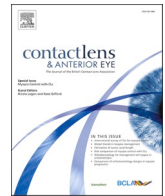




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The effect of corneal power distribution on axial elongation in children using three different orthokeratology lens designs

Zhe Zhang^{a,b,c}, Jiaqi Zhou^{a,b,c}, Li Zeng^{a,b,c}, Feng Xue^{a,b,c}, Xingtao Zhou^{a,b,c}, Zhi Chen^{a,b,c,*}

^a Department of Ophthalmology and Vision Science, Eye and ENT Hospital, Fudan University, Shanghai, China

^b NHC Key Laboratory of Myopia (Fudan University), Shanghai, China

^c Laboratory of Myopia, Chinese Academy of Medical Sciences, Shanghai, China

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ABSTRACT

Purpose: To investigate the correlation between spatial corneal power distribution and one-year axial length (AL) elongation using three *ortho-k* lens designs by a unified mathematical method.

Methods: A total of 137 subjects were included: 42 with Euclid lenses, 28 with DRL lenses, and 67 with CRT lenses. AL elongation, Xmax, Ymax and power exponent were compared among the three groups. One-year 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), Xmax, Ymax and power exponent was tested against one-year AL growth in a stepwise multiple linear regression model.

Results: The power exponent ($F = 7.29, P = 0.0012$) and Xmax ($F = 62.88, P < 0.0001$) of the DRL group was significantly smaller than that of the other two lens groups. Ymax was not significantly different among three lens groups ($F = 1.18, P = 0.31$). The one-year AL elongation of the DRL group (0.09 ± 0.14 mm) was significantly slower than that of the Euclid group (0.26 ± 0.14 mm, $P = 0.002$) and CRT group (0.32 ± 0.18 mm, $P < 0.0001$). AL elongation was significantly correlated with Xmax (standardized $\beta = 0.196, P = 0.003$), power exponent (standardized $\beta = 0.644, P < 0.001$), and age (standardized $\beta = -0.263, P < 0.001$), with R^2 being 0.608.

Conclusion: A smaller and more aspheric treatment zone may be beneficial for reducing axial elongation in children undergoing *ortho-k* treatment, regardless of their baseline myopic refractive error.

1. Introduction

The prevalence of myopia in children is increasing worldwide and proposes a major public health concern especially in the East Asian regions [1,2]. Extensive progression of myopia and axial elongation increases the risk of a series of myopia pathological changes, such as macular degeneration, posterior scleral staphyloma, and choroidal neovascularization. To curb these potential complications of myopia, many strategies have been developed to slow the progression of myopia in children and adolescents [3,4].

As one of the most effective methods to slow myopia progression and axial elongation, orthokeratology (*ortho-k*) has been widely used [5–10]. It is estimated that there are currently >1.5 million *ortho-k* lens users in China [11]. Reverse-geometry *ortho-k* contact lenses incorporate a base curve flatter than the central corneal curvature to flatten the central cornea and a steeper secondary curve to provide a negative hydraulic

force to aid centration of the lens and a speedy corneal reshaping effect, which is characterized by a flattened central treatment zone surrounded by a steepened mid-peripheral annular zone (“defocus ring”) after overnight lens wear. While the mechanism behind the myopia control effect of *ortho-k* is still unclear, it has been hypothesized that *ortho-k* lenses convert relative peripheral retinal defocus of the eye from being hyperopic pre-treatment to being myopic post-treatment and therefore retarding axial elongation [12,13], parallel to the findings in animal studies that indicated inhibitory effects of peripheral myopic defocus on axial elongation and myopia development [14,15].

Based on this assumption, various *ortho-k* lenses of different optical designs may result in different treatment zone profile and consequently different efficacy in myopia control. One previous study found that the change of relative corneal refractive power shift after *ortho-k* treatment was negatively correlated with two-year axial elongation [16]. However, that method did not take into consideration the power distribution

* Corresponding author.

E-mail address: peter459@aliyun.com (Z. Chen).

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profile within the treatment zone, which may provide further clues in understanding the mechanism underlying ortho-k's myopia control effect. For example, a smaller treatment zone size may bring the “defocus ring” closer to the pupil center, allowing more myopic defocus to fall within the pupil margin, therefore enhancing the myopia control effect of ortho-k. This hypothesis has been supported by a meta-analysis on bifocal or multifocal soft contact lenses intended for myopia control, which showed 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 [17].

In recent years, attempts have been made to improve ortho-k lens designs in order to increase myopia control efficacy. Some lens designs have shown promise in effectively decreasing the treatment zone diameter and bringing the mid-peripheral defocus ring closer to the pupil [18,19]. One recent study used a mathematical method to quantify the spatial corneal power distribution after ortho-k and revealed that the asphericity of the treatment zone plays a major role in reducing axial elongation in ortho-k [20]. In that study, however, the authors used only one ortho-k lens design (Paragon CRT, USA). The purpose of the current study was to explore whether this mathematical method can be applied to evaluate the spatial corneal power distribution in three ortho-k lens designs, and to investigate the correlation between spatial corneal power distribution and one-year axial elongation using these three ortho-k lens designs.

2. Methods

2.1. Study design

This study comprised of data collected from two independent clinical trials on ortho-k, with part of the results published previously [20,21]. In one of the two studies, subjects were randomly allocated to wear Euclid or DRL lenses. In the other, subjects were all assigned to wear CRT lenses. Both studies were conducted at the Eye and ENT Hospital of Fudan University and Eye Hospital of Wenzhou Medical University between 2020 and 2022, approved by the Ethics Committee of the two hospitals, and carried out in accordance with the tenets of the Declaration of Helsinki. All subjects and their parents received and signed an informed consent before enrollment.

2.2. Subjects

Inclusion criteria comprised subjects with age between 8 and 13 years, refractive error between -1.00 to -4.00 diopters (D), astigmatism below 1.50 D, and corneal refractive power along the flat meridian (FK) between 40.00 and 46.00 D, and monocular corrected distance visual acuity (CDVA) no worse than 20/20. Exclusion criteria comprised subjects with eye disorders or systemic disease, intraocular pressure outside the normal range, history of contact lens wear in the past 30 days, or atropine treatment for myopia control. Before treatment, all subjects underwent a comprehensive ocular examination assessment.

2.3. Contact lenses

Three ortho-k lens designs were used in this study, the Euclid (Euclid Systems Corporation, USA), Double Reservoir Lens (DRL) (Precilens, France) and Corneal Refractive Therapy (CRT) (Paragon Vision Sciences, USA). The detailed information about each lens design was provided by the manufacturer and listed in Table 1.

2.4. Lens fitting

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. All subjects and their guardians were educated as how to wear and care for

Table 1
Comparison of the Three Lenses Studied.

	Euclid	DRL	CRT
Design	Base Curve, Reverse curve, Alignment Curve 1, Alignment Curve 2, and Peripheral Curve	Base Curve, Reverse Curve 1, Reverse Curve 2, Alignment Curve and Peripheral Curve	Base Curve, Return Zone Depth and Landing Zone Angle
Back optic zone diameter	6.2 mm	5.0 mm	6.0 mm
DK	87(ISO)10 ⁻¹¹ (cm ² /seg)/(ml*mm Hg)	100(ISO)10 ⁻¹¹ (cm ² /seg)/(ml*mm Hg)	100 (ISO) 10 ⁻¹¹ (cm ² /s)/(mLO ₂ /mL*mmHg)
Material	Boston EqualensII	Boston XO	Paflucofon D

their lenses. They were instructed to wear the lenses overnight during sleep, with a recommended minimum of 8 h.

2.5. Axial length measurement

Axial length (AL) was measured at baseline, 6-month and 1-year follow-up visit by partial coherence interferometry (IOL Master, Carl Zeiss, Germany) for three times and the data were automatically averaged. AL measurement was done before cycloplegia.

2.6. Follow-up visits

Subjects were instructed to return for follow-up visits 1 day, 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months and 1 year after commencement of ortho-k treatment. At each visit, the subjects underwent measurements including visual acuity, manifest refraction for residual refractive error, slit-lamp examination and corneal topography. The subjects were measured between 9 and 11 am, and each follow-up visit was appointed to match the approximate time window of the first measurement to avoid diurnal variation.

2.7. Corneal topography and analysis

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

The methodology of calculating corneal refractive power was published previously [20]. In brief, the change in corneal refractive power normalized to the apical corneal refractive power 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 meridians (averaged on 0 and 180 degree) were selected to represent the overall relative corneal refractive power change (Fig. 1).

To calculate relative corneal refractive power change, topographic data were imported into MATLAB (Version 7.9; Math Works, USA) and were respectively fitted with a polynomial function using the equation $y = Ax + Bx^2 + Cx^3 + Dx^4 + \dots + Nx^n$. The maximum relative corneal refractive power change (Ymax) and its corresponding distance from corneal apex (Xmax) were output by the software according to the polynomial function (Fig. 2). To illustrate the spatial distribution of relative corneal refractive power change in a simple way, a monomial function using the form $y = x^n$ (where x is the distance from corneal apex, y is corneal refractive power change, and n is the power exponent). A lower power exponent represents a higher asphericity of the treatment zone.

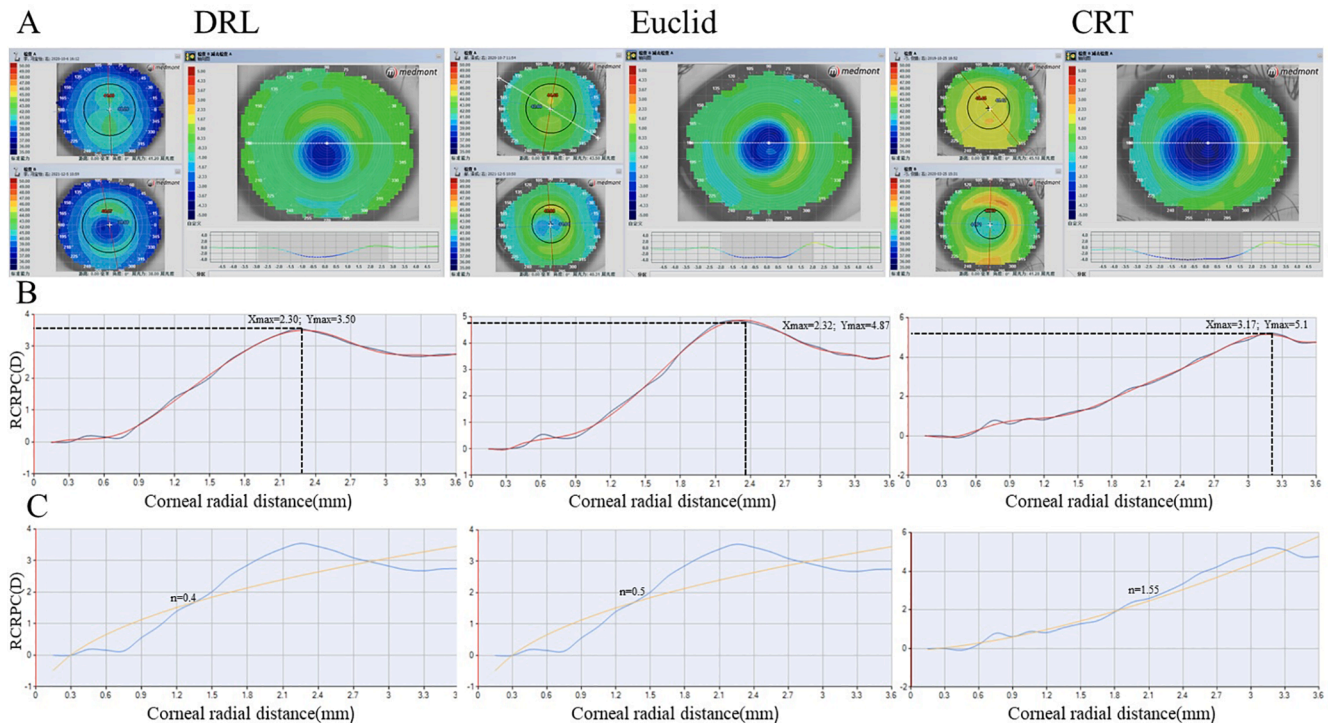


Fig. 1. (A) Axial differential corneal topography map, (B) relative corneal refractive power change, and (C) corresponding monomial function fitting after the treatment using three different orthokeratology lens designs. RCRPC = relative corneal refractive power change.

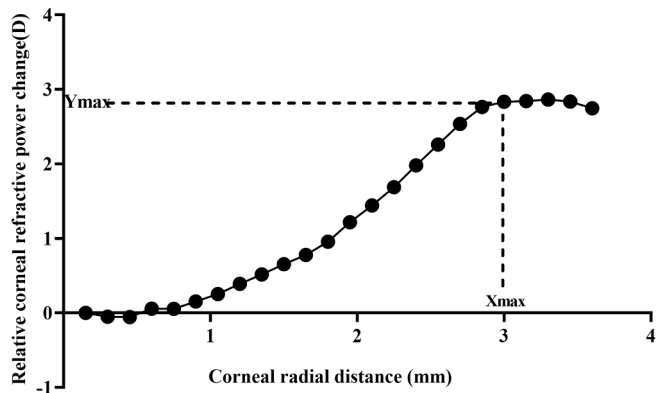


Fig. 2. Description of the curve fitted with a polynomial function. Standard deviation was removed for better profile comprehension.

2.8. Statistical analyses

Only data from the right eyes were included for analysis. All statistical analyses were performed using SPSS version 23 (IMB Corp, USA). Normality of data was assessed using the Shapiro-Wilk test and met in all cases. The variables including age, SER, AL elongation, Xmax, Ymax and power exponent were compared using one-way ANOVA. Tukey’s multiple comparison tests were used for pairwise comparisons. Subjects from the three lens groups were further divided into six sub-groups with SER of $-2.50D$ as the cut-off value for each lens group, and Xmax, power exponent, and AL elongation among the six sub-groups were compared using two-way ANOVA. Sidak’s multiple comparison tests were used for pairwise comparisons. Factors including age, baseline SER, Xmax, Ymax and power exponent were tested against one-year AL growth in a stepwise multiple linear regression model. A value $p < 0.05$ was considered statistically significant.

3. Results

A total of 137 subjects who completed the one-year study were included: 42 with the Euclid lenses of 6.2 mm back optic zone diameter (BOZD), 28 with DRL lenses of 5.0 mm back optic zone diameter, and 67 with CRT lenses of 6.0 mm back optic zone diameter. All treatments were uneventful, and no severe complications were observed.

Baseline biometrics and comparison among groups are shown in Table 2. There were no statistically significant differences among the lens groups as regard to gender, spherical equivalent refraction, corneal refractive power along the flat and steep meridians (all $p > 0.05$).

Relative corneal refractive power change for each lens design was displayed in Fig. 3. After *ortho*-k treatment, the cornea was flattest in the center of the treatment zone and steepened towards the mid-periphery and peaked at approximately 2 to 3 mm off the apex, showing an aspheric pattern. The DRL 5.0 mm back optic zone diameter group peaked faster than Euclid 6.2 mm back optic zone diameter and CRT 6.0 mm back optic zone diameter lenses.

The power exponent of the monomial function for the DRL group was significantly lower than that of the other two groups (one-way ANOVA, $F = 7.29$, $P = 0.0012$; Fig. 4A), indicating that the 5.0 mm back optic zone diameter design tended to induce a steeper slope of corneal power change from the center to the mid-periphery (more aspheric). The Xmax for the DRL group was also significantly smaller than that of the other

Table 2
Baseline ocular biometrics of the completed cases (Mean \pm SD).

	DRL	Euclid	CRT	p value
Age (year)Sex	10.63 \pm 1.76	9.93 \pm 1.63	10.02 \pm 1.69	0.12
(male/female)	14/14	22/20	30/37	0.73
SER (D)	-2.84 \pm 0.98	-2.68 \pm 0.90	-2.55 \pm 0.90	0.39
Kf (D)	42.24 \pm 1.07	42.21 \pm 1.18	42.66 \pm 1.41	0.30
Ks (D)	43.53 \pm 1.17	43.46 \pm 1.31	43.69 \pm 1.30	0.69
AL (mm)	24.86 \pm 0.71	24.92 \pm 0.77	24.64 \pm 0.66	0.15

SER = spherical equivalent refraction; Kf = keratometry along the flat meridian; Ks = keratometry along the steep meridian; AL = axial length.

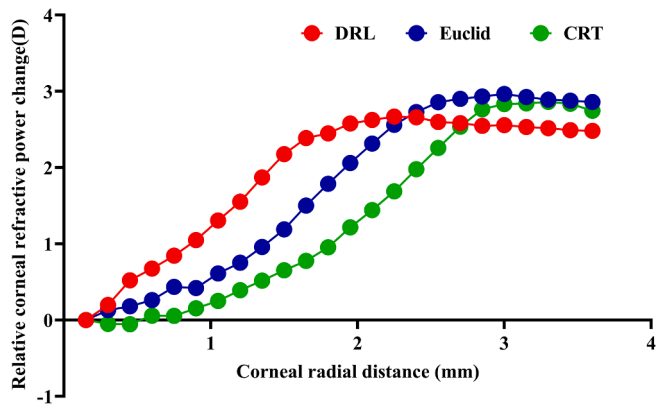


Fig. 3. Distribution of corneal refractive power change as a function of corneal radial distance. Standard deviation was removed for better profile comprehension.

two groups (one-way ANOVA, $F = 62.88$, $P < 0.0001$) (Fig. 4B). There was no significant difference in Y_{max} among the three groups (one-way ANOVA, $F = 1.18$, $P = 0.31$) (Fig. 4C).

When further divided into sub-groups using SER of $-2.50D$ as the cut-off value, X_{max} , power exponent and AL elongation were not significantly different between sub-groups within each lens group (all $P > 0.05$). However, X_{max} ($F = 41.26$, <0.0001), power exponent ($F = 13.53$, $P < 0.0001$), and AL elongation ($F = 12.96$, $P < 0.0001$) were

significantly different among the three lens groups, regardless of the subject's baseline refractive error (See Fig. 5).

The one-year AL elongation of the DRL group (0.09 ± 0.14 mm) was significantly slower than that of the Euclid group (0.26 ± 0.14 mm, $P = 0.002$) and CRT group (0.32 ± 0.18 mm, $P < 0.0001$). Stepwise multiple linear regression analysis showed that the change of AL was significantly correlated with X_{max} (standardized $\beta = 0.196$, $P = 0.003$), power exponent (standardized $\beta = 0.644$, $P < 0.001$), and age (standardized $\beta = -0.263$, $P < 0.001$), but not with the other factors being analyzed. The regression equation using X_{max} (X_1), power exponent (X_2) and age (X_3) as functions to predict one-year AL change (Y) was $Y = 0.169 + 0.065X_1 + 0.311X_2 - 0.032X_3$, with R^2 being 0.608 (See Fig 6).

4. Discussion

In the current study, by using a mathematical model, different spatial power distribution patterns of relative corneal refractive power change were found after the treatment using different *ortho-k* lens designs, which were significantly correlated with one-year axial elongation in these *ortho-k* lens wearers.

Two recent studies found that *ortho-k* lenses with smaller back optic zone diameter had a greater myopia control effect as compared to lenses with larger back optic zone diameter [22,23]. However, in Paune et al's study using DRL lenses, the average age of the enrolled subjects was 13 years, resulting in an overall minimal increase in AL [22]. Guo et al [23] used only one lens design in their study and did not analyze the effect of spatial distribution of relative corneal refractive power change on AL

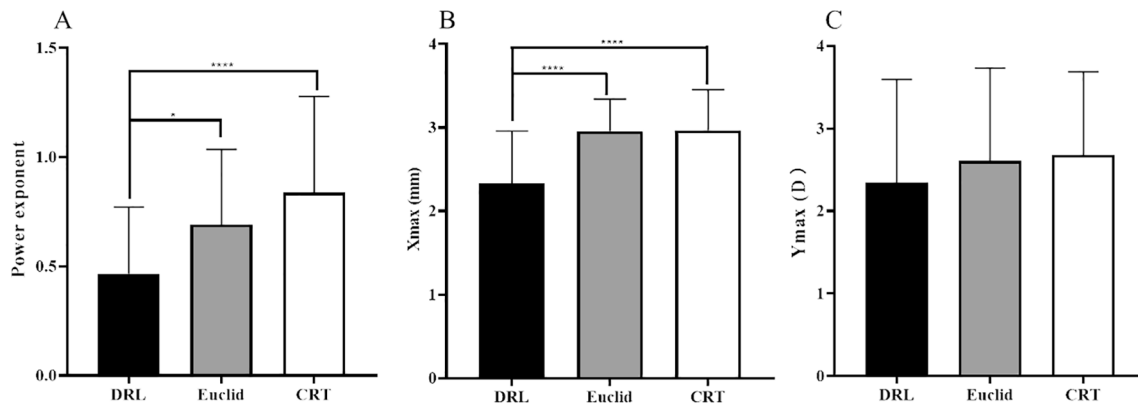


Fig. 4. Bar chart showing (A) power exponent of monomial function for the DRL group was significantly lower than that of the other two groups, (B) radial distance of the maximum relative corneal refractive power change (X_{max}) for the DRL group was also significantly smaller than that of the other two groups, and (C) maximum relative corneal refractive power change (Y_{max}) induced by different lens designs was not significantly different among the three groups (mean \pm SD). * $P < 0.05$, *** $P < 0.001$, **** $P < 0.0001$.

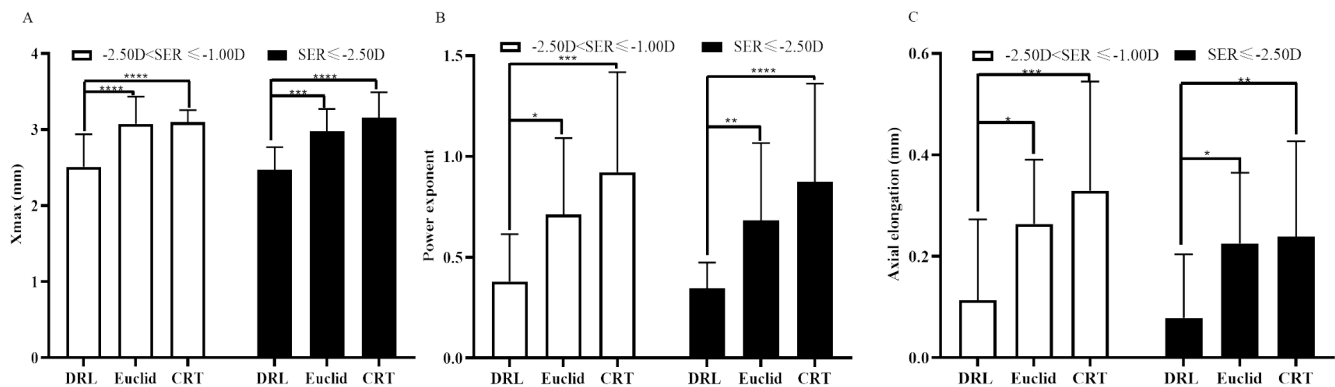


Fig. 5. Bar chart showing that (A) radial distance of the maximum relative corneal refractive power change (X_{max}), (B) power exponent of monomial function, and (C) axial elongation induced by different lens designs were significantly different among the three lens groups, but not different within each lens group using SER of $-2.50D$ as the cut-off value (all $P > 0.05$). * $P < 0.05$, *** $P < 0.001$, **** $P < 0.0001$.

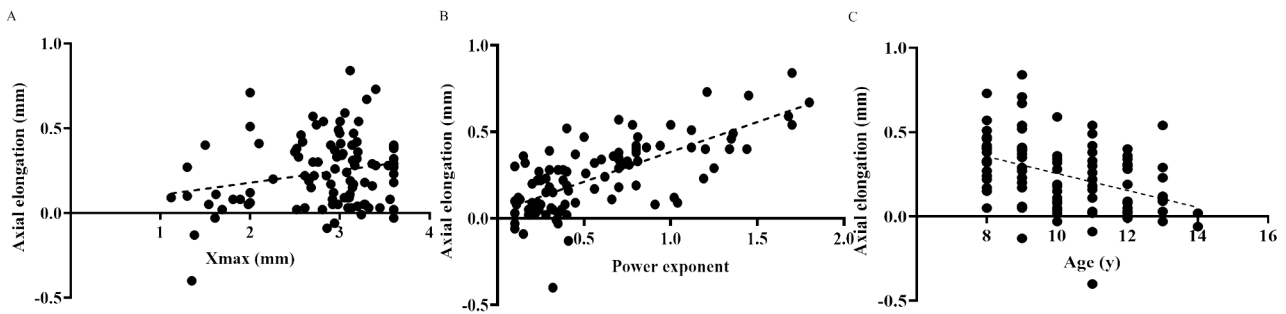


Fig. 6. Scatter plots showing the correlation between axial length elongation during one-year of orthokeratology treatment with (A) Xmax of polynomial function, (B) power exponent of the monomial function, and (C) age.

elongation. In one of the previous studies, DRL 5.0 mm back optic zone diameter lenses tended to induce a smaller and more aspheric treatment zone than that of Euclid 6.2 mm back optic zone diameter lenses [21]. In another study, Zhang et al. [20] further proved that the asphericity of the treatment zone had a significant correlation with axial elongation in children undergoing *ortho-k* therapy. Therefore, this study pooled the one-year treatment data using three different *ortho-k* lens designs to testify whether the effect of treatment zone profile on AL elongation can be applied to all lens designs. To our knowledge, this is the first study that used the same mathematical method to analyze the effect of relative corneal refractive power change on AL elongation after *ortho-k* treatment using over two *ortho-k* lens designs.

The current study found that lenses with a smaller back optic zone diameter (DRL 5.0 mm) tended to induce a smaller (2.33 ± 0.63 mm) Xmax value than CRT 6.0 mm back optic zone diameter (2.97 ± 0.49 mm) and Euclid 6.2 mm back optic zone diameter (2.96 ± 0.38 mm). This study found a positive correlation between Xmax and one-year AL elongation, which is not observed in the previous study [20]. This may be due to the fact that in the previous study, only CRT lenses were used, such that the Xmax values were very close among subjects [20]. In the current study, subjects were treated with different *ortho-k* lens designs with different back optic zone diameters, so Xmax became another factor affecting AL elongation other than treatment zone asphericity, although its effect was much smaller than the latter. The effect of Ymax on AL elongation was not significant in either study, suggesting that the location rather than the amount of maximum relative corneal refractive power change is more important for myopia control.

It should be noted that the effect of *ortho-k* induced relative corneal refractive power change on AL elongation can be explained not only by a converted peripheral defocus but also by an elevated higher-order aberration. Previous studies have shown that increased spherical aberration and coma after *ortho-k* treatment, even with a decentered treatment zone in some cases, was beneficial for myopia control, suggesting that high-order aberration can be used to partly explain *ortho-k*'s effect on AL elongation [24–26]. A smaller aspheric treatment zone after *ortho-k* should have yielded a higher spherical aberration, which was not measured in the current study and should be considered in future studies.

It is noteworthy that one-year axial elongation in the DRL 5.0 mm back optic zone diameter group is 0.09 ± 0.14 mm, being close to the “physiological” axial growth of emmetropic children in the Singapore Cohort Study of the Risk Factors for Myopia (SCORM) [27] and better than most of the previously published studies using conventional back optic zone diameter *ortho-k* lens designs [5–10]. In contrast, the AL elongation approximating 0.30 mm/year in Euclid and CRT lens groups was higher than that of most published *ortho-k* studies, which could have been affected by the lockdown during coronavirus (COVID-19) pandemic. Hu et al. reported that AL elongation speed in young children who experienced the COVID-19 pandemic lockdown was 0.08 mm faster than that in children who didn't experience such period over one year, with AL elongation in myopic children between the ages of 8 and 9

approximated a striking 0.60 mm in one year [28]. Taking this situation into consideration, Euclid and CRT lenses still reduced AL elongation by about 50%. By the same token, *ortho-k* lenses inducing a smaller and more aspheric treatment zone have a potential to enhance the myopia control effect even further, reaching about 85%, suggesting that future *ortho-k* lenses should adopt an optical design that can induce a smaller and more aspheric treatment zone as regard to myopia control.

This study has a few limitations. The first limitation was that despite consistent baseline biometrics, the sample size was not uniform among groups. Data were pooled from two independent studies, making a true randomization impossible. The second limitation is the short follow-up period of only one year. Whether the effect of relative corneal refractive power change on AL elongation can be sustained over time needs further investigation. The third limitation is that there was no control group in this study, with comparisons only available among *ortho-k* lens groups.

In conclusion, this study used a unified and repeatable mathematical model to analyze the relative corneal refractive power change post-*ortho-k* and used it to predict axial elongation across three different *ortho-k* lens designs. A smaller and more aspheric treatment zone induced by *ortho-k* lenses may be beneficial for reducing axial elongation in children and adolescents. Future *ortho-k* lenses should adopt an optical design that can induce a smaller and more aspheric treatment zone as regard to myopia control.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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