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Effect of daily disposable Defocus Incorporated Soft Contact lens on myopia control: a 1-year multicentre randomised controlled trial

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ABSTRACT

Aim To investigate the effect of the Defocus Incorporated Soft Contact (DISC) lenses on myopia progression and choroidal thickness (ChT) of Chinese mainland children over a period of 12 months.

Methods This was a prospective double-blind randomised controlled trial involving 84 myopic children. Subjects were randomly assigned to use of either DISC or single vision contact lens (SVL). Cycloplegic spherical equivalent refraction (SER), axial length (AL) and ChT were measured at 6 and 12 months.

Results For 12 months, the average changes in SER and AL in the DISC group were (−0.50±0.41) D and (0.22±0.13) mm. Corresponding values in the SVL group were (−1.23±0.50) D and (0.49±0.15) mm. Myopia control efficacy in SER was 59% and 55% in AL. For those aged under 10, myopia control efficacy in SER is higher at 95% in 6 months and 71.4% in 12 months. ChT increased by 0.16±24.46 µm in the DISC group, while in contrast, it thinned in the SVL group (−9.11±32.25 µm) after 12 months. ChT changes demonstrated a significant negative association with AL over 12 months in the DISC group but not in the SVL group. In contrast, ChT change over 12 months was significantly negatively associated with initial ChT in the SVL group, but not in the DISC group.

Conclusions DISC lenses effectively slowed myopia progression and AL compared with SVL, especially for younger children. Myopia defocus treatment changes the original intrinsic relationship between ChT and myopia progression, providing strong evidence that myopia defocus design controls myopia progression by changing ChT.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ In recent years, DISC lens has been proven to be safe and effective in myopia control, but the distinguished details with different age groups and the mechanism are still not so clear.

WHAT THIS STUDY ADDS

⇒ We found that the DISC lens has even higher myopia control achievable for children under the age of 10. Our study also provided strong evidence that the DISC lens could slow down the procedure of myopia progression by changing choroidal thickness.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ DISC lens is an effective and safe alternate treatment option for myopia children, especially towards the younger age group. The myopia-controlling mechanism is related to the changes of choroidal thickness.

INTRODUCTION

Myopia, commonly known as near-sightedness, is a growing public health concern worldwide, with its prevalence increasing at an alarming rate in many regions, particularly in Asia.[1 2] In China, the prevalence of myopia in children is significantly higher than in other countries, with as many as 80% of teenagers being myopic.[3 4] Myopia is not only a visual impairment but also a risk factor for several ocular pathologies, including retinal degeneration and glaucoma,[5 6] which can lead to severe visual impairment and blindness.

Several strategies have been developed to slow down myopia progression in children, including atropine eye drops, orthokeratology, bifocal lenses, progressive addition lenses (PALs) and red light therapy.[7–10]

However, these approaches have certain limitations. Orthokeratology requires overnight wear of contact lenses, which may not be suitable for younger children. In China, orthokeratology is currently only recommended for children aged 8 years and above. Bifocal lenses may only be effective for children with rapid myopia progression.[8] PALs have been shown to have insignificant effects on myopia control in some children[11] and should be used with caution for children with abnormal binocular vision, such as convergence insufficiency. Therefore, new approaches are needed to slow down myopia progression in children, especially for younger age groups.

Recently, the Defocus Incorporated Soft Contact (DISC) lens has been developed as a new approach to slow down myopia progression in children.[12 13] Unlike other approaches, DISC lenses incorporate concentric alternating

distance-correcting and defocusing zones covering the pupil. The correcting zones provide clear vision, while the defocusing zones simultaneously incorporate constant myopic defocus on the retina, which is believed to regulate emmetropisation and maintain the equilibrium between hyperopic and myopic defocus.[14]

DISC lenses have been shown to be safe and effective in controlling myopia progression in children.[14 15] However, previous studies did not provide details of the effects on different age groups, and there is less data for younger children's ages. In addition, the mechanism of action remains unclear. Given the high prevalence of myopia in younger children in many regions, including China, it is necessary to investigate the effects at different ages in more detail, especially for the younger age group. It is believed that the mechanism of myopia progression is related to choroidal thickness (ChT).[16–18] However, further study is needed to determine the mechanism by which DISC lenses control myopia progression.

This study aimed to investigate the safety and effectiveness of using DISC soft contact lenses for myopia control and follow-up investigation in children of different ages. The results may provide a valuable reference for early prevention and control of myopia in younger children.

MATERIALS AND METHODS

Study design

This study was a prospective, multicentre, randomised, double-blind, controlled study, registered as ChiCTR1800018696 in the Chinese Clinical Trial Registry. The clinical protocol (NO. 2019KY-16) included written informed consent procedures and was approved by the ethics committees of the Tianjin Medical University Eye Hospital before the commencement of the study. This study was conducted in accordance with good clinical practice and adhered to the guidelines of the Declaration of Helsinki. All investigators and key personnel were trained and certified on the study procedures prior to study commencement.

Participants

A total of 84 Chinese children attending Tianjin Medical University Eye Hospital, Wenzhou Medical University, Eye & ENT Hospital or Fudan University of Shanghai were recruited in this trial, and parental consent was obtained before data collection. The subjects were recruited between September 2019 and February 2020. Study subjects were randomised to the treatment and control groups in a 1:1 ratio using a block randomisation design. The first visit involved screening and provision of lenses. Participants were followed up after 1 week, 1 month, 3 months, 6 months and 12 months of lens wear. Follow-up visits included the assessment of external ocular health, axial length (AL) and cycloplegic refraction.

Inclusion criteria

1. Age at enrolment: 7—11 years old
2. Spherical equivalent refraction (SER): −1.00 D to −5.00 D
3. Astigmatism: equal to or less than 1.00 D
4. Best corrected visual acuity (BCVA): better than or equal to 1.0 (decimal chart).
5. No prior myopic control interventions

Exclusion criteria

1. Pre-existing systemic or eye disease that could influence contact lens wear
2. Dry eye with drug intervention within 30 days
3. Ocular injury or surgery
4. Contraindication for soft contact lens fitting
5. Previous use of other contact lenses
6. Abnormal intraocular pressure
7. Tear break up time of less than or equal to 5 s
8. Strabismus, amblyopia, Colour vision deficiency or other vision problems.
9. Previous myopia control intervention.

Interventions

The DISC lenses were hydrogel daily disposables. It has a water content of 55% and its oxygen transmissibility (DK/T) is 12.0×10^{-9} (cm/s) mLO2/(mL mm Hg). It is a custom-made bifocal soft contact lens with a structural design consisting of nine concentric rings. The central correcting zones matched the distance prescription of the participant, while a series of alternating defocusing zones (+3.0 D myopic defocus) extended towards the periphery.

The lens diameter is 14.2 mm, and the base curve ranges between 8.0 mm and 8.9 mm. It comprises a frontal surface with a correction zone in the centre of 3.0 mm diameter. The alternating rings of defocus to introduce myopic defocus for myopia progression control. The proportion of these defocusing and correction zones extending towards the periphery is 50:50. The design ensures clear vision is incorporated with myopic defocus. The (single vision) SV lenses were made using the same material with matching parameters, without any defocusing zones.

The children were recommended to wear DISC lenses for at least 8 hours per day and for a minimum of 5 days per week. The design of DISC lenses aims to project a myopic defocus signal to the retina for controlling eye growth.

Outcome variables

Baseline measurements, including refraction and AL under cycloplegia, BCVA and corneal curvature, were obtained. Refraction and AL parameters were collected by an autorefractor (KR-800, Topcon Corporation, Tokyo, Japan) and an optical biometer (Lenstar LS900, Haag-Streit AG, Köniz, Switzerland), respectively. Corneal curvature was measured by Medmont E300 Corneal Topographer (Medmont International Pty, Nunawading, Victoria, Australia) before cycloplegia.

The outcome variables were changes in SER and AL relative to baseline at the various follow-up time visits. BCVA was measured with a standard logarithmic visual acuity chart. SER measurements were measured at least 30 min after instillation of one or two drops of 1% cyclopentolate hydrochloric acid (HCL) administered three times 5 min apart. Five readings with an error of 0.25D or less for each measurement were averaged. SER was calculated by the sum of spherical refraction and half of cylinder refraction. Five AL measurements, with an error of 0.02 mm or less for each measurement, were collected and averaged. ChT was measured by swept source optical coherence tomography (VG200S, SVision Imaging, Henan, China) using the average three measurements, controlled within a 2 µm error.

Statistical analysis

All data from patients who completed the 1-year follow-up were analysed. Due to COVID-19, a total of 16 subjects (nine in DISC and seven in single vision contact lens (SVL)) were lost during follow-up, the rate of drop-out was insignificant ($\chi^2=0.309$, $p=0.578$). They were precluded from the final analysis consisting of 33 for DISC and 35 for SVL, which achieved 100% power to reject the null hypothesis of equal myopia progression with a significance level of 0.05.

The mean values for ocular parameters measured in the right eye were used, as no significant differences in changes in SER and AL were observed between the two eyes.

In this study, means and SDs were reported for continuous variables and N (%) for categorical variables. In univariate analyses, the Shapiro-Wilk test was employed for normality testing of quantitative variables. The Wilcoxon test, t-test, χ^2 test and Fisher's exact test were used to compare differences between comparable groups.

In addition, general linear models were used to observe the associations between changes in AL and SER with changes in ChT with the use of DISC and SVL. The correlation between the change in ChT to changes in AL and SER was also investigated. The association between ChT and changes in AL and SER was fitted using linear regression with a 95% prediction interval being calculated for changes (AL: 0.20 mm, 0.25 mm and 0.30 mm; SER: −0.25D, −0.50D and −0.75D).

All analyses were performed with SAS version 9.4 (SAS Institute, Cary, NC, USA) and two-sided P- value<0.05 was considered statistically significant.

RESULTS

Baseline measurements

Due to the COVID-19 epidemic, only 68 myopic children completed the 1-year study (DISC, n=33 vs SV, n=35). There were no statistically significant differences between the two groups in relation to BCVA, age, SER, AL, corneal power or ChT. BCVA with both lens types did not differ significantly (p=0.3435). The gender proportion ratio between the two groups did differ statistically, but adjustment of the involved centre, it had no statistical significance.

The change in SER and AL

A highly significant correlation was found between changes in SER and those in AL (R^2=0.73). Over 6 and 12 months, the mean myopia progression differed significantly between DISC and SVL groups (DISC: −0.24±0.34D, −0.50±0.41D and SVL: −0.70±0.34D, −1.23±0.50D, respectively) (p<0.0001). The myopia control efficacy measured using SER differed by 59% (difference of 0.73 D) and by 55% using AL (difference of 0.27 mm) (p<0.01) in 12 months. The total increases of AL in the 6th and 12th months present as: DISC group: 0.10±0.10 mm, 0.27±0.10 mm and SVL: 0.22±0.13 mm, 0.49±0.15 mm. However, with increasing age, the difference in myopia control efficiency (SER/AL) in two groups becomes smaller, indicating that the overall DISC control rate begins to decline by ordinary linear regression. Due to the different ages, the comparison of the myopia control results is shown in tables 1 and 2, respectively.

Table 1 Changes of AL and SER in different age and group after the 6th month's study

	Age	N	DISC group (6 months)	SVL group (6 months)	Control rate (%)
AL	7–9	32	0.04 (0.01, 0.07)	0.29 (0.24, 0.35)	**86.2**
	10–11	36	0.13 (0.08, 0.18)	0.24 (0.21, 0.27)	**45.8**
SER	7–9	32	−0.03 (−0.19, 0.13)	−0.73 (−0.90, −0.55)	**95.9**
	10–11	36	−0.36 (−0.51, −0.22)	−0.66 (−0.82, −0.49)	**45.5**

AL, axial length; DISC, Defocus Incorporated Soft Contact; SER, spherical equivalent refraction; SVL, single vision contact lens.

Table 2 Changes of AL and SER in different age and group after the 12th month's study

	Age	N	DISC group (12 months)	SVL group (12 months)	Control rate (%)
AL	7–9	32	0.19 (0.12, 0.25)	0.55 (0.48, 0.62)	**65.5**
	10–11	36	0.23 (0.17, 0.30)	0.41 (0.35, 0.48)	**43.9**
SER	7–9	32	−0.44 (−0.73, −0.15)	−1.33 (−1.58, −1.07)	**71.4**
	10–11	36	−0.57 (−0.77, −0.38)	−1.10 (−1.32, −0.88)	**48.2**

AL, axial length; DISC, Defocus Incorporated Soft Contact; SER, spherical equivalent refraction; SVL, single vision contact lens.

Change in ChT

Comparison of ChT between the two groups revealed that overall ChT increased in the DISC group, while decreasing in the SVL group. At the time of enrolment, there was no statistically significant difference in ChT between the two groups. However, at the 12-month follow-up, there was a statistically significant difference in ChT between the two groups, as well as in the change in ChT within each group.

Relationship between ChT and myopic progression

The changes in ChT in the DISC group were associated with changes in SER/AL (p<0.0001). The change in ChT was negatively correlated with the change in AL and positively correlated with the change in SER (figure 1). As shown in table 3, a 0.20 mm change of AL in 1 year was observed to be a leading range of corresponding ChT changes. Similarly, a 0.25 SER change in 1 year was also associated with different ChT changes (table 3).

If AL increased by more than 0.25 mm over 1 year, ChT decreased by an average of 4.75 µm. This implied that an annual AL change of 0.25 mm or more may be negatively correlated with ChT changes. For a 1-year SER change of −0.50D, ChT changed 0.16 µm. With a 1-year SER change of −0.75D (more than −0.50D), ChT tended to become thinner.

There was a significant correlation between ChT and SER/AL changes (p<0.05) in the 68 participants who completed the entire clinical trial. There was a relationship between the initial ChT and ChT changes in the SVL group (p=0.008), but no statistically significant association in the DISC group (p=0.648), as shown in figure 2.

During the course of the clinical trial, no cases of corneal infection or other serious adverse events were reported. Minor ocular adverse events, including ocular itching, conjunctival hyperaemia and dry eye, were observed but were transient in nature and resolved with routine medical management. There were no statistically significant differences in the safety profiles between the DISC and SVL groups. Compliance was high in both groups, with no significant differences observed in the average daily lens-wearing duration (7–9 hours) throughout the follow-up period.

DISCUSSION

The study has shown that DISC lens use resulted in a significant myopia control effect in children and young adolescents aged 7–11 years. This control effect was similar to that reported for orthokeratology.[19 20] In comparison to other soft contact lenses with defocus designs, the control effect of DISC lenses appears to be analogous.[21] Due to the higher risk of developing high myopia in young children,[22] as well as the requirement that ortho-k is largely restricted to children aged 8 and above in China,[18] it is crucial to pay attention to myopia control, particularly for children under the age of 10.

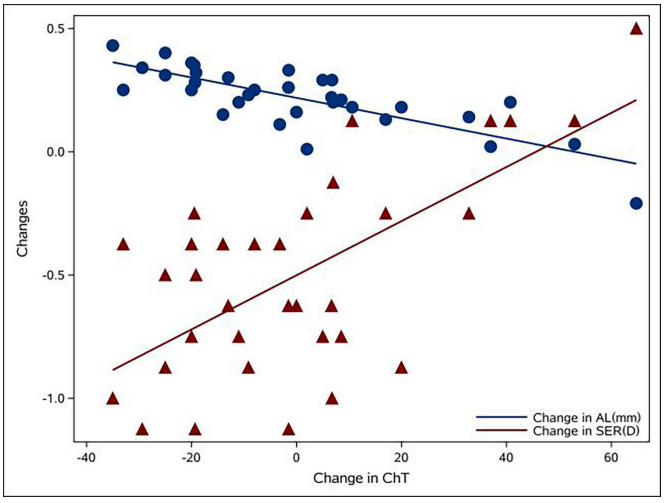

Figure 1 Correlation between ChT change and SER/AL change in the DISC group. The results of ordinary linear regression show that the changes in ChT change and SER/AL in the DISC group are correlated. Change in AL=−0.004*age+0.218 (P for β_{age}<0.001, R^2=0.619); change in SER=0.011*age−0.502 (P for β_{age}<0.001, R^2=0.424). AL, axial length; ChT, choroidal thickness; DISC, Defocus Incorporated Soft Contact; SER, spherical equivalent refraction.

In previous studies on myopia control methods, it has been observed that the primary influencing factor on myopia control effectiveness was the initial age at which myopia first develops, with unsatisfactory myopia control in younger children.[23] According to the previous consensus of experts on the AL reference interval in Chinese children and adolescents,[24] among those who do not have myopia until 15 years old, it is estimated that the average progress of AL is about 0.2 mm/year in the period of 7–10 years old, and the growth rate of AL slows down apparently after 10 years old, and it is about 0.02 mm/year until 14 years old.[24 25] In summary, during our study, we chose 10 years old as the age cut-off to better understand and identify the characteristics of AL changes across different age groups. To compare

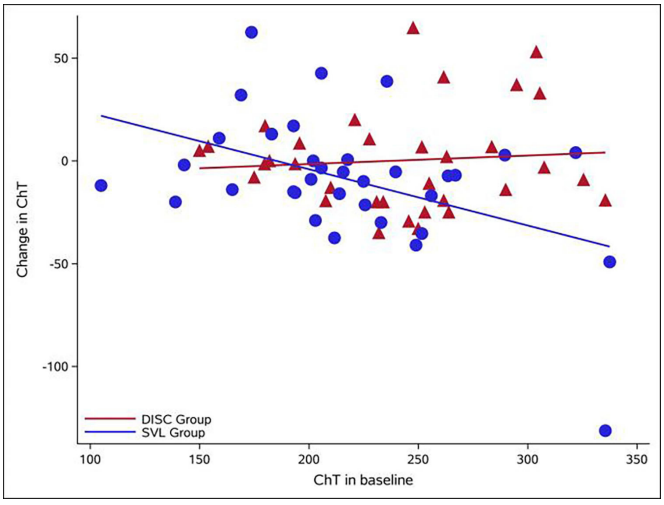

Figure 2 The relationship between the initial ChT and ChT change in DISC and SVL groups. DISC group: correlation between the initial ChT and ChT change; 0.08 (p=0.648); SVL group: correlation between the initial ChT and ChT change; −0.45 (p=0.008). AL, axial length; ChT, choroidal thickness; DISC, Defocus Incorporated Soft Contact; SER, spherical equivalent refraction; SVL, single vision contact lens.

Table 3 Corresponding changes in ChT with the variations in AL and SER in the DSIC group

Indicators	β	P	Criteria (mm/D)	Estimate (95% CI) ChT/ interval (μm)
Change in AL	−150.08	<0.001	0.20	2.75 (−29.01, 34.51)
			0.25	−4.75 (−36.54, 27.03)
			0.30	−12.26 (−44.21, 19.70)
Change in SER	38.66	<0.001	−0.25	9.82 (−29.43, 49.08)
			−0.50	0.16 (−38.87, 39.20)
			−0.75	−9.50 (−48.76, 29.75)

AL, axial length; ChT, choroidal thickness; DISC, Defocus Incorporated Soft Contact; SER, spherical equivalent refraction.

the effect of DISC and SVL, the differences in changes in AL and SER and control rates were calculated for groups of children aged 7–9 and 10–11.

This study has shown that the myopia control effect of DISC for children aged 7–11 was 59%, with even higher myopia control achievable for children under the age of 10 of 71.4%. These findings provide substantial support for implementing myopia prevention and control measures in younger children.

The explanation for these findings may be related to the developmental characteristics of young myopic children, and their myopic SER is often of moderate to low range. When wearing ortho-k, defocus tends to be less or unstable.[26] In contrast, DISC lenses can provide adequate and stable defocus for different children. Defocus is considered one of the effective principles for myopia control,[27 28] supported by ample evidence from both animal and human experiments.[29 30]

This study presents the first evidence of the effect of DISC lenses on ChT in children over a 1-year randomised controlled trial.

Considering both the experimental and control groups, there is a correlation between initial SER and initial ChT. Even after 12 months, there remains a relationship. This suggests that in the process of eye growth, ChT decreases in thickness as the eye grows. This observation aligns well with previous research findings.[16 31]

In addition, the study design placed significant emphasis on analysing the correlation between changes in myopia and changes in ChT, aiming to explore the potential causes and mechanisms behind myopia progression. The results revealed that after 12 months, there was a correlation between the changes in SER (including AL) and the changes in ChT. This suggests that myopia development may be linked to changes in ChT, implying that alterations in the choroid may influence the progression of myopia. This conclusion aligns with findings from previous research.[32–34]

Furthermore, in this study, it was observed that when there was an SER change exceeding −0.50D within a year, it was positively correlated with ChT changes. Previous studies have reported that physiological axial elongation in Chinese children aged 7–11 years did not exceed 0.2 mm per year. Therefore, when the AL exceeds the physiological growth range, and a significant change in myopia (0.50D) occurs, there should be a concurrent trend of choroidal thinning.

After 12 months, there was no correlation in the control group between the change in overall SER (and AL) and the change in ChT. This suggests that in adolescents without intervention, the development of myopia is not inherently correlated with changes in ChT. It is more likely that stronger influencing factors during myopia progression affect the development of

refraction and AL. However, in the control group, there was a correlation between the initial ChT and the change in ChT, while there was no similar correlation in the DISC group. This further indicates that after the DISC lenses intervention acts as a factor in myopia control, as the process of ChT change has been altered.

For the DISC group, the results show a significant correlation between the change in overall SER (and AL) and the change in ChT over 12 months. This suggests that the use of DISC lenses alters the change in ChT. It enhances the influence of ChT changes on myopia development, indicating a successful intervention effect on myopia development. It can be speculated that DISC may prevent progression of SER by modifying changes in ChT. This could potentially represent another mechanism for managing myopia in children using DISC lenses.

It was noted that over a 1-year period, the same +3D defocus produced different ChT changes in the treatment group and produced SER and AL changes that corresponded to the ChT changes. It is speculated this may be related to differences in eyeball shapes of individuals, and the corresponding +3D external input defocus of the lenses produces different amounts of actual defocus in the peripheral retina of different individuals, thereby leading to different ChT changes and corresponding SER and AL changes. Another possible explanation is that the retinas of different children have different sensitivity to defocus, which may also lead to such results.

It was also found that while myopia in the control group increased rapidly, the ChT tended to become thinner. However, the amount of change was not significantly related to the change in the SER and AL. It is possible that there is hyperopic defocus in the peripheral retinas of children with myopia. However, because this hyperopic defocus always exists and its increase is slow, the resulting change in ChT is also lower than that of the treatment group +3D myopic defocus. The changes in ChT caused by hyperopic defocus were small, and coupled with the small sample size, the random changes in ChT were large, so no statistically significant correlation was found.

The current study reports the 1-year results in Chinese mainland children wearing DISC lenses. It is a limitation of this study that future trials in other ethnic populations are needed. In the meantime, because of the impact of the COVID-19 pandemic, there was a loss in sample size, and we would conduct further studies with an expanded study cohort. Another limitation is that there should be more focus on the changes of choroid flow and the changes of ChT in different quadrants.

In summary, DISC lenses effectively slowed myopia progression and axial elongation compared with SVL in children. Among the treatment group, a larger treatment effect was achieved in younger children. No severe adverse events were reported, reflecting the comfort and safety of DISC lens for myopia control in children. Additionally, it can be speculated that DISC may be intervening in the progression of SER by modifying changes in ChT. These findings also underscore the complexity of ocular growth regulation and suggest that the ChT response to defocus may be a critical intermediary step in myopia development.

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Competing interests None declared.

Patient consent for publication Consent obtained from parent(s)/guardian(s).

Ethics approval This study involves human participants and was approved by the clinical protocol (NO. 2019KY-16), which included written informed consent procedures and was approved by the ethics committees of the Tianjin Medical University Eye Hospital before the commencement of the study. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. The datasets generated/analysed during the current study are available from the corresponding author on reasonable request.

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