancing the efficacy of myopia retardation. Yang et al.²⁴ further suggested that the areal summed corneal power shift within the central 4 mm zone may serve as a potential predictor of axial elongation during OK treatment. The present study are consistent with this framework: for a given pupil size, a smaller treatment zone allows more defocus signals to enter the pupillary area, which would align with the observation that larger pupil diameter is associated with less axial elongation¹⁷. Indeed, regression analysis confirmed a significant correlation between pupil diameter in the myopic eye and the change in interocular AL difference, lending indirect support to this hypothesis.

Treatment zone decentration is a common and clinically unavoidable phenomenon in OK lens practice. Multiple factors may contribute to decentration, including corneal asymmetry, lens fitting characteristics, lens diameter, and corneal astigmatism^{25,26}. Contrary to several previous studies that reported a significant association between treatment zone decentration and AL elongation^{19,27,28}, this analysis did not identify such a relationship. A plausible explanation for this discrepancy lies in the relatively small magnitude and narrow range of decentration in our cohort (0.56 ± 0.21 mm; range: 0.09 to 0.90 mm), which was markedly smaller than that reported by Li et al. (0.68 ± 0.35 mm; range: 0.05–1.49 mm) in 106 participants¹⁹ and by Chen et al. (0.72 ± 0.26 mm; range: 0–1.34 mm)²⁸. Furthermore, this study focused exclusively on decentration magnitude without considering decentration direction, which may have further limited statistical power to detect an association.

The present study carry meaningful clinical implications. In patients with significant anisometropia, binocular fusion may already be compromised, and spectacle correction is often poorly tolerated. In such cases, maximising the reduction of interocular refractive disparity becomes the primary therapeutic goal. When fitting OK lenses, reducing the back optic zone diameter to yield a smaller treatment zone may serve as an effective strategy to enhance anisometropia reduction. For patients with smaller baseline pupil diameters, combining OK lens wear with low-concentration atropine could potentially yield additional benefits. Conversely, in patients with milder anisometropia or older age—where binocular function is typically well-compensated and the natural progression of myopia has slowed—prioritising good visual quality may be more clinically appropriate. In these scenarios, opting for a larger back optic zone diameter to increase the treatment zone area might be a reasonable decision.

Several limitations of this study should be acknowledged. First, the follow-up

duration was relatively short (12 months), precluding assessment of the long-term effects of treatment zone characteristics on myopia control, as well as the subsequent progression pattern should the fellow eye eventually become myopic. Second, the retrospective design inherently carries a risk of selection bias and unmeasured confounding, despite our efforts to standardise data collection. Third, analysis of treatment zone decentration was limited to its magnitude; the potential influence of decentration direction warrants further investigation in future studies. Fourth, all participants were of Han Chinese ethnicity and recruited from a single centre, which may limit the statistical power and the generalizability of findings to other populations. Future prospective, randomised controlled trials with extended follow-up periods and multicentre collaboration are warranted to validate findings and to incorporate comprehensive assessments of binocular vision function, visual quality, and other potential modulating factors.

In conclusion, this study demonstrates that OK lens wear effectively controls axial elongation in the myopic eye and reduces anisometropia in monocularly myopic children. A smaller treatment zone area and a larger pupil diameter are associated with greater anisometropia reduction. These findings provide clinically actionable insights for optimising OK lens fitting strategies in this specific population.

Authors' contributions

Conceived and designed the experiments: HZ, XZ, LK, MY. Performed the experiments: HZ, LK, MY, YL, YG, DZ. Analyzed the data: LK, YG, HZ. Contributed materials/analysis tools: HZ, XZ, MY. Wrote the paper: HZ, LK. All authors read and approved the final manuscript.

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Data Availability Statement

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics Statement

This study was approved by the Ethics Committee of Xi'an No.1 hospital and followed the principles of the Helsinki Declaration (for the Shaanxi Provincial Key R&D Program, Project No. 2022-YBSF-155). Due to the

retrospective nature of the study and the use of fully de-identified data, the requirement for informed consent from individual participants was waived by the ethics committee.

Competing interests

The authors declare that they have no competing interests.

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