

Efficacy of Cylindrical Annular Refractive Elements (CARE) Spectacle Lenses in Slowing Myopia Progression Over 2 Years



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- **PURPOSE:** To evaluate over a 2-year period the efficacy of spectacle lenses incorporating cylindrical annular refractive elements (CARE) in slowing myopia progression compared with single vision (SV) spectacle wear.
- **DESIGN:** Double-masked, multicenter, randomized clinical trial.
- **METHODS:** A total of 240 Chinese children aged 6 to 13 years, with a spherical equivalent (SE) refractive error of -0.75 diopters (D) to -5.00 D, were randomized to 1 of 3 groups of SV spectacle lens: CARE spectacles (7-mm central clear zone surrounded by treatment zone incorporating CARE with mean surface power $+4.6$ D) and CARE S spectacles (9-mm central clear zone surrounded by treatment zone comprising CARE with mean surface power $+3.8$ D). Cycloplegic SE and axial length (AL) were measured at 6-month intervals.
- **RESULTS:** Progression (mean $\pm$ SD) in SV-wearing eyes after 24 months of SPL wear was -1.15 ± 0.63 D and 0.59 ± 0.26 mm with SV for SE and AL, respectively. In comparison, myopia progression was significantly slower with both CARE (-0.73 ± 0.63 D/ 0.40 ± 0.26 mm, $P < .0001$) and CARE S (-0.80 ± 0.56 D/ 0.44 ± 0.25 mm, $P < .0001$). Progression did not differ significantly between CARE lenses. Adjusting for site, group, age, gender, and baseline value at 24 months, CARE showed an absolute difference in SE of 0.44 D (95% CI, 0.21 - 0.66 D) and CARE S 0.41 D (95% CI, 0.18 - 0.63 D) compared with SV. AL reduction was 0.20 mm (95% CI, 0.10 - 0.30 mm) with CARE and 0.17 mm (0.07 - 0.26 mm) with CARE S compared with SV.
- **CONCLUSIONS:** Over a 2-year period, lenses incorporating CARE significantly slowed myopia progression

compared with SV lenses. (Am J Ophthalmol 2025;278: 203–211. © 2025 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>))

THE INCREASING PREVALENCE OF MYOPIA IN YOUNGER children and a rising trend to an early onset amplify the risk of severe progression and complications.¹ The evidence for the economic burden of myopia on individuals and society, and quality of life issues for affected individuals indicate the impact to be substantial.² Therefore, myopia control in children is of genuine public interest.

Strategies aimed at slowing myopia progression include manipulation of visual optics to offset the effects of myopiagenic factors such as hyperopic defocus and high contrast. In addition, there are also other pharmaceutical, light, and behavior-based approaches.^{3–5} Although various theories have been implied with these treatment approaches, the specific pathways and mechanisms underlying myopia progression remain unclear,⁶ but despite this, there have been many approaches that demonstrated efficacy in slowing myopia.^{4,5,7,8} Of the various methods, spectacle lenses are the least invasive and are safe for long-term use.⁹

In the current trial, a spectacle lens design that incorporates cylindrical annular refractive elements (CARE) was evaluated for its effectiveness in slowing myopia. The CARE lens includes a central zone for myopia correction and is surrounded by a treatment zone composed of multiple micro-cylinders arranged in concentric rings. The test lens 1 (CARE) has a central zone of 7 mm, and the nominal power of the cylindrical elements along the power meridian is $+9.2$ D, whereas test lens 2 (CARE S) has a larger central zone of 9 mm and the nominal power of the cylindrical elements is less at $+7.6$ D. The 2 lenses were selected to determine if a smaller central zone and a higher magnitude of defocus provide a greater treatment effect as evidence indicates that with orthokeratology smaller optical zone diameters have improved efficacy,¹⁰ and with aspherical lenslet based spectacle lenses there is a dose-dependent response to the magnitude of defocus.¹¹

The interim efficacy of CARE lenses after 1 year of lens wear was reported and demonstrated that both the lenses

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significantly slowed myopia.¹² We present the 2-year results of the efficacy of CARE spectacle lenses in slowing myopia progression. Previous studies have shown that many treatments exhibit diminishing efficacy beyond the first year.³ Therefore, by continuing to monitor the efficacy for a second year, this study provides data about the durability and persistence of the benefits observed during the first year on treatment.

METHODS

This is an ongoing, multicenter, prospective, parallel-group, double-masked clinical trial (NCT 05288335) conducted at 3 hospitals in China: Tianjin Eye Hospital Optometric Center in Tianjin (Site 1), Shenyang He Eye Hospital in Shenyang (Site 2), and Beijing Tongren Hospital in Beijing (Site 3). The methodology of this article has been published.¹² In brief, children were randomly assigned to wear single vision (SV), CARE (7-mm central zone; treatment zone extending to lens periphery and comprising CARE with a nominal power of +9.2 along power meridian and translating to a relative mean positive power of +4.6 D), or CARE S (9 mm central zone; treatment zone comprising CARE with a relative mean positive power +3.8 D) spectacle lenses.¹² The ethics committee of Tianjin Eye Hospital (KY202110), Shenyang He Eye Hospital Clinical Trials Organisation and Medical Ethics Committee (IRB(2021)K015.01), and the Medical Ethics Committee of Peking Tongren Hospital, Beijing (TRECKY2021-235) approved the trial. The trial was registered on clinical trials.gov (NCT 05288335), and the first participant in the trial registered on April 1, 2022. Consent for participation in the trial was provided by the parents or carers, and all the study procedures adhered to the Declaration of Helsinki for experimentation on human subjects.

- **PARTICIPANTS:** Children in the trials were of Chinese ethnicity aged 6 to 13 years, had a spherical refractive error from -0.75 to -5.00 D, astigmatism ≤ 1.50 D, anisometropia of ≤ 1.50 D, and best-corrected visual acuity of ≥ 1.0 in both eyes. None of the participants in the trial had any ocular or systemic conditions that may impact lens wear, used any myopia control products, or participated in any myopia clinical trial in the past 3 months.

- **STUDY PROCEDURES:** After an assessment of eligibility and a baseline examination, children were randomized to wear the CARE, CARE S, or control SV spectacle lenses with randomization in the ratio of 1:1:1 (block randomization using SAS software). The primary outcome measures of the trial were change in cycloplegic spherical equivalent (SE) refractive error and axial length (AL) measurements, which were performed by a masked examiner every 6

months. AL measurement was also performed at 3 months. The study procedure has been described in detail.¹²

- **STATISTICAL ANALYSIS:** All participants enrolled in the trial were considered, and the change in SE and AL from baseline was determined for each participant. Sample size was based on the control group progressing annually at a rate of 0.36 mm. With a 0.1-mm reduction in AL progression between the test and control groups with a pooled SD of 0.2 mm, an alpha level of 0.05, a power of 80%, and a dropout of 20% over 2 years, 80 participants were enrolled in each group. A total of 240 participants were enrolled and randomized to 80 children each to wear of CARE, CARE S, and SV lenses.

As with the previous 1-year analysis, only the right eyes of each participant were considered for the current analysis. A linear mixed model was conducted for SE refractive error and AL changes and included age at consent, gender, lens type, site, baseline SE refractive error or AL (depending on model), and lens type visit. Mean progression was estimated based on the model. Survival analysis was determined for progression over 24 months of ≥ 1.25 D based on reported progression data and a Cox proportional hazards regression model incorporating lens types, SE refractive error at baseline, age, gender, and site. A cutoff criterion of ≥ 1.25 D was chosen based on the average mean progression in SV wearers over 2 years. Additionally, compliance reported at 24 months for lens-wearing time was reported as means and SD. Multiple comparisons between groups were adjusted with Bonferroni correction. Statistical significance was maintained at $P < .05$. Statistical analyses were performed using R programming (version 4.4.1).

RESULTS

A total of 218 participants (74 with CARE, 72 with CARE S, and 72 with SV) completed 24 months in the trial. The trial flow is presented in [Figure 1](#), and demographic data of those who completed the trial are shown in [Table 1](#). During the trial, there were 5 discontinuations in the CARE group (1 related to unacceptable vision, 1 related to discomfort, 2 lost to follow-up, and 1 withdrew without citing reason), with an additional participant missing the study window period for the 24-month visit. In the CARE S group, there were 7 discontinuations (3 lost to follow-up, 3 withdrew from the study, and 1 switched to another treatment) and 1 participant presented out of the window period. In the SV group, there were 7 discontinuations (3 related to fast progression, 1 relocated to another city, 1 switched treatment, 1 lost to follow-up, and the remaining participant withdrew). An additional participant did not attend the 24-month visit because of health-related reasons.

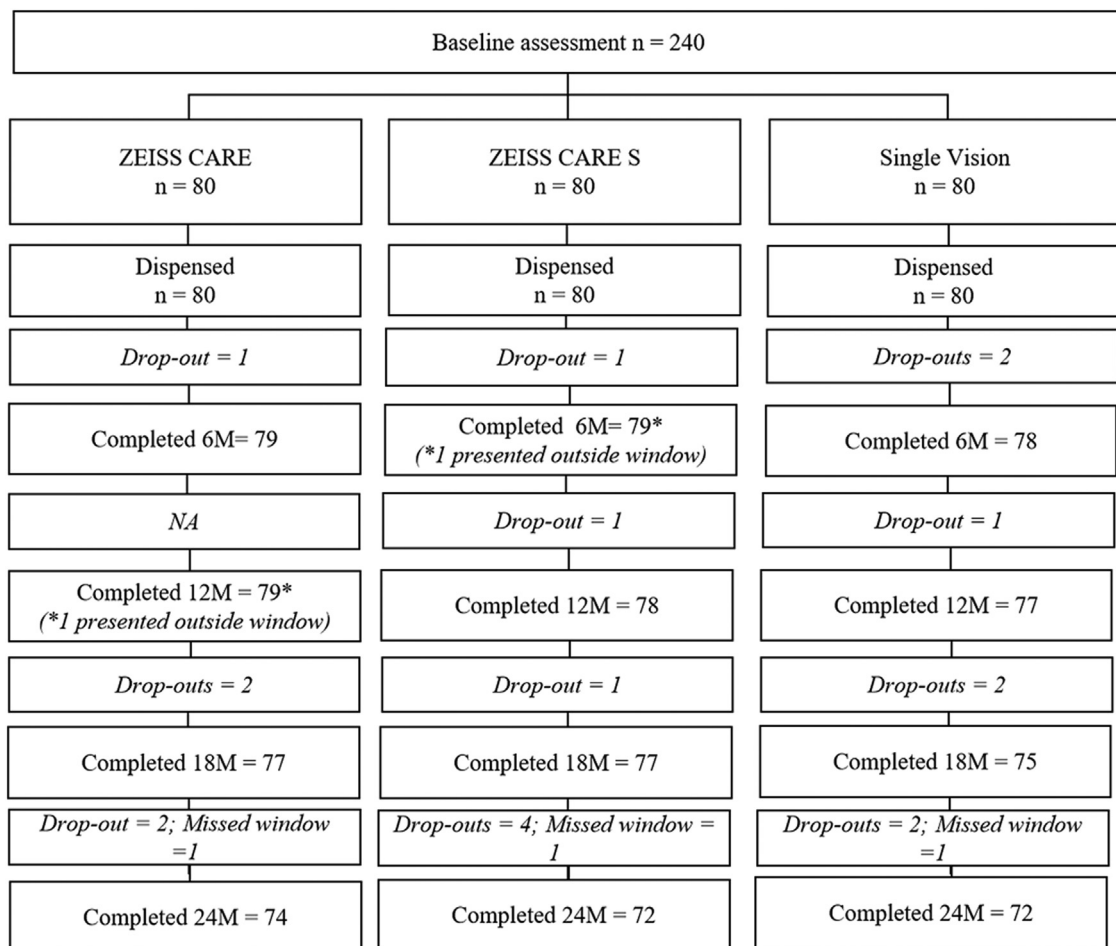


FIGURE 1. Participant flow for the 24-month period.

TABLE 1. Demographic Data of Children Who Completed 24 Months in the Trial

Characteristic	SV (N = 72)	CARE (N = 74)	CARE S (N = 72)	P Value
Age at consent (y)	9.8 ± 1.5	9.7 ± 1.7	10.0 ± 1.7	.635
Gender (male: female) (%)	50.0/50.0	50.0/50.0	56.9/43.1	.628
Parental Myopia (%)				
None	26.7	33.3	21.0	.642
1	35.0	33.3	37.1	
Both	38.3	33.3	41.9	
Cycloplegic SER (D)	-2.31 ± 1.02	-2.31 ± 1.07	-2.24 ± 0.95	.888
AL (mm)	24.45 ± 0.75	24.31 ± 0.71	24.44 ± 0.69	.413

AL = axial length; CARE = cylindrical annular refractive elements; D = diopters; SER = spherical equivalent refractive error; SV = single vision.

• **CHANGE IN SE REFRACTIVE ERROR AND AL:** The mean SE and AL recorded at baseline and 6-month intervals are provided in Table 2. With respect to SE, observed change from baseline to 24 months was -1.15 D (0.63) in the SV group. In comparison, myopia progressed slower with CARE at -0.73 D (0.63) and CARE S at -0.80 D (0.56). Likewise, with respect to AL, the observed change

in AL from baseline to 24 months was 0.59 mm (0.26) with SV spectacles, 0.40 mm (0.26) with CARE, and 0.44 mm (0.25) with CARE S.

A linear mixed effect model for SE and AL progression that accounted for lens types, trial visits, sites, age, gender, baseline SE, and interaction of lens type by study duration in months found significant differences for lens types (*P*

TABLE 2. Cycloplegic Spherical Equivalent Refractive Error and Axial Length at Scheduled Visits Across Groups

		CARE		CARE S		SV
Cycloplegic SE (D, mean $\pm$ SD)						
Baseline	N = 80	-2.30 $\pm$ 1.06	N = 80	-2.23 $\pm$ 0.98	N = 80	-2.31 $\pm$ 1.01
6 mo	N = 79	-2.40 $\pm$ 1.10	N = 79	-2.33 $\pm$ 1.00	N = 78	-2.58 $\pm$ 1.02
12 mo	N = 78	-2.67 $\pm$ 1.15	N = 78	-2.60 $\pm$ 1.06	N = 77	-2.95 $\pm$ 1.06
18 mo	N = 76*	-2.81 $\pm$ 1.16	N = 77	-2.72 $\pm$ 1.10	N = 75	-3.18 $\pm$ 1.13
24 mo	N = 74	-3.04 $\pm$ 1.26	N = 72	-3.03 $\pm$ 1.17	N = 72	-3.46 $\pm$ 1.10
AL (mm, Mean $\pm$ SD)						
Baseline	N = 80	24.34 $\pm$ 0.74	N = 80	24.44 $\pm$ 0.73	N = 80	24.43 $\pm$ 0.73
6 mo	N = 79	24.44 $\pm$ 0.74	N = 79	24.55 $\pm$ 0.74	N = 79	24.61 $\pm$ 0.73
12 mo	N = 78	24.54 $\pm$ 0.74	N = 78	24.68 $\pm$ 0.73	N = 77	24.76 $\pm$ 0.74
18 mo	N = 77	24.65 $\pm$ 0.73	N = 77	24.77 $\pm$ 0.71	N = 75	24.93 $\pm$ 0.75
24 mo	N = 74	24.71 $\pm$ 0.69	N = 72	24.88 $\pm$ 0.70	N = 72	25.03 $\pm$ 0.75

AL = axial length; CARE = cylindrical annular refractive elements; D = diopters; SE = spherical equivalent; SV = single vision.
 *One patient (ID1021) did not have cycloplegia performed at 18 months.

< .0001), study visits ($P < .0001$), sites ($P = .023$), and lens types by duration in trial ($P = .024$) for SE progression. For AL progression, lens types ($P = .001$), study visits ($P < .0001$), and lens types by duration in the trial ($P = .001$) were significant.

The adjusted or estimated mean for SE progression at 24 months based on the model was -1.19 D (95% CI, -1.33 to -1.05 D) in the SV group compared with -0.75 D (95% CI, -0.89 to -0.61 D) in the CARE group and -0.78 D (95% CI, -0.92 to -0.65 D) in the CARE S group (Figure 2, A). The adjusted mean for AL progression was 0.61 mm (95% CI, 0.55-0.67 mm) in the SV group, 0.41 mm (95% CI, 0.35-0.47 mm) in the CARE group, and 0.44 mm (95% CI, 0.38-0.50 mm) in the CARE S group (Figure 2, B). The absolute SE difference in adjusted means after 24 months of lens use showed 0.44 D (95% CI, 0.21-0.66 D) less progression with CARE and 0.41 D (95% CI, 0.18-0.63 D) with CARE S. With respect to axial elongation, slower progression was observed in CARE and CARE S lens-wearing eyes, with reduced axial elongation of 0.20 mm (95% CI, 0.10-0.30 mm) and 0.17 mm (0.07-0.26 mm), respectively. There were no differences in progression between CARE and CARE S lens-wearing eyes ($P = 1.000$ for both SE and AL).

• **COMPARISON OF CHANGES IN SE AND AL IN THE SECOND YEAR VERSUS THE FIRST YEAR:** In the first year, observed changes in SE with SV, CARE, and CARE S were -0.65 D (0.40), -0.37 D (0.39), and -0.38 D (0.38), respectively, and during the second year were -0.52 D (0.37), -0.37 D (0.40), and -0.43 D (0.37), respectively. Likewise, observed changes in AL in the first year were 0.32 mm (0.17), 0.20 mm (0.16), and 0.22 mm (0.15) and 0.28 mm (0.15), 0.21 mm (0.13), and 0.22 mm (0.14) in the second year, respectively. Compared with SV, the adjusted changes were significant for year 1 for both CARE and CARE S

($P < .0001$ for both SE and AL). In the second year, the differences in progression among the CARE, CARE S, and SV groups continued to be significant. Compared with SV, CARE progressed slower by 0.15 D (0.30-0.01) ($P = .026$) and AL elongation was lower by 0.07 mm (0.02-0.12) ($P < .001$). Likewise, progression with CARE S was slower by 0.08 D (0.23-0.06) ($P = .313$), and for AL it was 0.05 mm (0.00-0.10) ($P = .038$). Overall, although significant differences existed between SV and CARE lenses in both years 1 and 2, treatment effect was greater in the first year.

• **FREQUENCY DISTRIBUTION OF PROGRESSION AND SURVIVING PROGRESSION OF ≥ 1.25 D OVER 24 MONTHS:**

The frequency distribution of progression in SE refractive error and AL across SV, CARE, and CARE S lenses over the 2-year study period is provided in Figure 3, A and B. The data indicate that the distribution curve was more myopic with an increased axial elongation in the SV lens-wearing eyes compared with CARE and CARE S lens-wearing eyes.

The probability of surviving progression of 1.25 D or worse at 24 months across the 3 groups is presented in Figure 4 and was significant for lens groups (CARE and CARE S lenses vs SV), age at consent, and 1 of the sites (Cox regression model, $P < .01$).

Overall, at 24 months, only 50% of SV-wearing eyes survived progression of 1.25 D or greater compared with 75% and 71% of eyes wearing CARE and CARE S (Figure 4), indicating a higher chance of survival with CARE lenses.

• **COMPLIANCE:** At 24 months, reported compliance was high across the groups with a mean wearing time of 13.9 $\pm$ 0.9 hours, 14.0 $\pm$ 1.2 hours, and 14.0 $\pm$ 0.9 hours per day in the SV, CARE, and CARE S groups, respectively. Compliance was observed to improve with time across all groups with time, 13.1 $\pm$ 2.0, 13.5 $\pm$ 1.4, and 13.3 $\pm$ 1.2 at 12 months in the SV, CARE, and CARE S groups, respec-

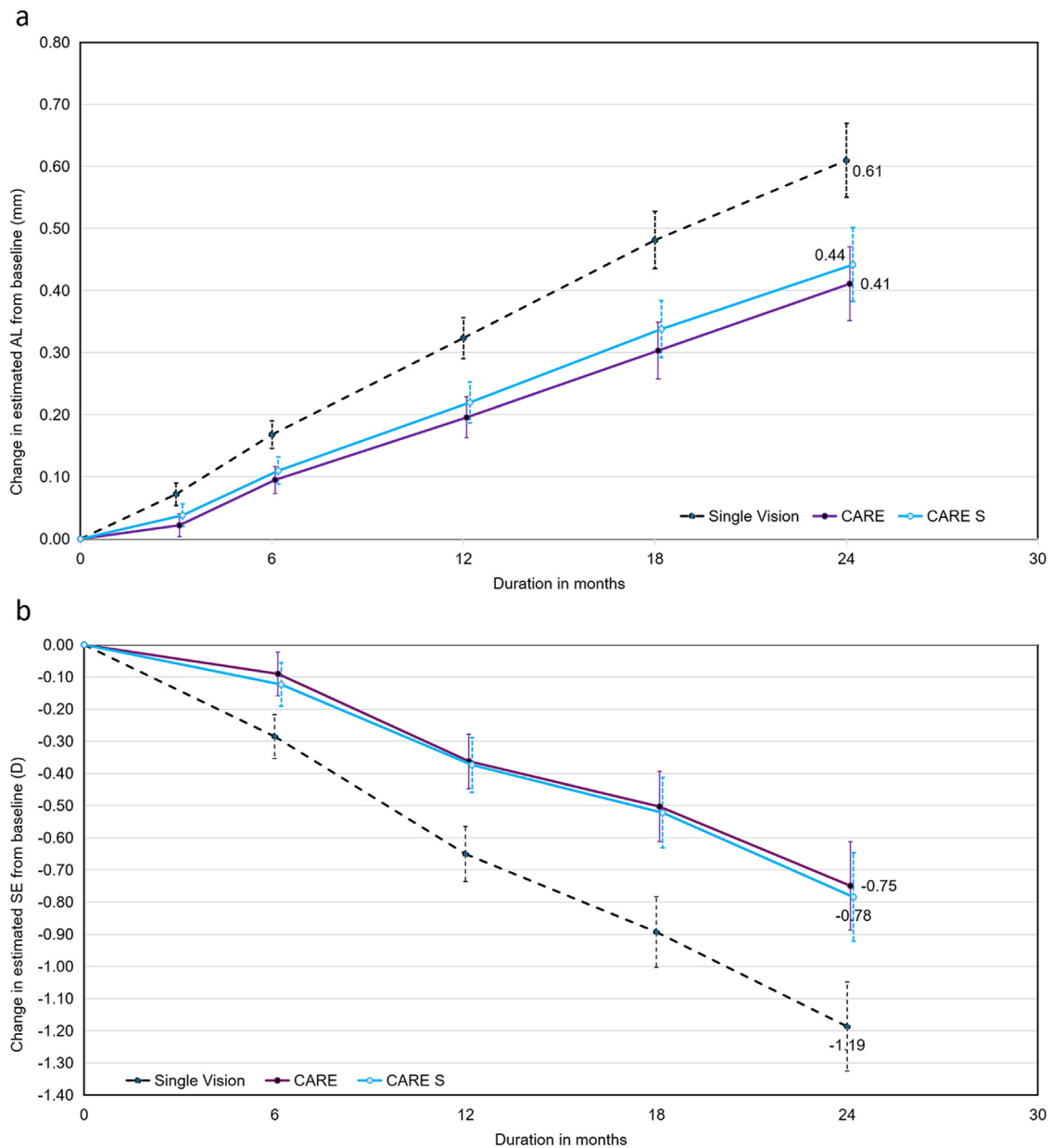


FIGURE 2. Changes in axial length (AL) (a), and spherical equivalent (SE) refractive error (b) from baseline to 24 months (error bars are 95% CI).

tively, and was greater than reported at 12 months (13.1 ± 2.0 , 13.5 ± 1.4 , and 13.3 ± 1.2 at 12 months in the SV, CARE, and CARE S groups, respectively). Approximately 18%, 22%, and 20% of SV, CARE, and CARE S wearers, respectively, reported wearing lenses for more than 14 hours, that is, for all waking hours. Thus, when progression was analyzed based on wearing time (>14 vs ≤ 14 hours), at 2 years, the observed change in SE/AL for those wearing lenses >14 hours were -1.18 D (0.58)/0.57 mm (0.18) for SV, -0.55 D (0.48)/0.34 mm (0.22) for CARE, and -0.77 (0.71)/0.40 mm (0.29) for CARE S. For those with wearing time of ≤ 14 hours/day, it was -1.19 D (0.63)/0.60 mm

(0.29) for SV, -0.79 D (0.67)/0.43 mm (0.27) for CARE, and -0.78 D (0.52)/0.45 mm (0.25) for CARE S. The differences were significant for CARE for both SE and AL ($P = .016$ and $.027$, respectively) but not for CARE S ($P = .172$ and $.144$, respectively).

DISCUSSION

The results of the present study indicate that over a 2-year period of lens wear, both CARE lenses resulted in slower SE

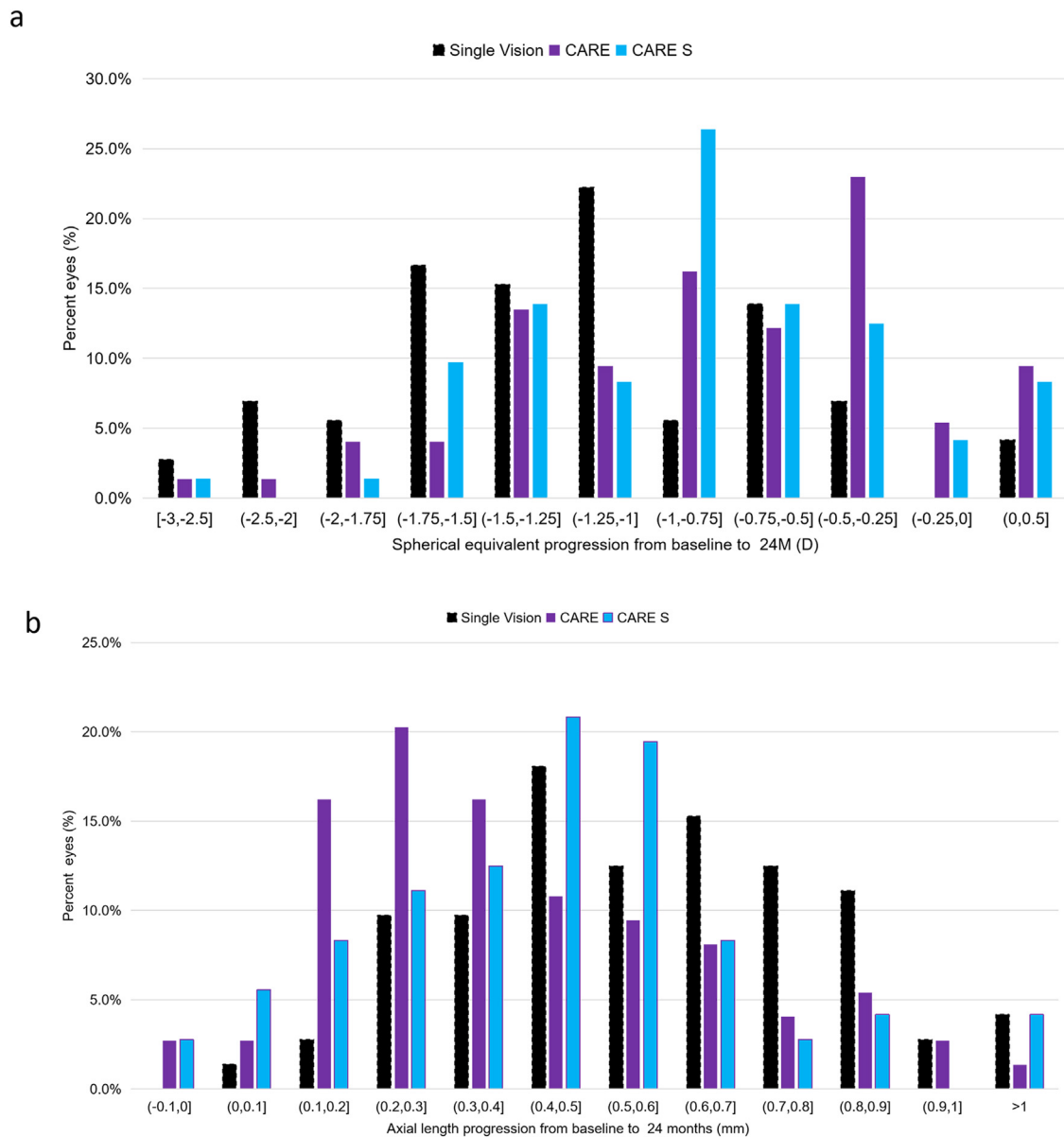


FIGURE 3. Distribution of progression in SE (A) and AL (B) from baseline to 24 months across the 3 groups.

progression and AL elongation compared with those wearing SV spectacles. There was 0.44 D and 0.41 D less progression in SE and 0.20 and 0.17 mm slower axial elongation. These findings are consistent with other reports, wherein lens designs that incorporate multiple segments/features to impose multifocality/defocus at the retina are able to meaningfully slow myopia.^{13,14} Overall, the results are in alignment with our first-year results. When we compared the first-year results with the second-year results, both CARE lenses (with the exception of SE for CARE S in year 2) were significantly effective in slowing myopia during both the years. However, the treatment effect was greater in the first year compared with the second year. This observation has been reported, but the reason remains unknown.^{4,15} Additionally, although the efficacy of both CARE lenses was

not different, based on these results, it appears there might be a relation between the features of the lens and efficacy. The 2 CARE designs differ from each other with respect to the size of the clear central zone and the power of the cylindrical annular elements. Although it is not clear as to which of these 2 factors may have played a role, published data with aspherical lenslets indicate that there may be a dose-response relationship with the magnitude of defocus.

Assessment of efficacy of myopia control strategies has evolved and can be assessed in multiple ways, including (1) comparison with a control SV group,^{3,4} (2) change from baseline,^{16,17} and (3) comparison with emmetropic or non-myopic eye growth.¹⁸⁻²⁰ The randomized, double-blind nature of the clinical trial with an SV control group and close monitoring of changes from baseline enable assessment of

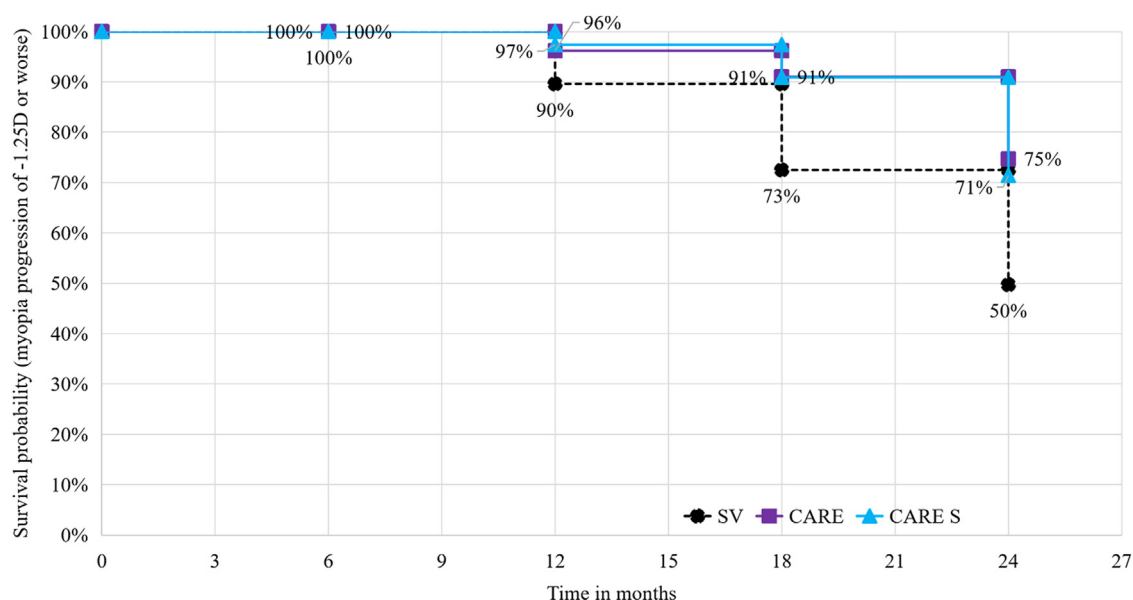


FIGURE 4. Probability of surviving fast progression of -1.25 diopters (D) or worse over 24 months. SV = single vision.

efficacy using the former 2 of these approaches.¹⁸⁻²⁰ Considering the first of these approaches, that is, comparison with progression with SV lenses, CARE lenses slowed myopia by 0.44 D and 0.20 mm, whereas CARE S slowed myopia by 0.41 D and 0.17 mm. In comparing these results with other spectacle lens designs, Defocus Incorporated Multiple Segments (DIMS) lenses with lenslets were found to slow myopia by a mean of 0.44 D and 0.34 mm.²¹ These results are similar to those observed with CARE lenses for SE difference, although DIMS exhibited a greater difference with respect to AL reduction. Interestingly, in a real-world, retrospective analysis involving Chinese children aged 6 to 16 years and propensity score matched to SV lens wearers, the difference at the end of 2 years in 735 pairs with DIMS was 0.35 D (0.06 SE).²² This indicates similar performance to that observed with CARE lenses. With spectacle lenses incorporating diffuse optics, 2-year progression data were not available for the full cohort; in those who met the criteria for full-time wearers, the difference in mean progression was 0.21 mm and 0.52 D and is similar to efficacy observed with CARE lenses.²³ In comparison, highly aspherical lenslet (HAL) lenses slowed myopia by a greater difference of 0.77 D and 0.34 mm, and a far greater difference of 0.99 D and 0.41 mm was observed in full-time wearers.¹³ In comparison, in those who wore lenses for >14 hours, CARE lenses slowed myopia by 0.63 D and 0.23 mm. Although as with other lens types, the higher treatment efficacy observed in those with longer wearing time differences between lens types is not fully understood. Although both HAL and CARE lenses aim to induce simultaneous defocus, differences exist between the design in terms of the elements used to introduce defocus, nominal power of the elements, and so forth. Additionally, dropout of fast progres-

sors during the trial can have a negative impact on the accuracy of efficacy assessment.²⁴ In the current trial, 19 participants (7 in the SV group, 5 in the CARE group, and 7 in the CARE S group) withdrew before the 24-month visit. Participants who withdrew had greater myopia progression compared with those who stayed in the trial (e.g., in SV group: -0.56 D/ 0.27 mm vs -0.27 D/ 0.16 mm at 6 months, -0.95 D/ 0.49 mm vs -0.63 D/ 0.31 mm at 12 months, and -1.46 D/ 0.62 mm vs -0.86 D/ 0.46 mm at 18 months). To evaluate the impact of early withdrawals, further analysis using data imputation (based on the last 6 month progression before withdrawal) resulted in an estimated 24-month progression of -1.21 D (-1.35 to -1.07) and 0.62 mm (0.56-0.68) in SV wearers versus -0.76 D (-0.89 to -0.62)/0.41 mm (0.35-0.47) in CARE and -0.78 D (-0.91 to -0.64)/0.44 mm (0.38-0.50) in CARE S wearers.

When adopting the second approach to assess efficacy, that is, simply considering the change from baseline without reference to an SV group, change with HAL lens-wearing eyes in a population from China over a 2-year period was -0.68 D and 0.34 mm.¹³ With CARE, the observed changes from baseline to 2 years were -0.75 D and 0.41 mm, showing similar results specifically in terms of SE change. In comparison, the observed change from baseline to 2 years with DIMS in a Hong Kong Chinese population was lower at -0.38 D and 0.21 mm.²¹ However, in a real-world retrospective analysis conducted on a population from China, 2-year SE progression with DIMS was higher at -0.88 D.²² It is possible that variations in trial designs and populations may be responsible for these variations, and a comparative study within a given population involving various lens types would indicate significant differences, if any, between the lens types. More important, these data are confirmatory for

the role of spectacle lens strategies that incorporate multiple segments/features, because their efficacy is greater than that observed with progressive addition of spectacle lenses and peripheral defocus spectacle lens strategies that involve a continuous or stepped shift in power profile.⁷ Furthermore, the progression observed in the current trial is similar to progression observed in contact lens wearers randomized to SV lenses or multifocal-like contact lenses in a Chinese population.²⁵

The distribution of SE error and AL elongation indicates that a greater myopic shift was observed with the SV lens wearers. The probability of surviving progression of 1.25 D or worse was lower with SV lens wearers. The absolute difference in efficacy after 1 year of treatment was 0.31 D and 0.29 D with CARE and CARE S, respectively.¹² After 2 years, the efficacy had accrued to 0.44 D and 0.41 D, which indicated the efficacy during year 2 was less in comparison with year 1 efficacy. This result was similar to that of other previous studies.^{3,26}

It was demonstrated in experimental animal models that imposing myopic defocus at the retina slows eye growth.²⁷ Furthermore, there is evidence from human clinical trials that use of optical interventions with relative positive power has a role in slowing eye growth.^{4,5} However, it is not fully understood if lens designs such as CARE lenses slow eye growth through imposing myopic defocus or via other mechanisms. Notably, a recent experiment concluded that although the various spectacle lens designs such as DIMS, HAL, and CARE vary from each other with respect to the type and magnitude of myopic defocus, the blur induced at the retina with all the designs appears to be similar at approximately 0.5 D.²⁸ Other suggested hypotheses include reduced contrast or specific reduction of image contrast at higher spatial frequencies, but these need to be explored further.^{29,30}

Previous data indicated that compliance plays a role in efficacy, with greater compliance or wearing time associated with improved efficacy.^{14,25} Although wearing time was generally high, a greater treatment effect was observed in those who wore CARE lenses for greater lengths of time. Although this finding aligns with the recommendation that increasing wearing time improves efficacy, further work is necessary to explore and understand the implications of compliance. Notably, the current trial did not include objective monitoring of wearing time.

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The strength of the study lies in its robust study design involving randomization, use of multiple sites, and double-masking of both examiners and trial participants. The limitations of the study as previously reported include the potential for recall bias in questionnaire-based assessments. Overall, there were few discontinuations from the trial, but not surprisingly, more children with fast progression discontinued from the trial and especially from the SV group. Additionally, although the participants were masked to the nature of the study lens, it would have been apparent to those randomized to the SV group that they were assigned to a control group because of the lack of features on the lens. It is possible that this may have been an additional factor for discontinuations from this group.

In summary, the clinical outcomes of this 2-year evaluation indicate benefits with significant slowing of myopia with CARE and CARE S spectacles. These results build on the interim 1-year efficacy and indicate that CARE spectacle lenses provide a convenient and safe means to manage myopia.

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

Xiaoqin Chen: Writing – review & editing, Writing – original draft, Validation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Min Wu:** Writing – review & editing, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Cui Yu:** Writing – review & editing, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Arne Ohlendorf:** Writing – review & editing, Formal analysis, Data curation. **Wayne Li:** Software, Formal analysis, Data curation. **Nicole Liu:** Writing – review & editing, Visualization, Formal analysis, Data curation. **Youhua Yang:** Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation. **Lihua Li:** Writing – review & editing, Supervision, Funding acquisition, Conceptualization. **Padmaja Sankaridurg:** Writing – review & editing, Formal analysis, Data curation.

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