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ORIGINAL ARTICLE

Myopia control using a modified optical defocus soft contact lens in schoolchildren—A 12-month randomised double masked control trial

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Abstract

Purpose: Defocus Incorporated Soft Contact (DISC) lenses with +2.50 D myopic defocus reduced myopia progression by 25% in a previous randomised clinical trial (RCT). The current study aimed to evaluate if a stronger myopic defocus, +3.50 D with variable myopic defocus (DISC3.5plus), could slow myopia progression compared with single vision (SV) soft contact lenses in a 12-month RCT.

Methods: Conducted from December 2018 to January 2021, the current RCT randomly assigned myopic children to wear DISC3.5plus ($n=87$) or SV ($n=80$) lenses. Myopia progression and axial elongation were compared between the two groups. Analyses were performed for both enrolled and completed participants.

Results: For all enrolled participants, the DISC3.5plus group had significantly less myopia progression (mean difference: −0.15 ± 0.07 D, $p=0.02$) and axial elongation (mean difference: 0.04 ± 0.02 D, $p=0.04$) than the SV group at 6 months but not at 12 months (myopia progression: $p=0.11$; axial elongation: $p=0.13$). For completed participants, the DISC3.5plus group ($n=33$) had reduced myopia progression at both 6 months (0.25 ± 0.07 D, $p=0.001$) and 12 months (0.19 ± 0.09 D, $p=0.049$) compared with the SV group ($n=40$), but not in axial elongation (6 months: $p=0.16$; 12 months: $p=0.32$). In January 2020, the coronavirus pandemic disturbed contact lens-wearing patterns.

Conclusion: DISC3.5plus lenses significantly slowed myopia progression and axial elongation compared with SV lenses for all enrolled participants over 6 months. The pandemic hindered longer term efficacy follow-up and sample size; thus, further investigation with more participants is needed to confirm sustained treatment effects.

KEYWORDS
contact lens, myopia control, myopic defocus, randomised clinical trial

INTRODUCTION

Myopia prevalence has increased in the last two decades and is reaching an alarmingly high level globally.[1,2] In fact, myopia is now considered an important concern by the World Health Organization's Global Initiative for the Elimination of Avoidable Blindness.[3] Highly myopic eyes have been reported to have a higher risk of developing blinding complications such as macular degeneration, retinal detachment[4,5] and glaucoma[6] that can reduce the

Hanyu Zhang and Ka Yan Leung contributed equally to this work and are considered co-first authors.

quality of vision and life. Several clinical interventions are currently used for slowing the progression of myopia based on both pharmacological and optical approaches.[7–20] The efficacy of myopia control has been reported to be in the range of 27%–67%.[8]

Animal studies have provided strong evidence that imposed myopic defocus inhibits eye growth, whereas hyperopic defocus promotes eye growth.[21] Studies using chicks,[22 23] guinea pigs,[24] marmosets[25] and rhesus monkeys[26] have demonstrated that myopic eye growth could be inhibited or reversed by applying myopic defocus using dual-powered or multifocal lenses. Simultaneous myopic defocus is likely to be the key mechanism underlying several current myopia control strategies, such as orthokeratology[12] and multifocal soft contact lenses.[14–20]

In 2014, we reported on the efficacy of a novel contact lens for myopia control that had simultaneous dual-power (distance prescription and myopic defocus) properties. The 'Defocus Incorporated Soft Contact' (DISC) lens was a custom-made bifocal contact lens, consisting of a central corrective zone for distance refractive error, and a series of concentric alternating myopic defocus (+2.50 D) and refractive error correction power zones towards the periphery.[14] A 2-year double-blinded randomised clinical trial (RCT) showed that myopia progression and axial elongation were slowed by wearing DISC lenses compared with single vision (SV) soft contact lenses, reaching up to 60% efficacy for children wearing the lens for >8 h daily.[14]

Myopic eyes tend to exhibit a prolate ocular shape[27] and prior studies have indicated an increase in hyperopic relative peripheral refraction (RPR) with eccentricity from the central retina.[27–30] The previous defocus incorporated multiple segments (DIMS) clinical trial[13,31,32] revealed that the nasal retina had a higher hyperopic RPR (>+2.50 D) in myopic children. Such findings were consistent with other studies.[29,30] Therefore, we postulated that a stronger and different dose of myopic defocus among individuals would be required to counteract hyperopic defocus resulting from accommodative lag and potentially the increasing relative hyperopic refraction at the periphery.

To address this issue, the DISC lens underwent some modifications. First, the myopic defocus was increased from +2.50 to +3.50 D to counterbalance adequately an accommodative lag of about 0.80 D (which was seen in our previous DISC study—unpublished data), while still providing sufficient myopic defocus. Given that power changes in increments of 0.25, 1.00 D is required to counterbalance the accommodative lag (0.80 D). The second modification was to incorporate concentric rings with variable myopic defocus based on calculated RPR. The first myopic defocus ring was +3.50 D as described above. The myopic defocus of the outer rings was +3.50 D plus the resultant hyperopic RPR; this was to counterbalance the hyperopic RPR and account for the prolate shape of the myopic eye. This resulted in the myopic defocus power of the outer rings in this current study ranging from +4.75 to +6.00 D. This modified DISC lens is called the 'DISC3.5plus' lens.

Key points

- The current design of the Defocus Incorporated Soft Contact lens incorporates a stronger myopic defocus of +3.50 D, along with variable myopic defocus zones, to enhance myopia control.
- Clinical findings indicate that the Defocus Incorporated Soft Contact lenses significantly reduced myopia progression and axial elongation compared with single vision lenses over a 6-month period.
- The COVID-19 pandemic impacted lens-wearing patterns, limiting long-term follow-up and reducing the sample size. This underscores the need for further research to confirm sustained efficacy of the lenses.

The objective of the current study was to evaluate whether a stronger and variable myopic defocus of +3.50 and >+3.50 D, varied at different eccentricities to account for retinal profile, would show more effective myopia control when compared with a single vision (SV) soft contact lenses in a 12-month RCT.

METHOD

The study was a 1-year prospective, double-masked RCT comparing the myopia control efficacy of DISC3.5plus and SV contact lenses, conducted from December 2018 to January 2021. Myopic children (–1.00 to –5.00 D) aged 8–13 years were recruited. Spherical equivalent refraction (SER) and axial length (AL) were measured at baseline, 6 months and 1 year. The changes in SER and AL between the DISC3.5plus and SV groups were compared over the study period. Data collection and eye examinations were carried out in the Centre for Myopia Research at the Hong Kong Polytechnic University (PolyU) and the Integrative Community Health Centre at Lai King, Hong Kong. Written assent and informed consent were obtained from the children and their parents before participation. The clinical trial was registered at ClinicalTrials.gov (Identifier: NCT03681366). The study was reviewed and approved by the Human Subjects Ethics Subcommittee of the Hong Kong Polytechnic University, and all procedures met the tenets of the Declaration of Helsinki.

Participant selection

Hong Kong Chinese myopic children aged from 8 to 13 years were recruited through promotion at primary and

secondary schools as well as optometry clinics affiliated with the university, including both on-campus and two satellite clinics in the local community. The selected age range is particularly relevant, as the myopia progression rate within this cohort has been found to be the fastest compared with other age groups, with a mean annual progression rate of approximately 1.00 D in myopic children.[33] The inclusion criteria were:

- Hong Kong Chinese children aged 8–13 years;
- Cycloplegic SER: −1.00 to −5.00 D; astigmatism: ≤−1.00 D; anisometropia: ≤1.25 D;
- Best-corrected monocular visual acuity (BCMVA) with spectacles: 0.00 logMAR or better;
- Contact lens BCMVA: 0.10 logMAR or better;
- Acceptance of random allocation of grouping and masking.

The exclusion criteria were:

- Prior use of myopia control treatment;
- Strabismus, decompensated heterophoria or binocular vision problems;
- Ocular and systemic diseases and abnormalities;
- Known contraindications for contact lens wear.

Phone and visual screenings were performed to determine whether the child met the study criteria.

Randomisation

The randomisation process was carried out by the unmasked investigator (UI). Eligible participants were subsequently assigned to either the treatment group, who wore DISC3.5plus lenses, or the control group, who wore SV soft contact lenses. The allocation was determined by following a predefined random sequence generated by Excel (Microsoft.com).

Intervention and control

The DISC3.5plus lenses (intervention) and SV (control) soft contact lenses were made of silicone-hydrogel (Efrofilcon A) with 74% water content and 60 Dk oxygen permeability. The DISC3.5plus lens comprised a central correction zone (2 mm diameter) with the distance prescription (SER), surrounded by a series of correction and defocusing zones in a ratio of 48:52 (13 rings of alternating myopic defocus and distance prescription, each 0.25 mm wide). Three types of DISC3.5plus lenses were designed, with myopic defocus of +3.50 D in the first ring, and each lens type providing a different dosage of myopic defocus in rings 2–13 varying from +4.75 to +6.00 D, advancing towards the periphery. The power of the distance prescription was determined by the UI based on SER power obtained from the cycloplegic refraction measured by the masked investigator (MI). Adjustments were made for back vertex distance if SER was between −4.25 and −5.00 D, inclusive. It was refined further by a spherical over-refraction of the contact lenses to achieve the best visual acuity with the least minus power. RPR at baseline for each participant was used to select the lens type with the minimum myopic defocus able to counteract the highest hyperopic RPR measured from each participant. A Maltese cross-target was placed at the straight-ahead position (centre) and 15°, 25°nasal (15N, 25N) and temporal (15T, 25T) retinal eccentricities for central and peripheral refraction measurements using an open-field autorefractor (Shin-Nippon NVision-K5001 or Grand Seiko WR-5100K, rexxam.co.jp). RPR was calculated as the central refraction subtracted from the peripheral refraction. Lenses were dispensed as 1-month disposal contact lenses upon successful learning of insertion and removal procedures, and the same lens type selected at baseline was dispensed for all visits (e.g., the myopic defocus dosage was kept the same for the entire trial).

At the 6- and 12-month follow-up visits, the contact lens prescriptions were updated if any one or more of the criteria listed below were met:

- Increase in myopia of 0.25 D (spherical over-refraction) if the latest contact lens-corrected monocular visual acuity was poorer than 0.10 LogMAR;
- Increase in myopia of 0.50 D or more (spherical over-refraction);
- Increase in hyperopia of 0.25 D or more in two consecutive visits (spherical over-refraction).

Masking and wear compliance

The same study protocol as in our previous randomised controlled trial using the DISC lenses was adopted.[14] The masking procedures fulfilled the CONSORT requirements.[34] According to the DISC study,[14] a certain effect of myopia control (46%) could be achieved by wearing a DISC lens for at least 5 h/day. The effect increased further to 58% when children wore the DISC lenses for ≥7 h/day. The marginal benefit from increased wearing was smaller when the wearing time reached 8 h. There was inadequate information about how much wearing time was needed until the effect levelled off. The Dk of the lens material limits daily wearing time to 10 h in the current DISC3.5plus lens. Since the DISC3.5plus lens has a higher defocus power than the DISC lens, it was assumed that the higher defocus power could maintain comparable myopia control effects of the DISC lens with less wearing time. Due to these considerations, participants in the current study were asked to wear the contact lenses for at least 6 h per day and to wear single vision spectacle lenses for the rest of the day. Six hours of contact lens wear per day could also decrease the drop-out

rate. Participants were asked to record contact lens wearing time in a logbook every day.

Measurement outcomes

The primary measurement outcome was the change in cycloplegic SER (in dioptres) from baseline to 12 months. One drop of Alcaine, 0.5% (Alcon-Couvreur NV, alcon.com/) followed by one drop of cyclopentolate HCL, 1% (Alcon-Couvreur NV), were instilled to induce cycloplegia in both eyes. Cycloplegia was confirmed by measuring the amplitude of accommodation using the push-up method, and cycloplegic refraction was measured when the residual amplitude of accommodation was ≤2.00 D. Cycloplegic refraction was quantified using an open-field autorefractor (Shin-Nippon NVision-K5001 or Grand Seiko WR-5100K) at the baseline, 6- and 12-month visits. Five measurements were obtained from each eye, and the average of the spherical equivalent refractions was used for analysis.

The secondary measurement outcome was the change in axial length (AL) from baseline to 12 months. Axial length was measured using partial coherence interferometry IOL Master 500 (Zeiss, zeiss.com/meditec/en/products/optical-biometers/iolmaster-500.html) at the baseline, 6- and 12-month visits. Five measurements were taken and averaged for each eye.

Distance high-contrast and low-contrast visual acuity (VA) were measured using the Logarithmic 2000 series Early Treatment of Diabetic Retinopathy (ETDRS) Chart and Sloan Letter Logarithmic Translucent Contrast Chart at 10% contrast (Precision Vision, precision-vision.com) at 4 m under 500% ± 10% lux. Near high-contrast and low-contrast VA were measured at 33 cm with the same room lighting using the high-contrast (90%) logarithmic visual acuity chart modified ETDRS near and intermediate VA charts and low-contrast (10%) logarithmic visual acuity chart modified ETDRS near and intermediate VA charts (Precision Vision, precision-vision.com/products/visual-acuity-reading-charts/letter-symbol/hand-held/sloan-etdrs-near-intermediate-vision/), respectively. The amplitude of accommodation was measured using the pull-away method with a Royal Air Force (RAF) ruler (Good-Lite, store.good-lite.com/products/537800). Stereoacuity was measured using the Randot stereo test (Stereo Optical, stereooptical.com/products/stereotests-color-tests/randot). All of the visual performance tests described above were conducted with the best refractive correction and contact lens wear without cycloplegia. Compliance (hours per day recorded in the log book) and adverse events were also collected.

Protocol adjustment due to unexpected incidence

From November 2019 to the end of 2020, two incidents disrupted the normal operation of the clinical trial. The Hong Kong PolyU campus experienced a lockdown, and the coronavirus pandemic led to the closure of the University campus, resulting in the suspension of all teaching and research activities. Appendix 1 provides a description of these incidents, their impact on data collection and the formulae adopted to recalculate the changes of SER, AL and other variables to reflect the actual changes at 6 and 12 months. The quadratic model was used for adjusting the data.

Sample size calculation

We employed 90% power to detect a 0.50 D difference (SD 0.6 D)[14] in myopia progression between the treatment and control groups, using a significance alpha level of 0.01 (2-tailed). This yielded a minimum of 43 participants in each group. As the dropout rate in contact lens studies in children is higher than spectacle investigations,[13,14] a 50% dropout rate was assumed, resulting in approximately 90 participants being required for each group (180 participants in total).

Statistical analysis

As there were no statistically significant differences found between data from the two eyes, only data from the right eye were used for analyses apart from when measurements were made binocularly, for example, amplitude of accommodation and stereoacuity. Data normality was checked and parametric data of the two groups were presented as the mean ± SD, while non-parametric methods were conducted where necessary. Baseline demographic data between the two groups were compared using an independent *t*-test; a chi-squared test was used for categorical data.

Approximately 15% of the data collection was delayed by >60 days from the expected assessment day. SER and AL data were adjusted by a quadratic model (details of the adjustment are described in Appendix 1). Visual function parameters were not adjusted. Correlations among adjusted myopia progression, adjusted axial elongation and wearing time were analysed using Pearson correlations. Multivariate analyses of variance were used to examine the effect of various factors, including age, gender and initial refraction, on treatment outcomes. Visual acuity before and after the study was compared using a paired *t*-test.

Given the reduction in sample size that resulted in insufficient statistical power, intention-to-treat (ITT) analyses were performed for myopia progression and axial elongation in all enrolled participants including those lost to follow up. Generalised estimating equations (GEE) were utilised to address the missing data. GEE incorporated a within-subject factor for time, a between-subject factor for group (DISC3.5plus and SV), as well as the interactions between time and group. A p-value <0.05 was considered statistically significant.

RESULTS

One hundred and sixty-seven schoolchildren (DISC3.5plus, $n = 87$, SV, $n = 80$) were enrolled in the trial between December 2018 and January 2020 (Figure 1). All of the participants in the DISC3.5plus ($n = 87$) group were prescribed the same lens type (+6.00 D myopic defocus) as this lens was the only one that had the minimum myopic defocus needed to counteract the highest hyperopic RPR, based on the peripheral refraction profile of each participant.

During the study, 69 (41.3%) participants (42 participants in the DISC3.5plus group and 27 participants in the SV group) withdrew from the trial for various reasons as

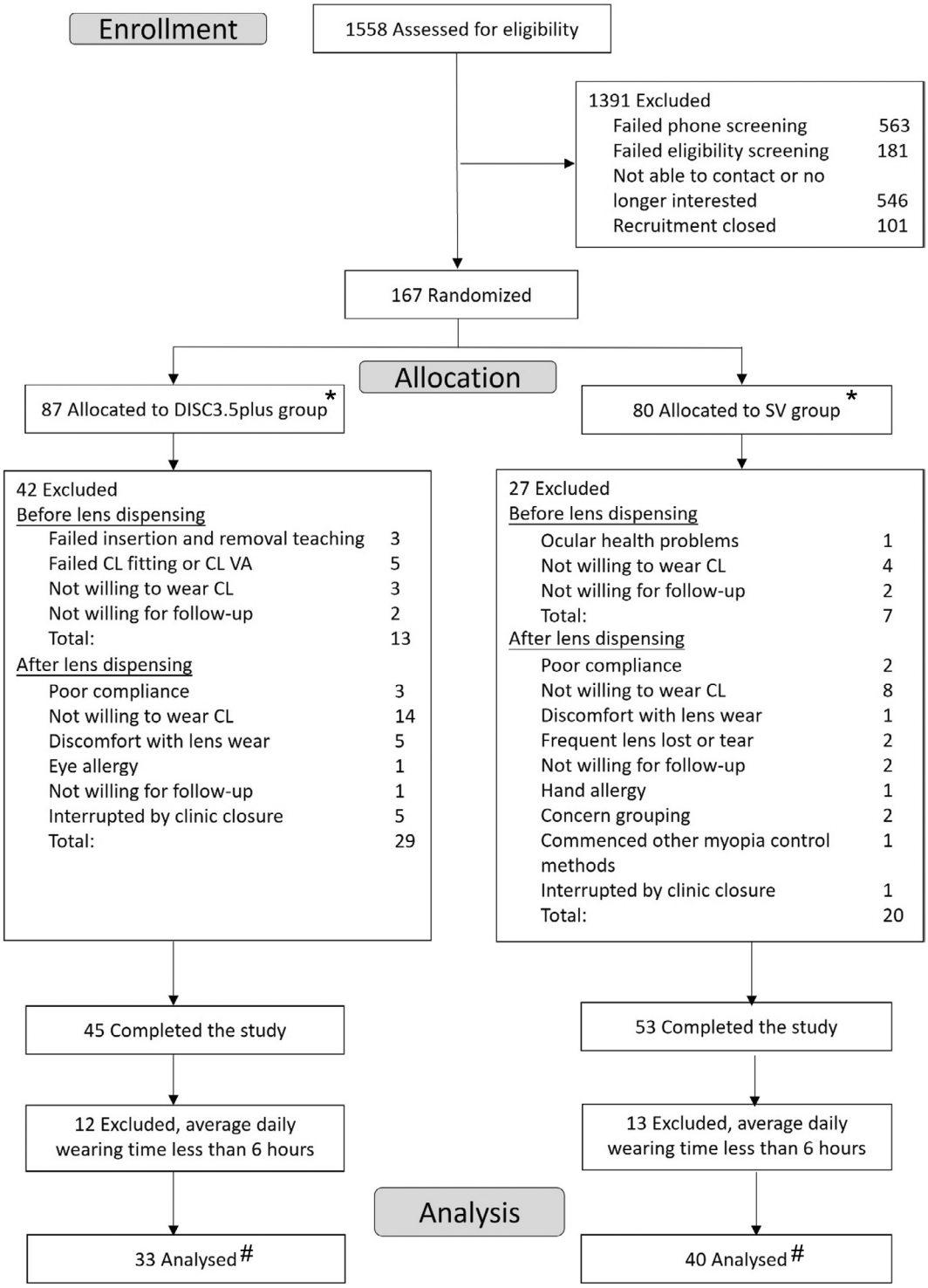

FIGURE 1 Consort flow diagram. *The number of participants was used for intention to treat analysis. #The number of participants used per protocol analysis. CL, contact lenses; DISC, Defocus Incorporated Soft Contact; SV, single vision; VA, visual acuity.

shown in Figure 1. Ninety-eight participants completed the study (45 participants in the DISC3.5plus group and 53 participants in the SV group); however, there was a dramatic drop in wearing time from January to May 2020 in some participants. Only those who wore the contact lens >6 h per day on average were included for analysis, resulting in 73 participants (33 DISC3.5plus group, 40 SV group) being analysed as 'completed participants'.

Baseline characteristics

Table 1 shows the demographic and baseline characteristics of all enrolled participants and those who completed the study. There were no statistically significant differences in age ($p = 0.58$), cycloplegic SER ($p = 0.13$) and axial length ($p = 0.26$) between the DISC3.5plus and SV groups at baseline. The mean initial myopia in the DISC3.5plus and SV groups was −2.40 ± 0.90 and −2.76 ± 1.09 D, respectively. The mean initial axial length was 24.65 ± 0.91 and 24.41 ± 0.85 mm in the DISC3.5plus and SV groups, respectively.

All recruited participants (ITT analyses)

Changes in spherical equivalent refraction

The GEE model (Table S1) indicated that group and time ($p < 0.0001$) had significant associations with the magnitude of myopia progression. Statistically significantly less myopia progression (−0.15 ± 0.07 D) was observed in the DISC3.5plus group compared with the SV group at 6 months ($p = 0.02$). However, this was no longer significantly different at 12 months ($p = 0.11$), where the DISC3.5plus and the SV groups were −0.44 ± 0.05 and −0.56 ± 0.06 D, respectively (Table 2).

Changes in the axial length

Only time ($p < 0.0001$) showed a significant association with the magnitude of axial elongation (Table S2). Significantly less axial elongation of 0.04 ± 0.02 D was observed in the DISC3.5plus group compared with the SV group at 6 months ($p = 0.04$). However, there was no statistically significant difference in axial elongation at 12 months ($p = 0.11$; Table 3).

All completed participants (per protocol)

Changes in the adjusted spherical equivalent refraction

A total of 33 and 40 participants in the DISC3.5plus group and the SV group, respectively, completed the study, adhering to the requirement of wearing the contact lenses for at least 6 h per day. The DISC3.5plus group

TABLE 1 Baseline demographics and characteristics of all the enrolled and completed participants.

	All enrolled			All completed		
	DISC3.5plus ($n = 87$)	SV ($n = 80$)	p-Value	DISC3.5plus ($n = 33$)	SV ($n = 40$)	p-Value
Age (years)	10.91 ± 1.93	10.80 ± 1.48	0.68	11.12 ± 1.47	10.92 ± 1.52	0.58
Gender						
Male	40.7%	44.8%	0.59	33.3%	30%	0.76
Female	59.3%	55.2%		66.7%	70%	
Cycloplegic SER (D)	−2.59 ± 1.02	−2.76 ± 1.03	0.28	−2.40 ± 0.90	−2.76 ± 1.09	0.13
Axial length (mm)	24.74 ± 0.76	24.58 ± 0.87	0.22	24.65 ± 0.91	24.41 ± 0.85	0.26
Pupil size (mm)						
Photopic	3.04 ± 0.36	3.12 ± 0.45	0.26	2.94 ± 0.40	3.11 ± 0.33	0.07
Mesopic	6.61 ± 0.87	6.59 ± 0.59	0.89	6.41 ± 1.03	6.60 ± 0.60	0.33

Abbreviations: DISC, Defocus Incorporated Soft Contact; SER, spherical equivalent refraction; SV, single vision.

TABLE 2 Comparison between myopia progression of DISC3.5plus and SV group at 6 and 12 months for all enrolled participants.

Time	Group	Mean (D)	Std. error	Mean difference (D)	Std. error	p-Value
6 Months	SV	−0.40	0.04	−0.15	0.07	0.02
	DISC3.5plus	−0.25	0.05			
12 Months	SV	−0.56	0.06	−0.12	0.08	0.11
	DISC3.5plus	−0.44	0.05			

Abbreviations: DISC, Defocus Incorporated Soft Contact; SV, single vision.

TABLE 3 Comparison between axial elongation of DISC3.5plus and SV group at 6 and 12 months for all enrolled participants.

Time	Group	Mean (mm)	Std. error	Mean difference (mm)	Std. error	*p* Value
6 Months	SV	0.15	0.01	0.04	0.02	0.04
	DISC3.5plus	0.11	0.01			
12 Months	SV	0.25	0.02	0.05	0.03	0.13
	DISC3.5plus	0.20	0.02			

Abbreviations: DISC, Defocus Incorporated Soft Contact; SV, single vision.

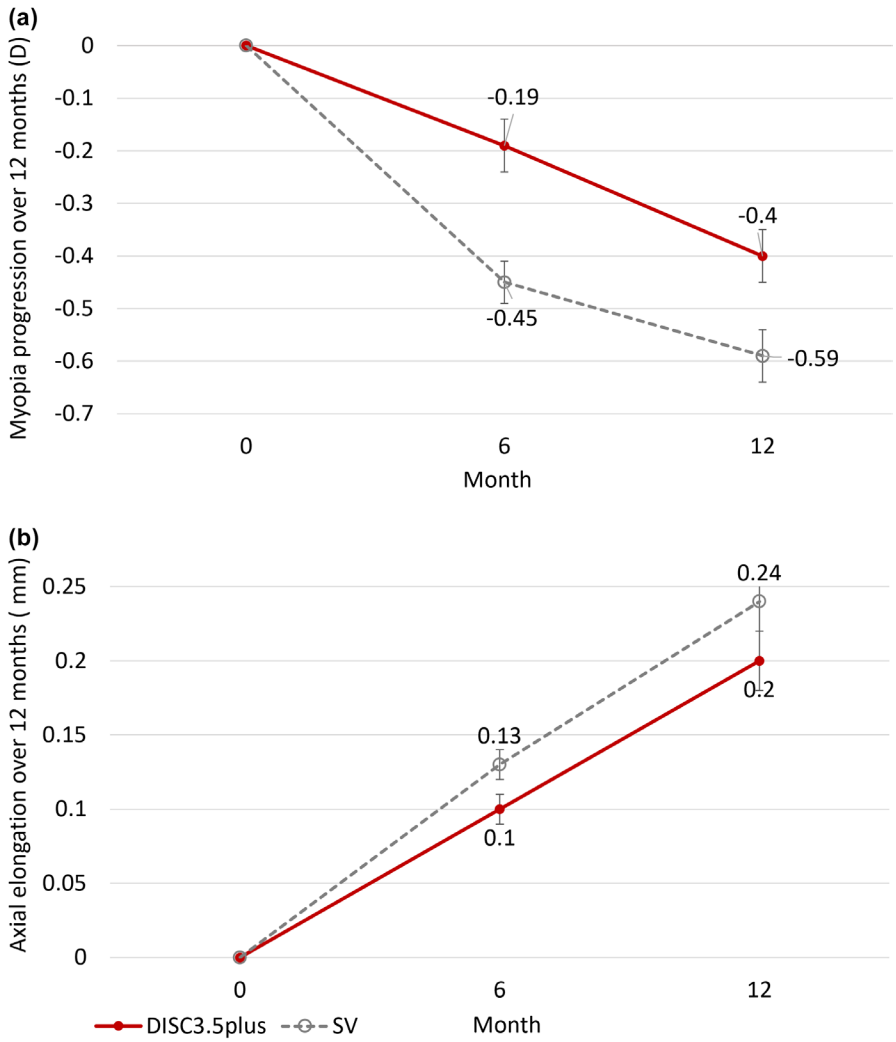

FIGURE 2 (a) Mean myopia progression and (b) mean axial elongation over 12 months. Error bars indicate 1 SEM. DISC, Defocus Incorporated Soft Contact; SV, single vision.

showed significantly less myopia progression than the SV group at the first 6-month visit (mean difference: 0.25 ± 0.07 D, $p = 0.001$) and at the 12-month visit (mean difference: 0.19 ± 0.09 D, $p = 0.049$). The mean myopia progression in the two groups over 1 year is shown in Figure 2a. Myopia progression was 56% and 32% less in the DISC3.5plus group than in the SV group at 6 and 12 months, respectively.

Changes in the adjusted axial length

The DISC3.5plus group showed less axial elongation compared with the SV group at 6 (0.03 ± 0.02 mm, $p = 0.16$) and 12 months (0.04 ± 0.04 mm, $p = 0.32$), but this difference did not reach statistical significance. The mean axial length elongation in the two groups over 1 year is shown in Figure 2b. Axial length elongation was 24% and 17%

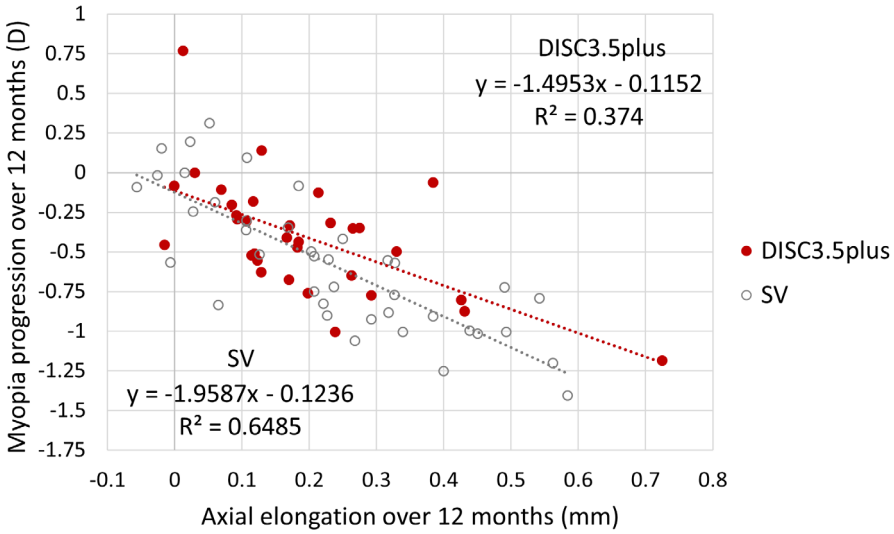

FIGURE 3 Correlation between myopia progression and axial elongation at 12 months. DISC, Defocus Incorporated Soft Contact; SV, single vision.

less in the DISC3.5plus group than the SV group at 6 and 12 months, respectively. Individual plots are shown in the Figure S1.

Correlation between myopic progression and axial elongation

There was a strong correlation between myopic progression and axial elongation in both groups (Figure 3). At 12 months, the correlation coefficient was −0.65 ($p < 0.0001$) for the DISC3.5 plus and −0.76 ($p < 0.0001$) for the SV group.

Myopic progression versus wearing time

The average daily wearing time of the DISC3.5plus and SV groups was 8.37 ± 1.67 and 9.17 ± 1.80 h/day, respectively. The SV group wore their lenses on average for 0.8 hours more per day compared with the DISC3.5plus group ($p = 0.05$). The correlation between myopia progression and lens-wearing time is shown in Figure 4. Notably, myopia progression showed no significant correlation with wearing time in either the DISC3.5plus ($r = -0.01$, $p = 0.98$) or SV ($r = -0.11$, $p = 0.51$) groups.

Visual performance of DISC3.5plus contact lens

The visual performance results at baseline and at 12 months are shown in Table 4. There were no significant differences in the distance high-contrast VA between the two groups at baseline and 12 months. The SV group showed significantly better low contrast VA at distance and low/high-contrast VA at near at both the baseline and 12-month visits. No statistically significant differences were found between the two lens types in influencing monocular accommodation. For stereoacuity, participants wearing SV contact lenses showed better stereoacuity than those wearing DISC3.5plus lenses at both the baseline and 12-month visits. However, the mean difference was only 5 s of arc, which was not clinically significant.

The median best-corrected spectacle distance visual acuity was similar for the DISC3.5plus and the SV groups at baseline (p-value = 0.87) and at the 12-month visit (p-value = 0.90). Table 5 shows the best-corrected spectacle visual acuity at distance for each group at baseline and at the12-month visits. A paired t-test showed significantly better visual acuity at 12 months in both groups.

The incidence of adverse events over 1-year was low and similar between the DISC3.5plus and SV groups (10 vs. 14 eyes, Table S3). None of these were classified as serious adverse events.

DISCUSSION

A modified design of our previous DISC lens was proposed, with stronger myopic defocus of +3.50 and >+3.50 D, varied by the retinal profile, and was named 'DISC3.5plus'. The current study documented that DISC3.5plus lenses have myopia control efficacy of 56% and 32% in the first 6 and 12 months, respectively. The myopia progression and axial elongation at 6 and 12 months were adjusted by the quadratic model (Appendix 1) since research activities were impacted from November 2019 to the end of 2020, and participants could not return back for follow-up on time. Previous studies have documented that the quadratic model could be used to estimate myopia progression.[35,36] Children who wore the DISC3.5plus lenses

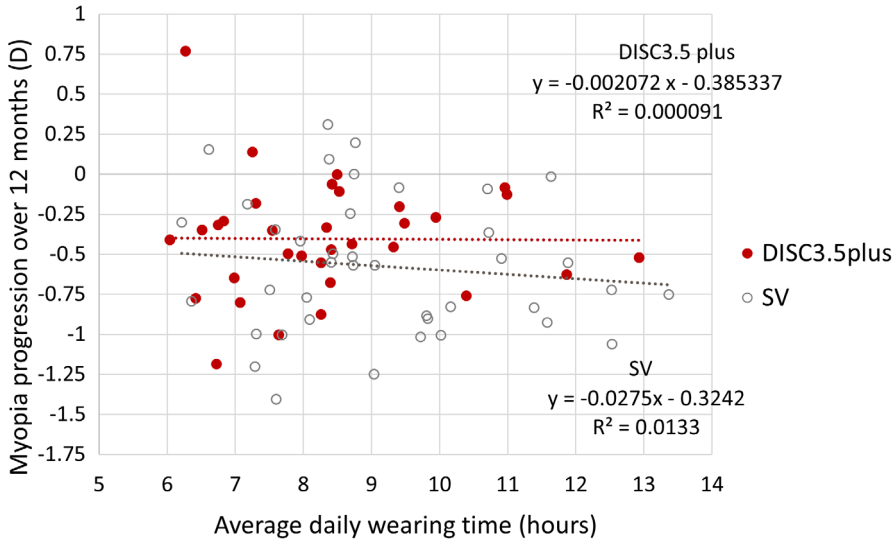

FIGURE 4 Correlation between myopia progression and contact lens daily wearing time at 12 months. DISC, Defocus Incorporated Soft Contact; SV, single vision.

TABLE 4 Distance visual acuity, near visual acuity (in LogMAR) and other visual performance with contact lens wear in the Defocus Incorporated Soft Contact (DISC3.5plus) group ($n = 33$) and the single vision (SV) group ($n = 40$).

	Baseline			12-month		
	DISC3.5plus	SV		DISC3.5plus	SV	
	Median ± IQR		*p*-Value			*p*-Value
Distance VA, high contrast	0.02 ± 0.08	0.02 ± 0.08	0.19	0.00 ± 0.06	0.01 ± 0.06	0.88
Distance VA, low contrast	0.36 ± 0.18	0.21 ± 0.15	<0.001**	0.34 ± 0.16	0.23 ± 0.24	<0.001**
Near VA, high contrast	0.10 ± 0.10	0.02 ± 0.12	<0.001**	0.06 ± 0.09	0.01 ± 0.12	0.02*
Near VA, low contrast	0.42 ± 0.17	0.20 ± 0.16	<0.001**	0.30 ± 0.15	0.13 ± 0.14	<0.001**
Monocular AA for right eye, D	12.33 ± 5.08	12.17 ± 4.88	0.64	12.5 ± 4.30	11.45 ± 2.5	0.21
Stereopsis, seconds of arc	30 ± 15	25 ± 10	0.02*	30 ± 25	25 ± 20	0.048*

Note: Statistically significant in *P*-value <0.05* or <0.001**.

Abbreviations: AA, amplitude of accommodation; D, dioptres; VA, visual acuity.

TABLE 5 Best-corrected spectacle visual acuity at distance (LogMAR).

	DISC3.5plus ($n = 33$)		SV ($n = 40$)	
	Baseline	1-Year	Baseline	1-Year
Best-corrected distance VA (median ± IQR)	0.00 ± 0.04	−0.04 ± 0.04	0.00 ± 0.08	−0.06 ± 0.04
p-Value	0.003*		<0.001**	

Note: Statistically significant *p*-value <0.05* or <0.001**.

Abbreviations: DISC, Defocus Incorporated Soft Contact; IQR, interquartile range; SV, single vision; VA, visual acuity.

had 56% less myopia progression and 24% less axial elongation than those wearing the SV lenses at 6 months. Furthermore, the model showed that children wearing the DISC3.5plus lenses had 32% less myopia progression and 17% less axial elongation than those wearing the SV lenses over 1 year. Table S4 summarises recent clinical trials of myopia control using soft contact lenses. Previous studies showed myopic defocus ≥+2.00 D retarded myopia progression from 25% to 54%.[14,15,17,18] Therefore, the myopia control efficacy of DISC3.5plus over 12 months was comparable with soft contact lenses having 2.00 or more dioptres of myopic defocus. The stronger myopic defocus (+3.50 to +6.00 D) in the DISCPlus3.5 lens may have improved the myopia control efficacy compared

with the DISC lens. This higher myopic defocus could also counterbalance the hyperopic RPR associated with accommodative lag.

It is noteworthy that the myopia control efficacy was reduced in the second 6-month period for all enrolled children, as well as those who completed the study. The coronavirus pandemic was a major challenge to the present study, as deviation from normal schooling caused longer near work and screen time. A local cross-sectional study evaluating the lifestyle of 6- to 8-year-old children in 2015–2021 found higher near-work and screen time with less outdoor time in 2020, compared with pre-COVID-19 levels.[37] They also reported that myopia prevalence was 23.5%–24.9% from 2015 to 2019, but increased to 28.8% in 2020.[37] Meta-analysis also showed rapidly accelerating myopia progression in children during the COVID-19 pandemic, compared with the pre-COVID-19 period,[38,39] especially in younger children.[39] There was also a significant reduction in contact lens wearing time after January 2020 in both groups of the current investigation, which was similarly observed in other studies.[40,41] The top three reasons that led to less contact lens wearing time were COVID-19 (21%), no need to go out (9%) and no lenses to wear (4%) (as we could not dispense the lenses during the clinic closure). The coronavirus pandemic caused some participants to withdraw from the study and disrupted the wearing pattern, which led to a reduction of the sample size as only those who wore the contact lenses >6 h per day on average were included for analysis. Therefore, one of the limitations of the current study was the reduction in sample size impacting the statistical power. This could also explain why the statistically significant difference only existed in myopia progression and not for axial elongation in the per-protocol analysis. Using ITT methods, where the participant pool was larger, a statistically significant slowing in axial elongation was noted in the DISC3.5plus group at 6 months (Table 3). Therefore, more participants are needed in the future study.

A high drop-out rate (41.3%) was the other limitation of the present study, and complete data were not available for all randomised participants. The main reason for drop-out in both groups was unwillingness to wear contact lenses (42% of the withdrawn participants). Similar to the DISC lens study,[14] most of the participants wanted to slow myopia progression at the beginning; however, they were unwilling to wear contact lenses every day afterwards due to a range of reasons such as it was too much of a rush to wear lenses in the early morning, they were too busy to clean the lenses and accessories or preferring to wear spectacles during the coronavirus pandemic as they believed that spectacles lenses may protect them from the coronavirus. Participants in the control group quit the study when they showed rapid myopia progression. This could result in attrition bias and hinder the treatment outcomes. For future trials, using daily disposable contact lenses (compared with monthly disposable contact lenses in this trial) to reduce the need for lens cleaning and having a cross-over control group for treatment may enhance the motivation of participants and parents, which may improve study retention.

Referring to the visual performance, the DISC3.5plus group had no significant difference in high-contrast distance visual acuity compared with SV contact lens groups, similar to the findings by Chamberlain et al.[17] who tested lenses with +2.00 D of myopic defocus. Walline et al.[18] tested the visual acuity with +2.50 D myopic defocus lenses and Cheng et al.[20] tested the visual acuity with positive spherical aberration lenses; Walline et al.[18] and Cheng et al.[20] found a significant reduction in high-contrast visual acuity compared with wearing SV contact lenses. The DISC3.5plus group had slightly worse distance visual acuities at low contrast, as well as low/high-contrast at near and also poorer stereo-acuity than the SV group, which were most likely due to the myopic defocus induced by the lens. Consistent with the DISC lenses,[14] no serious ocular adverse events were observed during the study, and no deteriorations in the best-corrected distance visual acuity were observed in the DISC3.5plus group, which supports that the DISC3.5plus lens is safe for use.

CONCLUSION

The DISC3.5plus lens showed statistically significant retardation of myopia progression and axial elongation at 6 months. The onset of the coronavirus pandemic disrupted the daily routine and wearing time of the participants and introduced unforeseen variables with indeterminate effects on the study. This disturbance hindered the longer term efficacy of follow-up, thereby necessitating further investigations to validate the sustainability of the treatment effect.

AUTHOR CONTRIBUTIONS

Hanyu Zhang: Conceptualization (equal); data curation (equal); writing – original draft (equal); writing – review and editing (equal). **Ka Yan Leung:** Data curation (equal); writing – original draft (equal); writing – review and editing (equal). **Myra Leung:** Data curation (equal); writing – original draft (equal); writing – review and editing (equal). **Wing Chun Tang:** Writing – review and editing (equal). **Chun Ki Wong:** Data curation (equal). **Ka King Liu:** Data curation (equal). **Dennis Yan Yin Tse:** Writing – review and editing (equal). **Paul H. Lee:** Writing – review and editing (equal). **Carly Siu Yin Lam:** Conceptualization (equal); funding acquisition (equal); project administration (equal); supervision (equal); writing – review and editing (equal).

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CONFLICT OF INTEREST STATEMENT

Patents titled 'Lens and method for retarding myopia progression' were granted in China (CN 114391121 B) and in Hong Kong SAR March 2024 and 7 June 2024, respectively.

DATA AVAILABILITY STATEMENT

The datasets and codes used within this paper are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX 1

PROTOCOL ADJUSTMENT DUE TO UNEXPECTED INCIDENCES

Two unexpected incidences

The Siege of the HK PolyU campus

The siege of the Hong Kong Polytechnic University took place during November 2019 as a serious event of the Hong Kong protests which started in early 2019. The PolyU campus was occupied by protestors from 11 November 2019, and both staff and students were advised not to return to campus. The campus was extensively damaged, and the University was forced to close from 11 November 2019 to early January 2020 for repair. Partial opening was allowed for teaching and learning purposes, and students could return for laboratory and clinical training. All clinical research was on hold during that time. Fortunately, the School of Optometry runs two satellite clinics in the community. We were able to borrow essential equipment from the instrument companies to start the clinical research. However, this was limited and mainly for subjects with urgent issues such as eye discomfort or spoiled lenses for re-order and collection.

Coronavirus pandemic

Since 29 January 2020, due to the outbreak of coronavirus in the Hong Kong community, the Hong Kong government imposed several lockdowns. The University followed government guidelines, and all campus facilities were closed. Most classes were offered as online lectures, and face-to-face practical work was not allowed.

Special work arrangements were implemented by The Hong Kong Polytechnic University from 29 January 2020 to reduce the risk of the spread of the coronavirus in the community. Except for staff providing emergency services, all other staff were required to work from home; hence, all the optometry clinics, including the satellite clinics, were closed from 29 January 2020 to 2 March 2020 and from 23 to 30 March 2020, and the later part of 2020 and early 2021 with partial openings.

As we could not provide face-to-face consultation, we contacted all the ongoing subjects by messaging apps and phone calls to check their status, such as whether there were any ocular signs and symptoms related to contact lens wear, the number of lenses they have for replacement and whether they have maintained the daily wearing time. There was a dramatic drop in wearing time from January to May 2020 in some subjects, as they or their parents worried about the spread of coronavirus due to poor hand hygiene; some believed that spectacles could be a protective device protecting the child from coronavirus. Some wore contact lenses less frequently due to class suspension, as they did not wear contact lenses when at home. We have talked to the subjects or their parents to inform them how to keep good hygiene and encourage them to maintain adequate wearing time (42 h per week) even when they were staying at home.

Data collection was resumed and prioritised whenever the optometry clinics were allowed to reopen. The number of cases were limited by the School of Optometry to reduce the client flow and social contact in clinics and that included all the research projects.

Some parents refused to let their child come for check-ups as they were worried about the spread of the

coronavirus, even with the tight infection control measures implemented at the university clinics.

Adjustment for 6- and 12-month follow-up criteria

All these factors caused about 15% of the data collection to be delayed by >60 days from the expected assessment day. In view that the delay in assessment may cause inconsistent comparison of the data for both the 6- and 12-month visits, we have revised the clinical protocol and adjusted the calculation of both the primary (change in SER) and secondary outcome (change in AL). Therefore, the change of SER and the change of AL presented were adjusted using the quadratic model.

Quadratic model for changes of SER

For each individual subject, the actual number of days of the dispensing appointment is the x-axis, and the corresponding change of SER is the y-axis. Therefore, there will be three key points:

At 0 days, there are 0 D SER changes.

After x_1 days, there are y_1 D SER changes (the first appointment for dispensing, this corresponds to the 6-month follow-up).

After x_2 days, there are y_2 D SER changes (the second appointment for dispensing, corresponds to the 12-month follow-up).

Utilising these three points could obtain a quadratic equation of the form:

$$y = ax^2 + bx + c$$

When $x = 183$ (6 months), the 'y' value from the equation represents the adjusted SER changes at 6 months. When $x = 366$, the 'y' value from the equation represents the adjusted SER changes at 12 months.

The same method was applied for the adjustment of AL changes.