· Clinical Research ·

Effects of different orthokeratology lens designs on slowing axial length elongation in children with myopia

Hai-Long Ni, Xiang Chen, Du-Ya Chen, Pei-Ke Hu, Zhi-Yi Wu

Eye Center, the Second Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou 310009, Zhejiang Province, China

Correspondence to: Hai-Long Ni. Eye Center, the Second Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou 310009, Zhejiang Province, China. 2101092@zju.edu.cn

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Abstract

● **AIM:** To elucidate whether differences exist in the impact on retarding the elongation of axial length (AL) among children with myopia when utilizing orthokeratology (ortho-k) lenses employing the corneal refractive therapy (CRT) design versus those employing the vision shaping treatment (VST) design.

● **METHODS:** This retrospective clinical trial aimed to collect and analyze AL data from individuals who wore ortho-k lenses for three years. A total of 654 subjects were enrolled and prescribed one of the three specific brands of ortho-k lenses: CRT, Euclid, and Mouldway. The study's primary focus was to compare the rates of AL elongation and myopic progression across these three brands of ortho-k lenses.

● **RESULTS:** In the 3-year follow-up, the AL elongation exhibited variations of 0.73±0.36 mm in the CRT lens group, 0.59±0.37 mm in the Euclid lens group, and 0.63±0.38 mm in the Mouldway lens group. A noteworthy disparity emerged between the CRT and Mouldway groups ($P<0.01$), as well as between the CRT and Euclid groups ($P<0.001$). Additionally, it was observed that 32.1% of participants who wore CRT lenses experienced a decelerated progression of myopia, in contrast to 47.2% in the Euclid group and 44.4% in the Mouldway group. Statistical analyses revealed a statistically significant distinction between the CRT and Euclid groups ($P<0.01$), and similarly, the CRT group demonstrated a statistically significant difference when compared to the Mouldway group ($P<0.05$).

● **CONCLUSION:** Ortho-k lenses represent a pragmatic strategy for mitigating the advancement of myopia. In contradistinction to ortho-k lenses utilizing the CRT design, those employing the VST design exhibited a more favorable impact regarding retarding AL elongation.

● **KEYWORDS:** myopia; orthokeratology; design; axial length
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INTRODUCTION

Myopia is a prevalent ocular condition from excessive axial length (AL) elongation and heightened corneal power. A mounting body of compelling evidence substantiates the involvement of inherent and acquired factors in the etiology of myopia[1]. Myopia is linked to a spectrum of sight-threatening complications, including but not limited to macular degeneration, retinal detachment, and cataracts. High myopia, which has the highest risk of complications[2], is particularly noteworthy. Onset at a younger age is a predictive factor for developing high myopia[3]. By 2050, it is estimated that the number of individuals with myopia worldwide will reach approximately 4758 million, with 938 million having high myopia[4]. Given myopia's significant prevalence and severe complications, its prevention and management have garnered substantial attention.

Myopia can be corrected using spectacles, contact lenses, and surgical interventions. The precise mechanisms underlying the onset and progression of myopia lack consensus, giving rise to various proposed hypotheses. Among these, the peripheral retinal optical defocus hypothesis is one of the predominant theories[5]. Peripheral retinal hyperopic defocus denotes a situation in which the retinal image falls behind the retina, resulting in choroidal thinning and rapid axial elongation. In contrast, peripheral retinal myopic defocus involves the retinal image positioned in front of the peripheral retina, leading to choroidal thickening and a gradual elongation of the AL[6-7]. Building upon the peripheral retinal myopic defocus hypothesis, many interventions have been formulated and implemented in clinical practice, including defocus spectacles[8-9], defocus soft contact lenses[10], and orthokeratology (ortho-k) lenses[11].

Table 1 Parameters of ortho-k lenses of CRT, Euclid, and Mouldway

Parameters	Design	Curve	Origin	Material	Dk (×10^{-11})	CT (mm)	BOZD (mm)
CRT	CRT	3	USA	HDS 100	100	0.16	6.0
Euclid	VST	5	USA	Boston Equalens II	95	0.22	6.2
Mouldway	VST	4	CHN	Boston XO	100	0.24	5.9

Dk: Oxygen permeability (cm^2/s) [mLO_2/(mL×hPa)]@35°C; CT: Central thickness; BOZD: Back optic zone diameter; CRT: Corneal refractive therapy; VST: Vision shaping treatment; ortho-k: Orthokeratology.

Ortho-k lenses are crafted from highly oxygen-permeable materials and engineered with reverse geometry, facilitating the reversible reshaping of the cornea and reduction of corneal power[8]. Numerous studies have consistently demonstrated the efficacy of ortho-k lenses in effectively slowing down myopia progression[12-16]. Systematic reviews have provided moderate-certainty evidence that ortho-k lenses effectively control myopia[17].

With the continual development of interventions aimed at myopia control, various ortho-k lens designs have emerged. Two primary designs of ortho-k lenses are available in the market: corneal refractive therapy (CRT) and vision shaping treatment (VST). CRT-design lenses feature three distinct zones, namely the optical zone, reverse zone, and landing zone. These lenses adhere to the tangential design of the cornea and are based on its sagittal height[18]. The zones of VST-designed lenses vary based on their respective brands. In contrast to VST-designed lenses, CRT-designed lenses provide enhanced comfort and adaptability for wearers. The selection process hinges upon comprehensive factors, including lens fit, parental perspectives, and practitioner preferences. Previous numerous studies primarily investigate the efficacy of ortho-k lenses relative to alternative myopia control interventions. Now, the divergence in myopia retardation effects between CRT and VST lenses arouse attention. Lu *et al*[19] discovered that VST lenses exhibited a better influence in decelerating AL elongation than CRT lenses.

Numerous brands with VST design, such as Euclid and Mouldway, have become available. Our study included different ortho-k lenses with VST design. The CRT, Mouldway, and Euclid lenses are the predominant ortho-k brands in China. Of particular significance, Mouldway lenses are the first ortho-k lenses produced by a Chinese manufacturer and have garnered a substantial number of wearers. Hence, this study aimed to discern the disparity in myopia control effectiveness between CRT and VST lenses. AL data from individuals who had worn ortho-k lenses for three years were compiled and subjected to analysis.

SUBJECTS AND METHODS

Ethical Approval The study adhered to the principles outlined in the Declaration of Helsinki and received approval from the Ethics Committee of the Second Affiliated Hospital of Zhejiang University School of Medicine (No.2022-1110). Written informed consent was obtained from the patients.

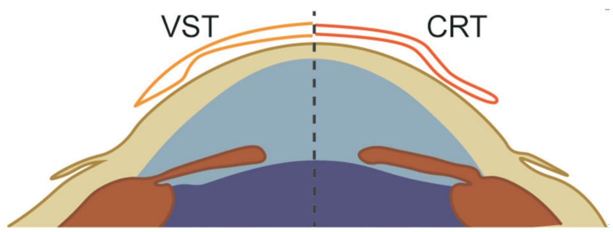

Figure 1 Schematic diagram of the ortho-k lenses with CRT and VST design VST: Vision shaping treatment; CRT: Corneal refractive therapy; ortho-k: Orthokeratology.

Study Design This retrospective clinical trial aimed to investigate the impact of different ortho-k lenses on retarding AL elongation. Data were extracted from the hospital's medical database. The study employed specific inclusion and exclusion criteria. The ortho-k lenses utilized in this investigation encompassed three distinct brands: CRT lenses (Paragon Vision Sciences, Inc., USA), Euclid lenses (Euclid Systems Corporation, Herndon, Virginia, USA), and Mouldway lenses (OVCTEK Inc., Hefei, China; Figure 1, Table 1).

Inclusion criteria: 1) The fitting of ortho-k lenses took place for the first time at the Eye Center of the Second Affiliated Hospital of Zhejiang University School of Medicine between January 1, 2018, and March 31, 2019; 2) A three-year follow-up assessment; 3) Excluding supplementary interventions, such as administering 0.01% atropine during treatment; 4) There has been no alteration in the brand of ortho-k lenses throughout the treatment period; 5) Intermittently discontinuing ortho-k lens wear for less than one-week duration during the treatment course.

Exclusion criteria: 1) History of 0.01% atropine usage; 2) Using ortho-k lenses from brands other than CRT, Euclid, and Mouldway; 3) Presence of ocular diseases other than refractive errors; 4) History of ocular surgeries and systemic diseases.

Orthokeratology Lens Fitting and Follow-Up All ortho-k lenses were fitted by skilled practitioners in accordance with the manufacturer's guidelines, following meticulous examinations and assessments. Patients were instructed to attend follow-up appointments at intervals of 1d, 1wk, 1mo, and every three months upon initiating ortho-k lens wear. During each visit, ophthalmologists evaluated the hygiene of ortho-k lenses and conducted anterior segment examinations

Table 2 Demography characteristics

Parameters	CRT	VST		*P*
		Euclid	Mouldway	
Numbers	268	127	259	-
Age	10.0 (9.0, 11.0)	10.0 (9.0, 11.0)	10.0 (9.0, 11.0)	0.0861
Male (%)	46.67	40.16	46.72	0.4246
Initial SE (D)	-3.25 (-4.00, -2.00)	-3.25 (-4.75, -2.50)	-2.75 (-3.75, -2.00)	0.0238[a]
Flat K (D)	42.50 (41.75, 43.25)	42.75 (42.00, 43.75)	42.50 (41.5, 43.5)	0.1755
Steep K (D)	43.75 (42.75, 45.00)	44.00 (43.00, 44.75)	43.75 (42.50, 44.75)	0.0400[a]
Initial AL (mm)	24.81±0.80	24.88±0.85	24.78±0.78	0.5715

[a]$P<0.05$. SE: Spherical equivalent; AL: Axial length; D: Diopter; CRT: Corneal refractive therapy; VST: Vision shaping treatment.

to detect corneal epithelium staining, corneal edema, and conjunctival congestion. Subsequent to the initial one-month follow-up, assessments of uncorrected visual acuity, corneal topography, and AL were conducted every three months, with corneal endothelial cell density measurements performed every six months.

Axial Length Measurement AL stands as a crucial metric in the assessment of refractive status. In this study, AL was measured utilizing the IOL Master (Carl Zeiss, Germany), a device capable of determining the distance from the corneal apex to the retinal pigment epithelium. The measurement procedure was executed five times, and an average value was computed. AL measurements were conducted at three-month intervals during follow-up visits.

Refractive State Measurement Objective refraction was ascertained utilizing an automatic refractor (Topcon, Japan) subsequent to cycloplegia induced by applying 0.5% tropicamide eye drops, administered three times at 10-minute intervals. It was tested three times and calculated an average value. Spherical equivalent (SE) was calculated using the following formula: SE=spherical degree+1/2(cylindrical degree). Flat K and steep K were detected by an automatic refractor three times to get a mean value.

Adverse Events Ocular safety was regularly evaluated and recorded by ophthalmologists during follow-up. Corneal staining and conjunctival inflammation are the primary adverse events of ortho-k lenses. This study collected the incidence of ocular adverse events caused by ortho-k lenses.

Statistical Analysis Normally distributed data were presented as mean±standard deviation. Non-normally distributed data were presented as median (P25, P75). Kolmmogorov-Smirnov test was used to test the normality of measurement data. One-way ANOVA analyses assessed the statistical significance of initial AL and AL elongation. Kruskal-Wallis test was used to analyze the statistical significance of initial SE, age, flat K and steep K. Subsequent multiple comparisons adjusted by the Bonferroni correction. Enumeration data including sex ratio, the incidence of adverse events and myopic progression rates was subjected to analysis using Pearson's Chi-square test, with subsequent multiple comparisons adjusted using the Bonferroni correction. The data from the right eyes were selected for analysis. $P<0.05$ was statistical significance.

RESULTS

The CRT lenses group comprised 268 subjects, the Euclid lenses group comprised 127 subjects, and the Mouldway lenses group encompassed 259 subjects. The median age of subjects in the CRT lenses group was 10.0y, which was same as the Euclid lenses group and the Mouldway lenses group. Concerning the median initial SE, it measured -3.25 D in the CRT lenses group, -3.25 D in the Euclid lenses group, and -2.75 D in the Mouldway lenses group. The average initial AL was 24.81±0.80 mm in the CRT lenses group, 24.88±0.85 mm in the Euclid lenses group, and 24.78±0.78 mm in the Mouldway lenses group. The median flat K was 42.50 D, while the median steep K was 43.75 D in the CRT lenses group. In the Euclid lenses group, the corresponding values were 42.75 D and 44.00 D, while in the Mouldway lenses group, they were 42.50 D and 43.75 D (Table 2).

There were no statistically significant differences in mean age, sex ratio, initial AL, and flat K among the three groups ($P>0.05$). Although there were notable distinctions in mean initial SE and mean steep K across the three groups, further statistical analysis indicated no significant differences between CRT and Euclid ($P>0.05$), as well as between CRT and Mouldway ($P>0.05$; Table 3). Therefore, these factors did not introduce any confounding influence in comparing myopia control effects between CRT and VST lenses.

Axial Length Elongation In the 3-year follow-up, the elongation of AL was observed to be 0.73±0.36 mm in the group wearing CRT lenses, 0.59±0.37 mm in the group wearing Euclid lenses, and 0.63±0.38 mm in the group wearing Mouldway lenses. Statistical analysis revealed a significant difference between the CRT and Mouldway groups ($P<0.01$), as well as between the CRT and Euclid groups ($P<0.001$). However, no significant difference was found between the Euclid and Mouldway groups ($P>0.05$; Figure 2).

Table 3 Statistical analysis results of initial SE and steep K between each two groups

Parameters	*P* (CRT *vs* Euclid)	*P* (CRT *vs* Mouldway)	*P* (Euclid *vs* Mouldway)
Initial SE (D)	0.2468	0.6347	0.0190[a]
Steep K (D)	0.0814	1.0000	0.0477[a]

[a]$P<0.05$. *P* value was adjusted using the Bonferroni correction. SE: Spherical equivalent; D: Diopter; CRT: Corneal refractive therapy.

Table 4 The comparison of the rate of myopic progression among three brands

Parameters	Slow progression	Moderate progression	Fast progression	*P*
CRT (*n*=268)	86 (32.1%)	141 (52.6%)	41 (15.3%)	0.009
Euclid[a] (*n*=127)	60 (47.2%)	57 (44.9%)	10 (7.9%)	
Mouldway[b] (*n*=259)	115 (44.4%)	114 (44.0%)	30 (11.6%)	

[a]Euclid had a significant difference with CRT ($P<0.01$); [b]Mouldway had a significant difference with CRT ($P<0.05$). CRT: Corneal refractive therapy.

Table 5 The comparison of the rate of adverse events among three brands

Parameters	CRT (*n*=268)	Euclid (*n*=127)	Mouldway (*n*=259)	*P*
Times (rate)	27 (10.1%)	8 (6.3%)	16 (6.2%)	0.195

CRT: Corneal refractive therapy.

Rate of Myopic Progression In this study, the mean AL elongation rates were approximately 0.24±0.12 mm/y in the CRT lenses group, 0.20±0.12 mm/y in the Euclid lenses group, and 0.21±0.13 mm/y in the Mouldway lenses group. Furthermore, within this study, 32.1% of participants who wore CRT lenses displayed a slow myopic progression, compared to 47.2% in the Euclid lenses group and 44.4% in the Mouldway lenses group. Notably, 15.3% of participants using CRT lenses exhibited rapid myopic progression, while these proportions were 7.9% in the Euclid group and 11.6% in the Mouldway group. Moreover, a majority of 52.6% of participants with CRT lenses showcased a moderate myopic progression, with corresponding figures of 44.9% in the Euclid lenses group and 44.0% in the Mouldway lenses group (Figure 3, Table 4). Following statistical analyses, a significant difference was observed among the three groups. Further pairwise comparisons revealed that the CRT group demonstrated a statistically significant difference when compared to both the Euclid group ($P<0.01$) and the Mouldway group ($P<0.05$).

Adverse Events The incidence of adverse events was 10.1% in the CRT lenses group, 6.3% in the Euclid lenses group, and 6.2% in the Mouldway lenses group in this study. Following statistical analyses, there was no significant difference among the three groups. In 3-year follow-up, no complications resulting in irreversible vision loss occurred in three brands of ortho-k lenses (Table 5).

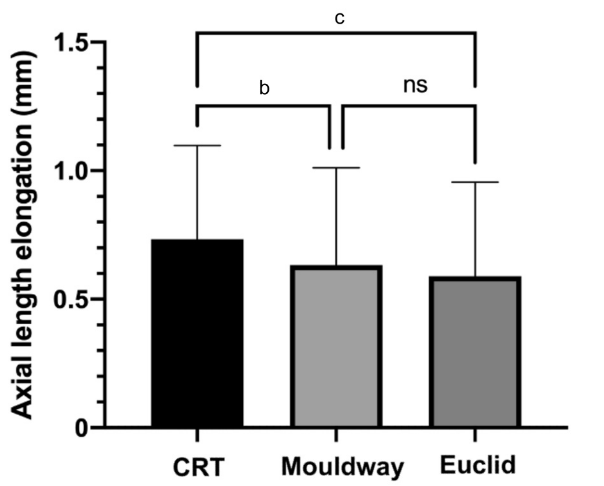

Figure 2 Quantitative analysis of the AL elongation in 3-year follow-up in the CRT, Euclid, and Mouldway lenses group [b]$P<0.01$, [c]$P<0.001$. CRT: Corneal refractive therapy; AL: Axial length; ns: Not significant.

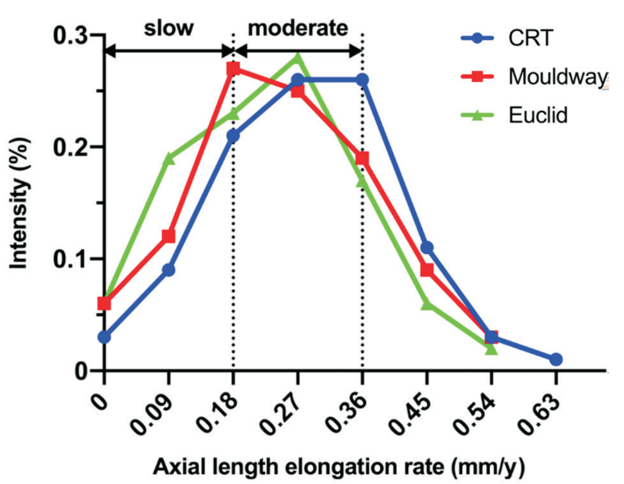

Figure 3 Line chart of the rate of myopic progression among three brands CRT: Corneal refractive therapy.

DISCUSSION

To figure out the differential effects on myopia control between CRT and VST lenses, our study examined the AL change over three years for patients wearing ortho-k lenses of the same brand. This project was a single center retrospective analysis, which ensured the uniform procedures of lens fitting. And it analyzed the three-year change of AL, which might be the most extended follow-up period in the studies of this kind. Lu *et al*[19] collected the 1.5-year AL elongation when wearing ortho-k lenses, while Chen *et al*[20] analyzed the two-year AL change. What's more, this study picks different brands from China and America. Mouldway, an established Chinese ortho-k lenses brand, was included in our study. As we acknowledged, it was the first study to compare Chinese brand of ortho-k lenses with foreign brands. The AL growth in the Mouldway lenses group was comparable to the Euclid lenses group, with no statistical difference. It means that Mouldway also exhibit a good effect on myopia control.

The progression of myopia is always associated with the growth of AL[21]. The rate of AL elongation serves as an indicator for assessing myopia progression. An average annual growth of AL below 0.18 mm/y is classified as slow progression, while a growth exceeding 0.36 mm/y is categorized as fast progression. Values falling between these thresholds indicate moderate progression[15]. In our study, the mean annual increase in AL was approximately 0.24±0.12 mm for the group using CRT lenses and 0.20±0.12 mm for the group using Euclid lenses. Other researchers have reported similar findings. For example, Zhang *et al*[22] found that the annual increase in AL for myopia patients aged 8 to 13 y who wore CRT lenses was 0.32±0.18 mm. Lu *et al*[19] also observed an increase in AL of 0.41±0.27 mm for those wearing CRT lenses and 0.29±0.24 mm for those wearing Euclid lenses over a 1.5-year follow-up period. Generally, the mean annual AL elongation in our study is similar with Lu *et al*'s[19] study, lower than Zhang *et al*'s[22] study. It might be attributed to the difference of the initial SE. The initial SE in our study was comparable with Lu *et al*'s[19] study, but higher than Zhang *et al*'s[22] study. The degree of refraction at baseline is linked to the effects of ortho-k lenses. Individuals with higher refractions who wear ortho-k lenses exhibit a smaller diameter of the treatment zone and a more pronounced plus power ring in the tangential topographic map[23]. Kakita *et al*[24] observed that ortho-k lens wearers with high myopia experienced less AL elongation than those with low myopia. Several studies support this notion, showing that ortho-k wearers with higher baseline SE had reduced elongation of AL[25-26].

Furthermore, it is essential to note that only a small number of participants in this study exhibited a rapid rate of myopic progression. Wearing ortho-k lenses can serve as a reliable method to control myopia to some extent. This perspective has been supported and accepted in numerous studies[27-28]. Individual variations, including genetic factors and external environmental influences, can impact the progression of myopia. Therefore, early interventions and regular monitoring play a significant role in managing myopia.

Additionally, we observed a significant difference in the reduction of AL elongation between CRT and VST lenses in statistical analysis. Specifically, ortho-k lenses with VST design exhibited a better effect in slowing myopia progression. The average AL elongation difference between the CRT and VST lenses was nearly 0.13 mm over three years. This translates to an approximately 0.25 D increase in refraction growth for the CRT lenses group compared to the VST lenses group. Namely, from a clinical perspective, it suggested the difference in three-year myopia control between CRT lenses and VST lenses is 0.25 D.

The lens's design significantly impacts the spatial distribution of corneal refractive power[22]. As the corneal refractive power changes from the central to the mid-peripheral region, it causes myopic defocus on the peripheral retina. Moreover, the lens design affects the size of the treatment zone. In a study by Marcotte-Collard *et al*[29], it was discovered that CRT lenses had a larger horizontal treatment zone compared to Dream lenses with the same 6-mm back optic zone diameter (BOZD). Another study by Zhang *et al*[30] found that a small and aspheric treatment zone could reduce AL elongation. Similarly, Pauné *et al*[31] designed ortho-k lenses with different BOZD and observed that ortho-k lenses with smaller BOZD induced slower AL elongation than those with larger BOZD. Guo *et al*[32] also found that ortho-k lenses with a smaller BOZD (5 mm) led to a 0.13 mm delay in AL compared to those with 6 mm BOZD after one year of wear. This was likely due to the smaller BOZD causing a sharper change in power, resulting in the defocus ring being closer to the visual axis and higher spherical aberration. As our understanding of myopia control continues, CRT lenses with a 5.0-mm BOZD have been proposed and implemented in clinical settings. The effectiveness of these lenses in retarding myopia progression has also been extensively studied[33-34]. Among the three types of ortho-k lenses investigated in the present study, Mouldway lenses had the smallest BOZD, followed by CRT lenses, while Euclid lenses were the largest. This aligns with our findings that the growth of AL in the Mouldway lenses group was lower than that in the CRT lenses group.

The addition of a compression factor is employed to account for the power of myopia regression during daytime[35]. The diameter of the treatment zone is also associated with the compression factor. Lau *et al*[36] discovered that an increased compression factor can decelerate AL growth. This phenomenon could be linked to higher-order aberrations[37-38], as enhancing the compression factor can induce alterations. Hiraoka *et al*[39] identified changes in coma-like aberration as the most reliable indicator of AL growth. A higher level of coma-like aberration signifies an asymmetric optical change in the cornea, which can result in a retardation of myopia progression. Consistent with the findings of this study, ortho-k lenses with VST design exhibited a more pronounced effect in slowing down AL elongation. As stated in the manufacturer's guidelines, the ortho-k lenses with CRT design have a compression factor of +0.50 D, while the ortho-k lenses with VST design have a compression factor of +0.75 D.

As mentioned above, the initial degree of refraction is related to the effects of ortho-k lenses. In our study, the SE at baseline was similar between CRT lenses and any lens with a VST design. Consequently, we concluded that ortho-k lenses with the VST design demonstrate a significantly greater efficacy in slowing down myopia progression than those with CRT design. However, there was a difference in the baseline SE between the two ortho-k lenses with VST design: the Mouldway lenses had a lower baseline SE than the Euclid lenses. The elongation of AL was slighter longer in the Mouldway group than the Euclid group. But there was no statistically significant difference in AL elongation, which suggests that there may be no discrepancy in myopia control between the two ortho-k lenses with VST design. However, further investigation is needed to confirm this inference.

There were several limitations in this study. First, the Euclid lenses group's sample size was smaller than the other two groups, potentially increasing the sampling error and influencing the statistical results. Additionally, this study assessed myopic progression by examining the rate of AL growth. However, refractive growth is also a critical indicator for determining the level of myopic progression. It is worth noting that wearing ortho-k lenses can alter the refractive error status. It takes at least three weeks for the refractive state to recover after discontinuing the use of ortho-k lenses. Lastly, this study was a retrospective clinical trial and did not fix the same time point for AL measurement. Human AL performs diurnal fluctuation[40-41]. We did not take this variable into consideration, which might influence the reliability of this study.

In conclusion, ortho-k lenses have proven to be an effective intervention in mitigating myopia progression. Notably, ortho-k lenses with a VST design demonstrate a better efficacy in myopia retardation when compared to ortho-k lenses with a CRT design.

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