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ORIGINAL ARTICLE

OPO THE COLLEGE OF OPTOMETRISTS

Clinical evaluation of MyoCare in Europe (CEME) for myopia management: One-year results

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Abstract

Aims: To evaluate the efficacy of CARE spectacle lenses in slowing myopia progression among European children.

Methods: In a 2-year randomised, parallel-group, double-masked, multicentre clinical trial, 234 European children aged 6–13 years were enrolled. All participants were myopic, with a cycloplegic spherical equivalent refractive error (SE) between −0.75 D and −5.00 D, astigmatism ≤1.50 D, anisometropia ≤1.00 D and myopia progression of at least 0.50 D in the previous year. The treatment group received MyoCare spectacle lenses with cylinder annular refractive elements (CARE), the control group single-vision lenses (SVL). Axial length (AL) and SE were measured at baseline, 6 and 12 months. Wearability questionnaires were administered at 1 week and 3 months. Central and peripheral visual acuity (VA) was recorded at dispensing and after 3 months. Generalised linear models estimated changes in SE and AL, adjusting for lens type, age and baseline measurements.

Results: After 12 months, children wearing CARE lenses showed less myopia progression, with a difference in SE and AL progression (compared to SVL) of −0.21 D (CI: 0.10 to 0.32 D) and 0.14 mm (CI: −0.17 to −0.10 mm), respectively. Central VA did not decrease with CARE lenses. Peripheral VA decreased by 0.10 and 0.09 logMAR in the nasal and temporal zones, respectively. Analysis of fast progressors indicated that 39.7% of SVL wearing eyes progressed by ≤−0.50 D/year compared to 21.1% with CARE ($p < 0.01$). For AL, 56.0% of SVL children had an elongation ≥0.20 mm compared to 21.3% with CARE ($p < 0.01$).

Conclusions: In European children, myopia progression was significantly slower with CARE lenses compared with SVL after 1 year of lens wear. Further monitoring will provide a comprehensive evaluation of long-term efficacy.

KEYWORDS
children, Europe, myopia control, ophthalmic lens

INTRODUCTION

With a high prevalence worldwide, the associated health, economic and social consequences of myopia have a significant global impact.[1] Although in the long term, high levels of myopia can lead to ocular complications such as myopic macular degeneration, retinal detachment, cataracts and glaucoma; notably, evidence suggests that at any level, the burden of myopia is considerable with each dioptre increase in myopia substantially increasing

the potential adverse consequences.[2] This highlights the importance of early intervention, and it is crucial that efforts are taken to mitigate the risk of the eye reaching higher levels of myopia. Various approaches exist to slow the progression of myopia, including atropine, orthokeratology (ortho-K), low-level red-light therapy, specialised contact and spectacle lenses, as well as combination treatments.[3]

With respect to spectacle lenses, several lens designs incorporating multiple segments that are considered to impose simultaneous defocus at the retina have been developed. In randomised clinical trials, lenses incorporating designs such as the Defocus-incorporated multiple segments (DIMS – Hoya®, MiyoSmart®, hoyavision.com) and highly and slightly aspherical lenslets (HALT and SALT – Essilor®, Stellest™, essilor.com) were found to be effective in slowing myopic eye growth.[4–6] Additionally, alternative strategies exist such as diffusion optics technology (DOT™—Sight Glass Vision Inc., sightglassvision.com) spectacles which are theorised to influence progression by reducing contrast across the retina.[7] A more recent spectacle lens design has been developed that incorporates cylindrical annular refractive elements (MyoCare®, henceforth referred to as CARE, Zeiss Vision Care, zeiss.com). The lens features a central optical zone that corrects for myopia and is encircled by a treatment zone featuring numerous micro-cylinders arranged in concentric circles. These annular cylindrical refractive elements are 0.5 mm wide and alternate with annular zones of equal width that possess the same refractive properties as the distance-correcting optic. The cylindrical annuli have a power of +9.2 D and 0.0 D in the radial and circumferential direction, respectively, yielding an average cylindrical power of +4.6 D. The cylindrical components are non-coaxial and create a caustic-like annular point spread function (PSF) at the plane of focus. The alternating cylindrical elements in conjunction with the clear zones are considered to induce simultaneous defocus at the retina.

Importantly, given the higher prevalence of myopia in Asia,[8] the majority of studies examining the effectiveness of the various myopia management strategies were conducted in that region with children of Chinese ethnicity.[3] However, the question exists whether the effectiveness of these treatments, determined based on studies conducted in Asia, could be extended and applied to European children with myopia,[9,10] given the variation in behavioural, environmental, epidemiological and genetic differences between children in Asian countries and Europe.[11]

This trial analysed the efficacy of CARE lenses (MyoCare®) in a randomised, parallel-group, double-masked, multicentre clinical trial involving European children with myopia. The objective was to determine the rate of myopia progression in terms of the change in spherical equivalent refractive error (SE) and axial length (AL) in European children wearing CARE myopia control spectacles when compared with single-vision spectacle lenses.

Key points

- This is the first trial from a European population confirming that spectacle lenses with cylinder annular refractive elements slow myopia when compared with single vision lenses.
- The impact on vision when looking through the treatment zone of lenses with cylinder annular refractive elements was minimal.
- Lenses with cylinder annular refractive elements may serve as an effective method to reduce the risk of fast myopic progression and future risks associated with higher levels of myopia.

MATERIALS AND METHODS

European myopic children aged 6–13 years were enrolled in a prospective, multicentre, randomised, double-blind controlled clinical trial. The multicentre trial involved six ophthalmology clinics across five cities in Spain and Portugal: Novovision (Madrid, Spain), ICQO (Bilbao, Spain), CPO (Lisbon, Portugal), Miranza (Seville, Spain), Novovision (Murcia, Spain) and IMO (Madrid, Spain). Ethical approval for the trial was obtained from the Hospital Clínico San Carlos Ethics Committee (June 2022, Approval code 22/384-EC_P) and the clinical trial was registered at clinicaltrials.gov (NCT05919654). All trial procedures adhered to the tenets of the Declaration of Helsinki for experimentation on humans. Before conducting any study procedures, written informed consent was obtained from all parents or legal guardians prior to randomisation and written assent was obtained from children 12 years of age or older. The parents/guardians also agreed for the child to wear the spectacles during the whole day, without removal for near tasks.

Inclusion criteria were European children 6–13 years of age, best-corrected monocular and binocular visual acuity (BCVA) of 0.00 logMAR or better, cycloplegic SE between −0.75 D and −5.00 D in both eyes, astigmatism of −1.50 D or less, anisometropia of 1.00 D or less. Additionally, children should have had myopia progression of at least 0.50 D in the year preceding enrolment in the trial. Children were excluded from the trial if there was ocular pathology, a history of eye surgery, any previous myopia control treatment, contraindications for using cycloplegic or anaesthetic eye drops or any other drug allergies.

Trial intervention

A total of 318 children were found to be eligible. After screening, 234 were included and randomly assigned either to the intervention or control groups. Children in the control group

wore single vision lenses (ClearView, ZEISS Vision Care, zeiss.com) (SVL) while children in the intervention group wore CARE lenses (Zeiss MyoCare®, ZEISS Vision Care, zeiss.com). The CARE lens design features two main components: (a) a central circular zone with a diameter of 7 mm that corrects the distance refractive error and (b) a treatment zone that surrounds this central area and extends to the edge of the lens. This treatment zone includes cylindrical annular refractive elements (CARE) alternating with zones that correct for the distance refractive error. The cylindrical microstructures have a nominal power of +9.2 D, resulting in an average additional surface power of +4.6 D.[12] Figure 1 shows a schematic illustration of the CARE spectacle lens.

Trial procedures

Children enrolled in the trial were randomised to wear either CARE spectacle lenses or SVL. They were examined at baseline, dispensing, 3 months, 6 months and thereafter at 6-monthly intervals. At baseline, children underwent visual acuity (VA) assessment, cycloplegic autorefraction and AL measurement. At the dispensing visit, measurement of distance VA with the allocated lenses was conducted for central and peripheral (20°) vision using the Freiburg Acuity Test (michaelbach.de/fract/). Additionally, questionnaires on wearability were administered. A telephone questionnaire was conducted at 1 week and 3 months; AL measurements, central and peripheral VA and wearability assessments were conducted. Thereafter, children were examined at 6-monthly intervals. A detailed description of the study procedures has been provided elsewhere.[13] At each visit, both uncorrected and best-corrected VA was measured monocularly and binocularly using Early Treatment of Diabetic Retinopathy Study (ETDRS) charts. Wearability questionnaires consisted of a series of questions that children, with the assistance of their parents, were asked to rate on a Likert scale from 1 to 10. The questions related to their distance vision, near vision, vision while walking or doing sports and vision when going up and down stairs. Additionally, they were asked to rate their visual experience at the end of the day.

One week after the dispensing visit, participants were asked about the time it took to adapt to the lenses. They were given four options, namely: (a) <3 h, (b) 1 day, (c) 3 days or (d) I have not yet adapted.

The primary outcome measures were the change in cycloplegic SE and AL after 6 months. Cycloplegic SE was measured using a wavefront-based autorefractor (i. Profiler; Carl Zeiss Vision, zeiss.com). Children were cycloplegged using two drops of 1% tropicamide, administered 5 min apart, and measurements were taken 30 min after the first drop of tropicamide was instilled. An average of three measurements was considered as the final value. Axial length was calculated as the mean of five measurements obtained using the biometer IOLMaster 700 (Carl Zeiss Meditec AG, Jena, zeiss.com).

Sample size and statistical analysis

The sample size was calculated based on a mean annual progression of 0.50 D in this population with the SVL

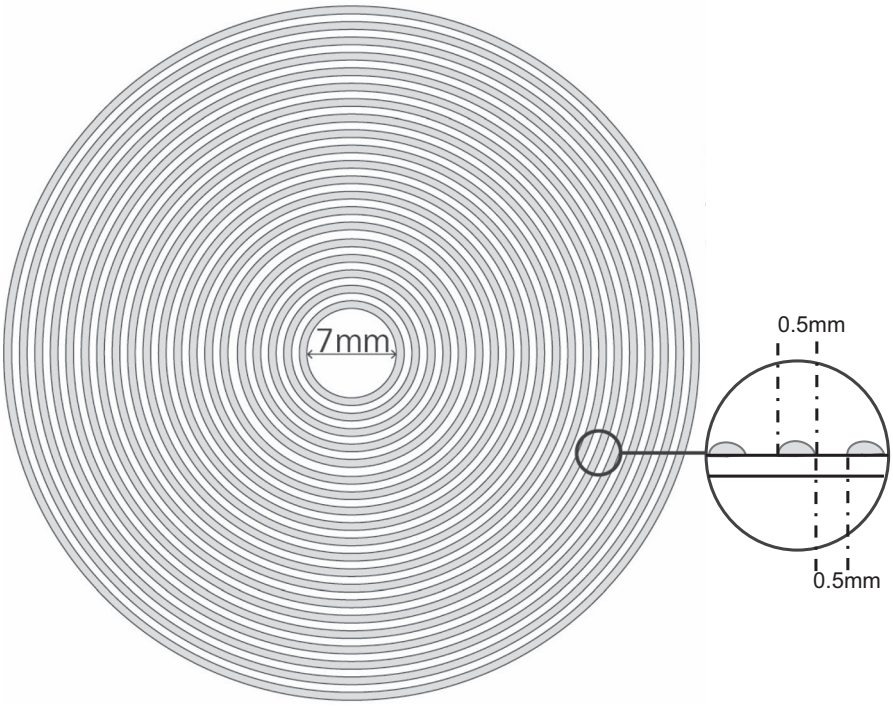

FIGURE 1 Schematic illustration of the features in the cylindrical annular refractive elements (CARE) spectacle lens.

(control group),[14,15] and a 50% reduction in myopia progression with CARE at a significance level of 5% and statistical power of 80%. Given a standard deviation for the refractive error progression of 0.65 D,[14,15] it was determined that a sample size of 106 participants per group would be necessary, resulting in a total of 212 participants for the study. Considering 10% potential dropouts, a total of 234 children were enrolled in the clinical trial.

Descriptive statistics were used to summarise the baseline characteristics of the study population such as age and gender, as well as the AL and SE at baseline and after 12 months. Continuous variables were presented as means and standard deviations, or medians and interquartile ranges [Q1, Q3] if the variable did not follow a normal distribution, as determined by the Shapiro–Wilk test. Categorical variables were presented as frequencies and percentages. Baseline characteristics of the children in the two groups were compared using either independent *t*-tests or Mann–Whitney *U*-tests for continuous variables that did or did not follow a normal distribution, respectively, with chi-squared tests being used for categorical variables.

The primary outcome of the trial was the change in AL and SE during the first 12 months of intervention (interim analysis). Generalised linear models (GLM) were employed to estimate changes in SE and AL from baseline, adjusted for lens type (CARE or SVL), qualitative variables such as sex, testing site and parental myopia (zero, one or two myopic parents). Additionally, quantitative variables included age and baseline SE or AL at the time of inclusion in the study.

No data imputation was performed; the models were built using data from children without missing values for any of the model variables. Adjusted values (obtained from the GLMs) of the SE and AL change at 12 months were compared between the two study groups (using independent *t*-tests) to determine the efficacy of the treatment lenses. A significance level of 5% was used for all statistical tests.

To identify factors affecting fast myopia progression (defined as a spherical equivalent (SE) progression exceeding −0.50 D after 12 months as well as AL elongation >0.20 mm), univariate and multivariate binary logistic regression models were conducted. Factors considered include the trial groups, categorical variables such as gender and parental myopia as well as continuous variables such as age, SE, baseline AL and reported age of myopia onset. To evaluate the strength and direction of association, the adjusted odds ratio (OR) for rapid progression and its 95% confidence interval were calculated for each associated factor. Analyses were conducted using the STATA v.17 software package (stata.com).

RESULTS

A total of 234 children were enrolled in the trial and randomised to either SVL or CARE lenses. Of these, 226 children completed the 12-month visit (117 and 109 wearing the SVL and CARE lenses, respectively).

Figure 2 presents the participant flow during the first 12 months. Eight subjects failed to complete the study. Of these, six were wearing CARE lenses (four participants were lost to follow up and two participants were lost due to non-adaptation to the spectacles). The remaining two discontinued subjects wore SVL (one participant was lost to follow up and the other moved to another country).

Table 1 presents the baseline characteristics. The mean age of the children enrolled in the trial was 10.0 ± 1.9 years and there were no significant differences between the groups for any of the baseline characteristics. Mean baseline cycloplegic SE was −2.12 ± 0.94 D with SVL and −2.28 ± 0.94 D with CARE, and baseline AL was 24.17 ± 0.75 mm with SVL and 24.34 ± 0.68 mm with CARE ($p = 0.12$ and 0.07, respectively). There were more females than males across both groups and the majority of children had one or both parents myopic. There were no significant differences between the groups for sex or parental myopia. Additionally, across sites, there were no significant differences in the number of children randomised to SVL and CARE groups.

When queried on indoor/outdoor time, 46% of the children reported spending <1.6 h per day outdoors and 78% reported engaging in near-vision activities for more than 2 h daily after school. Additionally, 37% of the children reported using digital devices for over 50% of the time during near-vision activities.

Efficacy after 6 and 12 months of lens wear: Change in spherical equivalent refractive error and axial length

The observed change in SE from baseline to 6 months was −0.23 ± 0.30 D in the SVL group. In comparison, the change in SE was significantly reduced at −0.07 ± 0.34 D in the CARE group. Similarly, the observed change in AL from baseline to 6 months was 0.11 ± 0.10 mm and 0.02 ± 0.10 mm in the SVL group and CARE group, respectively (Table 2). Overall, the difference between the groups was significant (0.16 D difference in SE and −0.09 mm difference in AL).

The SE progression from baseline to 12 months was −0.41 ± 0.41 D and −0.20 ± 0.41 D in the SVL and the CARE group, respectively. In terms of AL, the respective change from baseline was 0.23 ± 0.15 mm and 0.09 ± 0.14 mm (Table 2). Overall, the difference between the groups was significant (0.21 D difference in SE and −0.13 mm difference in AL).

After adjusting for confounders (lens, age, gender, baseline values, testing site and parental myopia), the estimated values for both the 6-month and 12-month visits are shown in Figure 3. The mean difference in SE progression between the CARE and SVL groups after 12 months of wear was 0.21 D (95% confidence interval [CI]: 0.10–0.32 D) and for AL was 0.14 mm (95% confidence interval [CI]: −0.17 to −0.10 mm) with the CARE wearing eyes showing slower myopic progression.

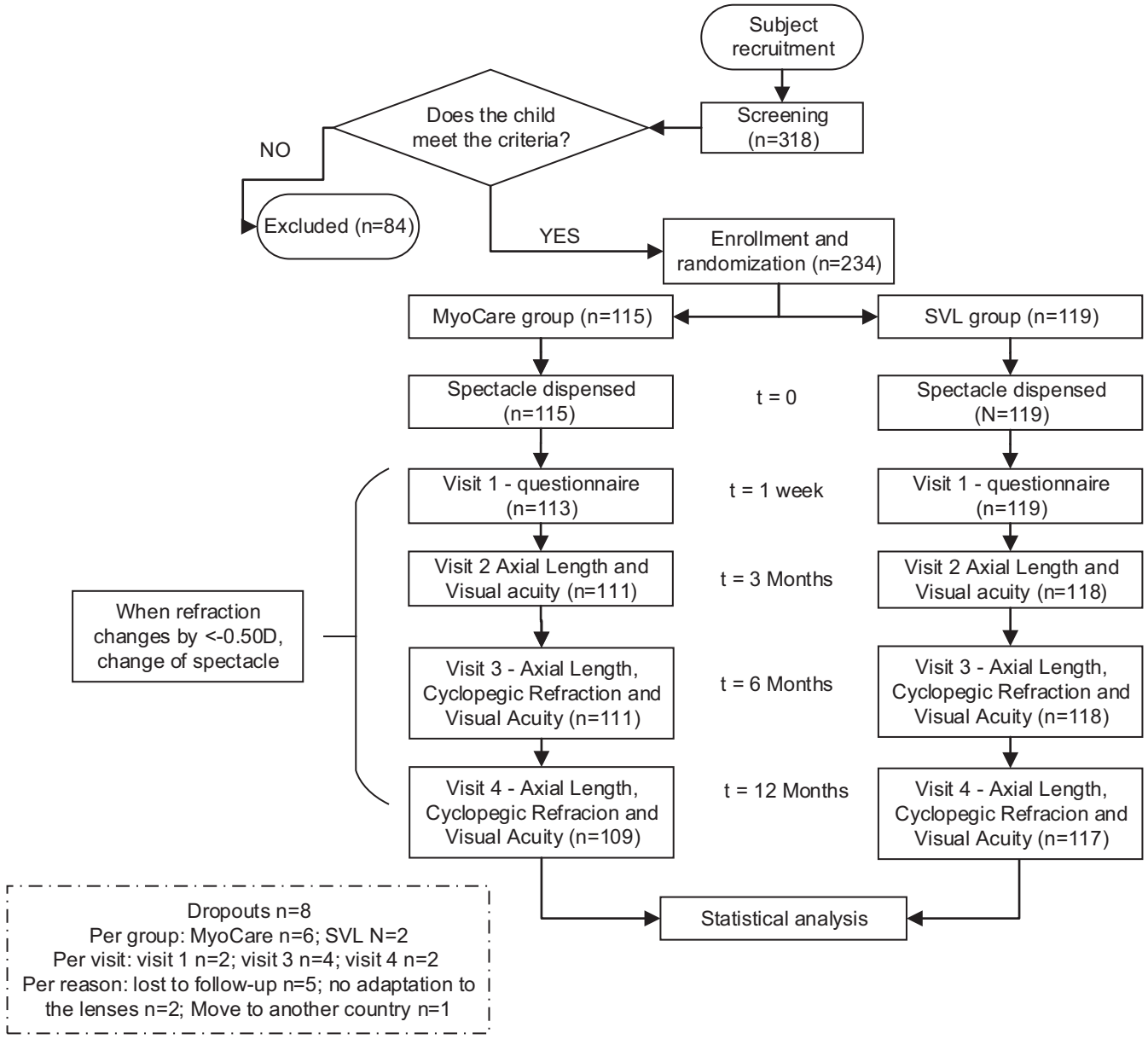

FIGURE 2 Study Flowchart. CARE, cylindrical annular refractive elements spectacle lens; SVL, single vision lens; t, time.

Wearability and vision between groups

Table 3 summarises the subjective responses to various aspects of lens wear, collected 1-week post dispensing and after 3 months of wear.

At the 1-week visit, children wearing SVL reported higher ratings for distance vision, near vision, vision while going up and down stairs and for overall vision, and significant differences with the CARE lens were observed. However, at the 3-month visit, there were no significant differences in the subjective ratings between the two lenses, except for near vision.

When queried about the time taken to adapt to the lenses, significant differences were observed between the two groups. Considering the SVL group, 53.8% of children reported adapting in less than 3 h, 30.8% within 1 day, 14.5% took 3 days, while only 0.9% had not adapted after 1 week. In comparison, the time to adaptation was greater with the CARE group, with only 15.7% of children reporting having adapted in 3 h, 28.7% within 1 day, 38.9% required 3 days and 16.7% had not adapted at the 1-week visit ($p < 0.01$).

Regarding VA, at the dispensing visit, VA was significantly different between groups. However, these differences were not clinically relevant when children looked through the clear zone. The mean values for distance VA were -0.00 ± 0.04 and 0.02 ± 0.06 ($p < 0.01$) for the SVL and CARE lenses, respectively. No significant differences were observed for near VA, with values of 0.01 ± 0.06 and 0.01 ± 0.04 for the SVL and CARE lenses, respectively ($p = 0.12$). The differences between groups when children looked through the treatment zone were significant, and some were also clinically relevant. When looking through

TABLE 1 Baseline variables and factors by group.

	Total	CARE	SVL	*p*-Value
No. of eyes	234	115	119	
Age (year)				
Median [Q1, Q3]	10 [9, 12]	10 [9, 12]	10 [9, 11]	0.07
Gender				
Male	103 (44.0%)	51 (44.3%)	52 (43.7%)	
Female	131 (56.0%)	64 (55.7%)	67 (56.3%)	0.92
AL (mm)				
Mean ± SD	24.26 ± 0.72	24.34 ± 0.68	24.17 ± 0.75	0.07
SE (D)				
Median [Q1, Q3]	−2.01 [−2.77, −1.47]	−2.17 [−2.89, −1.50]	−1.90 [−2.58, −1.43]	0.12
Reported age of myopia onset (year)				
Median [Q1, Q3]	8 [6, 9]	8 [6, 9]	8 [7, 9]	0.78
Number of myopia parents				
One parent	127 (54.5%)	62 (54.4%)	65 (54.6%)	
Both parents	57 (24.5%)	28 (24.6%)	29 (24.4%)	
None	49 (21.0%)	24 (21.0%)	25 (21.0%)	0.10
Reported outdoor time				
High (>2.7 h/day)	35 (15.0%)	16 (14.0%)	19 (16.0%)	
Moderate (1.6–2.7 h/day)	90 (38.6%)	46 (40.4%)	44 (37.0%)	
Low (<1.6 h/day)	108 (46.4%)	52 (45.6%)	56 (47.0%)	0.84
Reported time in near-vision activities				
High (>3 h/day)	82 (35.2%)	42 (36.9%)	40 (33.6%)	
Moderate (2–3 h/day)	100 (42.9%)	47 (41.2%)	53 (44.4%)	
Low (<2 h/day)	51 (21.9%)	25 (21.9%)	26 (22.0%)	0.85
Reported % of time in near-vision activities with digital devices				
High (>50%)	86 (36.9%)	40 (35.1%)	46 (38.6%)	
Moderate (25%–50%)	96 (41.2%)	47 (41.2%)	49 (41.2%)	
Low (<25%)	51 (21.9%)	27 (23.7%)	24 (20.2%)	0.77
Site				
Madrid (Novovisión)	57 (24.4%)	27 (23.5%)	30 (25.2%)	
Bilbao (ICQO)	19 (8.1%)	12 (10.4%)	7 (5.9%)	
Lisboa (CPO)	34 (14.5%)	11 (9.6%)	23 (19.3%)	
Sevilla (Miranza)	31 (13.2%)	15 (13.0%)	16 (13.4%)	
Murcia (Novovisión)	50 (21.4%)	27 (23.5%)	23 (19.3%)	
Madrid (IMO)	43 (18.4%)	23 (20.0%)	20 (16.8%)	0.29

Abbreviations: AL, axial length; mm: millimetres; CARE, cylindrical annular refractive elements spectacle lens; D, dioptres; SE, spherical equivalent; SVL, single vision lens.

the nasal zone, VA was 0.01 ± 0.05 with SVL and 0.10 ± 0.08 with CARE ($p < 0.01$). Looking through the temporal zone, the reported VA was 0.01 ± 0.05 and 0.09 ± 0.07 with SVL and CARE, respectively ($p < 0.01$). At the 3-month visits, significant differences were only observed when children looked through the treatment zone. For the SVL and CARE lenses, the mean values for distance VA were −0.01 ± 0.07 and −0.01 ± 0.06, respectively ($p = 0.38$). The respective values for near VA at the 3-month visit were 0.01 ± 0.04 and 0.02 ± 0.06 ($p = 0.07$). With respect to peripheral VA for the SVL and CARE lenses, VA was 0.02 ± 0.07 and 0.12 ± 0.10 through the nasal zone and 0.02 ± 0.06 and 0.11 ± 0.10 through the temporal zone (both $p < 0.01$), respectively.

Fast progressors over 12 months

With regard to fast progressors (≤−0.50 D progression over 12 months), there were significant differences between the two groups. Among the SVL group, 46 of 117 individuals (39.3%) experienced fast progression, compared with

TABLE 2 Observed progression values of cycloplegic spherical equivalent refractive error (SE) and axial length (AL), as well as comparison between baseline, 6- and 12-month (M) visits. Bold font indicates significant difference.

		Group											
		SVL					CARE						
Variables	Visit	*n*	Mean	SD	Min	Max	*n*	Mean	SD	Min	Max	*p*-Value*	Mean difference	% Reduction
SE progression	Baseline	119	**0.00**				115	**0.00**						
	6 M	117	**−0.23**	0.30	−0.95	0.99	111	**−0.07**	0.34	−1.25	0.89	***<0.01***	0.16	71%
	12 M	117	**−0.41**	0.41	−1.87	0.45	109	**−0.20**	0.41	−1.93	0.57	***<0.01***	0.21	51%
AL progression	Baseline	119	**0.00**				114	**0.00**						
	6 M	118	**0.11**	0.10	−0.18	0.43	110	**0.02**	0.10	−0.28	0.26	***<0.01***	−0.09	83%
	12 M	117	**0.23**	0.15	−0.12	0.83	108	**0.09**	0.14	−0.17	0.65	***<0.01***	−0.13	58%

Abbreviations: CARE, cylindrical annular refractive elements spectacle lens; Max, maximum; Min, minimum; SD, standard deviation; SVL, single vision lens.

*Statistical significance difference between two groups $p \leq 0.05$.

23 of 109 individuals (21.1%) in the CARE group ($p < 0.01$). Similarly, for fast axial elongation, that is, ≥0.20 mm over 12 months, there were significant differences with 70 of 117 SVL participants (59.8%) demonstrating fast axial elongation as compared with 23 of 108 individuals (21.3%) in the CARE group ($p < 0.01$).

Univariate and multivariate analysis of factors influencing fast progression indicated baseline SE to be a significant predictor of fast progression in the SVL group. Fast progressors in the SVL group had a more myopic baseline SE than the non-fast progressors ($p = 0.02$; OR = 0.41; CI 95%: 0.23, 0.75). On the contrary, fast progressors in the CARE group tended to have a less myopic baseline SE than the non-fast progressors ($p = 0.08$; OR = 2.58; CI 95%: 1.21, 5.47).

DISCUSSION

The results from this study are notable as it is the first trial to report the effectiveness of a spectacle lens with multiple segments or microstructures for myopia control in a European population. The results also confirm the previous findings of reduced myopia progression with the CARE lenses in a Chinese population and indicate that the lens is efficacious across ethnicity/race.[14] In the current trial, a difference in SE of 0.21 D and AL of 0.14 mm was observed with CARE lenses compared with SVL. In comparison, in the Asian population, the progression differences were 0.31 D and 0.13 mm, respectively.[16]

Other spectacle lenses are available that incorporate multiple segments or features across the treatment zone. Relevant among those with demonstrated efficacy are DIMS, HALs and DOT lenses.[17] However, with the exception of the DOT lenses where data are available from a mostly Caucasian population, the other lenses were primarily tested in Asian cohorts.

With respect to the DIMS lens, a trial conducted in Hong Kong reported differences in adjusted SE of 0.27 D and AL of 0.22 mm between DIMS and SVL, with slower progression being observed in DIMS wearers.[18] A more recent randomised double-blind trial conducted in China noted that DIMS produced a reduced mean difference in myopia progression and axial elongation of 0.28 D and 0.13 mm, respectively.[19] Additionally, a 1-year observational study of DIMS in a European population (65% white) observed a 12-month change in SER and AL of −0.36 ± 0.42 D and 0.18 ± 0.20 mm, respectively, but there was no comparative control group.[20] The results from the current study appear similar, with a difference in myopia progression of 0.21 D and axial elongation of 0.13 mm. It should also be noted that the myopia progression was slower in the European population compared with Asian eyes.[21]

With regard to HAL spectacle lenses, to date there have been no data reporting efficacy of these lenses for a non-Chinese population. After 1 year of lens wear in a Chinese population, the change from baseline in SE (adjusted) with HAL and SVL was −0.30 D and −0.79 D, respectively. The

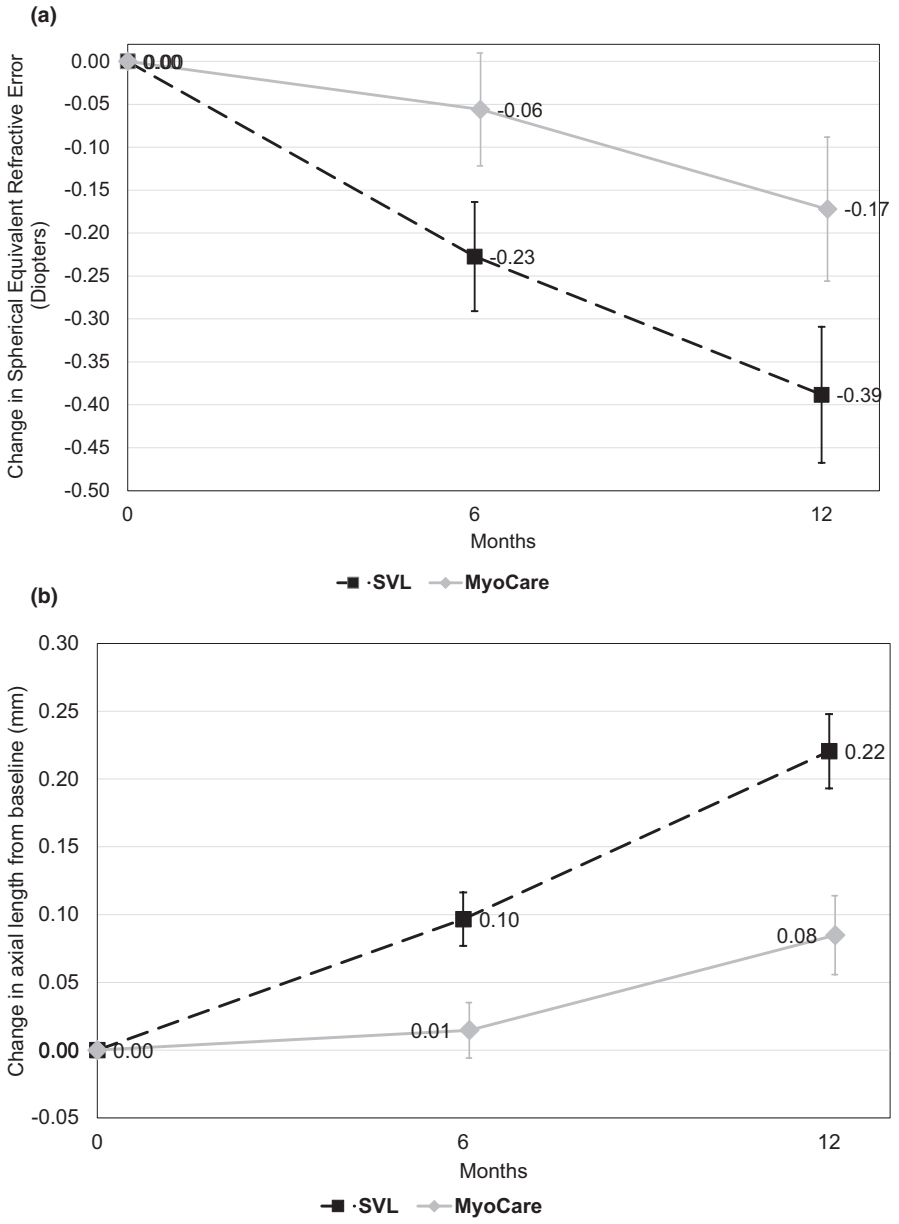

FIGURE 3 (a) Spherical equivalent refractive error progression over time; (b) Axial length progression over time. Study lens: Cylindrical annular refractive elements spectacle lens (MyoCare); Control, single vision lens (SVL).

adjusted AL change was 0.14 mm with HAL, compared with a 0.35 mm change in the SVL group.[22]

With DOT lenses following 12 months of lens wear, the adjusted SE change was −0.14 D, compared with an SVL change of −0.54 D. The adjusted AL change with DOT and SVL was 0.15 mm and 0.30 mm, respectively.[23] This study was conducted across 14 sites in North America, and the sample comprised 74% Caucasians, 19% African American and 7% of other ethnicities. The data observed with DOT lenses appear similar to that observed with CARE lenses, especially with respect to the AL difference between DOT and SVL.

Considering the cylindrical annular refractive elements, light along the power meridian is brought to a focus as a line image perpendicular to the meridian in front of the retina, whereas light along the axis meridian falls at or near the retinal plane. It is considered that the myopic defocus imposed by the rays focusing in front of the retina is responsible for slowing myopia progression, which is similar to the concept proposed for other lenses with defocus incorporated features such as DIMS or HAL.[24,25]

Despite these design principles, the precise mechanism by which myopia-control spectacle lenses slow myopia progression remains unclear. In a study conducted in Asia, two CARE lenses with varying power were assessed. While there were some differences between the groups having the CARE elements, with the 9.2 D power being more efficacious than the 7.6 D version, the differences were not significant.[16] However, in contrast to these results observed

TABLE 3 Subjective responses to vision 1 week and 3 months post dispensing.

			How is your distance vision	How is your near vision	How is your vision walking or doing sports	How is your vision going up and down stairs	How do you feel after wearing the spectacles all-day
One week	CARE	Median [Q1, Q3]	9 [8, 10]	10 [8, 10]	9 [8, 10]	10 [8, 10]	10 [8, 10]
		Mean ± SD	8.67 ± 1.43	8.99 ± 1.80	8.97 ± 1.30	8.94 ± 1.44	8.83 ± 1.68
	SVL	Median [Q1, Q3]	10 [9, 10]	10 [9, 10]	10 [9, 10]	10 [9, 10]	10 [9, 10]
		Mean ± SD	9.17 ± 1.31	9.52 ± 1.00	9.44 ± 0.80	9.57 ± 0.75	9.41 ± 0.96
	p-value		**<0.01**	**0.04**	**0.01**	**<0.01**	0.02
Three months	CARE	Median [Q1, Q3]	9 [8, 10]	10 [8, 10]	10 [8, 10]	10 [9, 10]	10 [8, 10]
		Mean ± SD	8.66 ± 1.79	8.82 ± 1.96	8.89 ± 1.69	9.05 ± 1.70	8.88 ± 1.93
	SVL	Median [Q1, Q3]	9 [8, 10]	10 [10, 10]	10 [8, 10]	10 [9, 10]	10 [9, 10]
		Mean ± SD	8.90 ± 1.23	9.47 ± 1.28	9.13 ± 1.42	9.41 ± 1.14	9.28 ± 1.34
	p-value		0.91	**<0.001**	0.33	0.17	0.12

Note: Numbers in bold font indicate statistical significance.

Abbreviations: CARE, cylindrical annular refractive elements spectacle lens; SVL, single vision lens.

with CARE lenses, a previous trial comparing HAL lenslets with slightly aspherical lenslets (SAL) found HAL to be more efficacious.[22] It is also of interest to observe that the effective power of the annular elements would be much higher at the pupil plane (approximately 10.5 D or greater) depending on the distance from the spectacle plane to the pupil plane. Therefore, it remains to be confirmed whether the power of the defocusing features plays a role. However, in a recent study, Schaeffel and Swiatczak reported that the image degradation produced by DIMS, HAL or CARE spectacle lenses was similar and only around 0.5 D.[26] Further investigations[27–29] have indicated that CARE lenses can either enhance or diminish contrast depending on the spatial frequency and eccentricity.[28] Gawne et al. reported that both CARE and other lenses may exhibit spatial frequency filtering properties, with CARE lenses reducing high spatial frequencies.[30] The precise mechanism underlying these lenses should be explored further.

When considering myopia management options, it is essential to look beyond efficacy alone, and include other aspects such as safety, vision quality and comfort. Of the various myopia control options, spectacle lenses are considered to be the safest choice, with no significant differences between the various designs.[31] The results with the CARE lens indicated no decrement in VA when looking through the central zone, although when viewing through the periphery, a decrease in VA of 0.10 and 0.09 logMAR was found when looking through the nasal and temporal zones, respectively. Regarding this reduction in peripheral VA, it is speculated that the blur from the annuli may reduce contrast. This effect is similar to that observed with DIMS lenses, where the induced blur can lead to a decrease in contrast sensitivity.[32] Subjective responses to lens wear were good, with most children reporting adaptation within 3 days.

Similar results have been reported for other myopia control spectacles. For example, with DIMS, central VA was not affected when compared to SVL; however, mid-peripheral near VA decreased by approximately 0.06 logMAR.[32,33] Similar values of best-corrected VA were found with HAL lenses and SVL. Furthermore, 90% of children adapted to HAL within 3 days, compared with 100% of SVL wearers.[22] Viewing through the peripheral treatment zone of DOT lenses did not produce a significant impact on distance or near high-contrast VA. However, for low-contrast measures, all lenses reduced distance and near VA.[34]

In addition, it was noted in the present study that CARE lenses significantly reduced the prevalence of fast progressors, with only 20% of children experiencing fast progression of their myopia in the CARE group compared with 60% in the SVL group. A more myopic baseline SE was associated with faster myopia progression in the SVL wearers, but not in the CARE group. Based on these results, it appears that CARE may serve as an effective method of reducing the risk of fast progression, while minimising the associated risks in adulthood.

The current trial suffered from some limitations. Although it was conducted on a double-blind basis, with most parents and investigators unaware of the lens assignment, it was possible to deduce the nature of the lens as the features of the CARE lens are visible when the lens is viewed obliquely or with back-lit illumination. However, the investigators remained blinded as children were required to attend their follow-up visits without their glasses. To ensure the blinding of investigators, VA measurements were performed by eye care professionals at locations where the lenses were cut, edged and fitted.

In conclusion, CARE lenses were shown to be effective in slowing the progression of myopia in a European population, with a slower change in SE and axial elongation compared with those wearing SVL. However, it is important to note that the effect was not uniform across all participants. It is likely that some participants may have experienced greater benefit than others. The study will continue to monitor the children for up to 3 years of lens wear to provide a more comprehensive evaluation of the long-term efficacy of CARE spectacle lens in myopia management.

AUTHOR CONTRIBUTIONS

Cristina Alvarez-Peregrina: Conceptualization (equal); formal analysis (equal); funding acquisition (equal); investigation (equal); methodology (equal); project administration (equal); supervision (equal); validation (equal); visualization (equal); writing – original draft (equal). **Padmaja Sankaridurg:** Methodology (equal); supervision (equal); validation (equal); writing – review and editing (equal). **Wayne Li:** Formal analysis (equal); software (equal); writing – review and editing (equal). **Arne Ohlendorf:** Methodology (equal); supervision (equal); validation (equal); writing – review and editing (equal). **Cesar Villa-Collar:** Conceptualization (equal); data curation (equal); investigation (equal); methodology (equal); writing – review and editing (equal). **Miguel Angel Sanchez-Tena:** Conceptualization (equal); investigation (equal); methodology (equal); supervision (equal); validation (equal); visualization (equal); writing – review and editing (equal). **Clara Martinez-Perez:** Resources (equal); software (equal); supervision (equal); writing – review and editing (equal). **Nicole Liu:** Validation (equal); visualization (equal); writing – review and editing (equal). **Beatriz de Corcuera-Terrero:** Data curation (equal); resources (equal); writing – original draft (equal).

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CONFLICT OF INTEREST STATEMENT

Padmaja Sankaridurg is an employee of Carl Zeiss Vision International GmbH and is an inventor on patents and patent applications assigned to Brien Holden Vision Institute and ZEISS Vision Care; Nicole Liu is an employee of Carl Zeiss Vision International GmbH; Arne Ohlendorf is an employee of Carl Zeiss Vision International GmbH; Wayne Li is an employee of ZEISS Vision Care Guangzhou; Cristina Alvarez is a member of the Zeiss Myopia Advisory Board. No conflicts of interest exist for the remaining authors.

CLINICAL TRIAL REGISTRATION

The clinical trial was registered at clinicaltrials.gov under the number NCT05919654.

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REFERENCES

1. Holden B, Wilson D, Jong M, Sankaridurg P, Fricke TR, Smith EL III, et al. Myopia: a growing global problem with sight-threatening complications. *Community Eye Health*. 2015;28:35. Accessed January 15, 2025. https://pmc.ncbi.nlm.nih.gov/articles/PMC4675264/pdf/jceh_28_90_035.pdf
2. Shah R, Vlasak N, Evans BJW. High myopia: reviews of myopia control strategies and myopia complications. *Ophthalmic Physiol Opt*. 2024;44:1248–60.
3. Lawrenson J, Shah R, Huntjens B, Lawrenson JG, Downie LE, Virgili G, et al. Interventions for myopia control in children: a living systematic review and network meta-analysis. *Cochrane Database Syst Rev*. 2023;2:CD014758. https://doi.org/10.1002/14651858.cd014758.pub2
4. Lam CSY, Tang WC, Zhang HY, Lee PH, Tse DYY, Qi H, et al. Long-term myopia control effect and safety in children wearing DIMS spectacle lenses for 6 years. *Sci Rep*. 2023;13:5475. https://doi.org/10.1038/s41598-023-32700-7
5. Li X, Huang Y, Yin Z, Liu C, Zhang S, Yang A, et al. Myopia control efficacy of spectacle lenses with aspherical Lenslets: results of a 3-year follow-up study. *Am J Ophthalmol*. 2023;253:160–8.
6. Liu X, Wang P, Xie Z, Sun M, Chen M, Wang J, et al. One-year myopia control efficacy of cylindrical annular refractive element spectacle lenses. *Acta Ophthalmol*. 2023;101:651–7.
7. Laughton D, Hill JS, McParland M, Tasso V, Woods J, Zhu X, et al. Control of myopia using diffusion optics spectacle lenses: 4-year

results of a multicentre randomised controlled, efficacy and safety study (CYPRESS). *BMJ Open Ophthalmol*. 2024;9:e001790. https://doi.org/10.1136/bmjophth-2024-001790
8. Grzybowski A, Kanclerz P, Tsubota K, Lanca C, Saw SM. A review on the epidemiology of myopia in school children worldwide. *BMC Ophthalmol*. 2020;20:27. https://doi.org/10.1186/s12886-019-1220-0
9. Rudnicka AR, Kapetanakis VV, Wathern AK, Logan NS, Gilmartin B, Whincup PH, et al. Global variations and time trends in the prevalence of childhood myopia, a systematic review and quantitative meta-analysis: implications for aetiology and early prevention. *Br J Ophthalmol*. 2016;100:882–90.
10. Sankaridurg P, Berntsen DA, Bullimore MA, Cho P, Flitcroft I, Gawne TJ, et al. IMI 2023 Digest. *Invest Ophthalmol Vis Sci*. 2023;64:7. https://doi.org/10.1167/iovs.64.6.7
11. Morgan IG, Wu PC, Ostrin LA, Tideman JWL, Yam JC, Lan W, et al. IMI risk factors for myopia. *Invest Ophthalmol Vis Sci*. 2021;62:3. https://doi.org/10.1167/iovs.62.5.3
12. ZEISS Vision Care. Resources & Publications. 2023 Accessed November 11, 2024. https://www.zeiss.com/myopia/en/resources--publications.html.
13. Alvarez-Peregrina C, Sanchez-Tena MA, Martinez-Perez C, Villa-Collar C, Montero-Torrejon A, Lopez-Muñoz A, et al. Clinical evaluation of MyoCare in Europe (CEME): study protocol for a prospective, multicenter, randomized, double-blinded, and controlled clinical trial. *Trials*. 2023;24:674. https://doi.org/10.1186/s13063-023-07696-0
14. Ruiz-Pomeda A, Pérez-Sánchez B, Valls I, Prieto-Garrido FL, Gutiérrez-Ortega R, Villa-Collar C. MiSight assessment study Spain (MASS). A 2-year randomized clinical trial. *Graefes Arch Clin Exp Ophthalmol*. 2018;256:1011–21.
15. Moriche-Carretero M, Revilla-Amores R, Gutiérrez-Blanco A, Moreno-Morillo FJ, Martinez-Perez C, Sánchez-Tena MÁ, et al. Five-year results of atropine 0.01% efficacy in the myopia control in a European population. *Br J Ophthalmol*. 2024;108:715–9.
16. Chen X, Wu M, Yu C, Ohlendorf A, Rifai K, Boeck-Maier C, et al. Slowing myopia progression with cylindrical annular refractive elements (CARE) spectacle lenses—year 1 results from a 2-year prospective, multi-centre trial. *Acta Ophthalmol*. 2024. https://doi.org/10.1111/aos.16795
17. Zhang XJ, Zaabaar E, French AN, Tang FY, Kam KW, Tham CC, et al. Advances in myopia control strategies for children. *Br J Ophthalmol*. 2024;109:165–76.
18. Lam CSY, Tang WC, Tse DY y, Lee RPK, Chun RKM, Hasegawa K, et al. Defocus incorporated multiple segments (DIMS) spectacle lenses slow myopia progression: a 2-year randomised clinical trial. *Br J Ophthalmol*. 2020;104:363–8.
19. Li X, Ma W, Song Y, Yap M, Liu L. Comparison of myopic progression and quality of life wearing either DIMS lenses or single-vision myopia correcting spectacles. *J Ophthalmol*. 2025;2025:9959251. https://doi.org/10.1155/joph/9959251
20. McCullough S, Barr H, Fulton J, Logan NS, Nagra M, Pardhan S, et al. 2-year multi-site observational study of MiYOSMART myopia control spectacle lenses in UK children: 1-year results. *Invest Ophthalmol Vis Sci*. 2023;64:ARVO E-Abstract 4945.
21. Naduvilath T, He X, Saunders K, Demir P, Leighton R, McCullough S, et al. Regional/ethnic differences in ocular axial elongation and refractive error progression in myopic and non-myopic children. *Ophthalmic Physiol Opt*. 2025;45:135–51.
22. Bao J, Yang A, Huang Y, Li X, Pan Y, Ding C, et al. One-year myopia control efficacy of spectacle lenses with aspherical lenslets. *Br J Ophthalmol*. 2022;106:1171–6.
23. Rappon J, Chung C, Young G, Hunt C, Neitz J, Neitz M, et al. Control of myopia using diffusion optics spectacle lenses: 12-month results of a randomised controlled, efficacy and safety study (CYPRESS). *Br J Ophthalmol*. 2023;107:1709–15.
24. Radhakrishnan H, Lam CSY, Charman WN. Multiple segment spectacle lenses for myopia control. Part 1: optics. *Ophthalmic Physiol Opt*. 2023;43:1125–36.
25. Wolffsohn JS, Gifford KL. Optical strategy utilising contrast modulation to slow myopia. *Ophthalmol Sci*. 2024;5:100672. https://doi.org/10.1016/j.xops.2024.100672
26. Schaeffel F, Swiatczak B. Mechanisms of emmetropization and what might go wrong in myopia. *Vis Res*. 2024;220:108402. https://doi.org/10.1016/j.visres.2024.108402
27. Arias A, Ohlendorf A, Artal P, Wahl S. In-depth optical characterization of spectacle lenses for myopia progression management. *Optica*. 2023;10:594–603.
28. Liu Y, Liu D, Hu X, Chen X, Liu H, Li L. Experimental and modeling analysis of lenses with concentric cylindrical annular refractive elements: impact on peripheral imaging. *Biomed Opt Express*. 2025;16:1344–58.
29. Gantes-Nuñez J, Jaskulski M, López-Gil N, Kollbaum PS. Optical characterisation of two novel myopia control spectacle lenses. *Ophthalmic Physiol Opt*. 2023;43:388–401.
30. Gawne TJ, Khanal S, Norton TT. An alternative mechanism for the anti-myopia effectiveness of diffusion optics technology (DOT) lenses. *Transl Vis Sci Technol*. 2025;14:15. https://doi.org/10.1167/tvst.14.1.15
31. Eppenberger LS, Grzybowski A, Schmetterer L, Ang M. Myopia control: are we ready for an evidence based approach? *Ophthalmol Therapy*. 2024;13:1453–77.
32. Liu KKK, Zhang HY, Leung DKY, Lam CSY. Evaluation of the peripheral visual performance of DIMS spectacle lenses versus single vision lenses. *Front Neurosci*. 2024;18:1460062. https://doi.org/10.3389/fnins.2024.1460062
33. Lu Y, Lin Z, Wen L, Gao W, Pan L, Li X, et al. The adaptation and acceptance of defocus incorporated multiple segment lens for Chinese children. *Am J Ophthalmol*. 2020;211:207–16.
34. Rani R, Chatha I, Lam HY, Logan NS, Sheppard AL, Wolffsohn JS, et al. Treatment zone visual acuity with myopia control spectacle lenses. *Invest Ophthalmol Vis Sci*. 2024;65:ARVO E-Abstract 2728.

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