Treatment zone decentration promotes retinal reshaping in Chinese myopic children wearing orthokeratology lenses

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Funding information
This work was supported by the Wenzhou Basic Medical and Health Science and Technology Project (grant no. Y2020030) and Zhejiang Provincial Leading Health Talent Project (Chen Hao).

Abstract
Purpose: To investigate whether the treatment zone (TZ) decentration in orthokeratology (OK) lenses affects retinal expansion in Chinese children with myopia.
Methods: Children aged 8 to 13 years (n = 30) were assessed over 13 months comprising 12 months of OK lens wear followed by discontinuation of lens wear for 1 month. Corneal topography was measured at 0, 1, 3, 6, 9, 12 and 13 months. TZ decentration of the OK lens was calculated, and subjects were subdivided into a small decentration group (group S) and a large decentration group (group L) based on the median value of the weighted average decentration (dave). Central axial length (AL) and peripheral eye lengths (PELs) at the central retina, as well as 10°, 20° and 30° nasally and temporally were measured at 0 and 13 months under cycloplegia. Second-order polynomial (\( y = ax^2 + bx + c \)) and linear fits (\( y = Kx + B \)) were applied to the peripheral relative eye length (PREL), and the coefficients ‘a’ and ‘K’ were used to describe the shape of the eye.

Results: Mean AL growth for one year was 0.28 ± 0.17 mm. In a multiple linear regression model, AL elongation was related to the baseline age (\( \beta = −0.41, p = 0.01 \)) and the dave (\( \beta = −0.37, p = 0.03 \)) (\( R^2 = 0.34, p = 0.002 \)). When compared with smaller dave (0.45 ± 0.15 mm), a larger dave (0.89 ± 0.17 mm) was associated with slower ocular growth (central: 0.20 ± 0.13 mm vs. 0.35 ± 0.17 mm, \( p = 0.009 \); 10° nasal: 0.26 ± 0.18 mm vs. 0.45 ± 0.21 mm, \( p = 0.02 \); 10° temporal: 0.17 ± 0.14 mm vs. 0.32 ± 0.19 mm, \( p = 0.02 \)) and more oblate retina shape (‘a’: −0.13 ± 0.02 vs. −0.14 ± 0.02, \( p = 0.02 \); \( K_{nasal} \): 0.35 ± 0.11 vs. 0.39 ± 0.09, \( p = 0.02 \); \( K_{temporal} \): −0.42 ± 0.08 vs. −0.46 ± 0.08, \( p = 0.004 \)).

Conclusions: Greater TZ decentration with the use of OK lenses was associated with slower axial growth and a more oblate retinal shape. TZ decentration caused local defocusing changes, which may inhibit myopic progression. These findings may have important implications for improving optical designs for myopia control.

KEYWORDS
axial length, decentration, myopia, orthokeratology, retinal shape

Xue Li and Yingying Huang contributed equally to this work and share the first authorship.

Trial registration: Chinese Clinical Trial Registry: ChiCTR1800018564, registered 25 September 2018-Retrospectively registered.

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INTRODUCTION

By 2050, it is predicted that 49.8% of the global population will have myopia, with 9.8% of people exhibiting high myopia. Currently, myopia is especially serious in Asia and has reached epidemic levels amongst children in China. More important than the considerable costs associated with this refractive condition is the fact that an increase in myopia is linked with a higher prevalence of myopic maculopathy, which can cause visual impairment. Therefore, slowing the progression of myopia is an important area of research.

In recent years, peripheral retinal defocus has been thought to play an important role in both the development and control of myopia. Mutti et al. suggested that peripheral hyperopic defocus may be a risk factor for myopia onset in children by examining the refractive error 30° temporal to the fovea before and after myopia development. By contrast, imposing myopic defocus on the peripheral retina has an inhibitory effect on myopia development in chicks, guinea pigs and marmosets, even in cases of sharp central vision. Therefore, some optical devices, such as multifocal soft contact lenses and overnight orthokeratology (OK) lenses, have been used to control myopia progression in children either by reducing peripheral hyperopic defocus or inducing peripheral myopic defocus. Compared with single-vision spectacles, OK lenses reduce axial elongation by 30%–50%. Although the OK procedure is used widely in clinical practice in China, the effectiveness of myopia control varies greatly, and treatment zone (TZ) decentration has been proposed to be associated with myopia control efficacy.

Treatment zone decentration during OK lens fitting is commonly performed. Therefore, it is necessary to understand whether TZ decentration affects the efficiency of myopia control. Chen found a weak negative correlation (r = −0.19) between TZ decentration and myopia control in a retrospective analysis of 101 children at 3 months after wearing OK lenses. Other studies have reported that greater TZ decentration can slightly but significantly reduce axial elongation. However, some investigations did not identify a correlation between the TZ decentration of OK lenses and myopia development. During the wearing period, the OK lens position is not static; rather, it shifts slightly with lens wear. Therefore, we speculate that TZ decentration of OK lenses based on a single time-point measurement could fail to represent the complete picture of lens position during the treatment period. This study proposed a time-weighted average TZ decentration to describe the OK lens position, and to explore the effects of TZ decentration for OK lenses on myopia progression and retinal shape.

MATERIALS AND METHODS

Study participants

This prospective study was conducted at the Eye Hospital of Wenzhou Medical University, Zhejiang, China. The study was approved by the Ethics Board of the Eye Hospital of Wenzhou Medical University. Both the children and their parents or guardians signed a consent form after the study procedures and possible risks were explained. The study process followed the tenets of the Declaration of Helsinki. Thirty myopic children aged between 8 and 13 years were enrolled in this study. All participants met the following inclusion criteria: spherical refractive error between −1.00 dioptre (D) and −5.00 D; astigmatism less than 0.75 D and monocular best-corrected visual acuity (BCVA) less than 0.10 logMAR. Furthermore, children with previous ocular surgery, amblyopia, strabismus, active ocular disease, epilepsy, or a history of medical or optical myopia prevention therapy were excluded.

Lens fitting

Each participant was fitted with OK lenses, namely a four-curve, reverse geometry lens (Euclid, euclidsys.com). The lenses were fitted according to the manufacturer’s recommended guidelines and fitting was performed by the same experienced clinician. Briefly, the initial trial lens was decided based on the simulated keratometry finding, eccentricity and horizontal visible iris diameter. After a 20 min trial, a fluorescein pattern was performed to assess the fitting. Good fitting was indicated by an optical zone covering the pupil, no apparent TZ decentration, and proper lens movement. After a proper lens fit was achieved, over-refraction was performed to determine the final order. Lenses were required to be worn for 8–9 h per night. OK lens aftercare visits (1 day, 1 week, 1, 3, 9 and 12 months after lens delivery) were performed to assess the cornea and lens fitting.
Measurements

Cycloplegic refraction was obtained with the WAM-5500 autorefractor (Grand Seiko, grandseiko.com). Cycloplegia was achieved with one drop of 0.5% proparacaine and two drops of 1% cyclopentolate, with the applications separated by 5 min.

Visual acuity (VA) and corneal topography (Sirius, CSO, csoitalia.it) were measured between 08:00 and 10:00 and within 2 h of OK lens removal at 0 month (baseline, i.e., before OK lens administration), 1, 3, 6, 9, 12 and 13 months (i.e., 1 month after discontinuation of OK lens wearing to assess the cornea recovering from OK treatment24). A multi-functional VA tester (MFVA-100, BriteEye Medical Tech Co. Ltd., 986875.51sole.com) was used to measure distance VA at 5.5 months at a luminance of 80 cd/m² (LCD computer monitor) with an average illuminance of 200 lux.9 Participants were asked to report the direction of a tumbling E optotype, and VA was recorded as the average of two logarithm of the minimum angle of resolution (logMAR) measurements.

An optical biometer (Lenstar, LS 900, Haag-Streit, haagstreit.com) with an optical apparatus attached to the headrest25–27 was used to measure the central axial length (AL), that is, anterior corneal surface to the retinal pigment epithelium, and peripheral eye length (PEL). The system comprised a 50:50 (transmittance: reflectance) beam splitter (Thorlabs, thorlabs.com), a Maltese cross target and a goniometer to accurately control gaze position. Eye length was initially measured at position 0° (central AL) first, followed by eccentricities of 30° temporal and nasal in 10° intervals at least 30 min after cycloplegia. Three measurements with differences within 0.02 mm were taken and averaged for analysis.28 The AL and PELs were performed at baseline (0 month, before fitting the OK lens) and at the final visit (13 months).

Evaluation of treatment zone decentration

All participants underwent corneal topography at least three times using a corneal topographer with a Scheimpflug camera and a 32-ring small Placido disc with 256 measurement points at each ring. All images were reviewed for good keratoscopy centration (>90%) and coverage (>85%). Corneal tangential difference maps were compared between each follow-up visit and the 0 month examination to quantify the TZ decentration, and the corneal tangential difference values were calculated. The TZ was considered as the flattened area in the central cornea, which was adjusted using the manual method described by Hiraoka.29 Sixteen inflection points were plotted (the corneal power changed from negative to positive) at 22.5° intervals to outline the margins of the TZ on both the tangential difference maps and tangential difference values. TZ decentration was determined using both pupil centre and corneal vertex methods, which showed good correlation ($r = 0.93, p < 0.001$), and therefore, only the corneal vertex value was used as the reference origin point for TZ decentration.17,30,31 The distance between the reference origin point and the centre of the fitting ellipse was defined as the TZ decentration of OK.17,30,31,32 The coordinate of the

\[FIGURE 1\] Example image for corneal topography (tangential difference diagram). The origin of coordinates ‘0’ represents the corneal vertex, and the ▲ represents the centre of the fitting ellipse. The distance between ‘0’ (the corneal vertex) and ▲ is the treatment zone (TZ) decentration of the orthokeratology (OK) lens.
centre of the fitting ellipse was calculated automatically using a data-analysis program (MATLAB 2017, MathWorks, mathworks.com) as shown in Figure 1. The weighted average of the TZ decentration \( \text{d}_{\text{ave}} \) was calculated by the following formula:

\[
\text{d}_{\text{ave}} = \frac{\sum_{i=1}^{5} (T_i - T_{i-1}) \times d_i}{12}
\]

with \( i \), number of follow-up visits and \( T_i - T_{i-1} \), visit time interval between two consecutive visits; \( d_i \), TZ decentration at each follow-up visit.

Participants were subdivided into a small TZ decentration group (group S) and a large TZ decentration group (group L) using the median of the TZ decentration.

**Statistical analysis**

The peripheral relative eye length (PREL) was calculated by subtracting the central AL from each eccentric retinal location. Second-order polynomial fits were applied to the PRELs for each participant: \( y = ax^2 + bx + c \), where \( x \) is the retinal angle in degrees and is taken as positive for the temporal retina. Linear fits were applied to the nasal and temporal PRELs for each participant: \( y = Kx + B \), where \( x \) is the retinal angle and is taken as positive for the temporal retina, one unit of \( x \) was equivalent to 10° on the x-axis. The coefficient \( a \) was used to describe the shape of the eye, and a larger absolute \( a \) indicates a more prolate retinal shape. \( s = -2a/b \times 10^\circ \) was used to describe the location of the axis of symmetry, and positive values of \( s \) indicated that the axis of symmetry passed through the temporal retina. Coefficient \( K \) represents the slope of the retina, which is positive and negative for nasal and temporal aspects, respectively, and a larger absolute value of \( K \) indicates a deeper slope.

Only the data for the right eye were used for analysis with SPSS software (version 25.0, IBM, ibm.com). Independent t tests were carried out to compare differences between two groups, and paired t-tests were used to compare the differences between the temporal and nasal sides of the retina. Linear regression analysis was performed to assess which factors significantly affected axial elongation. A \( p \) value < 0.05 was considered statistically significant.

**RESULTS**

Thirty children finished all follow-up measurements. Mean (±SD) values were as follows: age 9.9 ± 1.3 years (range 8 to 13 years, 13 boys and 17 girls); AL 24.89 ± 0.89 mm (range 23.25 mm to 26.54 mm); spherical equivalent refraction (SER) -2.63 ± 0.77 D (range −1.25 D to −4.00 D) and VA −0.09 ± 0.07 logMAR.

**Treatment zone decentration**

After orthokeratology wear, TZ decentration at 1 month was significantly deviated from the centre (corneal vertex), both horizontally and vertically (all \( p < 0.05 \)). However, there were no significant changes along the horizontal meridian (\( X \)-axis) during the follow-up visits, whereas a minor fluctuation occurred in the vertical meridian (\( Y \)-axis) at the 3 months and 6 months visits (Figure 2). The weighted mean \( \text{d}_{\text{ave}} \) for the OK lenses was 0.67 ± 0.27 mm (range, 0.26 mm ~ 1.29 mm); 20 eyes (67%) were inferotemporal, 8 eyes (27%) were supertemporal, and 2 eyes (6%) were inferonasal.

**Treatment zone decentration of the orthokeratology lens affected axial elongation**

After one year (13 months visit), the AL increased from 24.89 ± 0.91 mm to 25.16 ± 0.88 mm (\( t = −9.04 \), \( p < 0.001 \)). The mean AL elongation was 0.28 ± 0.17 mm. Moreover, both the baseline age (\( \beta = −0.41 \), \( p = 0.01 \)) and the \( \text{d}_{\text{ave}} \)
Treatment zone decentration of the orthokeratology lens affected ocular shape

Figure 3 and Table 4 show the changes in elongation orientation and symmetry. Both in 10-degree and 20-degree eccentricities of group S and group L, the nasal retinal eye length elongated significantly faster than the temporal retinal AL (p < 0.05).

To investigate the effect of TZ decentration on ocular shape, the fitted curves were compared between the two subgroups, that is, group S and group L (Figure 4), while the changes in the coefficients ‘a’, ‘s’ and ‘K’ are shown in Tables 5 and 6. At baseline (0 month), there were no significant differences between the two groups for the coefficients ‘a’ and ‘s’. However, after one year, coefficient ‘a’ was larger (and the absolute value smaller) in group L (p = 0.02), but was unchanged in group S. The coefficient ‘s’ was more negative in both groups S (p = 0.03) and L (p = 0.03). Group S showed a shift in axial symmetry from temporal to nasal, while group L moved further nasally.

After wearing OK lenses for one year, the absolute value of ‘K’ decreased in the nasal (K_N, p = 0.02) and temporal (K_T, p = 0.004) retina in group L, indicating that the retina became more oblate, whereas the slope for group S did not change significantly on either aspect (both p > 0.05). Additionally, no significant differences were observed between the two groups (all p > 0.05).

DISCUSSION

The present study demonstrated the effect of TZ decentration for OK lenses on myopia control and retinal shape. Peripheral eye length and TZ decentration of OK lenses were measured over a one-year period. Multiple linear regression showed that both the baseline age and the weighted mean $d_{ave}$ were significantly associated with AL elongation. Group L, with a larger weighted mean $d_{ave}$, exhibited better myopia control from the OK lens, showing slower central AL elongation and a more oblate retinal shape.

Previous studies have investigated the factors associated with myopia progression during treatment with OK lenses and found that the baseline age and SER were two important factors. In the current study, only baseline age was significantly correlated with axial elongation in a multiple linear regression (Table 1), showing that younger children showed greater axial elongation. While some studies do support this finding, Jacinto et al. did not find a significant correlation between age and AL elongation, probably due to their small sample size (n = 14). Baseline SER has also been reported as a critical factor affecting AL elongation, but this was not observed in the present study, probably due to the relatively narrow SER range here (−1.25 D to −4.00 D) compared with other studies having a wider baseline SER range (e.g., −0.75 D to −6.00 D).

Treatment zone decentration with OK lenses is a common phenomenon in clinical practice. It is mainly caused by paracentral corneal asymmetry or sleeping posture, eyelid tension and lens design. In the current investigation,
TZ decentration changed over time. Previous studies have monitored TZ decentration at a single point in time and were inadequate to describe the entire period of treatment, resulting in TZ decentration showing an inconsistent correlation with myopia progression. In this study, we calculated the time-weighted average TZ decentration ($d_{ave}$) as a pooled effect throughout the entire period of OK lens treatment. We found that $d_{ave}$ exhibited a moderate correlation with AL elongation ($r = -0.37$), thus supporting the influence of the TZ on myopia control. Therefore, the role of TZ decentration has likely been underestimated in the past. The mechanism whereby OK lenses control myopia progression has never been fully explained.

Recently, the retina-choroid-sclera signalling pathway has been proposed to explain the mechanism of myopia. In the current study, eye length elongation was not symmetrical, being faster in the nasal than in the temporal retina (Figure 3 and Table 3). A previous study showed that local defocus can control local eye growth and myopia. Thus, it was presumed that the peripheral retina defocus should be asymmetrical. Lin et al. demonstrated the peripheral defocus was indeed asymmetrical, with more myopic defocus in the temporal retina after the OK lens treatment. Thus, it was presumed that the peripheral retina defocus should be asymmetrical. In the current study, the OK lens was 6 mm, indicating that more positive defocus in the temporal retina increased with TZ decentration towards the temporal side. As in the current study, the OK lens decentred towards the temporal side (28/30, 94%) creating a more oblate eye shape. *p<0.05, **p<0.01.
entered the eye with larger TZ decentration. However, when the optic zone diameter was reduced, TZ decentration may not affect the peripheral defocus and myopia progression.

Previous studies have shown that myopic eyes are larger and relatively more prolate. Lim reported that the posterior eye shape in myopic eyes was less oblate, while Ehsaei also found that PREls in the temporal retina exhibited greater expansion than those in the nasal retina. Thus, in myopic eyes, the nasal-temporal retinal shape is not symmetrical, and the temporal retinal shape is steeper than the nasal retinal shape. Zhang et al. found that peripheral refraction with single-vision spectacle lens exhibited an asymmetric pattern of myopia development between the nasal and temporal retina, with greater myopia shift in the temporal retina. Similar to our previous study of myopic children wearing single-vision spectacles, asymmetrical growth expansion accentuated the asymmetry of ocular morphology. However, in myopic children who wore OK lenses for one year, the nasal and temporal aspects of the retina showed the opposite trend of expansion in which the eye length in the temporal region increased slower than that for the nasal side, compensating for preceding asymmetrical eye growth. In the current study, for group L with a larger d_{ave}, the AL elongated slower than for group S in the central and peripheral retina (eccentricity at N10 and T10), and the coefficient ‘a’ was larger (the absolute value was smaller) in group L (p = 0.04) after wearing the OK lens for one year, manifesting a more oblate retinal shape. The slope ‘K’ decreased in the nasal (K_{N}, p = 0.002) and temporal (K_{T}, p = 0.004) regions of the retina in group L, which manifested a flatter slope in both sides of the retina in this group, whereas the slope for group S remained unchanged (p > 0.05 – see Table 6). This finding indicates that the reduction in AL elongation from the OK lens may be regarded as compensating for temporal retinal overextension back to normal eye development, and that greater TZ decentration means stronger compensation to recover to normal ocular elongation. Zhang et al. showed a similar finding, in that wearing defocus incorporated multiple segment lenses maintained a relatively constant relative periphery myopic defocus while simultaneously slowing central AL elongation through alteration of retinal shape. We speculate that symmetrical growth of the retina promotes emmetropisation, and that abnormal temporal retinal extension promotes the development of myopia, so changing peripheral refraction in the temporal retina may be a good means of blocking or slowing excessive ocular extension. In the present study, we used a weighted average TZ decentration, considering that TZ decentration mainly occurred in the horizontal meridian. Future studies could employ the vector of TZ decentration to obtain more information based on a larger sample size.

A limitation of this study was only detecting retinal shape in the horizontal direction, although previous studies have shown that myopia has a greater effect on peripheral refraction along the horizontal aspect, rather than in the vertical meridian. In conclusion, an OK lens with a 6 mm optical zone diameter and greater TZ decentration (d_{ave}) contributed to myopia control by reshaping the retina to become more oblate. Further studies are required to assess the effect of improving the optical design of OK lenses on myopia control and the factors causing asymmetric retinal extension.
ACKNOWLEDGEMENTS
The abstract was presented at the 17th International Myopia Conference on 14 September 2019 in Tokyo, Japan.

CONFLICT OF INTEREST
All the authors have declared that there is no conflict of interest.

AUTHOR CONTRIBUTIONS
Xue Li: Formal analysis (equal); funding acquisition (equal); project administration (equal); writing – original draft (lead); writing – review and editing (lead).
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ORTHOKERATOLOGY DECENTRATION PROMOTES RETINAL RESHAPING

How to cite this article: Li X, Huang Y, Zhang J, Ding C, Chen Y, Chen H, et al. Treatment zone decentration promotes retinal reshaping in Chinese myopic children wearing orthokeratology lenses. Ophthalmic Physiol Opt. 2022;42:1124–1132. https://doi.org/10.1111/opo.12996