• Clinical Research •

A novel progressive defocus rigid gas permeable contact lenses for controlling axial elongation in myopic children: a retrospective study

Xue-Hui Zhang[1,2], Hui-Hu Zheng[2], Pan Li[2], Jin Wang[2], Xin Ai[2], Lin Kang[2], Cheng Pei[3]

[1]Health Science Center, Xi'an Jiaotong University, Xi'an 710061, Shaanxi Province, China
[2]Department of Optometry and Vision Science, Xi'an No.1 Hospital, Northwest University, Xi'an 710002, Shaanxi Province, China
[3]Department of Ophthalmology, the First Affiliated Hospital of Xi'an Jiaotong University, Xi'an 710061, Shaanxi Province, China
Correspondence to: Cheng Pei. Department of Ophthalmology, the First Affiliated Hospital of Xi'an Jiaotong University, Xi'an 710061, Shaanxi Province, China. peich71@163.com
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Abstract

• **AIM:** To evaluate the efficacy of progressive defocus rigid gas permeable (DRGP) contact lenses in slowing down myopic progression and analyze the factors may influence axial length (AL) elongation in myopic children.

• **METHODS:** This was a retrospective study conducted on school-age children with myopia of -5.00 D or higher who were fitted with DRGP lenses. A matched control group wearing single-vision (SV) spectacles was selected based on comparable baseline age and refractive error. The AL was measured at baseline and at 6-month intervals thereafter. Changes in AL were compared between the groups.

• **RESULTS:** The DRGP lenses group comprised 56 subjects (39 females, mean age 11.96±2.32y), the SV spectacle group comprised 53 subjects (29 females, mean age 11.09±2.33y). After a 12-month follow-up period, the mean axial elongation was measured to be 0.19±0.13 mm in the DRGP group and 0.45±0.20 mm in the SV group, respectively (P<0.001). The use of DRGP lenses by children resulted in a 57.8% lower AL of the eye compared to the use of spectacles over the one-year period. Concurrently, the treatment effect was found to be negatively correlated with the baseline age (r=-0.46, P<0.001) and flat keratometry (r=-0.34, P=0.010).

• **CONCLUSION:** Daily wearing of the DRGP lenses significantly curbs axial elongation in children when compared with SV lenses.

• **KEYWORDS:** rigid gas permeable contact lenses; progressive defocus; axial length; myopic children
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INTRODUCTION

Nowadays, the global prevalence of myopia continues to rise and has evolved into a serious public health challenge. Projections indicate that by 2050, approximately half of the global population may be affected by myopia, with about 10% of cases classified as high myopia[1-3]. It is important to emphasize that myopia cannot be simply corrected by wearing glasses; rather, it is fundamentally a functional eye disorder. As the age of onset of myopia increases, its long-term impact on visual health is becoming increasingly evident. High myopia (≤−6.00 D) is a high-risk factor for fundus pathologies, such as retinal detachment, macular degeneration, and glaucoma, which can lead to impairment vision impairment and even blindness[4-5]. Therefore, implementing effective myopia prevention and control measures during adolescence to curb its progression to high myopia holds significant clinical and public health importance.

Currently, a variety of interventions have been proven to delay the progression of myopia in school-aged children to some extent. These include different concentrations of atropine[6-8], orthokeratology (OK) lenses[9-10], soft contact lenses with peripheral defocus design[11-13], and spectacles with special optical structures[14-17]. From a mechanistic perspective, animal studies have clearly demonstrated that the basis for optical intervention in myopia control lies in altering the peripheral defocus state of the retina[18-20]. Although this mechanism has not been fully confirmed in humans, multiple animal studies consistently show that introducing myopic defocus effectively suppresses axial elongation[18,20].

Over the past decade, numerous studies have reported that inducing relative peripheral myopic defocus *via* contact lenses

can delay myopia progression in children by approximately 40%–60%. Such lenses currently mainly fall into two design categories: bifocal concentric lenses[11-12] and peripheral gradient lenses[13]. However, existing research predominantly focused on participants with low-to-moderate myopia (>−6.00 D), and evidence regarding the efficacy of contact lens interventions specifically in moderate or high myopia remains limited.

A systematic review[21] pointed out significant limitations of existing methods for controlling high myopia (≤−5.00 D): low-concentration atropine has limited efficacy (0.01%) while higher concentrations (1%) cause significant side effects; OK lenses have fitting difficulties in extreme myopia; and defocus incorporated multiple segments spectacles exhibit minimal effect on high myopia progression. These limitations highlight the urgent need for new intervention strategies.

Rigid gas-permeable (RGP) contact lenses, as an established vision correction method, can provide excellent visual quality and good ocular tolerance. However, it remains unclear whether RGP lenses are effective in controlling myopia especially in children with moderate-to-high myopia (≤−5.00 D)[22-24]. Li *et al*[25] reported slower axial elongation (mean: 0.07 mm) in children with unilateral high myopia wearing RGP lenses, yet robust evidence for bilateral moderate-to-high myopia remained scarce.

Based on this background, an RGP based on the myopic defocus theory, named the "progressive defocus RGP (DRGP)" lens, was developed. The investigational DRGP lenses feature three core characteristics: 1) progressive defocus rings, 2) high-order aspheric surfaces, 3) high oxygen transmission (Dk=125), making it functionally and structurally distinct from conventional RGPs.

This research study focuses on the efficacy of defocus RGP lenses in controlling axial elongation, a less investigated area compared to conventional RGP lenses or OK lenses studies, thereby providing robust clinical evidence of its efficacy in myopia control and offering a new corrective option for patients with moderate-to-high myopia.

PARTICIPANTS AND METHODS

Ethical Approval This study was conducted in strict accordance with the tenets of the Declaration of Helsinki and was approved by the Institutional Ethical Committee Review Board of the hospital [Approval No.(2022)LUNSHEN(1)].

Study Design This retrospective study utilized clinical records and device readouts from children who visited the Xi'an No.1 Hospital (Shaanxi Province, China) for vision correction with DRGP (Eyebright Co. Ltd., Beijing, China) or single-vision (SV) spectacles during the period from January 2021 to December 2022. The study employed specific inclusion and exclusion criteria.

Participants Inclusion criteria: 1) aged 6y to 18y; 2) spherical equivalent (SE) ≤−5.00 D; 3) received a full year of DRGP or SV treatment; 4) completed a 12-month follow-up assessment; 5) daily wear duration over 12h.

Exclusion criteria: 1) underlying ocular diseases such as retinopathy, prematurity, neonatal problems, a history of genetic diseases, neurodevelopmental conditions that might affect refractive development, or connective tissue disorders associated with myopia; 2) incomplete datasets, specifically lacking cycloplegic refraction, axial length (AL) measurements, or complete visit logs.

The control group was constituted by selecting participants from the SV cohort who matched to the DRGP group on baseline age and refractive error, using direct comparison of variable means±standard deviations.

According to research on the biological characteristics of the eyes of Chinese school-aged children and the prevalence of myopia, the myopia rate in the 13–18 age group is significantly higher than that in younger age groups, while the progression of myopia slows down markedly[26-27]. Therefore, using age 13 as the cutoff, participants were divided into two age subgroups: 6–12y and 13–18y, to compare the differences in axial elongation rates between these subgroups.

DRGP Lens Fitting and Follow-Up In this study, iBright® progressive DRGP (Eyebright Co. Ltd., Beijing, China) were utilized for the DRGP group and were worn daily. The DRGP lenses were made of fluorosilicone acrylate, featuring an oxygen permeability (Dk) of 125 (10^{-11} cm²×mL O_2)/(s×mL×mm Hg). The diameter of the lenses varied from 7.0 to 11.0 mm, while the power ranged from -25.00 to -1.00 D. The base curve radius of the lenses spanned from 7.00 to 8.50 mm.

Both surfaces of the iBright® DRGP were of an aspheric design. The front optic zones of the iBright® DRGP had a design that imitated the shape of the cornea formed by ortho-K[28]. Its refractive power distribution was flat in the central area for distance vision and steep in the paracentral area, providing a continuous progressive positive add power of up to +5.50 D at 6.0 mm (Figure 1). Due to the high-order aspheric technology, the refractive power profile of the lens across the optic zone was smooth, without clear boundaries at the critical regions.

A proper fit was evaluated based on the fluorescein pattern when the DRGP was on the eye as well as the corneal topography. Figure 2 shows the corneal topography after wearing the DRGP on the eye. The lenses were ordered according to the over-refraction targeted at plano. Follow-up visits were scheduled for 1d, 1wk, 1mo, 3mo, and then every 3mo after commencing DRGP wear.

Measurements For subjects in both groups, best-corrected visual acuity (BCVA), central refraction (using the KR-1

Table 1 Baseline data of subjects

Parameters	DRGP (*n*=56)		SV (*n*=53)		*P*
	Mean±SD	M (min, max)	Mean±SD	M (min, max)	
Age, y	11.96±2.32	12.00 (6.00, 16.00)	11.09±2.33	12.00 (7.00, 16.00)	0.070
Gender, male/female		17/39		24/29	0.055
Spherical power, D	-6.62±1.67	-6.25 (-12.00, -4.00)	-6.48±1.48	-6.25 (-10.00, -4.00)	0.853
Cylindrical power, D	-1.38±0.82	-1.25 (-4.50, 0.00)	-1.64±1.27	-1.50 (-7.00, 0.00)	0.486
SE, D	-7.31±1.76	-6.94 (-12.75, -4.63)	-7.30±1.62	-7.50 (-11.25, -4.38)	0.757
Flat K, D	42.82±1.32	42.75 (40.07, 45.78)	42.60±1.31	42.61 (39.34, 45.00)	0.383
Steep K, D	44.55±1.39	44.47 (41.14, 48.03)	44.41±1.56	44.35 (41.01, 47.80)	0.634
AL, mm	26.18±0.89	26.13 (24.32, 28.59)	26.02±0.90	25.95 (23.62, 28.31)	0.352
ACD, mm	3.68±0.33	3.72 (2.89, 4.19)	3.75±0.06	3.82 (2.88, 4.61)	0.346
CCT, μm	537.52±29.59	537.00 (484.00, 617.00)	543.91±28.83	546.00 (467.00, 615.00)	0.257
WTW, mm	11.96±0.37	11.91 (11.20, 12.98)	11.86±0.42	11.90 (11.00, 12.76)	0.605

SD: Standard deviation; M: Medium; min: Minimum; max: Maximum; DRGP: Progressive defocus rigid gas permeable contact lenses; SV: Single vision spectacle lenses; SE: Spherical equivalent; Flat K: Flat keratometry; Steep K: Steep keratometry; AL: Axial length; ACD: Anterior chamber depth; CCT: Central corneal thickness; WTW: White-to-white distance.

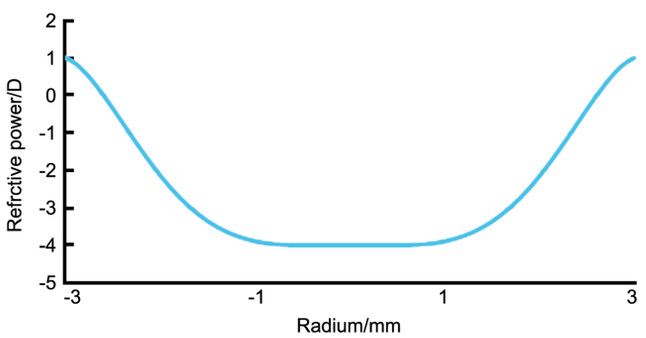


Figure 1 The refractive power design of progressive defocus rigid gas permeable contact lenses.

device from Topcon Corp., Tokyo, Japan), and AL (using the OA-2000 device from Tomey Inc., Nagoya, Japan) were assessed at baseline, 6mo, and 1y. Corneal topography (using the TMS-4 device from Tomey Inc., Nagoya, Japan) was measured at baseline.

Statistical Analysis Data were analyzed using Origin 2021 (Origin Lab Corporation, Northampton, MA, USA). Since no statistically significant differences were found between the two eyes, only data of the right eyes were analyzed. Normality was assessed with the Shapiro-Wilk test. The Mann-Whitney *U* test compared age, spherical power, cylindrical power, and SE (non-normally distributed), while the independent *t*-test compared AL change, keratometry, and other ocular biometric parameters (normally distributed). The Chi-square test was used for sex distribution. Within-group AL changes over time were analyzed by repeated-measures analysis of variance (ANOVA). The myopia control efficacy was calculated as: [(mean AL change in SV group-mean AL change in DRGP group)/mean AL change in SV group]×100%. Correlations and influencing factors were assessed by Spearman analysis and multiple linear regression, respectively. Statistical significance was set at $P<0.05$, with Bonferroni correction ($\alpha=0.025$) applied for subgroup analyses.

RESULTS

Baseline Characteristics Flowchart of the study and dropouts is shown in Figure 3. The DRGP lenses group comprised 56 subjects, the SV spectacle group comprised 53 subjects. The DRGP group had an average initial age of 11.96±2.32y, with 17 males (30%) and 39 females (70%), and the SV groups had an average initial age of 11.09±2.33y, with 24 males (45%) and 29 females (55%).

There were no statistically significant differences in baseline characteristics, including age, sex ratio, spherical powers, cylindrical powers, SE, flat keratometry (K), steep K, AL, anterior chamber depth, white-to-white distance, central corneal thickness between the two groups ($P>0.05$; Table 1).

Change in AL Changes in AL over time within the two groups as well as their respective linear fits were shown in Figure 4A. It was found that significant increases in AL occurred over time in both groups, and the relationship between AL change and time approximated linearity. Specifically, in the SV group, the coefficient of determination (r^2) was 0.9967, while in the DRGP group, it was 0.9985. In the SV group, a significant increase in AL was detected at the 6-month visit (26.27±0.12 mm) and the 12-month visit (26.47±0.12 mm), when compared to the baseline value (26.02±0.12 mm; all $P<0.001$). Moreover, the slope of the fit line for this group was determined to be 0.037 mm/mo. Conversely, in the DRGP group, a significant increase in AL was also identified at the 6-month visit (26.27±0.12 mm) and the 12-month visit (26.37±0.12 mm), relative to the baseline (26.18±0.12 mm; all $P<0.001$). Notably, the slope of the fit line in this group was 0.016 mm/mo, which was less than half of that in the SV group.

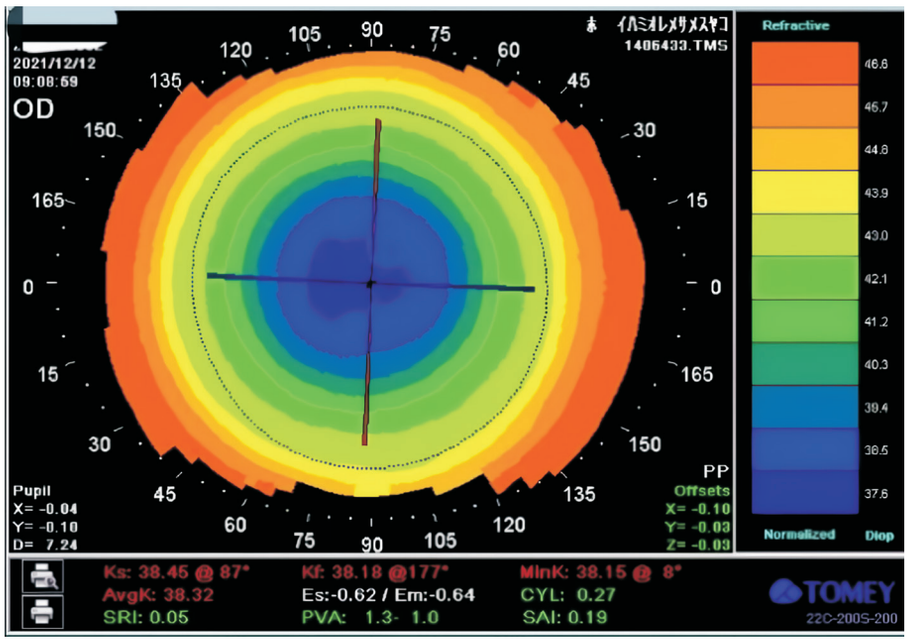


Figure 2 The corneal topography after wearing the progressive defocus rigid gas permeable contact lenses on the eye.

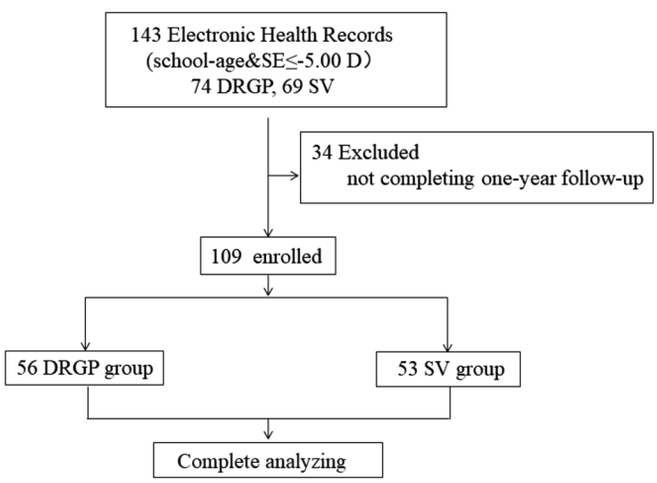


Figure 3 Flowchart of the study and dropouts DRGP: Progressive defocus rigid gas permeable contact lenses; SV: Single vision spectacle lens; SE: Spherical equivalent.

Notably, a disparity greater than 0.1 mm was found between the two groups at both the 6-month and 12-month visits (Figure 4B). The axial elongation of DRGP group progressed 64.0% less than that in the SV group within the first 6mo (0.09±0.09 *vs* 0.25±0.12 mm, P<0.001). Moreover, within 12mo, the axial elongation of DRGP groups progressed 57.8% less than that in the SV group (0.19±0.13 *vs* 0.45±0.20 mm, P<0.001).

Factors Affecting AL Growth Multivariable linear regression (adjusted for age and baseline SE) model showed that group (DRGP *vs* SV) was a significant predictor of axial elongation. This indicates that, wearing DRGP is significantly associated with a reduction in axial elongation at both 6mo (β=-0.747, P=0.046) and 12mo (β=-0.852, P=0.018; Table 2).

Age showed a significant negative association with axial elongation (6mo: β=-0.369, P=0.001; 12mo: β=-0.396, P<0.001). However, no significant association was found for the baseline SE or the group-by-age interaction (all P>0.05; Table 2).

Table 2 Factors relevant to axial elongation in DRGP and SV Group over 6 and 12mo

Factors	6mo		12mo	
	β	P	β	P
Group (DRGP/SV)	-0.747	0.046	-0.852	0.018
Age	-0.369	0.001	-0.396	0.000
SE	0.055	0.449	0.039	0.579
Group×age	0.230	0.557	0.316	0.402

DRGP: Progressive defocus rigid gas permeable contact lenses; SV: Single vision spectacle lens; SE: Spherical equivalent.

Table 3 Adjusted mean axial length change in each group

Mean axial length change	6mo		12mo	
	DRGP	SV	DRGP	SV
Adjusted mean (mm)	0.096	0.240	0.201	0.438
Standard error (mm)	0.014	0.014	0.021	0.021
P	<0.001		<0.001	

DRGP: Progressive defocus rigid gas permeable contact lenses; SV: Single vision spectacle lens.

The results of the adjusted mean AL change demonstrated that the DRGP group had a significantly smaller axial elongation than the SV group at both 6mo (0.096 *vs* 0.240 mm) and 12mo (0.201 *vs* 0.438 mm; both P<0.001; Table 3). This finding corroborates the significant association of the group factor identified in the regression model.

Factors Affecting AL Growth in DRGP Group Pearson's correlation analysis revealed a significant moderate correlation between axial elongation and age (r=-0.46, P<0.001) as well as corneal flat K (r=-0.34, P=0.010) within the DRGP group (Figure 5).

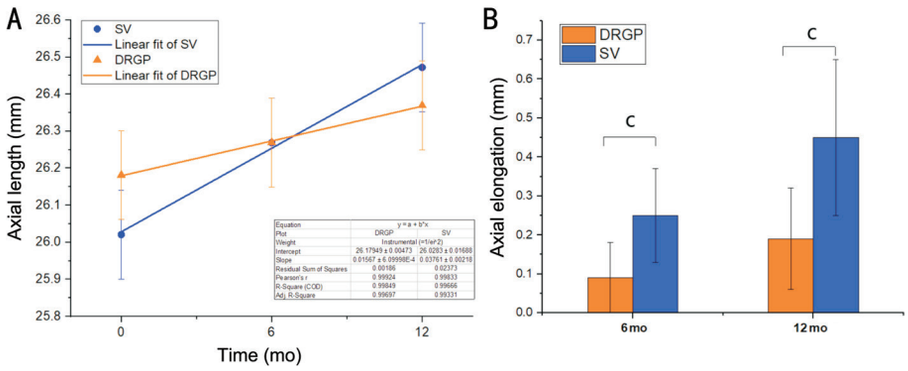


Figure 4 Axial length and its linear fit (A) and axial elongation (B) in the DRGP and SV groups over 12mo $^{c}P<0.001$; Error bars represent standard deviation. DRGP: Progressive defocus rigid gas permeable contact lenses; SV: Single vision spectacle lens.

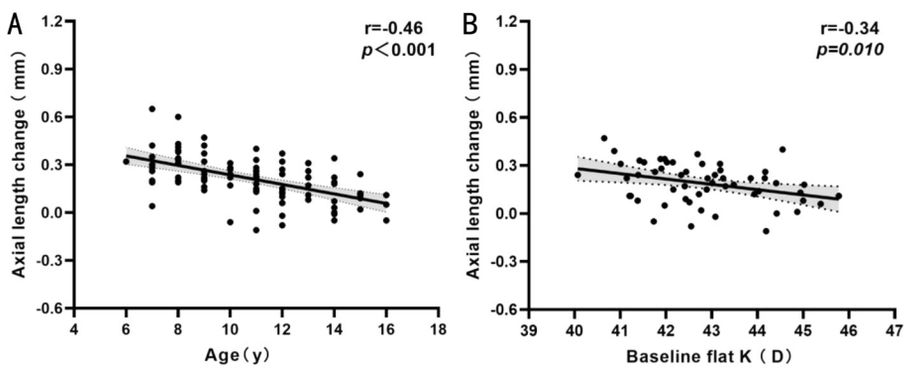


Figure 5 Scatter plots showing correlations of axial length elongation at 12mo of follow-up, with the baseline age (A) and baseline flat K (B) in DRGP group Flat K: Flat keratometry; DRGP: Progressive defocus rigid gas permeable contact lenses.

Regarding the comparison between older and younger subjects in each group at the 6-month follow-up, no significant differences were observed (all $P>0.05$). However, at the 12-month stage, it was found that subjects aged 13–18y demonstrated slower axial elongation compared to those aged 6–12y (all $P<0.05$, Bonferroni-corrected; Table 4).

DISCUSSION

The current study demonstrated that DRGP is a viable option for myopia control for high myopic children. Children wearing the DRGP had axial elongation reduced by 57.8% over 1-year, when compared to that of subjects wearing SV spectacles (0.19±0.13 *vs* 0.45±0.20 mm, $P<0.01$). This study adds to the limited evidence investigating the efficacy of DRGP for myopia control and is therefore highly valuable for guiding its clinical practice.

In recent years, numerous optical correction methods have been demonstrated to be effective in slowing the progression of myopia among children. Examples include defocus incorporated soft contact lenses[11], misight contact lenses[12], defocus incorporated multiple segments spectacles[14], highly aspherical lenslets[15], and so on. However, the majority of these studies did not incorporate children with myopia exceeding -5 D. Whether these methods are equally efficacious in retarding the progression of high myopia remains in the clinical exploration phase.

Table 4 Axial elongation change at 6- and 12-month visits in the two groups mean±SD

Axial elongation change	6–12y	13–18y	*P*
6-month follow up			
DRGP	0.10±0.11 (*n*=33)	0.07±0.07 (*n*=23)	0.080
SV	0.27±0.13 (*n*=37)	0.20±0.10 (*n*=16)	0.073
12-month follow up			
DRGP	0.21±0.14 (*n*=33)	0.15±0.10 (*n*=23)	0.032
SV	0.48±0.21 (*n*=37)	0.20±0.10 (*n*=16)	0.041

DRGP: Progressive defocus rigid gas permeable contact lenses; SV: Single vision spectacle lens; SD: Standard deviation.

DRGP is suitable for correcting moderate to high myopia and can also be applied in patients with significant astigmatism, distinguishing its applicability from that of OK lenses[29-31]. In recent years, as the prevalence of childhood myopia and the degree of astigmatism have continued to rise[32-33], this study confirms that after one year of wearing DRGP lenses, their effectiveness in slowing axial elongation reaches 57.8% compared to SV lenses. As one of the few studies supporting the efficacy of DRGP in myopia control, it holds significant importance for guiding its clinical application.

In our study, DRGP group exhibited an annual axial elongation of 0.19±0.13 mm, while the SV group demonstrated an annual axial elongation of 0.45±0.20 mm. It suggests that the rate of AL elongation over time in the DRGP group was relatively

slower compared to the SV group, potentially indicating a more favorable effect of the DRGP lens in terms of mitigating the progression of AL growth. Other researchers have reported similar findings. For example, Zhang *et al*[29], which observed an annual axial elongation of 0.18 mm for DRGP lenses compared to 0.33 mm for SV lenses. When compared with other myopia control strategies, the DRGP lens demonstrated significantly greater efficacy in slowing axial elongation in children (57.8%) than either progressive addition lenses (ranging from 10% to 35%)[16,34-35] or peripheral defocus spectacle lenses[36]. Moreover, the myopia control efficacy of DRGP is comparable to that of OK lenses (60%)[37], and bifocal soft contact lenses (50%–60%)[11-12,37], but lower than either high- or low-concentration atropine (>60%)[6-8,38].

In our study, it was found that older subjects wearing DRGP demonstrated a slower AL elongation after wearing DRGP or SV for 12mo. This is similar to the findings in Bao *et al*'s[15] research, where it was observed that a younger age was associated with a faster elongation of AL in the slightly aspherical lenslets (SAL) groups. Cho *et al*[39] also suggested that changes in the AL were related to the age of ortho-k subjects. Xu *et al*[40] also reported that atropine could achieve better efficacy in younger children. These results suggest that age plays a role in the progression of axial elongation, with older adolescents potentially experiencing a relatively slower increase in AL over time. It is hypothesized that the influence of age on the myopia-control efficacy of DRGP lenses stems from younger children exhibiting a larger magnitude of peripheral hyperopia. Consequently, the effective myopic defocus achieved at the retina is relatively diminished, resulting in an attenuated control effect.

In addition, this study also identified flat corneal keratometry at baseline as a significant factor influencing the axial elongation rate. This finding is consistent with the results reported by Zhang *et al*[29], whose research confirmed that the mean keratometry value affects the axial elongation rate in DRGP wearers. Likewise, age and corneal curvature have also been recognized as factors influencing the myopia control efficacy of OK lenses[41-43]. In several previous studies, wearing time was identified as a significant factor influencing the treatment effect of lenses, as exemplified by defocus incorporated soft contact lenses[11] and highly aspherical lenslets[15]. Specifically, the children in this study were capable of wearing DRGP lenses consistently, with an average wearing time of over 12h per day, demonstrating high compliance. This prolonged daily wear likely enhanced the treatment outcomes in the experimental group. Additionally, it was found that the size and position of myopic defocus were directly associated with the refractive changes in chicks[20].

This study has several limitations. First, its single-center design, recruiting subjects from an urban hospital, may limit the generalizability of the findings to broader populations. Furthermore, the one-year observation period is relatively short, leaving the long-term efficacy of DRGP lenses in doubt. Additionally, the retrospective design prevented the collection of detailed data on potential confounding factors such as time spent outdoors, near-work duration, and working distance. Future research should include multi-center, long-term prospective studies to validate these findings and explore the underlying mechanisms of the observed age-related differences.

The daily wear of the DRGP lens has been shown to significantly slow axial elongation in myopic schoolchildren when compared with wearing SV spectacle lenses. Additionally, it identifies age and corneal curvature as factors influencing the myopia control efficacy of DRGP. The study provides a new option for the correction and control of myopia in children with moderate to high myopia, while also offering insights for further research into the mechanisms of myopia progression.

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Authors' Contributions: Zhang XH designed the study, collected and analyzed the data, wrote the manuscript and acquired the funding; Zheng HH collected the data and wrote the manuscript; Li P, Wang J, Ai X, and Kang L collected and analyzed the data; Pei C managed and designed the study, and revised the manuscript.

Data Availability Statement: The datasets generated and analyzed in this study are available from the corresponding author on reasonable request.

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Conflicts of Interest: Zhang XH, None; **Zheng HH,** None; **Li P,** None; **Wang J,** None; **Ai X,** None; **Kang L,** None; **Pei C,** None.

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