To Evaluate the Efficacy and Safety of Orthokeratology Lenses with a Back Optical Diameter Of 5.0mm and 6.0mm in Controlling Myopia Progression in Chinese Children

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Abstract：

This study evaluates the efficacy and safety of orthokeratology lenses with back optical zone diameters (BOZD) of 5.0 mm and 6.0 mm in controlling myopia progression in Chinese children. The retrospective study included patients aged 6 to 15 years, divided into two groups based on BOZD. Over a one-year observation period, the group with a smaller BOZD (5.0 mm) showed significantly lower axial length growth (0.163 mm) compared to the group with a larger BOZD (6.0 mm), which had an axial length growth of 0.282 mm. This represents a 42.2% improvement in myopia control for the 5.0 mm group. The study also revealed that younger children (6-11 years) experienced better myopia control than older children (12-15 years), and the axial length growth was lower in children with high myopia compared to those with low myopia. Visual acuity remained similar between both groups, and no significant adverse events were reported. The results suggest that orthokeratology lenses with a smaller BOZD provide better myopia control in Chinese children.

keywords： Myopia，Orthokeratology Lenses，Back Optical Zone Diameter，Axial Length，Treatment Zone

Introduction：

Myopia is a common cause of vision loss, and uncorrected myopia is the leading cause of distance vision impairment worldwide. By 2050, it is projected that 4.758 billion people will have myopia (Holden et al., 2016). In Asia, the prevalence of myopia is even more severe, with myopia rates among young people in East Asia being very high, reaching 80% to 90%; myopia has become the leading cause of blindness in this region(Wu et al., 2016). Of particular concern is the rapidly increasing prevalence of myopia among children in China. The overall detection rate of myopia among children and adolescents aged 7 to 18 was 47.5% in 2005, 55.5% in 2010, and 57.1% in 2014 *(Dong et al., 2017)*. The prevalence of high myopia among adolescents continues to rise and increases with age, showing a trend toward younger ages (Qi et al., 2023). Myopia patients are at an increased risk of developing myopic macular degeneration, retinal detachment, cataracts, and glaucoma, with the risk escalating as the degree of myopia worsens (Shah et al., 2024).

According to the study by (Yam et al., 2019), effective clinical measures to reduce or slow the progression of myopia include the daily use of low-dose atropine eye drops, multifocal spectacle lenses, multifocal contact lenses, and orthokeratology lenses. Low-dose atropine eye drops have been shown to effectively control the progression of myopia (Yam et al., 2023); however, they may cause side effects such as increased pupil size, higher aberrations, reduced accommodative amplitude, elevated intraocular pressure, or allergic reactions, which could lower the patient's quality of life (Jonas et al., 2021). Additionally, the long-term safety of these drops requires further research. Multifocal spectacle lenses can easily slip during wear, leading to optical center displacement, which may decrease visual quality and reduce the effectiveness of myopia control (Lam et al., 2020).

Orthokeratology lenses are an effective and commonly used clinical method for myopia control (Cho & Cheung, 2012), and numerous studies have shown that they are highly safe, with adverse events being very rare when proper care procedures are followed (Santodomingo-Rubido et al., 2024). In recent years, experts in the field have proposed various methods to enhance the myopia control effectiveness of orthokeratology lenses. These methods include generating larger defocus rings, increasing higher-order aberrations, creating steeper defocus rings, reducing the diameter of the treatment zone, increasing the Jessen factor, using aspheric designs for the treatment zone, or combining orthokeratology with atropine treatment (Pauné et al., 2021a; Xu et al., 2023; Yam et al., 2023). However, these approaches may introduce several potential issues, such as decreased visual acuity, increased halos, and pupil enlargement, leading to visual problems (A. Fu et al., 2020).

For example, (Pauné et al., 2021a) found that reducing the back optic zone diameter (BOZD) of orthokeratology lenses from the traditional 6.0 mm to 5.0 mm

effectively decreased the treatment zone diameter, which better controlled myopia progression in patients, reducing axial elongation from 0.15 ± 0.11 mm to 0.09 ± 0.12 mm. Another study by(X. Li et al., 2023) showed that using CRT lenses with 5.0 mm and 6.0 mm BOZD resulted in less axial elongation with the smaller BOZD (0.13 ± 0.18 mm vs. 0.27 ± 0.15 mm). However, related studies are limited in number and duration, and further research is needed to validate their effectiveness and safety.

The methodology of this study involves using orthokeratology lenses with different back optic zone diameters (BOZD) to control myopia progression in Chinese children with myopia, with an observation period of one year. The aim is to evaluate the effectiveness and safety of different BOZD sizes in controlling myopia progression in Chinese children.

Method：

The methodology of this study involved the fitting and examination of all patients according to the initial fitting and examination procedures, which included the initial check and follow-up processes. These processes encompassed a medical history inquiry, uncorrected visual acuity (UCVA) examination, corrected visual acuity (CVA) examination, intraocular pressure (IOP) measurement, slit-lamp examination, fundus examination, corneal topography, and axial length measurement. All patients were fitted with the same brand of orthokeratology lenses by an experienced optometrist, following the manufacturer's recommended procedures for parameter selection, trial fitting, and final parameter determination. Prior to lens wear, patients and their guardians received training on lens handling and care procedures. The lenses were worn for 8-10 hours each night. In case of any ocular surface adverse events, lens wear was discontinued immediately and resumed after recovery.

The follow-up schedule included visits on the first day after lens wear, the first week, the first month, the third month, the sixth month, the ninth month, and the twelfth month. Baseline data were collected during the initial visit, and data collection was conducted at the third, sixth, and twelfth months of lens wear.

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Statistical analysis was performed using SPSS 27.0. The data analysis was conducted using SPSS 23.0 software. For continuous variables, normality and homogeneity of variance were first assessed. If the data met the assumptions of normality, the following analyses were performed: **Between-group comparison**: Independent sample t-tests were used to compare the means of two independent samples to assess the significance of differences between groups. **Within-group comparison**: Paired t-tests were used for comparing measurements taken under different conditions or at different time points within the same group of subjects. **Correlation analysis**: Correlation analyses (e.g., Pearson correlation coefficient or Spearman rank correlation coefficient) were used to assess the linear or non-linear

relationships between variables. **Analysis of categorical data**: Chi-square tests (χ^2 tests) were used to compare the frequency distributions of categorical variables between groups to assess the significance of group differences. All statistical tests were conducted with a significance level set at $P<0.05$. A P-value less than 0.05 was considered indicative of a statistically significant difference.

Subjects：

This retrospective study selected patients aged 6 to 15 years who were fitted with orthokeratology lenses at the Ophthalmology Outpatient Department of the First Affiliated Hospital of Army Medical University in Chongqing, China. Approximately 194 patients were included in the 5-MM group, where the lenses had a back optic zone diameter (BOZD) of 5 mm, and approximately 129 patients were included in the 6-MM group, where the lenses had a BOZD of 6 mm. The choice of group was made by the patients themselves. **Inclusion criteria**:1、Myopia ranging from -0.50D to -6.00D.2、Astigmatism less than -3.00D, with the axis within 180° ± 30°; other axes required astigmatism to be less than -0.50D.3、Best-corrected logMAR visual acuity of at least 0.1 in both eyes.4、Good ocular health in both eyes.5、Both the patient and their parents must be of Chinese nationality. **Exclusion criteria**:1、Presence of any organic eye disease in either eye.2、Previous or current use of any myopia control products.3、Any contraindications or allergic reactions to wearing contact lenses.

Result：

Axial Length Growth Over One Year: A total of 35 patients in the experimental group (5-MM) completed the 12-month axial length follow-up, representing approximately 56 eyes, while 22 patients in the control group (6-MM) completed the follow-up, representing 44 eyes. There were no statistically significant differences in their baseline characteristics, including gender, age, axial length, spherical power, cylindrical power, spherical equivalent, K1, and K2 ($P > 0.05$). The results are presented in Table 1.

Table 1 Baseline Data of Patients Who Completed One-Year Axial Length Measurement in Both Groups

Baseline	5-MM group	n	6-MM group	n	t/x2	p
Age	10.446±2.441	56	10.545±2.297	44	-0.207	0.837*
AL	24.526±0.855	56	24.705±0.735	44	-1.103	0.273*
DS	-2.339±1.195	56	-2.619±1.171	44	1.174	0.243*
DC	-0.772±0.641	46	-0.733±0.693	44	-0.276	0.783*
SE	-2.656±1.269	56	-2.986±1.146	44	1.344	0.182*
K1	42.609±1.556	56	42.452±1.180	44	0.558	0.578*
K2	43.938±1.779	56	43.884±1.457	44	0.16	0.873*

Female/male	35/21	56	23/21	44	0.680	0.410*

AL: axial length；DS：Diopters Sphere DC：Diopters Cylinders: Spherical Equivalent K1：Flat K；K2：Steep K* Independent t-test

The baseline axial length in the experimental group (5-MM group) was 24.526±0.855 mm. After 12 months of treatment with orthokeratology lenses with a BOZD of 5.0 mm, the axial length was 24.689±0.807 mm, showing a statistically significant difference (P<0.05). The axial length growth in this group was 0.163±0.216 mm. In the control group (6-MM group), the baseline axial length was 24.705±0.735 mm, and after 12 months of treatment with orthokeratology lenses with a BOZD of 6.0 mm, the axial length was 24.988±0.702 mm, also showing a statistically significant difference (P<0.05). The axial length growth in this group was 0.282±0.246 mm. The axial length growth after 12 months of treatment in the experimental group (0.163±0.216 mm) was significantly lower than that in the control group（0.282±0.246）, and the difference was statistically significant (P<0.05). The results are presented in Table 2

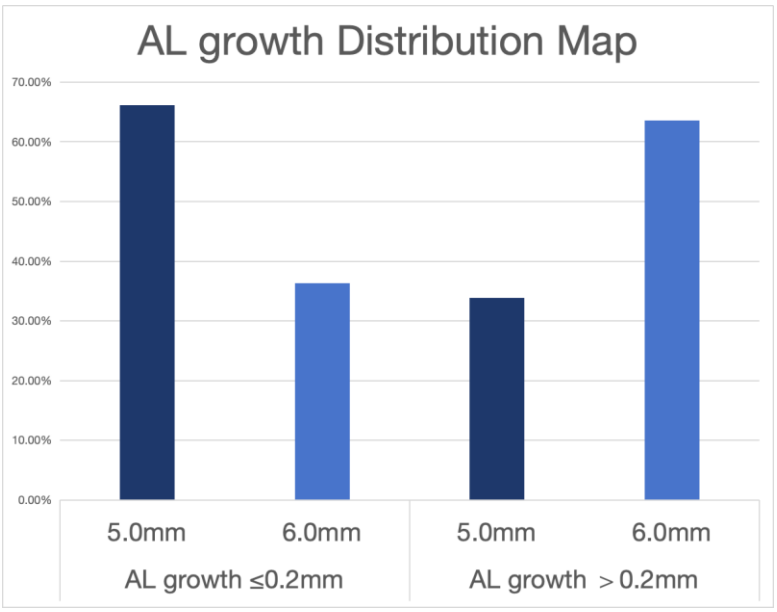
Table2 AL growth from baseline to 12-months treatment in the two groups (5-MM group and 6-MM group).

AL	n	AL baseline	AL（12 months）	AL growth	p
5-MM group	56	24.526±0.855	24.689±0.807	0.163±0.216	0.000***
6-MM group	44	24.705±0.735	24.988±0.702	0.282±0.246	0.000***
t		-1.103	-1.945	-2.59	
P		0.273	0.055	0.02	

AL: axial length；*p<0.05 **p<0.01 ***p<0.001

The number of subjects in the experimental group (5-MM group) with an axial length increase of less than or equal to 0.2 mm over one year was significantly higher than the number of subjects with an increase greater than 0.2 mm. In contrast, the control group （6-MM group） showed the opposite trend, with more patients experiencing an axial length increase of greater than 0.2 mm over one year. The results are presented in Figure 1

Figure 1 AL growth distribution map with less than or equal to 0.2mm or more than 0.2mm in two groups (5-MM group and 6-MM group).



The results show that the one-year axial length growth in the experimental group of children aged 6-11 years after orthokeratology treatment was 0.229±0.225, which is lower than the 0.353±0.254 observed in the control group. The difference is statistically significant ($P < 0.05$). The results are presented in table 3

Table 3 The one-year axial length growth comparison between the two groups of children aged 6-11 years.

Age (6-11)	AL baseline	AL（12 months）	AL growth	p
5-MM group	24.273±0.721	24.501±0.744	0.229±0.225	0.000**
6-MM group	24.549±0.517	24.902±0.495	0.353±0.254	0.000**
p	0.083	0.014*	0.039*	

The results show that the one-year axial length growth in the experimental group of children aged 12-15 years after orthokeratology treatment was 0.229±0.225, which is lower than the 0.353±0.254 observed in the control group. But the difference is no statistically significant ($P > 0.05$). The results are presented in table 4.

Table 4 The one-year axial length growth comparison between the two groups of children aged 12-15 years.

Age (12-15)	AL baseline	AL（12 months）	AL growth	p
5-MM group	24.983±0.903	25.027±0.823	0.044±0.138	0.175
6-MM group	25.039±1.008	25.170±1.016	0.131±0.146	0.005**
p	0.867	0.653	0.084	

The study compared the axial length growth over one year between low myopia and high myopia in both the experimental and control groups. In the experimental group, the axial length growth in the low myopia subgroup was significantly greater than that in the high myopia subgroup (0.213 mm ± 0.223 vs. 0.072 mm ± 0.174), and this result was statistically significant ($P < 0.05$). In the control group, although the axial length growth in the low myopia subgroup was also greater than that in the high myopia subgroup, the result was not statistically significant ($P > 0.05$). The results are presented in table 5.

Table 5 The axial length growth over one year for children with low myopia and high myopia in both the experimental group and the control group.

	0--3.00D	-3.00D--6.00D	P
5-MM group	0.213±0.223	0.072±0.174	0.019
6-MM group	0.310±0.221	0.250±0.250	0.234
p	0.103	0.029	

In the experimental group（5-MM group）, the difference in axial length growth between eyes with a baseline axial length of 24mm-25mm and those with a baseline axial length of 25mm-26mm is not statistically significant ($P > 0.05$). Similarly, in the control group（6-MM group）, the difference in axial length growth between eyes with a baseline axial length of 24mm-25mm and those with a baseline axial length of 25mm-26mm is also not statistically significant ($P > 0.05$).

Table 6 The axial length growth with different baseline axial lengths in the two groups.

	5-MM group AL growth	n	6-MM group growth	n	p
Baseline AL 24-25	0.187±0.230	29	0.319±0.238	15	0.081
Baseline AL 25-26	0.110±0.218	17	0.352±0.236	21	0.002
p	0.268		0.748		

A total of 82 patients in the 5-MM group, representing approximately 146 eyes, completed the 3-month visual acuity follow-up, while 53 patients in the 6-MM group, representing 97 eyes, completed the follow-up. In the experimental group, 78 eyes completed the 6-month visual acuity follow-up, while in the control group, 74 eyes completed the 6-month visual acuity follow-up. Additionally, 15 eyes in the

experimental group and 72 eyes in the control group completed the 12-month visual acuity follow-up. There were no statistically significant differences in their baseline characteristics (gender, age, axial length, spherical power, cylindrical power, spherical equivalent, K1, K2) ($P > 0.05$).

Table 6 Comparison of UVA of the two groups（5-MMgroup and 6-MM group）in 3months，6 months,12months of patients after treatment.

	UVA（3moths）	UVA（6moths）	UVA（12moths）
5-MM group	0.039±0.111	0.040±0.119	0.030±0.103
n	146	78	15
6-MM group	-0.009±0.125	-0.011±0.088	0.016±0.133
n	97	74	72
p	0.0029	0.0012**	0.459

There was no statistically significant difference in the frequency of adverse events

between the experimental group and the control group at the 3-month, 6-month, and 12-month follow-ups ($P > 0.05$).

Table 8 Comparison of cornea health of the two groups（5-MMgroup and 6-MM group）in 3months，6 months,12months of patients after treatment.

	Health/ adverse events（3moths）	Health/ adverse events（6moths）	Health/ adverse events（12moths）
5-MM group	137/9	75/3	15/0
n	146	78	15
6-MM group	90/3	72/6	69/2
n	93	78	71
X^2	0.505	0.0	0.0
p	0.477	1.0	1.0

Discussion:

The results indicate that after using orthokeratology lenses with different back optic zone diameters (BOZD), the axial length of children in the experimental group increased from 24.526 ± 0.855 mm to 24.689 ± 0.807 mm over one year, with an axial length growth of 0.163 ± 0.216 mm. In contrast, the control group's baseline axial length increased from 24.705 ± 0.735 mm to 24.988 ± 0.702 mm, with a growth of 0.282 ± 0.246 mm. The axial length growth in the experimental group was significantly lower than that in the control group, with a statistically significant difference ($P < 0.05$). The difference in axial length growth between the two groups was approximately 0.12

mm, indicating that the myopia control effect of the smaller BOZD was about 42.20% more effective than that of the larger BOZD.

This finding is consistent with the results of another study by(Pauné et al., 2021a), which showed that using ortho-K lenses with a smaller BOZD (in a double reservoir lens design, DRL) can reduce myopia progression by approximately 0.06 mm/year, or 40%. Another study by (X. Li et al., 2023) also demonstrated significant differences in myopia control effectiveness between BOZD of 6.0 mm and 5.0 mm, with the smaller BOZD (5 mm) resulting in about 0.14 mm less axial elongation per year compared to the larger BOZD (6 mm), representing a 51.8% improvement in myopia control.

Additionally, research by(Guo et al., 2021) on different BOZD sizes in myopia control concluded that a smaller BOZD leads to a smaller treatment zone size, with a 0.17 mm reduction in axial elongation over one year compared to a 6 mm BOZD. The study also found a significant positive correlation between treatment zone size and axial elongation.

Although the effects of larger and smaller BOZD on slowing axial elongation vary across different studies, possibly due to differences in racial demographics, inclusion criteria, and the use of different brands of orthokeratology lenses, the overall consensus is that reducing the BOZD can effectively enhance the myopia control effects of orthokeratology lenses.

In a study involving 8,546 myopic children aged 6 to 10 years who were untreated, it was found that the axial elongation in non-progressive myopic children was significantly lower than that in progressive myopic children. An axial length (AL) change of 0.20 mm/year was used as the cutoff value to differentiate between non-progressive and progressive myopia (Chen et al., 2023). Therefore, in this study, eyes in the experimental and control groups with an axial length increase of 0.2 mm or less were defined as the slow myopia progression group, while those with an axial length increase of more than 0.2 mm were defined as the rapid myopia progression group.

The results showed that approximately 66.1% of the eyes in the experimental group fell into the slow myopia progression group, whereas only 36.4% of the eyes in the control group were in this category. In the rapid myopia progression group, only 33.9% of the eyes in the experimental group belonged to this group, compared to 63.6% in the control group. This further demonstrates that orthokeratology lenses with a smaller BOZD provide better myopia control effects.

Orthokeratology lenses can effectively control the progression of myopia in children; however, the mechanisms behind this control are not yet fully understood. The peripheral defocus mechanism (Erdinest et al., 2023) and the increase in higher-order aberrations (Lau et al., 2020a)are widely recognized by many scholars as potential explanations. Both animal studies (Choo et al., 2008) and human studies (Zhang et al., 2020) have shown mid-peripheral corneal thickening after orthokeratology treatment. Previous research has found that this thickening is positively correlated with an increase in spherical aberration(Batres et al., 2020).

(Faria-Ribeiro et al., 2016) reported significantly higher 4th order spherical aberration and peripheral refraction (with more myopic defocus) in subjects with larger pupils, possibly due to a greater area being exposed to higher-order aberrations and peripheral refraction. This observation was further supported by(Pauné et al., 2021a), who also noted a substantial increase in 4th order spherical aberration and peripheral refraction among individuals with larger pupils, attributing it to the exposure of a wider region to these optical changes.

(Pauné et al., 2021b)observed that myopia control was more effective when the pupil diameter exceeded the peripheral defocus ring compared to when the pupil was smaller than the defocus ring, with an approximate improvement of 77% (0.04 mm ± 0.04 vs. 0.17 mm ± 0.02). This suggests that a larger pupil diameter may allow more defocused light to enter the eye, thereby influencing axial elongation. (Lau et al., 2020b)found similar results, noting that children with larger pupil diameters experienced less axial elongation during the orthokeratology treatment period and exhibited higher levels of higher-order aberrations, which were negatively correlated with axial elongation.

In myopic children undergoing orthokeratology treatment, the flattened central corneal area is referred to as the treatment zone. (Guo et al., 2023), in a two-year study, found that wearing orthokeratology lenses with BOZD of 6.0 mm and 5.0 mm resulted in different treatment zone sizes: 2.69 ± 0.28 mm versus 3.84 ± 0.39 mm horizontally, and 2.65 ± 0.22 mm versus 3.42 ± 0.34 mm vertically ($p < 0.001$). The smaller treatment zone size was associated with higher aberrations, including a significant increase in total higher-order aberrations (HOA), total spherical aberration (SA), and primary SA, while secondary SA decreased. Among these ocular aberrations, total HOA, total SA, and primary SA were negatively correlated with axial elongation (AE) over the two-year period.

In this experiment, both larger and smaller BOZD orthokeratology lenses were used, and similar conclusions were reached: a smaller optical zone can better control myopia progression. It is hypothesized that the possible reason for this is that the smaller back optic zone diameter (BOZD) creates a smaller treatment zone on the anterior surface of the cornea in myopic children, leading to an increase in higher-order aberrations within the eye, which in turn slows down the rate of axial elongation.

Additionally, according to a related meta-analysis, myopia progresses faster in Chinese patients aged 9-11 years, and the study by(Y. Li et al., 2020) found that after the age of 12, myopia progression slows significantly compared to before the age of 12. From a physiological development perspective, the annual increase in myopia gradually decreases until it stabilizes after onset. Therefore, this study used age 12 as the dividing line. The study analyzed the progression of myopia in children aged 6-11 years and 12-15 years in both the experimental and control groups.

The results showed that in the one-year experiment with children aged 6-11 years, the axial length in the experimental group increased from a baseline value of 24.273 ± 0.721 mm to 24.501 ± 0.744 mm, with an increase of 0.229 ± 0.225 mm, while in the control group, the axial length increased from a baseline value of 24.549 ± 0.517 mm to 24.902 ± 0.495 mm, with an increase of 0.353 ± 0.254 mm. This indicates that younger children experienced better myopia control with smaller optic zone diameters, resulting in less axial elongation (0.353 ± 0.254 mm vs. 0.353 ± 0.254 mm), and the results were statistically significant ($P < 0.05$).

For children aged 12-15 years, in the one-year experiment, the axial length in the experimental group increased from a baseline value of 24.983 ± 0.903 mm to 25.027 ± 0.823 mm, with an increase of 0.044 ± 0.138 mm, while in the control group, the axial length increased from a baseline value of 25.039 ± 1.008 mm to 25.170 ± 1.016 mm, with an increase of 0.131 ± 0.146 mm. This suggests that even in older children, smaller optic zone diameters still provide better myopia control than larger optic zone diameters, but the difference in axial length increase between the two groups was not statistically significant ($P = 0.084 > 0.05$), possibly due to the small sample size.

Comparing the axial length growth in younger and older children within both the experimental and control groups, it was found that in both groups, the axial length growth in younger children was higher than that in older children. This suggests that age has a certain impact on the effectiveness of orthokeratology in controlling myopia progression in children. A similar study(Lv et al., 2023)also found a significant relationship between age and axial length growth ($P < 0.01$), with the AL growth rate in subjects aged 10 and 11 years being faster than in children aged 13, 14, 15, and 16 years. There was no significant difference between subjects aged 13 and 12 years, indicating that the older the age, the lower the axial length growth.

In this experiment, a correlation analysis between age and axial length growth was also conducted in both groups. The results in both groups showed $P < 0.01$ and a negative correlation.

According to the results of (Lv et al., 2023), the initial age is also related to the effectiveness of orthokeratology in controlling myopia. As the initial AL (axial length) increases, the growth rate of AL slows down ($P = 0.045$). In this experiment, a correlation analysis between age and axial length growth was also conducted in both groups. A comparative analysis of axial length growth was performed in the experimental group between eyes with a baseline axial length of 24mm-25mm and those with 25-26mm. It was found that eyes with a baseline axial length of 24mm-25mm had higher axial length growth compared to those with 25-26mm (0.187mm ± 0.230 vs. 0.110mm ± 0.218), but the difference was very small. In the control group, it was found that eyes with a shorter baseline axial length had lower growth compared to eyes with a longer baseline axial length (0.319mm ± 0.238 vs. 0.352mm ± 0.236), but

again, the difference was very small, and the results in both groups were not statistically significant (P > 0.05). This is contrary to the findings of other studies and may be due to the small sample size and measurement errors.

(A.-C. Fu et al., 2016)conducted a cohort study involving 115 Chinese children (115 right eyes) wearing orthokeratology lenses. The study collected data on gender, age, baseline SER (spherical equivalent refraction), corneal refractive power, corneal astigmatism, and AL (axial length) before and after 2 years of wearing orthokeratology lenses. Univariate analysis and trend tests were used to estimate the relationship between AL changes and baseline SER. The study found that children with higher initial SER had less axial length growth.

In this study, a classification analysis was also conducted based on different initial SE (spherical equivalent), dividing the initial myopia degree into low myopia (-0.50 to -3.00D) and moderate to high myopia (-3.00D to -6.00D), and the axial length growth in the experimental and control groups was observed separately. It was found that in the experimental group, the axial length growth in low myopia was indeed higher than that in high myopia (0.213 ± 0.223 vs. 0.072 ± 0.174), with a difference of 0.141 mm, and the results were statistically significant (P < 0.05). In the control group, it was also found that the axial length growth in low myopia was higher than that in high myopia (0.310 ± 0.221 vs. 0.250 ± 0.250), but the difference was small, only 0.06 mm, and the results were not statistically significant (P > 0.05), possibly due to the small sample size.

On the other hand, (Lv et al., 2023)reached different conclusions in their study. They observed 84 Chinese children over a period of 48.00 ± 4.01 months and compared initial AL, initial age, gender, and SE. They found that higher initial SE and longer baseline AL were associated with faster axial length growth. However, when baseline age was considered, the influence of initial AL and SE became insignificant in the analysis. The main factors leading to slower axial length growth were older initial age and larger lens diameter.

This experiment also conducted a statistical analysis of the visual acuity outcomes in the experimental and control groups over the course of one year. It was found that at the 3-month mark, there was a significant difference in uncorrected visual acuity between the experimental and control groups, with the control group exhibiting better visual acuity than the experimental group, and this difference was statistically significant (P < 0.05). However, both groups had very good visual acuity, and the difference was minimal (-0.009 ± 0.125 vs. 0.039 ± 0.111), sufficient to meet the demands of daily life. A similar difference was observed at the 6-month mark (P < 0.05), with the control group again showing better visual acuity than the experimental group (-0.011 ± 0.088 vs. 0.040 ± 0.119), but the difference remained very small, and both groups maintained clear vision. By the one-year mark, the difference between the experimental and control groups was no longer significant (P > 0.05), and the gap between the two groups had further narrowed. This may be attributed to a slight decline in visual acuity in the control group due to axial elongation.

This finding is similar to the results reported by(Guo et al., 2021)in a study involving 34 subjects in the 6-MM group and 36 subjects in the 5-MM group, where no differences in uncorrected visual acuity were observed at the 6-month and 12-month follow-ups. The smaller back optic zone diameter resulted in a smaller treatment zone and increased aberrations, which may lead to a decline in visual quality, potentially causing adverse effects such as ghosting and glare. In this study, some patients in the experimental group occasionally reported experiencing glare and ghosting during follow-up visits, whereas such complaints were almost absent in the control group. However, specific statistics on these issues were not collected, and further research is needed to determine whether subjective visual quality declines in patients undergoing treatment with orthokeratology lenses with smaller back optic zone diameters.

In the study of the experimental and control groups, the incidence of corneal adverse events was statistically analyzed over the one-year period. During the 3-month follow-up, it was found that in the experimental group, a total of 146 eyes were examined for corneal safety. Among them, 137 eyes were in a healthy condition, while 9 eyes showed mild corneal staining. These 8 patients were instructed to stop wearing orthokeratology lenses, and after approximately 3 days, their corneas recovered to a healthy state, with no more severe adverse events occurring, and they were able to continue treatment. One patient experienced bulbar conjunctival hyperemia, which resolved after discontinuing the use of orthokeratology lenses.

In the control group, 93 eyes were examined for corneal safety, with 90 eyes showing healthy corneas. Three patients experienced mild corneal staining, which was promptly treated by an optometrist, and no further severe adverse events occurred. At the 6-month follow-up, 3 cases of corneal staining were reported in the experimental group, compared to 6 cases in the control group. At the twelve-month follow-up, no adverse events were reported in the control group, while 2 cases of corneal staining were reported in the experimental group.

Overall, during the one-year observation of both the experimental and control groups, no severe adverse events were observed. Most of the cases involved corneal staining, and after intervention by an optometrist and discontinuation of orthokeratology lens wear, the corneas quickly returned to a healthy state. The incidence of adverse events in both groups was similarly low. The results of (Guo et al., 2021) also demonstrated similar conclusions.

In summary, there was a significant difference in the myopia control effectiveness between orthokeratology lenses with back optic zone diameters of 5.0 mm and 6.0 mm in Chinese children. In the experimental group (5-mm group), the axial length increases after one year of wear was 0.163 mm ± 0.216 mm, whereas in the control group (6-mm group), the axial length increase was 0.282 mm ± 0.246 mm. The smaller BOZD reduced axial length growth by 0.12 mm, corresponding to a 42.20% improvement in myopia control effectiveness.

Regarding corneal safety, there was no significant difference between the experimental group (5-mm group) and the control group (6-mm group), with no severe adverse events occurring. A small number of patients experienced mild adverse events, but they quickly recovered under the guidance of an optometrist. The unaided visual acuity after treatment also showed similar results, with no significant differences at 3 months, 6 months, and 12 months, and both groups of patients were satisfied with their visual outcomes.

However, it is important to be aware that this approach might lead to a decline in visual quality, especially at night, as larger pupils could result in more aberrations, leading to poorer visual quality. When fitting orthokeratology lenses with a smaller BOZD, it is essential to do so under the guidance of a professional optometrist, considering the child's age, visual needs, pupil size, and lens fit to ensure the best outcomes.

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