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Impact of wearing dual-focus soft contact lenses on myopia progression: a one-year randomized clinical trial in Chinese school-age children

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Abstract

Background Myopia is prevalent in China; however, trials involving Chinese children wearing dual-focus soft contact lenses (DFSCL) are limited. Thus, the purpose of this study is to investigate the efficacy of DFSCL among Chinese school-age children.

Methods Sixty-four children aged 8–12 years with spherical equivalent refraction (SER) between −0.75D and −4.00D were recruited in this randomized controlled clinical study. The control group (32 subjects) wore single-vision spectacles (SVS), while the DFSCL group (32 subjects) wore daily disposable + 2.00 D defocus MiSight DFSCL. Follow-up examinations were performed every 3 months to compare the axial length (AL) growth and SER change between the groups for a period of 12 months by using the independent samples *t*-test or the Mann-Whitney *U* test. Statistical differences with a $P < 0.05$, when compared to the control group, are considered indicative of an effective intervention. Multivariate analysis and regression analysis were used to eliminate the effects of confounding factors on the results.

Results A total of 58 subjects, with 30 in the SVS group and 28 in the DFSCL group, completed the follow-up. After adjusting for baseline age, gender, AL and SER, AL growth was 0.33 ± 0.02 mm in the SVS group and 0.23 ± 0.03 mm in the DFSCL group ($P = 0.004$). SER change was −0.53 ± 0.06 in the SVS group and −0.44 ± 0.06 in the DFSCL group ($P = 0.308$). In the DFSCL group, AL and SER increased 0.11 mm and 0.09 D less than in the SVS group, respectively. Moreover, initial wear of DFSCL may cause occasional blurriness in near vision, and prolonged wear may lead to increased ocular discomfort symptoms such as dryness, itchiness, and foreign body sensation.

Conclusion MiSight DFSCL showed a reduction in AL growth during the first three months of wear. However, no significant benefits were observed during the subsequent nine months. No significant differences in the changes of SER were found.

Trial registration Chinese Clinical Trial Registry: ChiCTR2200064731. Registered 15 October 2022, http://www.chictr.org.cn/.

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Keywords Contact lenses, Lens design, Axial growth, Myopia progression, School-age children

Background

Myopia has become a major public health problem worldwide, imposing a substantial economic burden on society. In recent years, with the popularity of electronic products and changes in lifestyle, the prevalence and progression rate of myopia have sharply increased, especially among East Asia, such as Singapore, China, South Korea and Japan [1]. A cross-sectional study conducted in 2018 in Zhejiang Province, China, randomly selected 4801 students, showed that the myopia rate among children and adolescents was as high as 63.1%, with 9.4% of the population suffering from high myopia [2]. Myopic individuals have an increased risk of maculopathy, retinal detachment, cataract, and glaucoma [3], and there is a correlation between earlier age of onset and high myopia in adulthood [4, 5]. Thus, timely intervention and control of the development of myopia is crucial.

Research on the emmetropization mechanism in animals has shown that the quality of peripheral retinal images is closely related to the development of myopia - even if there is a clear image at the fovea, defocus signals from the peripheral retinal areas may mediate eye growth and development [6]. Lenses with relatively peripheral myopic defocus optics are a viable option for slowing the progression of myopia in children [7, 8]. The advantages of defocus soft lenses include their convenience, as they do not require regular cleaning or storage care, offer less foreign body sensation than rigid lenses, and have a lower incidence of complications related to ocular surface inflammation [9]. A meta-analysis by Li et al. [10] on dual-focus soft contact lenses (DFSCL) and multifocal soft contact lenses (MFSCL), finding that defocus soft lenses significantly reduce axial length (AL) growth and myopia progression in children and adolescents aged 6 to 18. In their study, during the first year of wear, AL increased 0.12 mm less in children wearing DFSCL than in those in the control group.

MiSight is a +2.00 D add DFSCL. Longitudinal research on its effectiveness in controlling myopia in Chinese children and adolescents remains sparse [11, 12]. Therefore, this study aims to following up the myopia progression of school-age children with myopia wearing DFSCL for one year, and explore its efficacy on myopia control.

Methods

Clinical research ethics

This study in line with CONSORT guidelines and conformed to the guidelines of the Declaration of Helsinki. Participation in the study was entirely voluntary. After explaining the purpose, procedures and potential risks of the research, informed consent form was obtained from the guardians of all eligible participants.

Research design

This trial was a prospective, longitudinal, single-center, randomized control trial (RCT). It was conducted at the West China Hospital in Chengdu, Sichuan Province, for one year.

Subjects who met the inclusion criteria were randomly divided into single-vision spectacles (SVS) group and MiSight DFSCL group by randomly picking one of the sequentially numbered sealed envelopes made by the third-party. Follow-up examinations were scheduled at baseline (pre-intervention), and at 1 day, 1 week and 1, 3, 6, 9 and 12 months after initiating lens wear. Figure 1 illustrates a flowchart of the study's implementation.

Research subjects

Inclusion criteria: age 8 to 12 years old; spherical equivalent refraction (SER) between −0.75 and −4.00 D and astigmatism < 1.00 D measured by cycloplegic refraction test; the best corrected visual acuity (BCVA) in both eyes ≥ 20/25; corneal curvature between 40.00 D and 46.00 D; tear breakup time ≥ 10 s; intraocular pressure in the range of 10–21 mmHg (1 mmHg = 0.133 kPa). Exclusion criteria: anisometropia ≥ 1.00 D; use of contact lenses, devices (e.g., desktop devices for repeated low-level red-light treatment), or eye drops to control myopia in the last 6 months; history of ocular trauma or surgery, history of contact lens wear, contraindications related to contact lens wear, or any systemic or ocular disease that may affect eye growth, such as strabismus. Research termination criteria: subjects have poor compliance; have bad hygiene habits; unable to follow the doctor's instructions for regular follow-up visits; have poor fitting adaptation to wearing contact lenses or have serious corneal fluorescein staining, ocular inflammation and other adverse events.

Intervention methods

Two types of lenses were used: the intervention group wore daily disposable concentric DFSCL (MiSight 1 day, Omafilcon A; CooperVision Inc., Eastleigh, UK), comprising four optical zones which include two vision correction zones alternating with two +2.00D myopic defocus (additional positive power) zones, creating peripheral secondary focus in front of the retina. Its refractive index is 1.395, water content 60%, oxygen permeability coefficient 25×10^{-11} (cm^2/s) (ml O_2)/(ml·mmHg), total diameter 14.2 mm, base curve 8.7 mm.

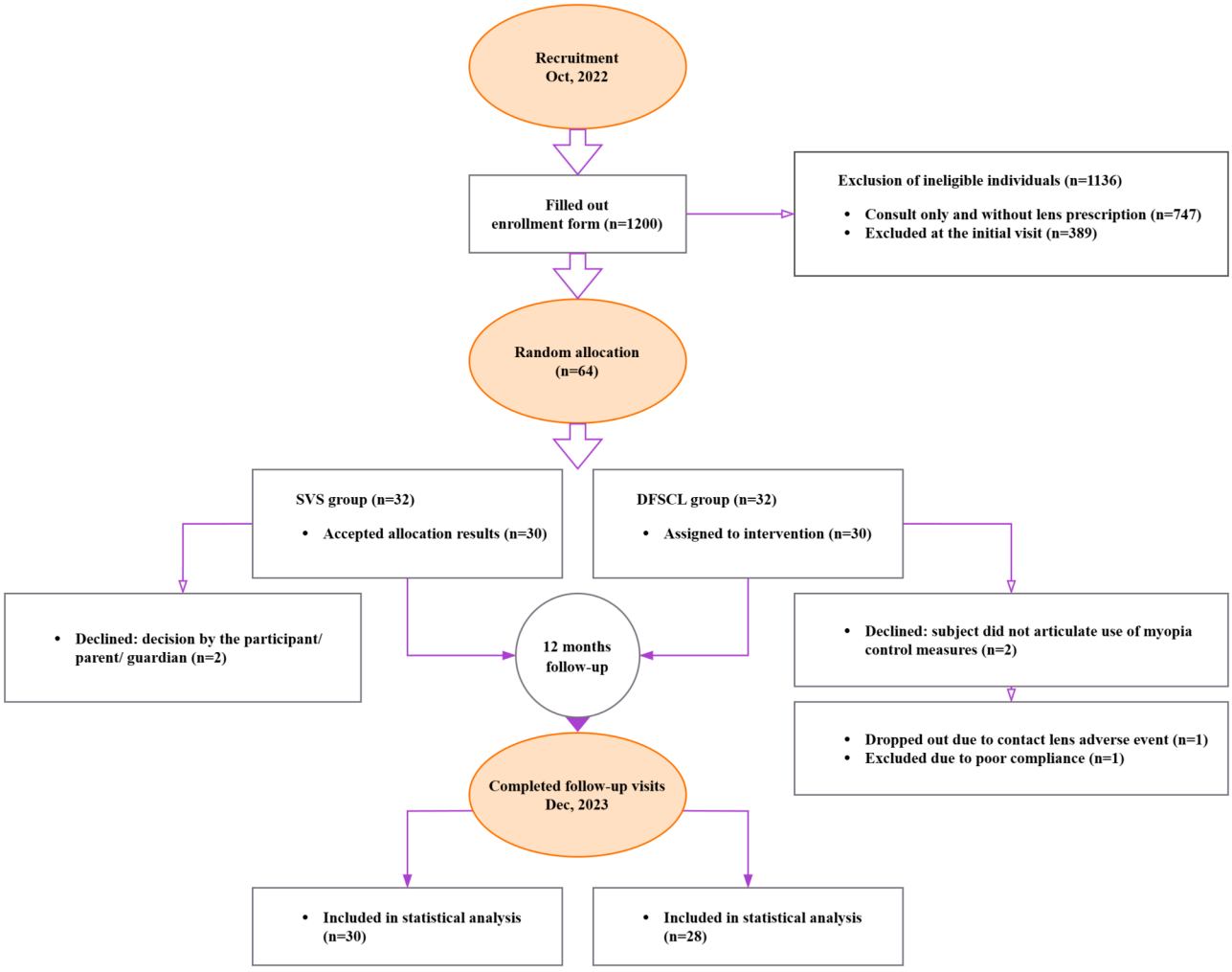

Fig. 1 Flowchart of recruitment and allocation and issues with cessation of intervention

The control group wore Kodak aspheric single vision lenses with a refractive index of 1.56.

According to the instruction manual of MiSight, this study stipulates the wearing duration for the DFSCL group as follows: 4 h on the first day, with an increment of 2 h daily, until reaching 12 to 15 h per day starting from the 6th day; the lenses must be worn for at least 6 days a week, with a minimum daily wearing time of 10 h and not exceeding 15 h; wearing should be ceased if symptoms of ocular or physical discomfort occur, and the subject should wear backup full-correction SVS instead. The SVS group was required to wear the lenses throughout the day. At each follow-up visit, all subjects were supervised and instructed on their lens use and eye care practices.

Sample size

The sample size was calculated with reference to previous literature using DFSCL of the same brand and design [13, 14], which showed that the change in ocular AL from baseline and after 12 months of lens wear was −0.09 mm, with a standard deviation of 0.13 mm and 0.12 mm, respectively. Based on the sample size estimate for comparing two independent samples, taking $1\text{-}\beta=90\%$ and $\alpha=0.05$, the number of subjects required for each group was calculated to be at least 25. Considering the 20% loss to follow-up rate and experience, at least 60 people were planned to be included after adjustment.

Data collection

This study was conducted under the same protocol and using the same equipment calibration and instructions, with standardized measurements at each time point to ensure consistency in data collection.

To ensure the ocular health of the subjects, corneal sodium fluorescein epithelial staining tests were performed using the Slit lamp Topcon SL7 and Topcon IMAGE net (Topcon Corporation, Japan) to observe the anterior segment of the eye and tear film break-up time, and to assess lens fitting. The safety assessment was mainly based on the corneal status and the number and

morphology of corneal endothelial cells at follow-up. If adverse events such as corneal staining were observed, they were graded using the Efron grading standard and treated accordingly, and the lenses were replaced with new one or discontinued wearing if necessary.

Main observational indicators included ocular biometry and cycloplegic refraction. Cycloplegia was induced using 0.5% tropicamide eye drops, administered four times at five-minute intervals, with one drop per eye each time, followed by a ten-minute period of eyes closed for rest. Thirty minutes after the initial administration, pupil measurement data from the i-Trace wavefront aberrometer (Tracey Technologies Inc., Houston, Texas, USA) were used to minimize the influence of pupil size on refraction under cycloplegia. Once pupil dilation reached a diameter of ≥6 mm or the accommodative amplitude was less than 2.00 D with no pupillary reaction, retinoscopy and subjective refraction were conducted based on maximum plus to maximum visual acuity, in an examination room with illumination conditions of 400 lx. Visual acuity was assessed using a standard logarithmic chart positioned 5 m from the subject. Refractive errors were calculated as SER, which is the sum of the spherical value plus half the cylindrical value. AL was measured using a Zeiss IOL Master-700 (Carl Zeiss Meditec, Jena, Germany), which is gauged from the optical distance from the corneal apex to the foveal retinal pigment epithelium [15]. IOL Master-700, a new non-invasive optical biometer, utilizes swept source optical coherence tomography (SS-OCT) with a wavelength of 1050 nm. For data analysis, the average of six consecutive readings was used, accepting only measurements with a signal-to-noise ratio (SNR) greater than 2.1.

Statistical analysis

Data from subjects who completed the 12 months follow-up were analyzed using IBM SPSS Statistics 27 software. Data were collected from both eyes in the trial, due to the high correlation between the two eyes, only data from the right eye of each subject were used in the analysis.

Normality of the data was determined with Kolmogorov-Smirnov test. Comparisons between the two groups were analyzed by independent samples *t*-test or Mann Whitney *U* test, and categorical data by chi-square test. Pearson or Spearman correlation analysis was used for the correlation between AL and SER. Using a multivariate linear model with analysis of covariance, baseline confounding factors were controlled for, and causal relationships were quantified using linear regression. Binary logistic regression analysis was utilized to assess the impact of various factors on the likelihood of rapid AL growth (≥0.4 mm/year) and progressive myopia (≥0.75 D/year). All tests were two-tailed with 95% confidence intervals. P value < 0.05 was considered statistically significant.

Table 1 Baseline characteristics

	SVS ($n=30$)	DFSCL ($n=28$)	P
Age, y/o	9.92 ± 1.22	9.91 ± 1.11	0.962
Gender, F:M	20:10	17:11	0.644
AL, mm	24.57 ± 0.66	24.21 ± 0.73	0.051
Cycloplegic SER, D	-1.95 ± 0.68	-1.88 ± 0.79	0.733

Mean ± SD; AL = axial length, SER = spherical equivalent refraction

Results

Among the 64 subjects recruited to participate in the study from October 2022, a total of 58 completed the one-year follow-up examination in December 2023. The baseline characteristics are shown in Table 1, all participants were Asian. There were no statistically significant differences in baseline age, gender ratio, AL, SER, and BCVA between the groups (P≥0.05).

As shown in Fig. 1, two subjects in the SVS group withdrew due to personal reasons (not accepting group assignment) during the course of the study. In the DFSCL group, four subjects withdrew: two were excluded upon discovery that they had not disclosed prior use of myopia control measures; one was unable to comply with follow-up appointments; and one was unable to adapt to contact lens use, resulting in grade 2 corneal staining. No serious adverse events occurred in either group of subjects.

In the questionnaire assessment, all participants in each group reported the lenses were well adapted. In the survey for the DFSCL group (rated on a 3-level scale; good, average, and poor), 23 children (82%) of the children were able to learn to wear lenses on their own within one week. After three months of lens wear, all children in the group reported clear distance vision, although 3 children (11%) experienced occasional blurriness in near vision. Four children (14%) reported moderate comfort after a full day of wear, noting symptoms of eye dryness or foreign body sensation. At 12 months, responses regarding both distance and near vision were positive from all children. Yet, 8 children (29%) reported moderate comfort, indicating symptoms of eye dryness, itching, or foreign body sensation. Such issues were not reported in the SVS group. These feedbacks suggest potential side effects associated with DFSCL use.

Regarding AL, the SVS group was 24.57 ± 0.66 mm at baseline and 24.91 ± 0.65 mm after 12 months, while the DFSCL group was 24.21 ± 0.73 mm at baseline and 24.43 ± 0.73 mm after 12 months. Figure 2 (A) depicts the distribution of eye growth among the subjects. The linear regression model shows that age may explain 11% of the factors in AL progression (R^2 = 0.108, P=0.007, unstandardized B = -0.045), with advancing age associated with less AL progression. Gender (R^2 = 0.012, P=0.202) had minimal impact on AL progression. After controlling for

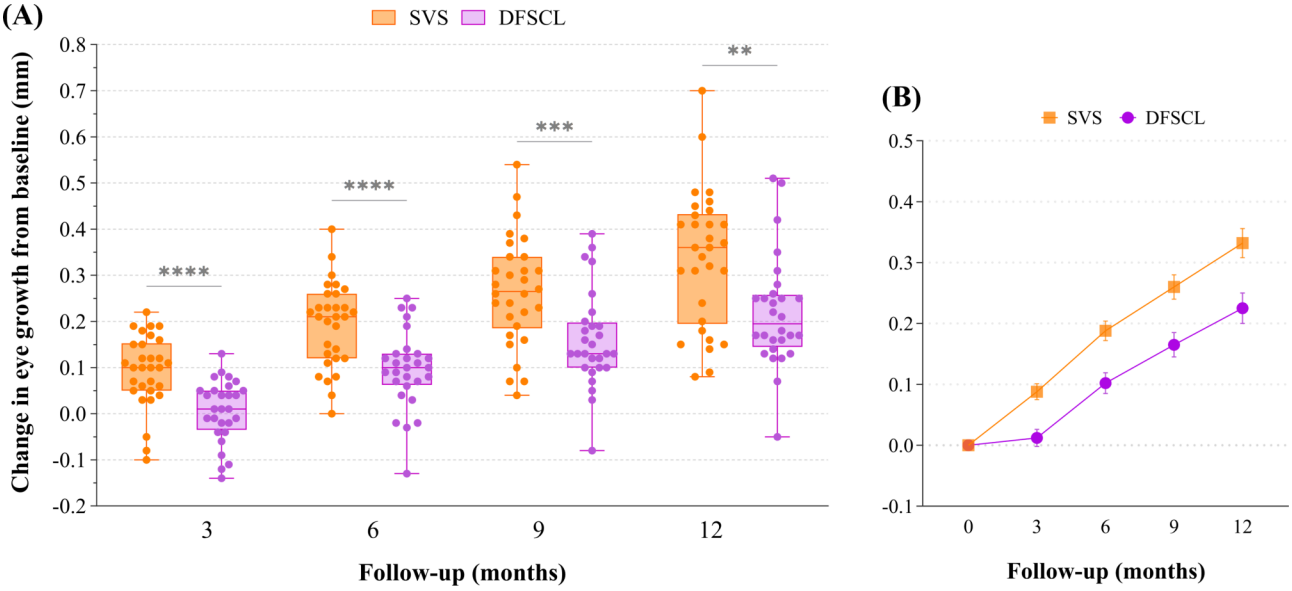

Fig. 2 AL growth over 12 months depicted in: **(A)** box plot (Median ± SD, mm), illustrating more dispersed data in the SVS group compared to the DFSCL group, indicated by higher boxes. **(B)** line chart of adjusted AL changes (Mean ± SD, mm), showing the trend and variations over time. Statistical significance **** $P < 0.0001$ *** $P < 0.001$ ** $P < 0.01$

Table 2 Mean changes from baseline in adjusted AL and SER in each group

Axial length, mm				
Visit	Group	Change from baseline	Difference	*P*
3 mo.	SVS	0.09 ± 0.01	-0.08 ± 0.02	< 0.001 [a]
	DFSCL	0.01 ± 0.01		
6 mo.	SVS	0.19 ± 0.02	-0.09 ± 0.02	< 0.001 [a]
	DFSCL	0.10 ± 0.02		
9 mo.	SVS	0.26 ± 0.02	-0.10 ± 0.03	0.002 [b]
	DFSCL	0.17 ± 0.02		
12 mo.	SVS	0.33 ± 0.02	-0.11 ± 0.04	0.004 [b]
	DFSCL	0.23 ± 0.03		
Cycloplegic SER, D				
Visit	Group	Change from baseline	Difference	*P*
3 mo.	SVS	-0.05 ± 0.03	0.03 ± 0.05	0.501
	DFSCL	-0.01 ± 0.04		
6 mo.	SVS	-0.20 ± 0.04	0.01 ± 0.06	0.872
	DFSCL	-0.19 ± 0.05		
9 mo.	SVS	-0.31 ± 0.06	0.01 ± 0.08	0.886
	DFSCL	-0.30 ± 0.06		
12 mo.	SVS	-0.53 ± 0.06	0.09 ± 0.09	0.308
	DFSCL	-0.44 ± 0.06		

Mean ± SD; SER = spherical equivalent refraction; [a] $P < 0.001$ [b] $P < 0.01$ indicates significantly different between groups

confounding variables including baseline gender, age, and AL, the axial elongation for each group is represented by a curve in Fig. 2 (B). Table 2 details the specific numerical values of growth at each time point from baseline, and provides comparisons between groups. The control effect was particularly pronounced in the first three months ($P < 0.001$). Despite significant differences in axial elongation rates between the two groups after 12 months of lens wear from baseline ($P = 0.004$), quarterly comparisons revealed less significant changes after three months: $P = 0.520$ between 3 and 6 months, $P = 0.465$ between 6 and 9 months, and $P = 0.391$ between 9 and 12 months. Axial elongation ≥ 0.4 mm in one year is considered rapid growth [16]. There were 12 subjects (40%) with rapid growth in the SVS group, in comparison with 3 subjects (11%) in the DFSCL group ($P = 0.01$), highlighting a higher rate of rapid growth in the SVS group.

As for SER, it was −1.95 ± 0.68 D at baseline and −2.48 ± 0.76 D at 12 months in the SVS group, and −1.88 ± 0.79 D at baseline and −2.32 ± 0.90 D at 12 months in the DFSCL group. Data distributions are depicted in Fig. 3 (A). Despite linear regression analysis showing that neither gender ($R^2 = 0.034$, $P = 0.088$) nor age ($R^2 = 0.032$, $P = 0.095$) significantly influenced SER progression, adjustments for baseline gender, age, and SER were made to enhance data reliability, with results detailed in Table 2. As Fig. 3 (B) demonstrates, there were no statistically significant differences in myopia progression between the two groups over 12 months ($P = 0.308$). Quarterly comparisons yielded $P = 0.501$ for 0–3 months, $P = 0.646$ for 3–6 months, $P = 0.977$ for 6–9 months, and $P = 0.185$ for 9–12 months. Furthermore, the pupil sizes measured post-cycloplegia showed no statistically significant differences between the groups from baseline to 12 months ($P > 0.05$). Over the year, the pupil sizes in the SVS group were 8.15 ± 0.47 (7.18–8.99), 8.15 ± 0.41 (7.21–8.90), and 8.26 ± 0.43 (7.22–9.16) mm at baseline, 6 months, and 12 months, respectively. In the DFSCL group, the measurements were 8.17 ± 0.42 (7.36–9.11),

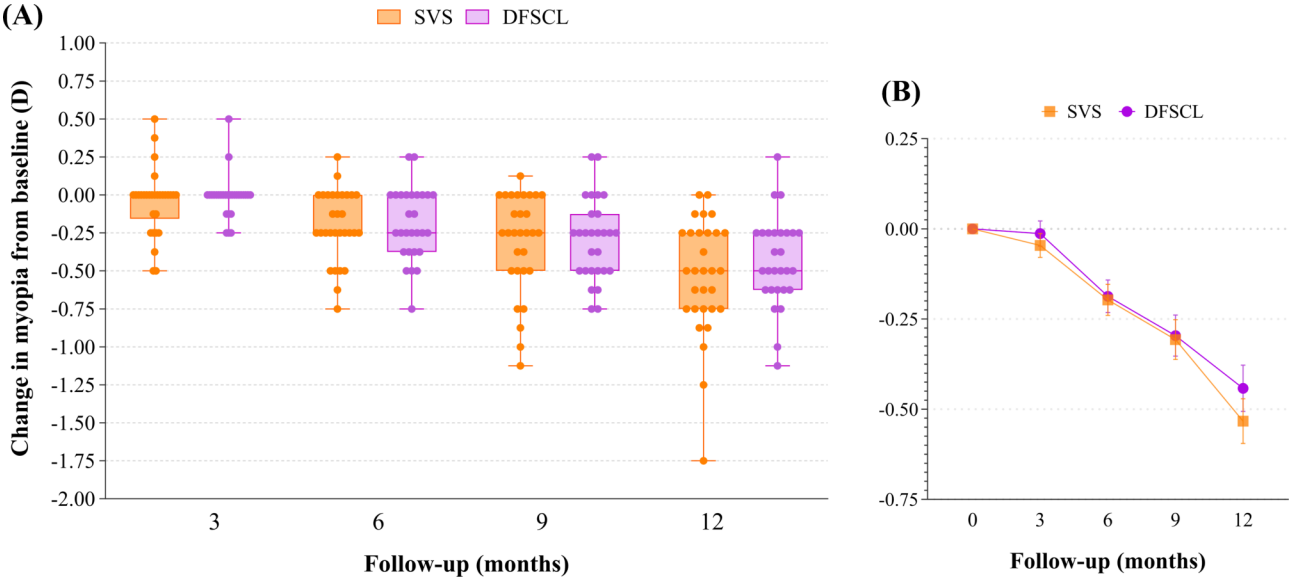

Fig. 3 SER changes over 12 months depicted in **(A)** box plot (Median ± SD, diopters); **(B)** line chart of adjusted SER changes (Mean ± SD, diopters), showing no significant differences between groups over time

8.12±0.44 (7.06–8.99), and 8.14±0.41 (6.81–8.81) mm at these respective time points.

People with myopia progression of ≥0.75 D in one year are defined as progressive myopia [17]. During the study period, 10 subjects (33%) with progression of ≥0.75 D were in the SVS group compared to 4 subjects (14%) in the DFSCL group (P=0.09). A higher rate of rapid myopia progression was observed in the SVS group.

Correlation analysis showed that there was a significant association between increases in AL and changes in SER over 12 months of lens wear (Spearman correlation coefficient r = -0.649, P<0.0001). However, while lens type showed no correlation with myopia progression (Spearman correlation coefficient r=0.106, P=0.426), it was significantly related to AL growth (Spearman correlation coefficient r = -0.386, P=0.003).

Discussion

The effectiveness of concentric bifocal soft lenses and multifocal soft lenses for myopia control has been supported in several studies [10, 18], but there are few long-term studies on the myopia control of DFSCL with medium to high defocus add in China. The design of MiSight DFSCL features a+2.00 D add power, and its concentric rings configuration produces a superimposed defocused image on the clear distance vision image. According to a 3-year RCT conducted in Portugal, the United Kingdom, Singapore, and Canada in 2019, the deferred effects on AL and SER after one year with MiSight DFSCL were −0.15 mm and 0.40 D, respectively, compared with SV SCL [13]. The MASS (MiSight Assessment Study Spain) in 2017, a two-year study using SVS as a control, showed that after one year, AL and SER progression were 0.12 mm and 0.26 D lower, respectively, compared to the control group [14]. The age requirement for the participants in both studies was the same as in the present study, 8 to 12 years old. Based on the results of our study, in the DFSCL group, AL and SER increased 0.11 mm and 0.09 D less than in the SVS group, respectively. Whereas the difference between groups in this study was statistically significant in terms of adjusted AL growth (P=0.004), which was consistent with previous studies; however, the difference was not statistically significant with respect to adjusted SER (P=0.308). A similar situation was noted in the study by Liu et al. [19], which explores the myopia control outcomes over one year of treatment using cylindrical annular refractive element spectacle lenses in comparison with SVS.

Firstly, excluding the lens itself, a variety of factors, such as compliance with lens wear, duration of outdoor activities [20], or parental myopia [21], may influence the control effects on myopia or AL. The MASS study [22] found that in their research, the duration of outdoor activities (over 3–4 h per week) in children using MiSight DFSCL was the primary factor in effectively controlling AL during the first two years. Secondly, AL is positively correlated with body height and may have some common biological pathways [23]. Girls aged 8–13 years had greater height growth than boys in China [24]. In this study, the proportion of females was relatively higher in SVS group with a sex ratio of 2.0, versus 1.5 in the DFSCL group. Although the intergroup gender differences were not statistically significant, disparities in physical growth and development could still be one contributing factor to the accelerated eye axial elongation seen in the SVS group. However, in linear regression

analysis, gender accounted for only 1% of the variance in AL growth. Hence, to fully exclude potential influences, considerations of body height and physiological increases in AL should also be taken into account in such analyses. Thirdly, children have stronger accommodation compared to adults, making complete cycloplegia crucial for accurate retinoscopy. Even though the majority of subjects in this study achieved a pupil diameter of ≥7 mm, which generally indicates full cycloplegia (i.e., nonreactive) [25], the variation in the rate of pupil dilation and the ciliary paralysis process suggests that the potential effects of cycloplegic agents cannot be entirely ruled out [26]. Since cyclopentolate is the cycloplegic agent recommended by the American Academy of Ophthalmology [27]; the use of 1% cyclopentolate may provide more accurate refractive assessments than 0.5% tropicamide.

Binary logistic regression analysis was conducted in this study to evaluate the factors influencing whether AL is categorized as rapid growth. The results indicated that the model fit was satisfactory, as evidenced by the Hosmer-Lemeshow test, and the Nagelkerke R^2 showed that gender, age, baseline AL, and SER accounted for approximately 23% of the variance in the dependent variable. Among the included variables, age was the only factor that demonstrated a statistically significant association with rapid AL growth ($P=0.018$), indicating that age may be an important determinant of rapid AL growth. In contrast, when assessing the influence on progressive myopia, the model also showed a good fit, but the Nagelkerke R^2 was lower (0.163), indicating that the explanatory power of the variables was limited. None of these variables significantly influenced progressive myopia ($P>0.05$), suggesting that their predictive power in this model is weak, and further investigation of other potential factors may be necessary.

Furthermore, the accuracy of refractive error measurements remains controversial, and may vary because of measurement bias among researchers, subject status and sensitivity, devices used, or cycloplegic agents. The FDA-sponsored symposium "Controlling the Progression of Myopia: Contact Lenses and Future Medical Devices" prioritized axial elongation as the primary efficacy endpoint for evaluating myopia [28]. In a retrospective analysis by Brennan et al. [29] targeting the justification and application of myopia control efficacy, it was concluded that although SER change is highly correlated with AL growth for cross-sectional studies. Whereas, when myopia has occurred and progression needs to be monitored, measuring AL by partial coherence interferometry (PCI) measurements is the preferred criterion for assessing myopia progression. The ocular biometry data in this study were obtained from a new non-invasive optical biometer, the IOL-Master 700, which is an objective instrument used to measure AL with this technique and has been shown to be highly replicable, precise, and efficient in clinical AL metrology [15, 30, 31]. Accordingly, in this study, the AL growth (mm/year) was determined to be the better indicator of the myopia control outcome of DFSCL. The results regarding AL growth indicate that the efficacy of the lenses was initially better following the onset of wear but appeared to diminish over time. In the Cochrane analysis [32], it was found that using MFSCL in the first year could potentially reduce AL elongation, with an average difference of -0.11 mm (95% CI: -0.13 to -0.09), and an average difference of -0.15 mm two years later (95% CI: -0.19 to -0.12). The initial stages show notable effects, but the incremental benefits in later stages are relatively smaller compared to other interventions, which is similar to the findings of this study. Therefore, it is crucial to monitor children's compliance and assess the long-term effectiveness of the lenses.

The limitations of this study are the absence of SV SCL as a control group and the paucity of subject and examiner blinding. Despite these issues, the measurements adhered to standard protocols, and randomized allocation methods were used. Additionally, the data of the present study may have been affected by the COVID-19 pandemic, which experienced an elevated rate of myopia progression in Chinese children in contrast to previous years [33]. Given the protective effects of the duration and intensity of outdoor activities in mitigating myopia progression [20, 34], the decreased outdoor activity during the pandemic could influence myopia development. At each follow-up visit in this study, the researchers emphasized the importance of consistent lens wear and outdoor activities to the participants and their parents, yet this study lacks corresponding records. Moreover, the AL is generally highly correlated with the refractive error [35]. Unlike rigid lenses, soft contact lenses do not alter the shape of the cornea. Besides, before the onset of myopia, the crystalline lens of the eye becomes thinner and flatter, and after this initial change, both the lens and corneal curvature tend to stabilize [36]. Therefore, the refractive changes of the eye, in theory, should not be affected by the cornea or the crystalline lens. The reasons for the discrepancies between AL and SER in the first three months of lens wear remain unclear.

As for the side effects associated with wearing DFSCL, it is hypothesized that they are related to the hydrogel material or the concentric ring design [37, 38]. Compared to SV SCL made from the same material, the concentric ring design may have an impact on tear film stability. As such, potential ocular discomfort, such as dryness, that may arise from prolonged wear of hydrogel DFSCL should be carefully considered.

Future studies could consider additional myopia-related parameters, such as choroidal thickness. Extended, large-scale clinical trials are necessary to validate the efficacy

of MiSight DFSCL in managing myopia among East Asia, with a need to assess whether its impact persists over time. Also, in spite of combination therapy being considered a strategy to optimize myopia control [39], evidence from two three-year studies—BLINK (Bifocal Lenses In Nearsighted Kids) and its adjunct study BAM (Bifocal & Atropine in Myopia) [40], which used 0.01% atropine combined with +2.50 D Biofinity MFSCL, and Erdinest et al. [41], which used 0.01% atropine with MiSight—showed no advantage of combination therapy over monotherapy with defocus soft lenses. The efficacy of combining DFSCL with low-concentration atropine for myopia control requires further evaluation. Based on recent systematic reviews, 0.01% atropine has been implied to be ineffective in slowing AL progression, while 0.05% has shown good efficacy; Asian studies also support 0.05% atropine as the optimal choice for children in the region [42, 43]. Additionally, 0.05% low-dose atropine and outdoor activities have been regarded as cost-effective methods for controlling myopia progression in children [44]. Consequently, the combination of DFSCL and 0.05% atropine presents a potential avenue for further exploration.

Overall, this study represents the first long-term RCT to assess the efficacy of MiSight DFSCL in managing myopia among school-aged myopic children in China. The results demonstrated a statistically significant benefit in AL elongation (0.08 mm) during the first three months, but in the following nine months, no statistically significant benefit was found (0.03 mm). No statistically significant benefit in the change of SER was observed. While these findings provide initial evidence for the short-term impact of MiSight DFSCL, further studies are needed to evaluate its long-term clinical benefits. The high retention rate, with 91% of participants completing all follow-up visits, supports the reliability of the data. This study forms part of the foundation for future research on the development and clinical application of defocus lenses.

Abbreviations

DFSCL	Dual-focus soft contact lenses
SER	Spherical equivalent refraction
SVS	Single-vision spectacles
AL	Axial length
MFSCL	Multi-focal soft contact lenses
RCT	Randomized control trial
BCVA	Best corrected visual acuity
SS-OCT	Swept source optical coherence tomography
SNR	Signal-to-noise ratio
PCI	Partial coherence interferometry

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Not applicable.

Author contributions
YC was responsible for the conceptualization, formal analysis, investigation, and project administration, with a leading role in data curation and writing the original draft, as well as reviewing and editing the manuscript. BY contributed equally to the funding acquisition, and project administration, supervised the project, and participated equally in reviewing and editing the manuscript. JK played a role in the conceptualization, investigation, and project administration, with a supporting role in formal analysis. LL led the funding acquisition, supervised the project, and contributed equally to the project administration and the review and editing of the manuscript.

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Data availability
All data supporting these findings are contained within this manuscript.

Declarations

Ethics approval and consent to participate
This study was approved by the Biomedical Ethics Review Committee of West China Hospital of Sichuan University (approval No. 131 in 2022), complies with the principles of the "Declaration of Helsinki" and the "Measures for Ethical Review of Biomedical Research Involving Humans" issued by the National Health Commission of the People's Republic of China. Informed consent form to participate were obtained from all participants' parents or legal guardians.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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