• Clinical Research •

Efficacy and ocular surface safety of different correction methods for adolescents with high myopia

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Abstract

● **AIM:** To investigate efficacy and ocular surface safety of 3 kinds of different correction methods for correction of high myopia in adolescents.

● **METHODS:** A prospective, randomized, controlled clinical trial was conducted. From January 2022 to December 2022, 62 adolescents with high myopia (124 eyes) were recruited, with spherical refractive errors ranging from -6.00 to -7.50 diopters (D) and refractive astigmatism ≤1.50 D. All participants were randomly assigned to three groups: the orthokeratology combined with single-vision spectacle lenses (OK+SVLs) group (20 cases, 40 eyes), the peripheral defocus rigid gas permeable contact lenses (Defocus RGPCL) group (22 cases, 44 eyes), and the single-vision spectacle lenses (SVLs) group (20 cases, 40 eyes). All of them were followed up for 1.5y. The observation indicators included refractive error, axial length (AL), tear break-up time (BUT), percentage of hexagonal corneal endothelial cells (CEC), CEC density, and ocular surface adverse reactions.

● **RESULTS:** The three groups had mean age of 14.84±1.87y, 14.57±1.91y, and 14.80±1.52y, respectively. No statistically significant differences were found in age, gender, corneal curvature, AL, and spherical equivalent among the groups (all $P>0.05$). At the 6mo, 1, and 1.5y follow-ups after spectacle lens wear, the improvements in refractive error in the OK+SVLs and Defocus RGPCL groups were significantly superior to those in the SVLs group ($F=4.221$, $P=0.017$; $F=7.226$, $P=0.001$; $F=16.140$, $P<0.001$), while no significant difference was observed between the OK+SVLs and Defocus RGPCL groups (all $P>0.05$). Intergroup comparisons of AL changes revealed statistically significant differences at all follow-up time points ($F=3.493$, $P=0.034$; $F=9.930$, $P<0.001$; $F=20.570$, $P<0.001$), with no notable difference between the OK+SVLs and Defocus RGPCL groups (all $P>0.05$). After 1.5y of lens wear, the intergroup comparison of BUT showed a statistically significant difference ($F=5.783$, $P=0.004$), whereas no significant differences were found in the percentage of hexagonal CEC and CEC density among the three groups (all $P>0.05$). No severe complications were observed in the two contact lens groups; only 5 eyes presented with grade 1 or 2 bulbar conjunctival hyperemia and corneal epithelial staining. All adverse reactions were well controlled by temporary lens discontinuation or medication, and resumed lens wear subsequently, with no statistically significant difference in the incidence of adverse reactions between the two contact lens groups ($P>0.05$).

● **CONCLUSION:** Orthokeratology lenses and peripheral defocus RGPCL yield better visual acuity correction and superior image quality, which can minimize retinal image aberrations induced by high refractive errors. Both interventions achieve satisfactory corrective vision and effective myopia control effects in adolescents with high myopia, with no significant adverse reactions observed during the follow-up period, indicating a high level of wearing safety for clinical application.

● **KEYWORDS:** orthokeratology; peripheral defocus rigid gas permeable contact lenses; high myopia; myopia control; safety

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INTRODUCTION

Myopia is a highly prevalent condition worldwide. Currently, the global prevalence of myopia exceeds 28.3%, and it is projected to reach 49.8% by 2050, with the rate of high myopia escalating from the current 4.0% to 9.8%[1-2]. Epidemiological surveys in China have shown an annual increase in the prevalence of myopia among primary and secondary school students, with trends toward younger

ages and higher degrees of myopia[3]. The prevalence of myopia in children and adolescents aged 6 to 18 is about 53.6%, and in senior high school students, the rate of high myopia reaches 20%[4]. Compared to low to moderate myopia, high myopia increases the risk of pathological changes due to excessive elongation of the eyeball and continuous increase in diopter[5]. Among individuals with high myopia, the incidence of blinding eye diseases such as cataracts, glaucoma, myopic macular degeneration, retinal detachment, and myopic optic neuropathy is significantly higher than in those with normal vision[6]. Pathological myopia leading to retinal lesions has become the leading cause of irreversible blindness in China. Thus, the prevention and control of high myopia are urgently needed.

Currently, methods for correcting high myopia range from traditional single vision spectacle lenses (SVLs) to myopia control spectacle lenses, and rigid gas permeable contact lenses (RGPCLs), and orthokeratology (OK) lenses. These methods have been clinically validated over decades both nationaly and internationally. Defocus RGPCLs and OK lenses have proven effective in controlling the progression of myopia compared to other correction methods[7-9]. However, there has not yet been a clinical efficacy comparison reported for these two types of contact lenses. Defocus RGPCLs are primarily worn during the day but are less comfortable, whereas OK lenses are worn at night but require the use of a low-diopter spectacle frame during the day. To better serve clinical needs, this study examines the effectiveness of myopia control and ocular surface safety among adolescents with high myopia using OK lenses, defocus RGPCLs, and SVLs in our outpatient clinic, to better substantiate this viewpoint and more effectively control the progression of high myopia, thus reducing the harm caused by myopia.

PARTICIPANTS AND METHODS

Ethical Approval This study's Clinical Trial Registry Number is ChiCTR2400085673 (Chinese Clinical Trial Registry), it was approved by the Ethics Committee of Ningbo Eye Hospital (Approval number: 2022-014), adhered to the Helsinki Declaration, and informed consent was obtained from all participants, signed by the patients themselves or their guardians.

Participants A total of 62 patients (124 eyes) with high myopia ranging from -6.00 to -7.50 D, who visited the optometry clinic of Ningbo Eye Hospital between January 2022 and December 2022, were selected. Using a completely randomized digit table method, participants were divided into three groups: OK+SVLs group (20 patients, 40 eyes), Defocus RGPCL group (22 patients, 44 eyes), and SVLs group (20 patients, 40 eyes). All participants underwent pre-fitting examinations including slit-lamp examination, fundoscopy, corneal endothelial cell evaluation, and tear film assessment to rule out ocular diseases. Refraction and corneal curvature were measured using objective refraction post-cycloplegia, administered with compound tropicamide eye drops every 10min for three doses, followed by measurements with an autorefractor, with at least three readings taken per eye. The data for both eyes were collected and followed up for 1.5y.

Inclusion criteria: 1) aged 12-18y; 2) myopic spherical equivalent (SE) ranging from -6.00 to -7.50 D and refractive astigmatism of 1.50 D or less, with an interocular difference of ≤1.00 D; 3) visual acuity tested with a standard logarithmic visual acuity chart, recording a best corrected distance visual acuity (BCDVA) of ≥1.0; 4) corneal refractive power between 39.50 and 46.50 D horizontally, and 39.50 to 47.00 D vertically; 5) atropine users must have ceased usage three weeks prior to examination; 6) fundoscopic examination grades 0 and 1 indicating simple high myopic retinal changes; 7) follow-up observations of over 1.5y with complete data.

Exclusion criteria: 1) binocular vision anomalies; 2) regular astigmatism ≥2.00 D or irregular astigmatism ≥1.00 D; 3) presence of anterior segment diseases, retinal diseases, ocular trauma, or surgical history; 4) history of other contact lens wear; 5) systemic immune diseases; 6) use of atropine or any other medication affecting refractive status during past or follow-up periods. Classification of high myopia[10]: based on the diagnostic standards for myopic macular degeneration set by the Asian Academy of Optometry, the Asian Optometric Association, and the American Academy of Ophthalmology, the classification is determined by the symptoms in the macular region and graded as: Grade 0 (no myopic retinal degenerative lesions); Grade 1 (tigroid fundus); Grade 2 (diffuse choroidal retinal atrophy); Grade 3 (patchy choroidal retinal atrophy); Grade 4 (macular atrophy) along with other injuries such as lacquer cracks, myopic choroidal neovascularization, and Fuchs spot. It is important for ophthalmic and optometric professionals to recognize that Grades 0 and 1 represent simple high myopic retinal changes, while Grades 2 and above indicate pathological high myopic changes.

Methods Fitting procedure for the OK and Defocus RGPCL groups: strict adherence to the fitting protocols for OK lenses and defocus RGPCL was maintained[11]. This included a medical history review, pre-fitting examinations [using the international standard logarithmic visual acuity chart to assess uncorrected distance visual acuity (UDVA), which was then converted to logMAR for recording and analysis], refraction, intraocular pressure, axial length (AL), corneal topography, tear film break-up time (BUT), endothelial cell count, and slit-lamp fundus examinations. The OK lens group utilized corneal refractive therapy (CRT) lenses, with trial lenses selected based on parameters provided by the CRT scale for

Table 1 Comparison of baseline data of participants

Parameters	OK+SVLs (*n*=40)	Defocus RGPCL (*n*=44)	SVLs (*n*=40)	χ^2/F	*P*
Number of cases (eyes)	20 (40)	22 (44)	20 (40)		
Gender (M/F)	11/9	12/10	10/10	0.124	0.940
Age (y)	14.84±1.87	14.57±1.91	14.80±1.52	0.285	0.753
SE (D)	-6.75±0.73	-6.81±0.56	-6.67±0.61	0.511	0.601
AL (mm)	26.89±0.74	26.94±0.89	26.78±0.76	0.431	0.651
Flat K (D)	43.67±1.87	43.52±1.58	43.73±1.54	0.179	0.837
Steep K (D)	45.46±1.38	45.09±1.51	45.32±1.67	0.634	0.532
Corneal endothelial cells (cells/mm^2)	3188±223	3111±197	2978±235	2.706	0.071
BUT (s)	10.87±2.07	10.37±1.89	10.93±2.14	0.975	0.380

OK: Orthokeratology; SVLs: Single-vision spectacle lenses; Defocus RGPCL: Defocus rigid gas permeable contact lenses; SE: Spherical equivalent; AL: Axial length; Flat K: Flat keratometry value; Steep K: Steep keratometry value; BUT: Break-up time; M: Male; F: Female.

assessment and trial fitting. In cases of high astigmatism or limbus-to-limbus corneal astigmatism, CRT-E lenses were used. Fitting assessments, adjustments, finalization of lens parameters, and customization followed. Follow-ups were scheduled for one day, one week, one month, three months, and then every three months thereafter (or sooner if issues such as eye redness, itchiness, or displacement occurred), with each visit documented. For the Defocus RGPCL group, an average corneal curvature radius was used for trial fitting. Lens fitting, adjustment, vertex distance conversion for prescription selection, and SE transformation for astigmatic corrections were performed, culminating in the final lens prescription. Regular follow-ups were scheduled for one month, three months, and then every three months thereafter (with timing adjusted for any issues), with each visit documented. Lens replacement was typically required after approximately 1.5y, but earlier replacement was necessitated if a decline of two lines or more in BCDVA occurred, or if lens damage such as cracks was observed. All fittings for both OK lenses and defocus RGPCL were conducted by the first author. At the study's conclusion after 1.5y, patients in the OK lens group were advised to cease wearing the lenses for at least three weeks, and those in the Defocus RGPCL group for one week, followed by evaluations of both uncorrected and corrected visual acuities, corneal curvature, refractive status, AL, corneal topography, BUT, percentage of hexagonal corneal cells, and endothelial cell density. Additionally, during post-fitting follow-ups, assessments of lens fit, position, mobility, cleanliness, and conjunctival and corneal health were conducted.

Materials and Equipment OK lens materials were Paragon CRT100 lenses (Paragon Vision Sciences, Gilbert, AZ) made of HDS100 (Paflufocon D, Dk=100 barrer). Defocus RGPCL lenses (Eagle Vision, Taiwan, China) were composed of fluoromethacrylate, with a DK value of 109×10^{-11} (cm^2/s), hardness of 83HSD, and a refractive index of 1.439. The spectacle lenses used were Essilor single-vision aspheric lenses. The examination equipment included an automatic refractometer (TOPCON KR8100PA, Japan), a comprehensive refractometer (HUVITZ, Korea), IOL-Master (Carl Zeiss, Germany), a corneal topographer (oculus Pentacam, Germany; all participants underwent Pentacam corneal topography to check the anterior and posterior corneal surfaces and exclude conditions such as keratoconus), endothelial cell counter (Carl Zeiss), and BUT measurement device (Carl Zeiss).

Statistical Analysis All data were processed using SPSS 25.0 statistical software. Normally distributed quantitative data are presented as mean±standard deviation. Differences between multiple groups of quantitative data were compared using one-way analysis of variance (ANOVA), followed by pairwise comparisons using the LSD-T test. The significance level (α) was set at 0.05, with $P<0.05$ considered statistically significant.

RESULTS

Baseline Characteristics of Participants All participants completed the study with no dropouts. Baseline characteristics of the enrolled subjects showed no significant differences ($P>0.05$), as detailed in Table 1.

Changes in Spherical Equivalent Among Groups The changes in refractive error at 6mo, 12mo, and 1.5y were compared among the three groups. Both the OK+SVLs group and the Defocus RGPCL group showed significantly better effects in slowing myopia progression compared to the SVLs group, with statistically significant differences ($F=4.221$, $P=0.017$; $F=7.226$, $P=0.001$; $F=16.140$, $P<0.001$). There was no statistically significant difference between the OK+SVLs group and the Defocus RGPCL group. Within the OK+SVLs group, the increase in refractive error was -0.53±0.09 D ($F=6.629$, $P<0.001$), in the Defocus RGPCL group, it was -0.68±0.13 D ($F=8.575$, $P<0.001$), and in the SVLs group, it was -1.47±0.38 D ($F=39.832$, $P<0.001$), as detailed in Figure 1.

Changes in Axial Length The comparison of AL changes at 6mo, 1y, and 1.5y among the three groups showed statistically significant differences ($F=3.493$, $P=0.034$; $F=9.930$, $P<0.001$; $F=20.570$, $P<0.001$). There was no statistically significant difference between the OK+SVLs group and the Defocus

RGPCL group. Within the OK+SVLs group, the AL increased by 0.38±0.16 mm (F=67.762, P<0.001), in the Defocus RGPCL group, it increased by 0.41±0.08 mm (F=46.193, P<0.001), and in the SVLs group, it increased by 0.84±0.27 mm (F=93.712, P<0.001). Both the OK+SVLs group and the Defocus RGPCL group showed significantly better effects in slowing the increase in AL compared to the SVLs group, as detailed in Figure 2.

Comparison of BUT, Percentage of Hexagonal Corneal Cells, and Corneal Endothelial Cell Density Among the Three Groups The comparison of BUT, percentage of hexagonal corneal cells and corneal endothelial cell density among the OK+SVLs, Defocus RGPCL, and SVLs groups after 1.5y of wearing lenses showed statistically significant differences, as detailed in Table 2.

Ocular Surface Complications Due to high myopia, the use of OK lenses requires greater molding pressure on the central cornea, which increases the risk of corneal complications. In this study, the OK+SVLs group primarily experienced corneal epithelial staining in 2 eyes, corneal pigmentation in 2 eyes, and conjunctival congestion in 1 case associated with RGPCL wear. These conjunctival and corneal complications generally resolved after a short period of lens discontinuation, medication, or lens adjustment. Additionally, a few patients exhibited allergic reactions, which were managed by switching the care solution or discontinuing lens wear. The incidence of adverse reactions, including conjunctival congestion, corneal epithelial staining, and corneal pigmentation, showed no statistically significant difference among the groups, as detailed in Table 3.

Fluorescence Patterns of Defocus RGPCL and OK Lenses Base curve (BC) shows slight contact with the central cornea, approximately 4 mm in diameter. The circumferential adjustment marker indicates no fluorescence leakage. Best fit ring (BFR) is closed and complete. If the lens fit is too tight, the BFR will appear very narrow or may not appear at all. Conversely, if the lens fit is too loose, there will be fluorescence pooling within the BFR. Peripheral curve (PC) staining width is moderate, ensuring adequate tear exchange. The OK lens displays a small central BC and a wide reverse curve (RC) design (Figures 3 and 4).

DISCUSSION

"Experts Consensus on the Prevention and Control of High Myopia (2023)", published by Chinese Optometric Association *et al*[12], further emphasizes the dangers and severity of high myopia. A cohort study of 10 000 highly myopic individuals in the Chinese population indicated that the average rate of high myopia among children and adolescents aged 6 to 18 increased from 4.11% (June 2019) to 4.99% (June 2020)

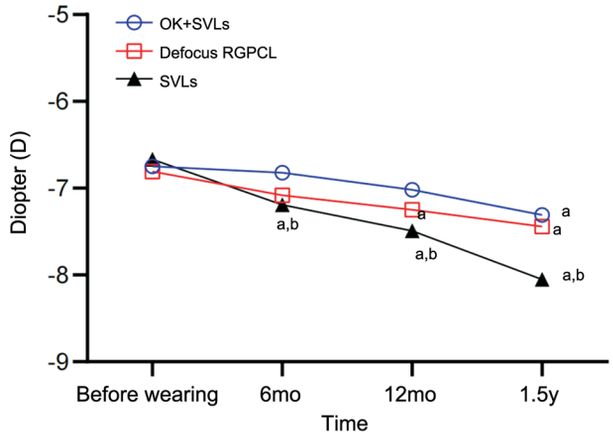

Figure 1 Changes in refractive error over time among OK+SVLs, Defocus RGPCL, and SVLs groups [a]P<0.05 within the group compared to before wearing; [b]P<0.05 compared to the OK+SVLs group. OK: Orthokeratology; SVLs: Single-vision spectacle lenses; Defocus RGPCL: Defocus rigid gas permeable contact lenses.

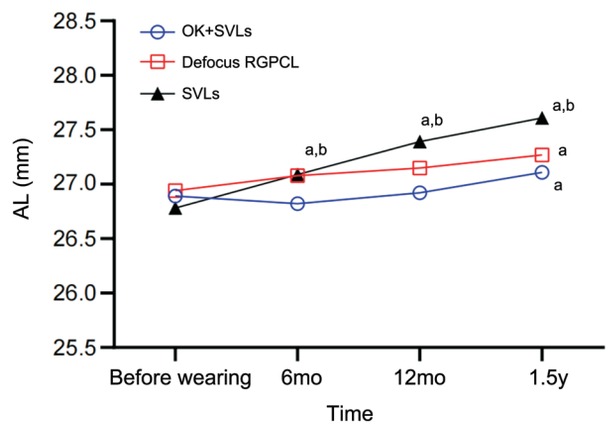

Figure 2 Comparison of AL (mm) among OK+SVLs, Defocus RGPCL, and SVLs groups [a]P<0.05 within the group compared to before wearing; [b]P<0.05 compared to the OK+SVLs group. AL: Axial length; OK: Orthokeratology; SVLs: Single-vision spectacle lenses; Defocus RGPCL: Defocus rigid gas permeable contact lenses.

during the pandemic[13]. The main hazards of high myopia lie in its complications. Excessive axial elongation caused by high myopia can lead to structural damage to the macula, resulting in posterior pole hemorrhage, Fuchs spots, choroidal neovascularization, retinal tears, macular holes, and retinal detachment, all of which impair visual function[14]. During adolescence, especially under the age of 18, the refractive state is in a constant state of flux due to genetic and physiological factors as well as environmental influences. This period is marked by a heavy academic workload and prolonged near work, leading to rapid myopia progression[15-16]. Finding safe and effective methods to halt the progression of myopia during this critical period is a key concern for ophthalmologists and parents. This study aims to address this significant issue.

The results of this study show that the uncorrected visual acuity of high myopia patients significantly improved after

Table 2 Comparison of BUT, percentage of hexagonal corneal cells, and corneal endothelial cell density before and after wearing lenses in the OK+SVLs, Defocus RGPCL, and SVLs groups

Parameters	OK+SVLs (*n*=40)	Defocus RGPCL (*n*=44)	SVLs (*n*=40)	*F*	*P*
BUT (s)					
Before wearing	10.87±2.07	10.37±1.89	10.93±2.14	0.975	0.380
18mo	9.09±2.23	10.33±1.76	10.53±2.19	5.783	0.004
t	3.697	0.103	0.826		
P	<0.001	0.918	0.411		
Percentage of hexagonal corneal cells (%)					
Before wearing	83.71±15.37	89.62±12.05	87.42±11.72	2.157	0.120
18mo	78.59±12.16	86.43±12.99	87.32±10.82	4.456	0.062
t	1.657	1.312	0.04		
P	0.102	0.191	0.968		
Corneal endothelial cell density (cells/mm^2)					
Before wearing	3188± 223	3111±197	2978±235	2.706	0.071
18mo	2998±161	3071± 121	3051±152	1.658	0.195
t	4.375	1.857	-1.651		
P	<0.001	0.072	0.103		

BUT: Break-up time; OK: Orthokeratology; SVLs: Single-vision spectacle lenses; Defocus RGPCL: Defocus rigid gas permeable contact lenses.

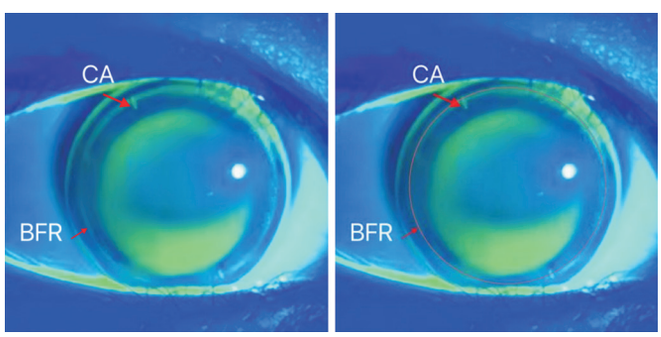

Figure 3 Fluorescence patterns of defocus RGPCL BFR: Best fit ring; CA: Cylinder adjustment; Defocus RGPCL: Defocus rigid gas permeable contact lenses.

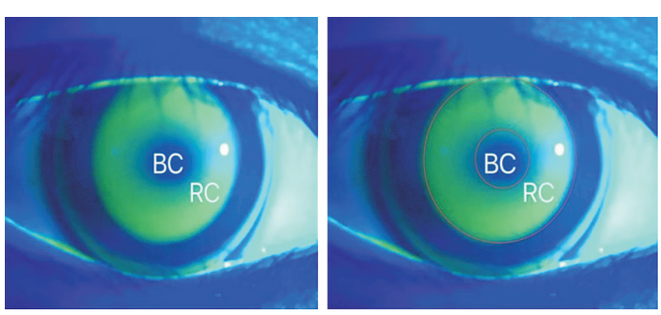

Figure 4 Fluorescence patterns of OK lenses BC: Base curve; RC: Reverse curve; OK: Orthokeratology.

wearing OK lenses, with a statistically significant difference compared to pre-wearing values. This finding is consistent with the research of Zhu and Zhou[17] and Zhang[18]. The reverse geometry design of OK lenses reshapes the corneal morphology, flattening the central cornea to achieve better uncorrected visual acuity. However, due to the refractive error of high myopia exceeding the maximum correction capacity of OK lenses, visual acuity stabilizes after one month of lens wear. Most wearers have daytime uncorrected visual acuity

Table 3 Comparison of complications among OK+SVLs, Defocus RGPCL, and SVLs groups

Parameters	OK+SVLs (*n*=40)	Defocus RGPCL (*n*=44)	SVLs (*n*=40)
Conjunctival congestion	0	1 (2.27%)	1 (2.5%)
Corneal epithelial staining	2 (5%)	0	0
Corneal pigmentation	2 (5%)	0	0
Total adverse reaction rate	4 (10%)	1 (2.27%)	1 (2.5%)
χ^2	3.418		
P	0.181		

OK: Orthokeratology; SVLs: Single-vision spectacle lenses; Defocus RGPCL: Defocus rigid gas permeable contact lenses.

between 0.5 and 0.6, and some require additional use of spectacles during the day to enhance their uncorrected vision. Comparison of refractive errors among the three groups after 1.5y showed that both the OK+SVLs group and the Defocus RGPCL group had a better myopia control effect compared to the SVLs group (P<0.05). The refractive error increase in the OK+SVLs group was -0.53±0.09 D, in the Defocus RGPCL group was -0.68±0.13 D, and in the SVLs group was -1.47±0.38 D. The control of high myopia was better in the OK+SVLs group than in the Defocus RGPCL group, although the difference between these two groups was not statistically significant (t=1.145, P>0.05). These results are consistent with the findings of Zhang *et al*[19] and Xue[20]. The reshaping effect of OK lenses on the cornea, and the peripheral defocus of RGPCL lenses closer to the retina, reduce peripheral hyperopic defocus, thereby slowing the axial elongation of myopic eyes. Currently, Yang *et al*[21] and others believe that the optical defocus control technique, which transforms peripheral hyperopic defocus into myopic defocus, has gradually

been applied to control myopia progression in children and adolescents with high myopia, becoming one of the important methods.

AL and corneal curvature are considered the most significant factors influencing refractive status. The more pronounced the peripheral myopic defocus on the retina after wearing OK lenses, the better the myopia control effect. Similarly, Li *et al*[22] demonstrated that wearing peripheral defocus RGPCLs reduces central corneal refractive power while significantly increasing peripheral corneal refractive power, making the peripheral cornea relatively more myopic. Peripheral defocus RGPCLs achieve myopia control and slow axial elongation by adding positive power to the peripheral optical zone of the lens to reduce peripheral retinal hyperopic defocus, thus creating peripheral myopic defocus. Our study results show that the AL increase in the OK lens group and the peripheral defocus RGPCL group was slower compared to the spectacle lens group. Queirós *et al*[23] found that higher myopic refractive errors correlate with better AL control, particularly in high myopia populations. Peripheral Defocus RGPCLs not only avoid the prism effect and magnification issues but also significantly reduce higher-order aberrations in extreme refractive errors, which is especially beneficial for patients with high corneal astigmatism and irregular astigmatism, thereby improving retinal image quality[22]. Defocus RGPCLs create a new optical system comprising the lens, tear film, and cornea. This tear film lens can correct 90% of the corneal surface astigmatism, effectively eliminating local aberrations on the corneal surface. Coupled with the superior optical quality of RGPCLs, this improves retinal image quality and achieves better visual outcomes. Conversely, myopia progression continues in children wearing spectacles. The prism effect and magnification effect of high-powered spectacle lenses increase higher-order aberrations, such as spherical aberration, chromatic aberration, and coma, thus affecting retinal image quality and consequently the best-corrected visual acuity and visual quality[24]. Figure 2 indicates a statistically significant difference among the three groups. Lyu *et al*[25] found that AL elongation is a risk factor for dry eye onset in myopic participants. The longer the AL, the more severe the dry eye is. Additionally, SE exhibit negative correlations with dry eye symptom scores and ocular surface parameters. It is more significant for controlling the AL of high myopia.

The results indicate that after wearing lenses for 1.5y, there were no significant changes in BUT, the percentage of corneal endothelial cells, or corneal endothelial cell density compared to pre-wearing values in all three groups. In the OK lens group, the reduction in BUT, percentage of corneal endothelial cells, and corneal endothelial cell density was slightly less favorable than in the other two groups, but these differences were not statistically significant. This is consistent with the findings of Zhang *et al*[26] and Michaud *et al*[27], confirming that overnight wear of OK lenses is relatively safe, causing no discomfort or reduction in BUT in the short term. The CRT lens material, co-developed with NASA, features high oxygen permeability, good light transmittance, anti-deposition properties, and is safe and reliable. With an oxygen transmission rate of 100%, the material offers superior oxygen permeability. Defocus RGPCLs create a new optical system comprising the lens, tear film, and cornea. The movement of the lens on the ocular surface facilitates tear exchange during wear that ocular surface in patients with different degrees of myopia.

High myopia has long been considered a contraindication for OK lenses. However, with the gradual improvement in lens design and materials, complications associated with lens wear have decreased. Jonas *et al*[28] and others have demonstrated the safety of using OK lenses combined with low-power spectacles to control high myopia in adolescents. This finding is consistent with the results of our study. In the OK lens group, two eyes exhibited corneal epithelial staining, and two eyes showed corneal pigmentation. In the peripheral Defocus RGPCL group, one case of conjunctival hyperemia was observed. These conjunctival and corneal complications generally resolved after a short-term discontinuation of lens wear, combined with medication or lens adjustment. Additionally, a few patients experienced allergic reactions, which were controlled by changing the care solution or discontinuing lens wear. There were no statistically significant differences between the three groups, indicating that the use of OK lenses for controlling high myopia is associated with few complications.

There are several limitations to this study. First, the sample size was relatively small, and further large-scale studies are needed to confirm these findings. Second, the follow-up period was only 1.5y, which is insufficient to evaluate the long-term safety of OK lens wear on the cornea. Third, for high myopia patients who discontinued wearing OK lenses for more than three weeks, although corneal topography showed that the central corneal morphology was essentially normal without imprints, the corneal curvature was flatter than before. This suggests that in some patients, the refractive error might not have fully reverted. Therefore, future research will focus on further monitoring changes in corneal curvature.

In conclusion, with the gradual improvement in the design and materials of OK lenses, the combination of OK lenses and low-power spectacles has shown effective myopia control. The safety profile is comparable to that of peripheral defocus RGPCLs, making it a good option for adolescents with high myopia during the progression period. However, fitting OK lenses and peripheral defocus RGPCLs for high myopia

patients is more complex and involves multiple factors. Regular examinations to monitor the ocular surface and fundus are necessary, following the guidelines outlined in the "Myopia Management White Paper (2022)"[29].

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