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ORIGINAL ARTICLE

One-year results for myopia control with aspheric base curve orthokeratology lenses: A prospective randomised clinical trial

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Abstract

Purpose: To compare the effect of orthokeratology (ortho-k) using aspheric or spherical base curve (BCA vs. BCS) contact lenses on axial elongation and the relative peripheral refraction change (RPRC) in Chinese children.

Methods: Children aged 8–12 years with myopia between −0.75 and −4.00 D and astigmatism ≤1.00 D were randomly assigned to the BCA or BCS group. Peripheral refraction was assessed at 10°, 20° and 30° along the temporal and nasal retina at baseline and at the 12-month visit. Axial length (AL) was measured under cycloplegia at baseline and at the 6- and 12-month visits. Only right eye data were analysed. Repeated-measures analysis of covariance was performed to examine the differences in axial elongation and the RPRC between the BCA and BCS groups.

Results: The 1-year results from 31 BCA and 32 BCS subjects were analysed. No significant between-group differences were found at baseline ($p \geq 0.28$). At the 12-month visit, the BCA lens produced a greater absolute RPRC along the horizontal meridian than the BCS lens ($p < 0.001$). Axial elongation was slower in the BCA group (0.19 ± 0.20 mm) than in the BCS group (0.29 ± 0.14 mm; $p = 0.03$). Axial elongation was correlated with the RPRC at 10° ($r = 0.43$, $p = 0.02$) and 20° ($r = 0.39$, $p = 0.03$) along the temporal retina in the BCA group; however, these correlations were not observed in the BCS group.

Conclusion: The BCA ortho-k lens could improve the efficacy of slowing axial elongation in children. The improved myopia control observed in the BCA group may be the result of a larger myopic shift in relative peripheral refraction within 20° along the temporal retina.

KEYWORDS
aspheric base curve, axial elongation, orthokeratology lens, relative peripheral refraction

INTRODUCTION

Uncorrected refractive error is the second most common cause of blindness worldwide,[1] much of which is due to myopia.[2] The prevalence of myopia has increased over time, especially in Asia.[3] It has been estimated that approximately half of the world's population will be myopic by 2050.[4] In China, the prevalence of myopia exceeds 80% amongst university students.[5] Myopia progression is associated with an increased risk of ocular comorbidities,[6–8] leading to a heavy economic burden on individuals and communities.[9]

It is well documented that orthokeratology (ortho-k) is an effective optical procedure for slowing myopia progression.[10,11] Previous studies have suggested that an ortho-k contact lens could inhibit axial elongation by 36%–63% in children compared with single-vision spectacles.[12–14] An ortho-k lens has been shown to flatten the corneal centre

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and steepen the mid-peripheral area,[15,16] inducing a myopic shift in the RPR, which describes the peripheral refractive profile relative to the central refraction. Currently, the myopic shift in the relative peripheral refraction (RPR) is one of the most accepted hypotheses underlying the myopia control effect of an ortho-k lens.[17,18]

Previous studies have examined the relationship between the relative change in corneal refractive power and axial elongation in children undergoing ortho-k lens treatment.[19,20] They suggested that a larger change in relative corneal power was associated with slower myopia progression. Recently, several studies have suggested that it is not only the summed relative corneal refractive power change but also its distribution that was associated with better efficacy of myopia control following ortho-k treatment.[21,22] A larger relative corneal refractive power change at a shorter distance from the corneal apex could contribute to reduced axial elongation. Hence, a more aspherical treatment zone with ortho-k treatment may result in enhanced retardation of ocular growth.[23] Indeed, Kang and Swarbrick[24] suggested that the peripheral refraction change was related to the corneal refractive power change. Additional evidence from both animal[25] and human studies[26] revealed that a more myopic defocus closer to the fovea would be more valuable in regulating refractive development, which indicates that relative peripheral myopia and its distribution may play a critical role in slowing myopia progression with ortho-k. Therefore, one potential mechanism subserving control efficacy could be that a more aspheric treatment zone leads to a greater myopic shift of the RPR in the near-peripheral retina. It has been demonstrated that the asphericity of the treatment zone could be affected by different ortho-k lens designs, including different optic zone diameters or different lens brands with various zone parameters.[27,28] Moreover, it has been reported that an ortho-k lens with an aspheric base curve (BCA) could produce a more aspherical treatment zone than a spherical base curve (BCS) ortho-k lens.[29] However, whether an ortho-k lens with an BCA could contribute to better myopia control is still unknown.

The main purpose of this study was to investigate whether BCA ortho-k lenses could produce an enhanced myopia control effect in comparison with BCS ortho-k lenses in Chinese children.

Key points

- The use of an aspheric base curve orthokeratology lens could contribute to a larger myopic shift in the relative peripheral refraction along the near-peripheral retina.
- The aspheric base curve orthokeratology lens slowed axial elongation in children 34% more than the spherical base curve ortho-k lens.
- The myopic shift in relative peripheral refraction observed 20° temporally could be a better predictor of the control effect.

METHODS

Study design

This prospective, randomised, controlled, single-masked trial compared axial elongation in myopic children wearing similar ortho-k lenses but with two different designs of base curves (aspheric vs. spherical). The subjects were randomly assigned to the BCA and BCS groups using an interactive web-response system (Eyebright; ebmedical.com). The subjects were masked as to their assignment during the study period.

This study was registered with chictr.org.cn (ChiCTR-2000040990) and approved by the Ethics Committee of West China Hospital of Sichuan University. All procedures followed the tenets of the Declaration of Helsinki. All subjects and their parents were informed of the study content and potential risks of inflammation after lens treatment before participating. The guardians signed informed consent forms based on the principle of voluntary participation.

Subjects

Subject recruitment was advertised on the WeChat app (wechat.com) and at West China Hospital, Sichuan University. Primary school children with low-to-moderate myopia in both eyes were recruited according to the criteria shown in Table 1. Subjects in each group were fitted with the BCA or BCS ortho-k lenses in both eyes. They were asked to wear the lenses for 8–10 h overnight and for a minimum of 6 days a week except when experiencing sickness or abnormal ocular symptoms.

Subjects who were noncompliant with scheduled follow-up visits, had a recurrent corneal epithelial injury or an unsatisfactory lens fit were excluded from the study.

TABLE 1 The inclusion and exclusion criteria of subjects.

Inclusion criteria	Exclusion criteria
• Age: 8–12 years • Myopia between −0.75 and −4.00 D • Astigmatism ≤1.00 D • Anisometropia ≤1.00 D • Corneal astigmatism ≤1.50 D with axis 180° ± 30° • Monocular best-corrected distance visual acuity ≤0.1 logMAR • Agreed to attend the scheduled and aftercare visits • Agreed to be randomised	• Strabismus • Contraindications for wearing contact lenses • Systemic diseases (e.g., Marfan syndrome and Down syndrome) • History of myopia control treatment (e.g., bifocal or multifocal spectacle lenses, soft multifocal contact lenses, orthokeratology and atropine eye drops)

Fitting procedure

The lens parameters were determined by importing the horizontal visible iris diameter, corneal topographical data and subjective refraction into the software provided by the contact lens manufacturer (i calculator; ebmedical.com). Lens-fitting evaluations were performed by the same clinically experienced optometrist using fluorescein 0.5 h after lens insertion. For a satisfactory lens fit, the ortho-k lens was well centred on the cornea, moved by approximately 1 mm in a blink and did not cause significant tear leakage underneath the lens during blinking. The overall fluorescein pattern showed a classic bull's eye pattern, with central touch surrounded by a narrow and deep annulus of tears trapped in the reverse curve. Corneal topography (TMS-4, tomey.com) was performed 40 min after the optimum trial lens insertion to confirm the fitting status of the lens. After ortho-k lens treatment, a plus-power ring could be observed in the corneal tangential difference map, and the centre of the treatment zone was located on the corneal vertex or showed a slight decentration. An unsatisfactory lens fit was regarded as moderate decentration: >0.5 mm with compromised vision or significant decentration: >1.0 mm.

Lenses

The subjects in the BCA and BCS groups were fitted with four-curve ortho-k lenses (Eyebright, ebmedical.com), manufactured using a fluoro silicone-acrylate material with a gas permeability of 125×10^{-11} ($cm^2 \times mLO_2$)/($s \times mL \times mmHg$). The lenses had a central thickness of 0.22 mm, a compression factor of 0.75 D and a total diameter ranging from 10.2 to 11.0 mm. The back optic zone diameter (BOZD) varied with the total diameter of the lens and ranged from 6.0 to 6.4 mm with an interval step of 0.2 mm. The BOZD values for lens diameters of 10.2/10.4 mm, 10.6/10.8 mm and 11.0 mm were 6.0, 6.2 and 6.4 mm, respectively. Detailed information on the total diameter of the lens, BOZD and base curve design for the two groups is shown in Table 2. There was no significant difference in the total diameter or BOZD between the two groups.

Interventions

Subjects were required to attend routine ortho-k aftercare visits at 1 day and 1 week, as well as 1, 3, 6, 9 and 12 months after lens delivery. At each follow-up visit, unaided visual acuity (ETDRS charts; precision-vision.com), the health of the anterior segment of the eye (using a slit-lamp biomicroscope; topcon.com) and corneal topography were assessed prior to the instillation of cycloplegia.

Subjective and objective refractions were assessed under cycloplegia. Objective refractions were measured using an autorefractor (KR-1; Topcon.com). Cycloplegia was achieved by instilling one drop of 0.5% tropicamide four times every 5 min, and all measures were assessed 30 min after the induction of cycloplegia. Peripheral refractions were measured at baseline and at the 12-month visit using an open-field autorefractor (Grandseiko WAM-5500; grandseiko.com) in high-speed mode. Refractive errors were measured at central (0°) and 10°, 20° and 30° locations along the nasal and temporal retina while the subjects kept their head still and moved their eyes to fixate on an on-axis target and six peripheral targets subtending the respective nasal and temporal angles. Ten spherical equivalent refraction (SER) readings were recorded for each location and averaged for data analysis. The RPR was determined by subtracting the central refraction from the peripheral refraction at each location. The relative peripheral refraction change (RPRC) was calculated by subtracting the RPR at baseline from the RPR at the 12-month visit.

Axial length (AL) was obtained with an IOLMaster 700 (Zeiss; zeiss.com) at least 30 min after cycloplegia at baseline and at 6 and 12 months. The first five AL readings with a signal-to-noise ratio >5 and a maximum between-differences of 0.02 mm were averaged for data analysis.

TABLE 2 The orthokeratology (ortho-k) lenses used in the BCA and BCS groups.

	BCA ortho-k lens	BCS ortho-k lens	*p*
BC design	Aspheric	Spherical	–
TD (mm)			
Median [range]	10.6 [10.2, 11.0]	10.6 [10.2, 11.0]	0.51
Median (IQR)	10.6 (10.6–10.8)	10.6 (10.6–10.75)	
BOZD (mm)			
Median [range]	6.2 [6.0, 6.4]	6.2 [6.0, 6.4]	0.75
Median (IQR)	6.2 (6.2–6.2)	6.2 (6.2–6.2)	

Abbreviations: BC, base curve; BCA, aspherical base curve; BCS, spherical base curve; BOZD, back optic zone diameter; IQR, interquartile range; TD, total diameter of the lens.

Sample size

The sample size was calculated based on the Variation of Orthokeratology Lens Treatment Zone (VOLTZ) study.[30] In order to detect a 0.13 mm difference in axial elongation between the two groups and achieve a power of 80% at an $\alpha = 0.05$, a sample size of 23 was required for each group, allowing for a dropout rate of 20%.

Statistical analysis

Statistical analyses were performed by SPSS version 23.0 (IBM; ibm.com). The Shapiro–Wilk test was used to detect the normality of the data. The Mann–Whitney *U* test and an unpaired *t*-test were used to detect differences in non-normal and normally distributed data between the two groups, respectively. The sex composition between the two groups was compared with the chi-square test. Repeated-measures analysis of covariance (RM ANCOVA), adjusted for the BOZD, SER and AL at baseline, was performed to detect the difference in axial elongation between the BCA and BCS groups. In addition, RM ANCOVA, adjusted for the BOZD and SER at baseline, was performed to detect differences in the RPR and RPRC between the two groups at the 12-month visit. Repeated-measures analysis of variance (RM ANOVA) was used to examine the changes in AL and RPR over time in the two groups. Bonferroni corrections were applied for post-hoc comparisons. Spearman correlation analysis was applied to indicate the association between the RPRC and axial elongation in the two groups. Only right eye data were analysed, and a *p*-value < 0.05 was considered as statistically significant.

RESULTS

In all, 70 subjects were enrolled and randomly assigned to the BCA and BCS groups (35 subjects each; see Figure 1). Subjects were recruited from December 2020 to July 2021, and the study was completed in September 2022. In the BCA group, two subjects dropped out of the study due to noncompliance with the lens care procedures and two dropped out due to significant decentration of the lens. In the BCS group, a total of three subjects dropped out: one due to noncompliance with the care procedures, one due to significant decentration of the lens and one due to persistent corneal staining during the first month of ortho-k lens wearing. The corneal epithelium repaired after discontinuation of ortho-k lens wear. Thus, 31 BCA subjects and 32 BCS subjects completed the study. The baseline data did not differ significantly between the two groups (Table 3).

Residual refraction and visual acuity

At the 6- and 12-month visits, the residual objective spherical refraction in the BCA group was more hyperopic than for the BCS group ($p \leq 0.01$, for all; Table 4). In addition, no significant difference in unaided distance visual acuity between the two groups was found at the 6- or 12-month visits ($p \geq 0.20$, for all) (Table 4).

Peripheral refraction

The central refraction exhibited a significant hyperopic shift in both the BCA and BCS groups after treatment with ortho-k lenses ($p < 0.001$, for all). In addition, a hyperopic shift in the mean peripheral refraction was observed along the horizontal meridian for most locations after treatment, except for 30° along the temporal retina, where a myopic shift was observed in both groups. However, the hyperopic shift in the mean peripheral refraction was not significant at 30° along the nasal retina in both groups ($p = 0.11$ and 0.07, respectively) and further was non-significant at 20° along the temporal retina in the BCA group ($p = 0.23$).

The mean RPR along the horizontal meridian before and after wearing the ortho-k lens for 12 months in the two groups is plotted in Figure 2. No significant difference was found in the mean RPR at baseline between the two groups

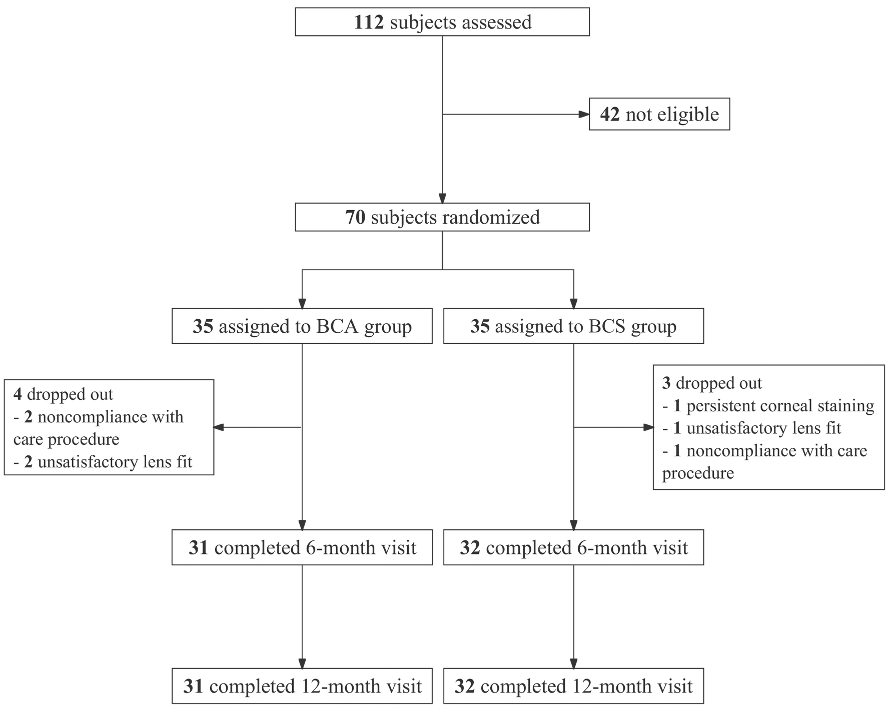

FIGURE 1 Flowchart of the study and dropouts. BCA, aspheric base curve orthokeratology lens; BCS, spherical base curve orthokeratology lens.

($p = 0.09$). After treatment, the RPR exhibited a significant myopic shift at all locations in the BCA group ($p < 0.001$, for all). In the BCS group, a significant myopic shift in the RPR was observed at most locations ($p \leq 0.004$, for all), except at 10° along the nasal retina ($F_{1,62} = 0.06$, $p = 0.80$). Compared with the BCS group, there was more myopic RPR in the BCA group at all locations except at 20° ($F_{1,59} = 2.87$, $p = 0.10$) and 30° ($F_{1,59} = 1.43$, $p = 0.24$) along the nasal retina after treatment (Figure 2a,b). These results suggest that the use of a BCA ortho-k lens could result in a more myopic RPR than the BCS ortho-k lens.

Furthermore, an asymmetrical distribution of the mean RPR along the horizontal meridian, both pre- and post-treatment was observed in the BCA ($p = 0.04$ and $p < 0.001$, respectively) and BCS groups ($p = 0.005$ and $p < 0.001$, respectively). In both groups, the mean RPR was more hyperopic along the nasal than the temporal retina before wearing the ortho-k lens; after treatment, the RPR along the horizontal meridian was more myopic in the temporal retina than in the nasal retina (Figure 2).

TABLE 3 Baseline data for the two groups.

	BCA group ($n = 31$)	BCS group ($n = 32$)	p
Age (years)	9.68 ± 1.22	9.57 ± 1.11	0.73
Male/Female	17/14	18/14	0.91
SER (D)	−2.45 ± 0.82	−2.64 ± 0.89	0.38
Refractive error (D)	−2.28 ± 0.73	−2.45 ± 0.83	0.48
Astigmatism (D)	−0.34 ± 0.33	−0.40 ± 0.31	0.44
Axial length (mm)	24.65 ± 0.64	24.64 ± 0.55	0.93
Flat-K (D)	42.59 ± 1.26	42.51 ± 1.15	0.78
Steep-K (D)	43.48 ± 1.26	43.37 ± 1.22	0.73
Es	0.57 ± 0.10	0.57 ± 0.11	0.87
Em	0.57 ± 0.07	0.55 ± 0.08	0.28
CCT (μm)	525 ± 33	532 ± 28	0.41
IOP (mmHg)	16.46 ± 2.24	16.36 ± 2.92	0.88

Note: Data are expressed as the mean ± standard deviation.

Abbreviations: BCA, aspheric base curve orthokeratology lens; BCS, spherical base curve orthokeratology lens; CCT, central corneal thickness; Em, eccentricity of an ellipse approximating the corneal shape at the meridian of minimum corneal power; Es, eccentricity of an ellipse approximating the corneal shape at the steep meridian; Flat-K, flat meridian corneal curvature; IOP, intraocular pressure; SER, spherical equivalent refractive error; Steep-K, steep meridian corneal curvature.

Relative peripheral refraction change

In Figure 3, the mean RPRC at the 12-month visit for the two groups is illustrated. The RPR manifested a myopic shift at all locations along the horizontal meridian in both groups. Compared with the BCS group, the BCA group exhibited a larger absolute RPRC along the horizontal meridian ($F_{1,59} = 20.44$, $p < 0.001$). The results of post-hoc analysis showed that the mean RPRC at most locations was more myopic in the BCA group than that in the BCS group ($p \leq 0.01$, for all), except at 30° temporally ($F_{1,59} = 3.54$, $p = 0.07$), which suggests that the BCA ortho-k lens could result in a larger myopic shift of the RPR in the near-peripheral retina (10° and 20°).

Axial length

In Figure 4a, the changes in AL over time in the two groups are illustrated. The AL increased over time in both groups. In the BCA group, a significant increase in AL was observed at the 12-month visit (24.84 ± 0.69 mm) compared to baseline (24.65 ± 0.64 mm) ($p < 0.001$). However, there was no significant difference in the AL between the 6-month visit (24.71 ± 0.66 mm) and baseline (24.65 ± 0.64 mm) ($p = 0.07$). In contrast, in the BCS group, a significant increase in AL was found at the 6-month (24.79 ± 0.53 mm) and 12-month (24.93 ± 0.54 mm) visits compared to baseline (24.64 ± 0.55 mm) ($p < 0.001$, for all). These results indicate that there may be a difference in the timeline of the changes in AL between the BCA and BCS groups.

Furthermore, RM ANCOVA was performed to detect the difference in axial elongation between the BCA and BCS groups at the 6- and 12-month visits (Figure 4b). After 12 months of ortho-k lens wear, axial elongation was significantly slower in the BCA group than in the BCS group ($F_{1,58} = 5.04$, $p = 0.03$). Subsequently, post-hoc comparison was applied to compare the difference in axial elongation between the two groups at each follow-up visit. We found a significant difference in axial elongation between the two groups at the 6-month ($F_{1,58} = 8.62$, $p = 0.005$) and 12-month ($F_{1,58} = 5.04$, $p = 0.03$) visits. A difference of 0.1 mm was observed between the two groups at both the 6- and 12-month visits (Table 5). Nevertheless, no significant difference in axial elongation between the two groups was found in the second 6-month period ($F_{1,58} = 0.01$, $p = 0.91$),

TABLE 4 Residual cycloplegic objective refraction and unaided visual acuity at the 6- and 12-month visits in the two groups.

	6-month			12-month		
	BCA	BCS	p	BCA	BCS	p
UVA (logMAR)	−0.01 ± 0.07	−0.02 ± 0.09	0.48	−0.00 ± 0.11	0.03 ± 0.13	0.20
Sphere (D)	0.30 ± 0.92	−0.38 ± 0.69	0.002	0.05 ± 0.97	−0.55 ± 0.79	0.01
Astigmatism (D)	−0.62 ± 0.38	−0.72 ± 0.57	0.74	−0.78 ± 0.56	−0.57 ± 0.45	0.12

Note: Data are expressed as mean ± standard deviation.

Abbreviations: 6-month, 6-month visit; 12-month, 12-month visit; BCA, aspheric base curve orthokeratology lens; BCS, spherical base curve orthokeratology lens; UVA, unaided distance visual acuity.

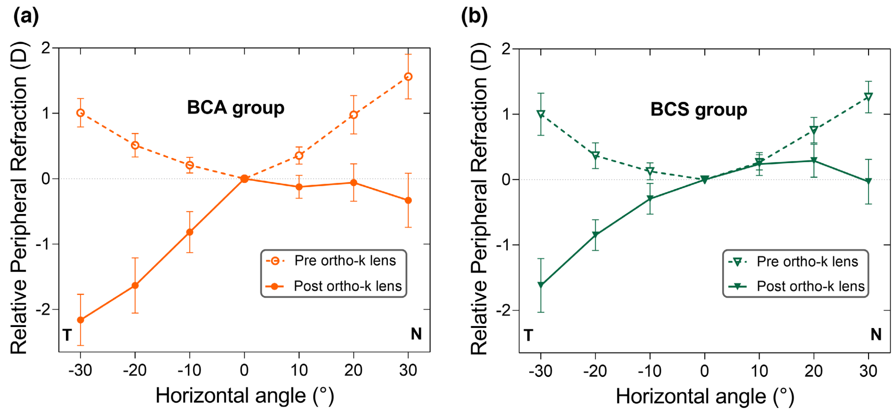

FIGURE 2 Mean relative peripheral refraction along the horizontal meridian before and after wearing the orthokeratology (ortho-k) lens for 12 months in the BCA (a) and BCS (b) groups. BCA, aspheric base curve ortho-k lens; BCS, spherical base curve ortho-k lens; N, nasal retina; T, temporal retina. Error bars represent 95% confidence intervals.

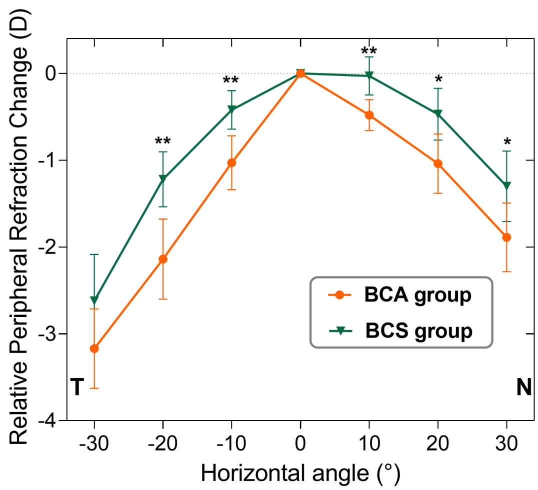

FIGURE 3 The relative peripheral refraction change at the 12-month visit in the BCA (orange) and BCS (green) groups. T, temporal retina; N, nasal retina; BCA, aspheric base curve orthokeratology lens; BCS, spherical base curve orthokeratology lens. Error bars represent the 95% confidence interval. $^{**}p < 0.01$, $^{*}p < 0.05$.

that is, between the 6- and 12-month visits (Table 5). These observations indicate that axial elongation in the BCA group was slower than that in the BCS group.

Additionally, a significant moderate correlation was found between axial elongation and the RPRC at 10° and 20° along the temporal retina at the 12-month visit in the BCA group ($r = 0.43$, $p = 0.02$; $r = 0.39$, $p = 0.03$, respectively) (Table 6), with a greater myopic shift in the RPR being associated with less axial elongation, but these correlations were not observed in the BCS group (Table 6).

DISCUSSION

In the present study, treatment with BCA ortho-k lenses showed a higher absolute RPRC at the 12-month visit and less axial elongation at the 6- and 12-month visits compared with treatment with a BCS ortho-k lens. This suggests that the use of an ortho-k lens with an BCA is more effective in increasing the efficacy of myopia control in children than an ortho-k lens with a BCS.

In baseline observations, a hyperopic RPR along the horizontal meridian was found in both groups. This finding is in line with previous studies,[31,32] which indicated that the peripheral refraction was less myopic relative to the central refraction before ortho-k lens wear. In addition, the RPR was more hyperopic on the nasal than on the temporal retina in both groups, which is also in accordance with previous observations.[33,34] The asymmetrical distribution of the RPR at baseline may be due to the asymmetrical shape of the retina.[35,36]

Consistent with previous investigations[31,35,37] after ortho-k treatment, a myopic shift in the RPR was observed in both groups. Relative peripheral myopia was observed along the horizontal meridian in the BCA group (Figure 2a); however, in the BCS group, relative peripheral hyperopia was still present at 10° and 20° along the nasal retina (Figure 2b). The greater myopic shift in the RPR along the near-peripheral retina in the BCA group may be associated with the more aspheric treatment zone produced by the BCA ortho-k lens.[29] Additionally, the present results indicated that the RPR was distributed asymmetrically along the horizontal meridian at the 12-month visit in the two groups. After ortho-k, the RPR was more myopic temporally than nasally. It seems likely that the flatter curvature of the nasal cornea[38–40] may contribute to the temporal decentration of the ortho-k lens,[15,41] subsequently resulting in an asymmetrical distribution of the RPR.

Notably, the BCA group showed less axial elongation than the BCS group, suggesting that the BCA ortho-k lens could improve the effectiveness of myopia control. In addition, although the axial elongation observed here was slightly higher than reported in previous studies,[11,42,43] it was comparable with that of a recent investigation, which reported axial elongation in the control ortho-k group of approximately 0.30 mm.[44] Indeed, it has been suggested that myopia progression was faster during COVID-19 pandemic than in prior years.[45–47] Moreover, Erdinest et al.[48] reported decreased

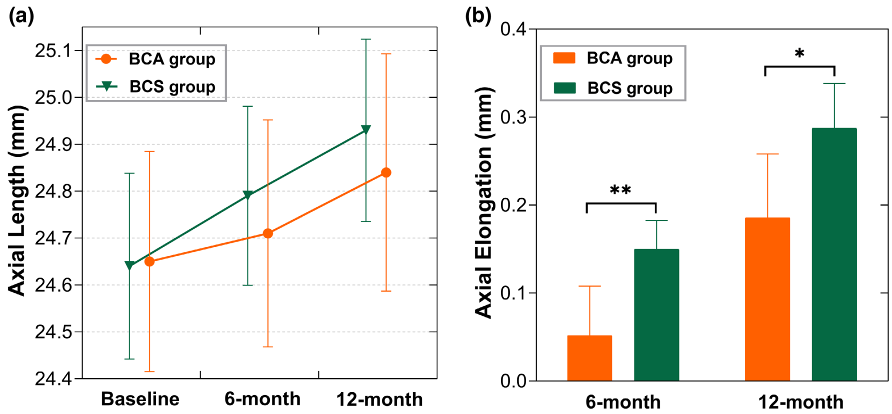

FIGURE 4 Axial length (a) and axial elongation (b) in the BCA (orange) and BCS (green) groups over 1 year. BCA, aspheric base curve orthokeratology lens; BCS, spherical base curve orthokeratology lens; **$p < 0.01$, *$p < 0.05$; Error bars represent 95% confidence interval.

TABLE 5 Axial elongation at the 6- and 12-month visits in the BCA and BCS groups.

	BCA group ($n = 31$)	BCS group ($n = 32$)	p
AE at 6 months (mm)	0.05 ± 0.15	0.15 ± 0.09	0.005
AE at 12 months (mm)	0.19 ± 0.20	0.29 ± 0.14	0.03
AE between 6 and 12 months (mm)	0.13 ± 0.08	0.14 ± 0.08	0.91

Note: Data are expressed as mean ± standard deviation.

Abbreviations: 12 months, 12-month visit; 6 months, 6-month visit; AE, axial elongation; BCA, aspheric base curve orthokeratology lens; BCS, spherical base curve orthokeratology lens.

TABLE 6 Correlation analysis of the relative peripheral refraction change and axial elongation at the 12-month visit in the BCA and BCS groups.

	BCA group		BCS group	
Location (°)	r	p-value	r	p-value
N10	0.19	0.31	−0.20	0.27
N20	0.22	0.23	−0.30	0.09
N30	0.31	0.09	−0.29	0.11
T10	0.43	0.02	0.20	0.28
T20	0.39	0.03	0.07	0.72
T30	0.14	0.46	0.24	0.18

Abbreviations: BCA, aspheric base curve orthokeratology lens, BCS, spherical base curve orthokeratology lens; N, nasal retina; T, temporal retina.

efficacy of 0.01% atropine treatment for myopia control in children during the COVID-19 lockdowns. Hence, the slightly higher axial elongation in the current study could well be associated with the COVID-19 pandemic.

The present results showed that the AL increased over time in the BCA and BCS groups. Li et al.[49] reported that corneal thickness decreases in the first month of ortho-k lens wear, which may have a small impact on AL measurements. Therefore, the actual axial elongation may be impacted by the reduction in corneal thickness, which may be slightly greater than the value measured in the current study. In addition, the enhanced effect in the BCA group was mainly observed during the first 6 months after treatment, since no significant difference in axial elongation in the second 6 months of treatment was found between the two groups. Similar results were also found by Guo et al.[30] who reported that the enhanced effectiveness of the ortho-k lens with a smaller BOZD was only observed during the first 6 months. Previous studies have demonstrated that peripheral refraction, which was probably associated with the control effect,[50–52] stabilised within 3 months following ortho-k lens treatment, and there was no subsequent change thereafter.[37,53] Consequently, this may explain why there was an improvement in the control effect in the first 6 months of treatment, but non-significant differences were found in the second 6 months of treatment between the two groups.

In the BCA group, moderate, statistically significant correlations were observed between the RPRC at 10° and 20° along the temporal retina and axial elongation at the 12-month visit. An increased myopic shift in the RPR was associated with less axial elongation. Li et al.[54] reported that the total RPR, as well as the RPR along the nasal retina, between 15° and 30°, and within 30° were positively correlated with the rate of axial growth in children following ortho-k lens treatment. Ni et al.[55] found that the total RPR may be associated with the control effect of the ortho-k lens. These findings are not consistent with the results of the current study, which may be due to the different techniques used to measure the RPR. However, these results offer evidence that a myopic shift in the RPR may provide a visual signal that slows ocular growth in children after wearing an ortho-k lens. In addition, the association between the RPRC and axial elongation was observed only within 20° temporally. It has been suggested that a more myopic RPR closer to the visual axis may be a better predictor of the control effect.[25] Meanwhile, it was reported that the sensitivity to defocus may differ in the temporal and nasal retina.[56] A significant correlation was observed between the RPRC and axial elongation in the BCA group but not for the BCS group, indicating that the BCA ortho-k lens may provide better regulation of ocular growth by increasing the myopic shift of the RPR within 20° temporally.

One limitation of this study was the lack of a single-vision spectacle group as a control. However, the current study sought to investigate whether the effect of retarding axial elongation could increase if an ortho-k lens with an BCA was used in comparison with a spherical ortho-k lens. A further limitation was that the study had a single-masked design, and the observer was not masked during the study period. However, the measurements obtained were primarily objective, so that the single-masked trial design may not have affected the outcome. Finally, a further limitation was the absence of fluorescein pattern assessment and comparison between the two groups because there is no objective method to measure and compare fluorescein patterns. Further research is necessary to develop objective fluorescein pattern analysis tools that will help to reduce subjectivity in fluorescein pattern assessment in both research and clinical practice.

In conclusion, the present study is the first randomised clinical trial to confirm that a BCA ortho-k lens could increase the efficacy of retarding axial elongation in children compared to a BCS ortho-k lens. The myopic shift in the RPR was moderately associated with axial elongation in the BCA group, supporting the hypothesis that the enhanced myopia control of the BCA ortho-k lens may be related to a greater myopic shift in the RPR within 20° temporally. It is possible that this myopic shift in the RPR could be a better predictor of the control effect. Whether the improved efficacy of the BCA ortho-k lens in slowing myopic progression will be sustained over time requires more extended data.

AUTHOR CONTRIBUTIONS

Tong Liu: Conceptualization (equal); data curation (equal); formal analysis (equal); investigation (equal); methodology (equal); writing – original draft (lead); writing – review and editing (lead). **Changxu Chen:** Conceptualization (equal); data curation (equal); formal analysis (equal); investigation (equal); writing – review and editing (equal). **Wei Ma:** Conceptualization (equal); data curation (equal); formal analysis (equal); funding acquisition (equal); methodology (equal); writing – review and editing (equal). **Bi Yang:** Conceptualization (supporting); data curation (supporting); funding acquisition (equal); writing – review and editing (supporting). **Xi Wang:** Conceptualization (supporting); formal analysis (supporting); funding acquisition (equal); methodology (supporting); writing – original draft (supporting); writing – review and editing (supporting). **Longqian Liu:** Conceptualization (lead); data curation (equal); funding acquisition (lead); methodology (lead); supervision (lead); writing – original draft (equal); writing – review and editing (equal).

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CONFLICT OF INTEREST STATEMENT

The authors have no conflict of interest.

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