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Change in Corneal Power Distribution in Orthokeratology: A Predictor for the Change in Axial Length

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Purpose: To investigate the correlation between the change in spatial corneal power distribution and axial length (AL) elongation during orthokeratology (Ortho-k) treatment using mathematical methods.

Methods: Seventy-six subjects aged from eight to 13 years were fitted with Paragon CRT ortho-k lenses. Manifest refraction and corneal topography were checked at baseline and one day, one week, two weeks, one month, three months, six months, nine months, and one year after lens wear. AL was measured at baseline and the six-month and one-year follow-up visits. Relative corneal refractive power change (RCRPC) was calculated by a polynomial function and a monomial function. Factors including age, baseline spherical equivalent refractive error (SER), power exponent and RCRPC were tested against one-year AL growth in a stepwise multiple linear regression model.

Results: A total of 67 subjects completed the one-year study, with nine dropouts. The SER significantly reduced after the first month of lens wear ($P < 0.001$). AL significantly changed over time ($P = 0.0003$) with the annual growth being 0.32 ± 0.18 mm. Power exponent and RCRPC were stable throughout the follow-up visits (all $P > 0.05$). Change of AL was significantly correlated with baseline age (standardized $\beta = -0.292$, $P < 0.001$) and power exponent (standardized $\beta = 0.691$, $P < 0.001$), but not with the other factors being analyzed. The regression equation using baseline age (X_1) and power exponent (X_2) as functions for 1-year AL change (Y) was $Y = 0.438\text{-}0.034X_1 + 0.309X_2$, with R^2 being 0.752.

Conclusions: The asphericity of the treatment zone may affect axial elongation in children undergoing ortho-k therapy.

Translational Relevance: Because the ortho-k lens design may affect myopia control effect in children undergoing ortho-k therapy, future ortho-k lenses should consider applying these designs to obtain a better myopia control effect in children.

Introduction

Myopia has become a worldwide public health issue, affecting 1.4 billion people around the world. China has the highest prevalence of myopia in the world, with a prevalence of up to 50% according to the report of World Health Organization.[1,2] Although the cause of myopia is not fully understood at present, the progression of early-onset myopia is usually attributed to a faster-than-normal axial length (AL) elongation.[3,4] Therefore various methods including optical and pharmaceutical measures have been used to halt myopia progression and axial elongation, namely, myopia control.

Orthokeratology (Ortho-k) is an optical treatment that uses a reverse geometry–designed gas-permeable contact lens to be worn overnight.[5,6] The ortho-k lens reshapes the corneal surface during sleep to correct refractive error, yielding a flattened central cornea and a steepened mid-peripheral cornea. Ortho-k has been proved to be effective in reducing myopia

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progression by 30% to 50% in comparison with single-vision spectacle or soft contact lens wear in children.[7–10] It has been hypothesized that the aspheric change from the flattened central cornea to the steepened mid-peripheral cornea will induce a relative peripheral myopic defocus on the retina, which in turn prevents axial elongation.[11–13]

It has been suggested in numerous researches involving chicks that eye growth is regulated not only by the direction but also by the strength of defocus imposed on the retina.[14,15] In one study on rhesus monkeys, researchers found that imposed defocus beyond about 20° from the fovea does not consistently alter central refractive development.[16] Consistent with these findings is that one study investigated the influence of pupil size on myopia control efficacy in ortho-k, and the authors found that axial elongation was slower in children subjects who had larger-than-average pupil diameter. They hypothesized that a larger pupil size may allow more peripheral defocus to fall within the pupil margin and therefore provide greater myopia control efficacy.[17] Studies involving dual-focal and multifocal soft contact lenses to slow myopia progression also suggested that lenses with defocus rings closer to the visual axis had a greater control effect than those with defocus rings closer to the lens edge, regardless of the defocus power.[18] These findings opened the possibility that ortho-k lens design can be modified to enhance its myopia control efficacy, most likely through inducing a more aspheric optical zone and more subsequent relative myopic defocus closer to the visual axis.

Early attempts on ortho-k lens design did not involve a change in optical zone diameter or asphericity and therefore failed to alter the retinal image profile as compared to conventional lens designs.[7,19] More recent lens designs have shown promise in effectively decreasing the treatment zone size and bringing the mid-peripheral defocus ring closer to the pupil.[20,21] However, most previous studies investigating the effect of corneal refractive power change on axial elongation after ortho-k did not analyze the spatial corneal power distribution (e.g., asphericity and diameter of the optical zone).[22] The current study used a mathematical method to quantify the spatial corneal power distribution after ortho-k and aimed at investigating the correlation between the change in spatial corneal power distribution and AL elongation during short-term ortho-k treatment in a group of myopic Chinese children.

Methods

Study Design

This prospective study was conducted at the Fudan University Eye and ENT Hospital, Shanghai, China, from November 2019 to November 2020. This study was approved by the Ethical Committee of the Hospital, and all work was carried out in accordance with the tenets of the Declaration of Helsinki.

Subjects

Seventy-six subjects who met the inclusion criteria were enrolled in this study. The detailed inclusion criteria and exclusion criteria were listed in Table 1. Before treatment, all subjects underwent a comprehensive ocular examination assessment, including uncorrected distance visual acuity, corrected distance visual acuity, manifest refraction, slit lamp examination, corneal topography, AL and intraocular pressure.

Contact Lens Fitting

After baseline measurements, eligible subjects were fitted with Paragon CRT reverse geometry gas-permeable contact lenses. The lens material was paflufocon D, with oxygen permeability (Dk) of 100 (ISO) 10^{-11} (cm^2/s)/(mLO$_2$/mL × mm Hg). Lens fitting was performed following the manufacturer's fitting guide and lenses ordered based on subjects' manifest refractions, fluorescein patterns on slit-lamp examination, and corneal topography. To achieve a better refractive correction, either spherical or dual axis lenses were used in this study, based on the anterior corneal toricity. Lenses were ordered with over-refraction targeted at +0.50D to +1.00D. The subjects were requested to wear lenses every night for at least eight consecutive hours. All subjects and their guardians were educated regarding how to wear and care for their lenses. Their lens-wearing compliance was collected and logged with the researchers during every follow-up visit.

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria
Refractive error between −1.00 to −4.00 D
Astigmatism below 1.50 D
FK between 40.00 and 46.00 D
Monocular CDVA no worse than 20/20
Age ≤ 14 years
Exclusion Criteria
Any eye disorders
Any systemic disease
IOP greater than 21 mm Hg
History of CL wear in the past 30 days
Atropine treatment for myopia control

FK, corneal refractive power along the flat meridian; IOP, intraocular pressure; CDVA, corrected distance visual acuity; CL, contact lens.

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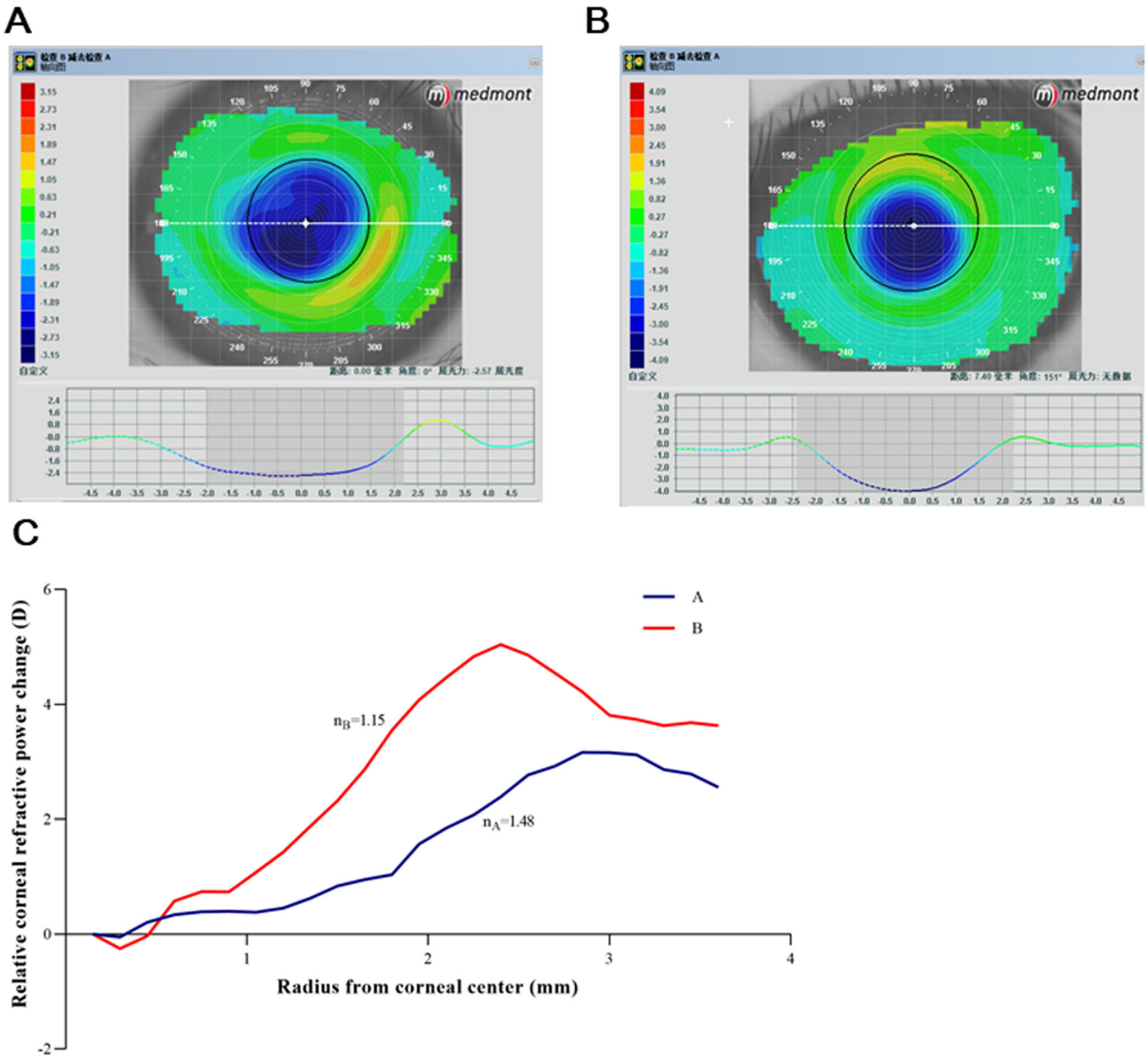

Figure 1. Power difference topography maps showing different power distribution patterns of two eyes with (A) lower aspheric treatment zone and (B) higher aspheric treatment zone. Relative corneal refractive power change and power exponent (n_{A}, n_B) corresponding to the two eyes shown above (C).

Follow-up Visits

Subjects were instructed to return for follow-up visits one day, one week, two weeks, one month, three months, six months, nine months, and one year after commencement of ortho-k treatment. At each visit, the subjects underwent measurements including visual acuity, manifest refraction, slit-lamp examination and corneal topography. AL was measured at baseline and the six-month and one-year visits.

Corneal Topography and Analysis

As the central data was of greatest importance in this research, axial maps from the topographer (Medmont E300; Medmont International Pty Ltd., Nunawading, Australia) were used for calculation of corneal refractive power (CRP). Data from the central cornea are more accurate on the axial map because the averaging algorithms in the software assume the cornea to be a spherical surface.

The change in CRP normalized to the apical CRP was defined as relative corneal refractive power change (RCRPC). First, the baseline and one-year axial power maps were compared using a differential map. Then, data along the horizontal and vertical meridians (averaged on 0°, 90°, 270°, and 180°) were selected to represent the overall RCRPC in this study. To calculate RCRPC, topographic data were imported into MATLAB (Version 7.9; Math Works, Natick, MA, USA) and were respectively fitted with a polynomial function using the form $y = Ax + Bx^2 + Cx^3 + Dx^4 + \ldots + Nx^n$. The maximum RCRPC ($Y_{max}$) and the corresponding distance from corneal apex (X_{max})

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were output by the software according to the polynomial function. To illustrate the spatial distribution of RCRPC in a simple way, a monomial function using the form $y = x^n$ (where x is the distance from corneal apex and y is RCRPC, n is the power exponent) was also used. A lower power exponent represents a higher asphericity of the treatment zone. Figure 1 illustrates the corneal topography maps and the corresponding RCRPC in two representative subjects.

Statistical Analyses

Only data from the right eyes were included for analysis. Normality of data was tested by the Shapiro-Wilk test. The baseline biometric data were compared using unpaired *t* testing. The variables including SER, AL, power exponent, and RCRPC of each follow-up visit were compared using repeated-measures analysis of variance. Factors including age, baseline SER, power exponent and RCRPC were tested against one-year AL growth in a stepwise multiple linear regression model. The minimum sample size to predict one-year AL change with an effect size of 0.25, α of 0.05, and power of 80% is 42, calculated using G power software version 3.1 (Universität Düsseldorf, Düsseldorf, Germany). The other statistical analyses were performed using SPSS version 23 (IMB Corp, USA). P values <0.05 were considered statistically significant.

Results

A total of 67 subjects completed the one-year study. Nine subjects missed two or more visits during the study and were considered dropouts, and their data were excluded from the final analysis. Data comparison between the 67 completed cases and the 9 dropouts were shown in Table 2 (all $P > 0.05$). All the 67 cases completed this study uneventfully and no severe adverse events were seen (Table 3).

Corneal power distribution one month and one year after ortho-k treatment was displayed in Figure 2. CRP did not significantly change from one month to one year ($P > 0.05$). After ortho-k treatment, the cornea became flattest in the center of the treatment zone and steepened toward the mid-periphery and peaked at approximately 3 mm off the apex, showing an aspheric pattern.

Stepwise multiple linear regression analysis showed that the change of AL was significantly correlated with baseline age (standardized $\beta = -0.292$, $P < 0.001$) and power exponent (standardized $\beta = 0.691$, $P < 0.001$), but not with the other factors being analyzed (Fig. 3). The regression equation using baseline age (X_1) and power exponent (X_2) as functions to predict one-year AL change (Y) was $Y = 0.438\text{-}0.034X_1 + 0.309X_2$, with R^2 being 0.752.

Table 2. Baseline Ocular Biometrics of the Completed Cases and the Dropouts (Mean ± SD)

	Completed Cases (n = 67)	Dropouts (n = 9)	*P* Value
Age	10.02 ± 1.69	10.44 ± 1.81	0.49
Sex (male/female)	30/37	3/6	0.39
SER (D)	−2.55 ± 0.90	−2.36 ± 1.2	0.58
Kf (D)	42.66 ± 1.41	42.47 ± 0.89	0.51
Ks(D)	43.69 ± 1.30	43.49 ± 0.90	0.41
AL(mm)	24.64 ± 0.66	24.59 ± 0.93	0.84

In the 67 eyes being analyzed, the SER reduced significantly after the first month of lens wear ($P < 0.001$). AL significantly changed over time ($P = 0.0003$) with the annual growth being 0.32 ± 0.18 mm. Power exponent and RCRPC were stable throughout the follow-up visits (all $P > 0.05$).

Table 3. Ocular Biometrics of the 67 Subjects (Mean ± SD)

	Baseline	1 Month	3 Month	6 Month	9 Month	1 Year	*P* Value
SER (D)	−2.55 ± 0.90	−0.02 ± 0.15	−0.19 ± 0.47	−0.21 ± 0.46	−0.43 ± 0.73	−0.53 ± 0.81	<0.0001
AL (mm)	24.64 ± 0.66	—	—	24.86 ± 0.65	—	24.96 ± 0.68	0.04
AL elongation (mm)				0.21 ± 0.11		0.32 ± 0.18	0.0003
Y_{max} (D)	—	0.74 ± 0.49	0.78 ± 0.43	0.72 ± 0.53	0.73 ± 0.52	0.72 ± 0.49	0.91
X_{max} (mm)	—	3.06 ± 0.30	2.97 ± 0.24	3.08 ± 0.35	3.014 ± 0.29	3.03 ± 0.35	0.46
Power exponent	—	0.63 ± 0.46	0.65 ± 0.41	0.53 ± 0.41	0.57 ± 0.48	0.52 ± 0.44	0.46

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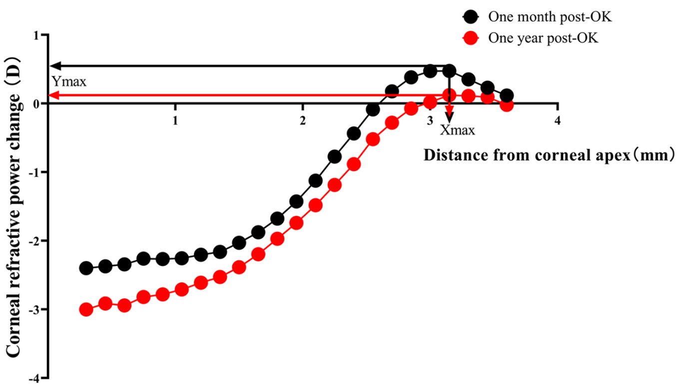

Figure 2. Curves showing corneal power distribution after orthokeratology lens wear. Standard deviation was removed for better profile comprehension.

Discussion

In the current study, by using a mathematical model, we found a significant impact of the spatial distribution of RCRPC after corneal reshaping on AL growth in children wearing ortho-k lenses. Children with a more aspheric treatment zone after ortho-k and older baseline age had less AL growth after one year of ortho-k treatment.

One previous study suggested that the cumulative corneal power change within a certain area (e.g., 3.6 mm in radius) was negatively correlated with axial elongation after ortho-k treatment.[22,23] Another study investigated the correlation between AL growth and change in corneal power at 2, 3, and 4 mm away from the apex along the principal meridians after ortho-k lens wear and found that a slower axial elongation was associated with a greater change in refractive power at some of these tested locations.[24] Despite their findings on the relationship between corneal power change and axial elongation, these studies did not answer the question regarding what specific elements (e.g., size and asphericity of the treatment zone) are responsible for the individual variation in myopia control effect after ortho-k treatment. The spatial distribution of CRP rather than the cumulative amount of corneal power change may be more important in explaining the variance in myopia control effect.

A recent study used Fourier transformation to decompose the RCRPC distribution after ortho-k treatment and found that a larger modulation of maximal RCRPC was associated with a slower axial elongation at one year.[25] The authors found that the threshold of Y_{max} (maximum RCRPC) to have an 80% chance of achieving clear control effect (annual axial elongation <0.3 mm) was 4.5 D. In contrast, the current study did not reveal a significant correlation between Y_{max} and axial elongation. The disparity between the two studies may be explained in a few ways. First, the subjects in this study (mean, 10.0 years) were much younger than those enrolled in the previous study (mean, 11.8 years), and age has been shown to interplay with corneal power change in their effect on axial elongation in the current study. Second, the lens design differs between the two studies (CRT vs. Euclid), which may have a profound impact on the spatial distribution of CRP (e.g., the size and asphericity of the treatment zone).

Experiments involving chicks and monkeys suggest that an integrated peripheral myopic defocus can reduce axial elongation in these animal models.[14,15,26] Recently, an experiment on rhesus monkeys further suggested that myopic defocus in the near periphery can slow axial growth, but those beyond about 20° from the fovea do not consistently alter central refractive

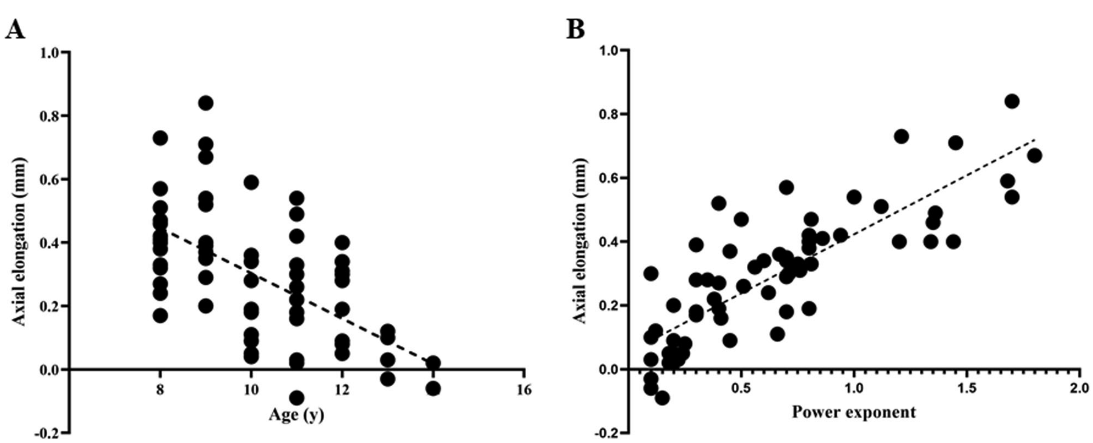

Figure 3. Scatter plots showing the correlation between axial length elongation during one year of orthokeratology treatment with (A) age and (B) power exponent of the monomial function.

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development.[16] If the same philosophy can be applied to human eyes, X_{max} (location of maximum RCRPC), rather than Y_{max}, plays a more important role in myopia control during ortho-k treatment. Interestingly, the X_{max} value of the current study ranged from 2.26 mm to 3.60 mm, corresponding to approximately 20° to 30° from the fovea,[27] beyond where induced myopic defocus is most effective on axial growth. Therefore the spatial distribution of corneal power within the "effective zone" is critical, with higher-asphericity (representing the speed of approaching Y_{max}) corneas inducing more myopic defocus within the pupil margin, which in turn reduces axial elongation.

Two recent studies compared axial elongation in juveniles wearing ortho-k lens designs with different back optic zone diameter (BOZD). Both studies found that the lenses with smaller BOZD had a greater myopia control effect as compared to lenses with larger BOZD.[28,29] We measured RCRPC in subjects wearing ortho-k lenses with 5 mm and 6 mm BOZD in a pilot study (unpublished) and found that 5 mm BOZD lenses tended to induce a smaller (≈2.0 mm) and more aspheric treatment zone than that of 6 mm BOZD lenses (2.5–3.0 mm). If decreasing the BOZD has a mutual effect on the asphericity of the treatment zone, which in turn enhances the myopia control effect, then ortho-k lenses with an effective reduction in treatment zone size will in theory benefit those fast myopia progressors. More studies are needed to testify this hypothesis.

Another possible explanation for better myopia control effect in the subjects with smaller optical zone as opposed to those with larger optical zone after ortho-k is that a greater higher-order aberration may have been induced in the former group. Previous studies have suggested that ortho-k induced higher-order aberration, including spherical and coma-like aberration, may play a role in the myopia control effect seen in ortho-k treatment.[30] However, results from these studies, including the current one, revealed the correlation rather than the causal relationship between different variables and axial elongation. Further studies are needed to clarify which of the above-mentioned variables is the most critical for myopia control.

The strength of this study was that we adopted a methodology of calculating RCRPC with maximum retention of the real corneal power change, which remained consistent throughout the study. The first limitation was that we only used one lens design and therefore could not answer the question regarding whether manually modifying the size and asphericity of ortho-k lens treatment zone had any impact on AL growth. The second limitation is the relatively short study period. Studies with longer terms are needed to illustrate whether the impact of spatial distribution of CRP on axial elongation can be sustained over time.

In conclusion, the current study provided a simplified and repeatable methodology to illustrate the detailed corneal refractive power change during ortho-k treatment. The results indicated that the asphericity of the treatment zone may affect axial elongation in children undergoing ortho-k therapy. Future ortho-k lenses should consider applying designs that can induce a more aspheric treatment zone to enhance myopia control efficacy in children.

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