Myopia Control Efficacy of Spectacle Lenses With Aspherical Lenslets: Results of a 3-Year Follow-Up Study

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• PURPOSE: To investigate myopia control efficacy in children who continued wearing spectacle lenses with highly aspherical lenslets (HAL) or switched from spectacle lenses with slightly aspherical lenslets (SAL) and single-vision spectacle lenses (SVL) to HAL for 1 year after a 2-year myopia control trial.

• DESIGN: This was a 1-year extension of a randomized clinical trial.

• METHODS: Of 54 children who had worn HAL for 2 years, 52 continued wearing HAL (HAL1 group), and of the 53 and 51 children who had originally worn SAL or SVL, 51 and 48 switched to wearing HAL (HAL2 and HAL3 groups) in year 3, respectively. A new SVL (nSVL) group of 56 children was recruited, matched for age, sex, cycloplegic spherical equivalent refraction (SER), and axial length (AL) of the HAL3 group at extension baseline, and used for a comparison of third-year changes. SER and AL were measured every 6 months in year 3.

• RESULTS: During year 3, the mean (SE) myopia progression in the nSVL group was −0.56 (0.05) diopters (D). Compared with nSVL, the changes in SER were less in HAL1 (−0.38 [0.05] D, P = .02), HAL2 (−0.36 [0.06] D, P = .01), and HAL3 (−0.33 [0.06] D, P = .005). The mean (SE) AL elongation in the nSVL group was 0.28 (0.02) mm. Compared with nSVL, the elongation in AL was less in the HAL1 (0.17 [0.02] mm, $P < .001$), HAL2 (0.18 [0.02] mm, $P < .001$), and HAL3 (0.14 [0.02] mm, $P < .001$) groups. Myopia progression and axial elongation were comparable in all 3 HAL groups (all $P > .05$) in year 3.

• CONCLUSIONS: Myopia control efficacy has remained in children who wore HAL in the previous 2 years. Children who switched from SAL or SVL to HAL in year 3 had slower myopia progression and axial elongation than that in the control group. (Am J Ophthalmol 2023;253: 160–168. © 2023 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/))

"THE MYOPIA BOOM" HAS BEEN WIDELY NOTICED IN recent decades because of the high incidence and young age of myopia onset.[1–3] Recent research predicted that nearly half of the world's population would be myopic by the year 2050, with 10% high myopia.[4] Patients with high myopia are more susceptible to myopia-associated complications, which may cause substantial visual impairment and large health care costs.[5–7] Therefore, strategies to control myopia progression have gained more attention.[8]

A variety of myopia control interventions, such as orthokeratology,[9] multifocal contact lenses,[10,11] bifocal and progressive addition spectacles,[12,13] spectacle lenses with lenslets,[14,15] and atropine[16,17] have been shown to be effective. However, treatment efficacy has been found to vary over time, and this efficacy change is inconsistent among different treatments.[12,14–16] The 2- to 3-year period of myopia control studies showed that defocus-incorporated multiple segment spectacle lenses had the greatest effect in the first 6 months,[18] bifocal spectacles had the greatest treatment effect in the first year,[18] and the efficacy of orthokeratology lenses decreased over time[19,20]; however, 0.01% atropine appeared more effective in slowing myopia progression in the second year than in the first year.[21,22] Treatment efficacy has been thought to be affected by age, baseline refraction, relevant dose, and compliance.[23–25] It is important for clinicians to have long-term efficacy information on any new myopia intervention.

Recently, spectacle lenses with aspherical lenslets (SAL), which generate myopia control signals prior to the retina, have been introduced in clinics for myopia control in chil-

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dren because of their promising myopia control efficacy.[15,26] The results of a 2-year trial[15] showed that spectacle lenses with highly aspherical lenslets (HAL) and SAL slowed myopia progression and axial length (AL) elongation by 0.80 diopters (D), 0.42 D, 0.35 mm, and 0.18 mm, respectively. Our aims in this study are 1) to determine if myopia control efficacy would be sustained in the third year of HAL wear, 2) to determine if myopia control efficacy is exhibited for myopic children who switched from the original SAL or single-vision spectacle lenses (SVL) wear to HAL correction for 1 year, and 3) to evaluate the long-term myopia efficacy of continued treatment of HAL over 3 years.

METHODS

• **STUDY DESIGN:** Subjects completing the 2-year, double-blind, randomized clinical trial[15] (RCT, ChiCTR1800017683) were invited for an extended third-year non blinded study. The subjects who had worn HAL in the RCT continued to wear HAL in the third year (HAL1 group), and the subjects in the original SAL or SVL groups switched to wearing HAL (HAL2 or HAL3 groups, respectively). A new control group (nSVL group) was recruited to evaluate myopia progression in the third year and was combined with the original SVL group to assess the myopia control efficacy of HAL for all 3 years. The Ethics Committee of the Eye Hospital of Wenzhou Medical University approved this study, and all work was carried out following the tenets of the Declaration of Helsinki. Written informed consent and assent were obtained from the subjects and their parents or guardians after verbal and written explanations of the objectives and possible consequences of the study were provided.

• **STUDY PROCEDURES AND DATA COLLECTION:** The procedures of data measurement followed those in the 2-year RCT.[15] Spherical equivalents of cycloplegic autorefraction (SER) and AL were measured every 6 months. SER was obtained using a KR-800 autorefractor (TOPCON Corp, Tokyo, Japan). AL was measured with an optical low-coherence reflectometry device (Lenstar 900, Haag-Streit AG, Koeniz, Switzerland). For cycloplegia, 2 drops of 1% cyclopentolate were instilled 5 minutes apart, and refraction was performed ≥30 minutes after the last drop. The average values of 10 autorefraction measurements and 5 AL measurements were used for data analysis.

• **NEW CONTROL GROUP (NSVL GROUP):** A new control group was recruited from the Eye Hospital of Wenzhou Medical University from July to September 2020. The subjects and their parents or guardians were fully informed and explained the clinically available myopia interventions and provision of only SVL in this study. Inclusion criteria for the nSVL group were based on the participants of the HAL3 group at extension baseline, ie, between 10-15 years of age, with SER ranges −1.75 to −6.00 D, and AL ranges of 23.3-27.0 mm. Moreover, nSVL participants had no history of using myopia control. Annual myopia progression and AL changes in the nSVL group were compared with the third-year changes in the HAL1, HAL2, and HAL3 groups.

• **STATISTICAL ANALYSIS:** Statistical analyses were performed using SPSS software (version 25.0; IBM Corp, Chicago, Illinois, USA). Baseline characteristics and the changes in SER and AL are presented as mean (SE) or as numbers (%). Only right-eye data were included in the analysis because of a strong correlation in the change in SER (r = 0.75, P < .001) and AL (r = 0.84, P < .001) between the 2 eyes over a 3-year period. Following Kolmogorov-Smirnov tests for distribution, unpaired t tests, Mann-Whitney U tests, or repeated-measures analysis of variance tests were used as appropriate. P < .05 was considered statistically significant in all cases.

For the HAL1, HAL2, and HAL3 groups, myopia progression and AL elongation during years 1, 2, and 3 were calculated and compared by repeated-measures analysis of variance and post hoc pairwise comparisons using the least significant difference test. Myopia progression and AL elongation in the nSVL were compared with the third-year changes in the 3 treatment groups (HAL1, HAL2, and HAL3) by a generalized linear model approach with adjusting confounding covariates, such as age, sex, numbers of myopic parents, and baseline SER or AL. For intergroup comparisons, the least significant difference test (when P < .05) was used.

RESULTS

• **STUDY SUBJECTS:** One hundred seventy myopic children with a mean (SE) age of 10.4 (0.1) years, ranging from 8-13 years, were originally recruited for the 2-year RCT. After 2 years, 151 (89%) participants continued the 1-year extension study (Supplemental Table 1). Fifty-six participants were recruited in the nSVL group, and their age, sex, SER, AL, and number of myopic parents matched the extension baseline of the HAL3 group (Supplemental Table 2). In total, 191 children (HAL1, n = 51; HAL2, n = 50; HAL3, n = 42; and nSVL, n = 48) completed the third year of follow-up (Figure 1).

• **CHANGES IN SER DURING THE THIRD YEAR:** The average (SE) myopia progressions in the third year were −0.38 (0.05) D, −0.36 (0.06) D, −0.33 (0.06) D, and −0.56 (0.05) D in the HAL1, HAL2, HAL3, and nSVL groups, respectively (Figure 2, A and Table 1). Compared with the nSVL group, the mean (SE) SER progression was less in the HAL1 (−0.18 [0.08] D, P = .02), HAL2 (−0.20 [0.08] D, P = .01), and HAL3 (−0.23 [0.08] D, P = .005) groups,

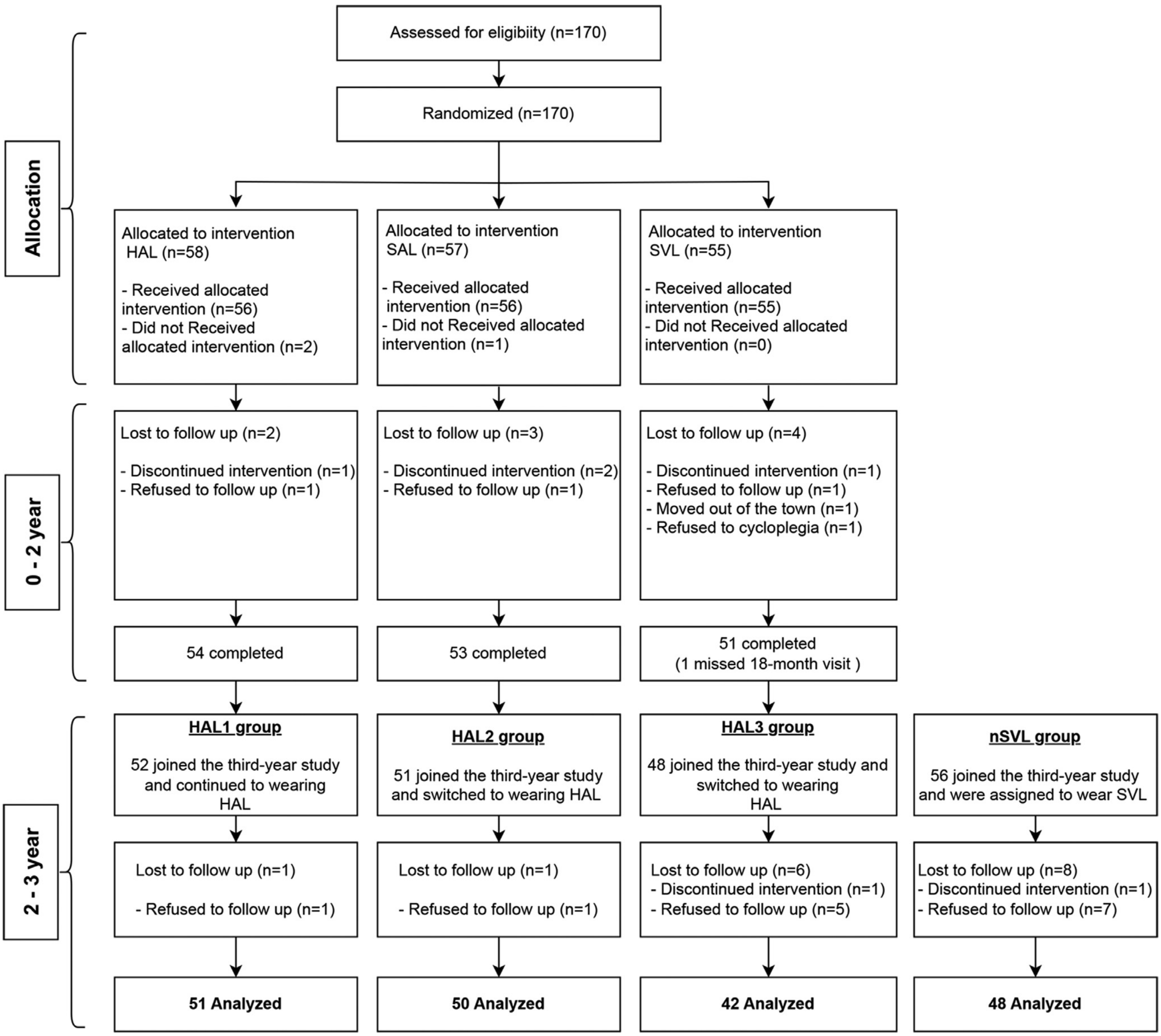

FIGURE 1. Flowchart of the study, showing participant numbers over 3 years. HAL: spectacle lenses with highly aspherical lenslets; SAL: spectacle lenses with slightly aspherical lenslets; SVL: single-vision spectacle lenses; nSVL: new single-vision spectacle lenses group as a control; HAL1: children who had worn HAL in the previous 2-year study and continued wearing HAL in the 3rd year; HAL2: children who had worn SAL in the previous 2-year study and had switched to wearing HAL in the 3rd year; HAL3: children who had worn SVL in the previous 2-year study and had switched to wearing HAL in the 3rd year.

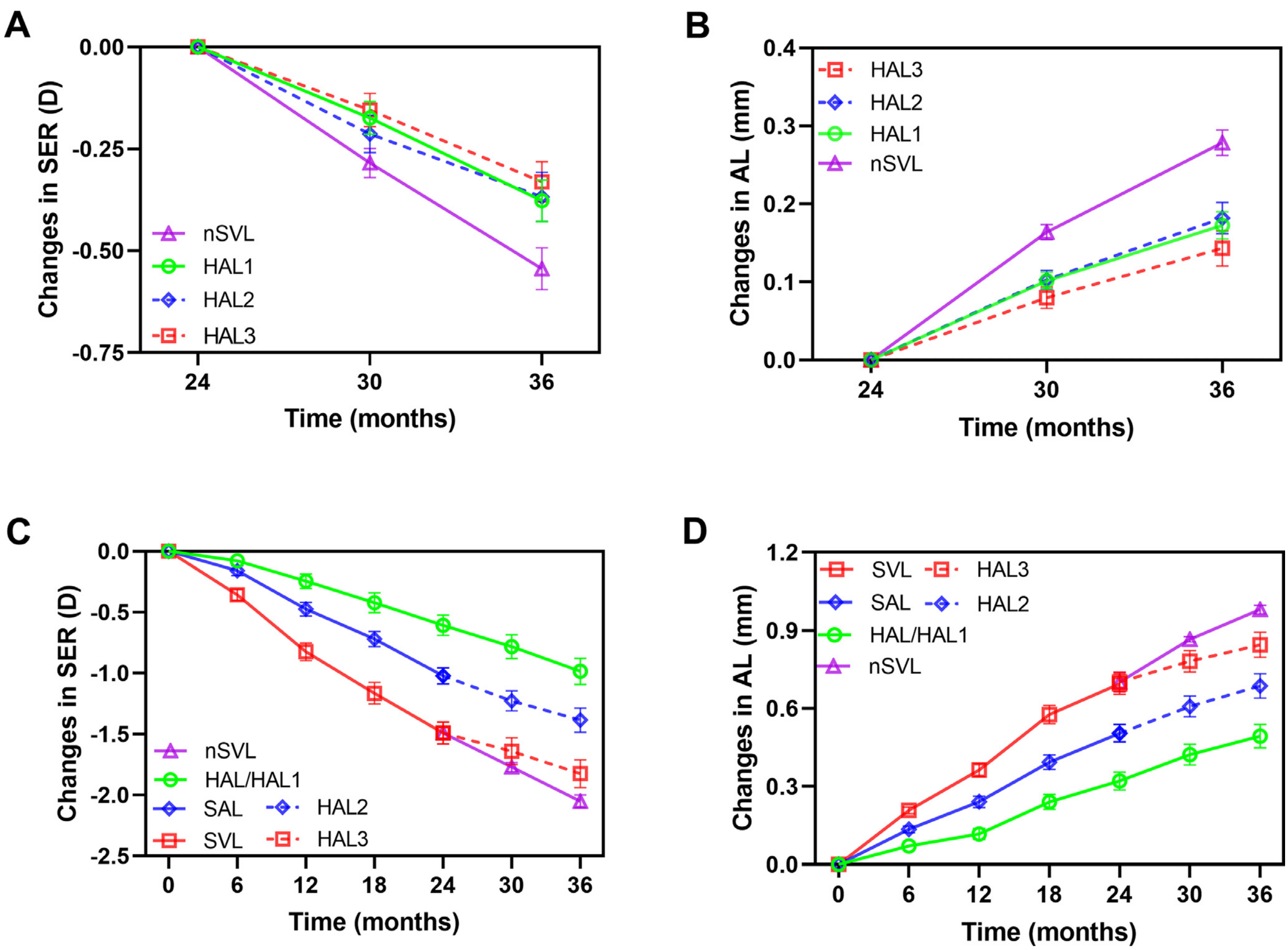

FIGURE 2. The 3rd year changes in SER (A) and AL (B) in the HAL1, HAL2, HAL3 and nSVL groups, and changes in SER (C) and AL (D) from baseline to 36 months. The blue and red dotted lines represent the period (24-36 months) during which the previous SAL and SVL groups wore HAL. The green line shows changes in the HAL group, and the rose red line shows changes in the nSVL group. HAL: spectacle lenses with highly aspherical lenslets; SAL: spectacle lenses with slightly aspherical lenslets; SVL: single-vision spectacle lenses; nSVL: new single-vision spectacle lenses group as a control; HAL1: children who had worn HAL in the previous 2-year study and continued wearing HAL in the 3rd year; HAL2: children who had worn SAL in the previous 2-year study and had switched to wearing HAL in the 3rd year; HAL3: children who had worn SVL in the previous 2-year study and had switched to wearing HAL in the 3rd year.

with no difference among the 3 HAL intervention groups (all $P > .05$).

In the generalized linear model analysis, the extension baseline age (95% confidence interval [CI] 0.015-0.104; $P = .008$) was significantly associated with SER progression. Table 2 shows model-adjusted changes in myopia progression in the third year. Compared with the nSVL group, the differences in myopia progression were −0.13 (0.08) D in the HAL1 ($P = .09$), −0.18 (0.08) D in the HAL2 ($P = .02$), and −0.22 (0.08) D in the HAL3 ($P = .005$) groups.

Among all participants who completed the third year of follow-up, no SER progression was in 20% of the HAL1 group, 18% of the HAL2 group, 24% of the HAL3 group, and 6% of the nSVL group. In contrast, the proportion of participants who showed myopia progression of >0.50 D was 46% in the nSVL group, 25% in the HAL1 group, 26% in the HAL2 group, and 26% in the HAL3 group ($\chi^2 = 9.76$, $P = .14$) (Figure 3).

• **CHANGES IN AL DURING THE THIRD YEAR:** The mean (SE) AL elongations in the third year were 0.17 (0.02) mm, 0.18 (0.02) mm, 0.14 (0.02) mm, and 0.28 (0.02) mm in the HAL1, HAL2, HAL3, and nSVL groups, respectively (Figure 2, B and Table 1), with no differences among the 3 HAL intervention groups (all $P > .05$). Compared with the nSVL group, the mean AL elongations were less in the 3 HAL groups, with mean AL differences (SE) of −0.11 (0.03) mm (HAL1, $P < .001$), 0.10 (0.03) mm (HAL2, $P < .001$), and 0.14 (0.03) mm (HAL3, $P < .001$).

TABLE 1. Mean (SE) and 95% confidence interval of the SER and AL from baseline to 36 months in HAL/HAL1, SAL/ HAL2, SVL/HAL3 and nSVL groups.

Time (months)	HAL/HAL1 (n=51)	SAL/ HAL2 (n=50)	SVL/ HAL3 (n=42)	nSVL (n=48)	HAL/HAL1 (n=51)	SAL/ HAL2 (n=50)	SVL/ HAL3 (n=42)	nSVL (n=48)
	SER (D)				Myopia progression (D)			
0	-2.72 (0.15) [-3.00, -2.42]	-2.33 (0.13) [-2.59, -2.06]	-2.35 (0.13) [-2.61, -2.08]	-	-	-	-	-
6	-2.79 (0.14) [-3.08, -2.51]	-2.49 (0.14) [-2.76, -2.21]	-2.70 (0.13) [-2.96, -2.45]	-	-0.08 (0.04) [-0.17, -0.01]	-0.16 (0.04) [-0.24, -0.08]	-0.36 (0.05) [-0.45, -0.26]	-
12	-2.96 (0.14) [-3.24, -2.67]	-2.80 (0.14) [-3.08, -2.52]	-3.17 (0.13) [-3.43, -2.91]	-	-0.25 (0.06) [-0.36, -0.13]	-0.48 (0.06) [-0.59, -0.36]	-0.82 (0.07) [-0.97, -0.68]	-
18	-3.14 (0.16) [-3.45, -2.82]	-3.05 (0.14) [-3.33, -2.76]	-3.53 (0.14) [-3.81, -3.25]	-	-0.42 (0.08) [-0.58, -0.26]	-0.72 (0.06) [-0.85, -0.59]	-1.16 (0.09) [-1.34, -0.99]	-
24	-3.32 (0.16) [-3.63, -3.01]	-3.35 (0.15) [-3.64, -3.05]	-3.84 (0.14) [-4.11, -3.56]	-3.73 (0.14) [-4.02, -3.44]	-0.61 (0.08) [-0.77, -0.44]	-1.02 (0.07) [-1.16, -0.89]	-1.49 (0.09) [-1.67, -1.31]	-
30	-3.50 (0.16) [-3.82, -3.17]	-3.55 (0.15) [-3.85, -3.26]	-3.99 (0.15) [-4.29, -3.68]	-4.01 (0.15) [-4.30, -3.71]	-0.78 (0.10) [-0.98, -0.58]	-1.23 (0.08) [-1.39, -1.06]	-1.64 (0.11) [-1.86, -1.42]	-0.28 (0.04) [-0.35, -0.20]
36	-3.70 (0.16) [-4.03, -3.37]	-3.71 (0.16) [-4.04, -3.38]	-4.17 (0.15) [-4.48, -3.86]	-4.29 (0.15) [-4.58, -3.99]	-0.99 (0.11) [-1.20, -0.77]	-1.39 (0.10) [-1.58, -1.19]	-1.82 (0.11) [-2.05, -1.59]	-0.56 (0.05) [-0.67, -0.45]
Time (months)	AL (mm)				AL elongation (mm)			
0	24.78 (0.10) [24.59, 24.97]	24.41 (0.11) [24.20, 24.63]	24.68 (0.10) [24.47, 24.89]	-	-	-	-	-
6	24.85 (0.10) [24.65, 25.05]	24.55 (0.11) [24.33, 24.77]	24.88 (0.10) [24.69, 25.09]	-	0.07 (0.01) [0.04, 0.10]	0.14 (0.01) [0.11, 0.16]	0.21 (0.01) [0.18, 0.23]	-
12	24.90 (0.10) [24.69, 25.10]	24.66 (0.11) [24.44, 24.87]	25.04 (0.10) [24.84, 25.23]	-	0.12(0.02) [0.08, 0.16]	0.24 (0.02) [0.20, 0.28]	0.36 (0.03) [0.31, 0.41]	-
18	25.02 (0.11) [24.81, 25.23]	24.81 (0.11) [24.59, 25.03]	25.28 (0.10) [25.08, 25.47]	-	0.24 (0.03) [0.18, 0.30]	0.39 (0.03) [0.34, 0.45]	0.59 (0.03) [0.52, 0.66]	-
24	25.10 (0.11) [24.88, 25.32]	24.92 (0.11) [24.69, 25.14]	25.38 (0.10) [25.18, 25.58]	25.47 (0.12) [25.24, 25.71]	0.32 (0.03) [0.25, 0.39]	0.50 (0.03) [0.44, 0.57]	0.70 (0.04) [0.63, 0.78]	-
30	25.20 (0.11) [24.98, 25.42]	25.02 (0.11) [24.80, 25.25]	25.46 (0.10) [25.26, 25.65]	25.64 (0.12) [25.40, 25.87]	0.42 (0.05) [0.34, 0.50]	0.61 (0.04) [0.53, 0.69]	0.78 (0.04) [0.70, 0.86]	0.16 (0.01) [0.14, 0.18]
36	25.27 (0.11) [25.05, 25.50]	25.10 (0.11) [24.87, 25.33]	25.52 (0.10) [25.32, 25.72]	25.75 (0.12) [25.52, 25.99]	0.49 (0.05) [0.40, 0.58]	0.69 (0.05) [0.59, 0.78]	0.84 (0.05) [0.75, 0.94]	0.28 (0.02) [0.25, 0.31]

AL, axial length; SER, spherical equivalent refraction; HAL: spectacle lenses with highly aspherical lenslets; SAL: spectacle lenses with slightly aspherical lenslets; SVL: single-vision spectacle lenses; nSVL: new single-vision spectacle lenses group as a control; HAL1: children who had worn HAL in the previous 2-year study and continued wearing HAL in the 3rd year; HAL2: children who had worn SAL in the previous 2-year study and had switched to wearing HAL in the 3rd year; HAL3: children who had worn SVL in the previous 2-year study and had switched to wearing HAL in the 3rd year.

TABLE 2. Adjusted changes in SER and AL (mean [SE], 95%CI) in the 3rd year in HAL1, HAL2, HAL3 and nSVL groups.

Time	HAL1 (n=51)	HAL2 (n=50)	HAL3 (n=42)	nSVL (n=48)	Overall P values	Comparisons P values (4 vs. 1; 4 vs. 2; 4 vs. 3; 3 vs. 1; 3 vs. 2; 2 vs. 1)[#]
Myopia progression (D)[a]	-0.41 (0.05) [-0.51, -0.30]	-0.35 (0.05) [-0.46, -0.25]	-0.32 (0.06) [-0.43, -0.21]	-0.54 (0.05) [-0.64, -0.43]	0.03[a]	0.09; 0.02; 0.005; 0.27; 0.66; 0.48
AL elongation (mm)[a]	0.19 (0.02) [0.15, 0.22]	0.18 (0.02) [0.15, 0.22]	0.14 (0.02) [0.10, 0.18]	0.27 (0.02) [0.23, 0.31]	<0.001[a]	0.001; <0.001; <0.001: 0.06; 0.11; 0.79

[a]Values were generated by a generalized linear model approach adjusted sex, age, number of myopic parents, SER and AL at 24 months, with LSD test applied for pairwise comparisons.

[#]1: HAL1; 2: HAL2; 3: HAL3; 4: nSVL.

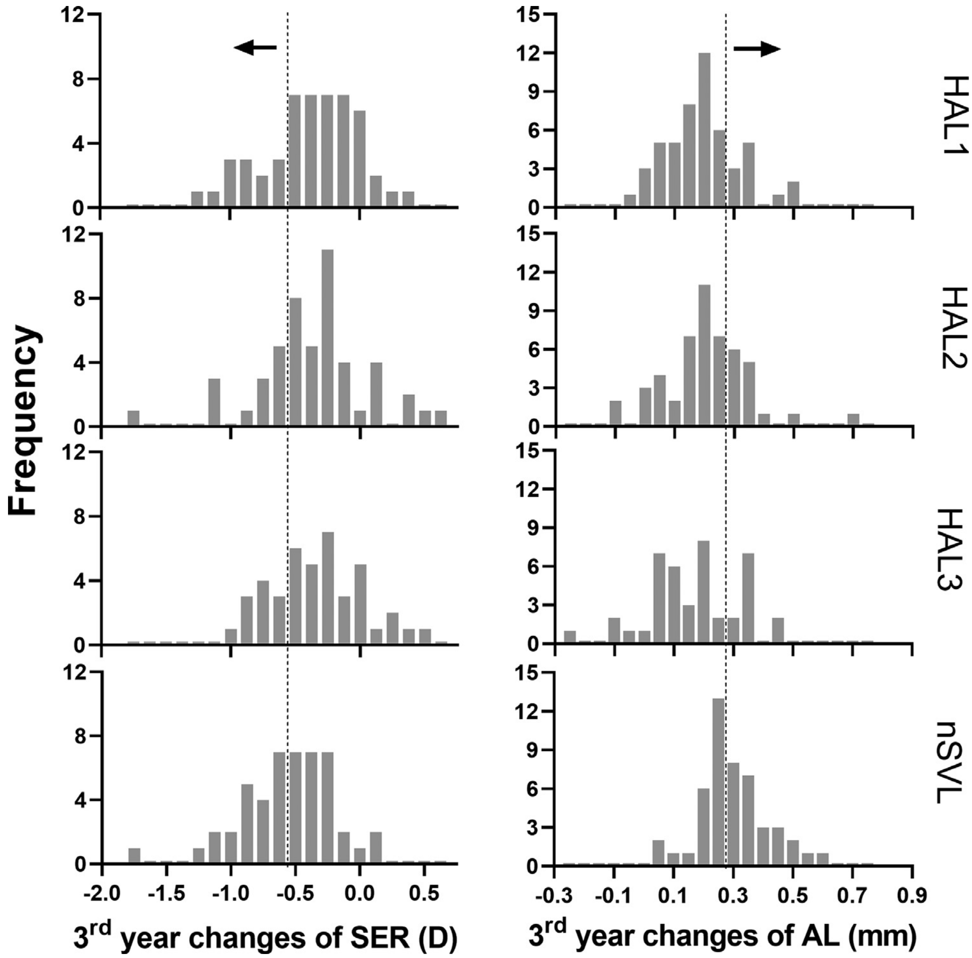

FIGURE 3. Distribution of changes in SER (left panel) and AL (right panel) among treatment groups during the one-year extension follow-up (the 3rd year). The dash lines and arrows pointed to greater myopia progression and AL elongation. (AL, axial length; SER, spherical equivalent refraction; HAL1: children who had worn HAL in the previous 2-year study and continued wearing HAL in the 3rd year; HAL2: children who had worn SAL in the previous 2-year study and had switched to wearing HAL in the 3rd year; HAL3: children who had worn SVL in the previous 2-year study and had switched to wearing HAL in the 3rd year.)

In the generalized linear model analysis, extension baseline age (95% CI −0.047 to −0.017; $P < .001$) was significantly associated with AL elongation. Table 2 shows model-adjusted mean (SE) AL changes in the third year. Compared with the nSVL group, the differences in AL elongation were 0.08 (0.03) mm in the HAL1 ($P = .001$), 0.09 (0.03) mm in the HAL2 ($P < .001$), and 0.13 (0.03) in the HAL3 ($P < .001$) groups.

AL elongations ≤0.10 mm were 6% in participants in the nSVL group but were 29% in the HAL1 group, 24% in the HAL2 group, and 43% in the HAL3 group. In contrast, the proportion of AL elongations ≥0.3 mm was 40% in the nSVL group, 16% in the HAL1 group, 18% in the HAL2 group, and 24% in the HAL3 group ($\chi^2 = 22.82$, $P = .001$) (Figure 3).

• **CHANGES IN SER AND AL OVER 3 YEARS IN EACH INTERVENTION GROUP:** In the HAL/HAL1 group, the mean changes in SER and AL were −0.99 (0.11) D and 0.49 (0.05) mm over 3 years (Table 1). The annual rate of myopia progression was similar in each of the 3 years for the HAL group ($F_{2,100} = 2.15$, $P = .12$), but the AL elongation changed significantly ($F_{2,100} = 8.21$, $P = .001$). Post hoc analyses indicated that the axial elongation in the third year was significantly faster than that in the first year (mean difference of 0.06 [0.02] mm, $P = .02$) but similar to that in the second year (mean difference of −0.03 [0.02] mm, $P = .13$) (Figure 2, C and D).

In the SAL/HAL2 group, the mean changes in SER and AL in the third year were -0.36 (0.06) D and 0.18 (0.02) mm, respectively. The annual rate of myopia progression was similar in each of the three years. ($F_{2,98}$=3.01, P=0.05). While the AL elongation in the third year was less than those in the initial first and second years ($F_{2,98}$=6.89, P=0.002, mean differences [SE] of -0.06 [0.03] mm, -0.08 [0.02] mm; $P = .02$ and $P < .001$).

In the SVL/HAL3group, SER (-0.33 [0.06] D, [$F_{2,82}$ = 19.33, $P < .001$]) and AL (0.14 [0.02] mm, [$F_{2,82}$ = 42.39, $P < .001$]) changes in the third year were less than those in the first year (mean differences [SE] of 0.49 [0.08] D, -0.22 [0.03] mm; all $P < .001$) and the second year (mean differences [SE] of 0.33 [0.07] D, 0.19 [0.03] mm; all $P < .001$).

• **COMPLIANCE AND ADAPTATION:** No significant difference was observed in the proportion of participants who adapted to HAL or SVL within 3 days among the HAL1, HAL2, HAL3, and nSVL groups (100%, 100%, 98% and 100%, respectively; $P = .31$). Only one participant from the HAL3 group complained of blurred vision, but then adapted well in one week. No adverse events were reported during the extended study period.

DISCUSSION

This study presented the results of a clinical trial extended to 3 years, in which one group wore HAL for 3 years, and the other two groups wore HAL for 1 year after completing the initial 2 years of wearing either SAL or SVL. Over three years, the mean myopia progression and AL elongation were -2.05 D and 0.98 mm in the control group (combined initial SVL and nSVL groups); and -0.99 D and 0.49 mm in the HAL/HAL1 group, resulting in a total difference in myopia progression of 1.06 D (52%) and AL elongation of 0.49 mm (50%).

In the HAL/HAL1 group, myopia progression did not change significantly over 3 years ($F_{2,100} = 2.15$, $P = .12$). However, AL elongation in the second and third years was slightly greater than in the first year (mean difference, 0.09 mm and 0.06 mm, respectively), with no difference between the second and third years. The small change may come from the choroidal thickening caused by HAL in the first year.[27] Moreover, during the second and third years (July 2019 to September 2021), the COVID-19 has spread, resulting in temporary lockdown and more online learning at home, which might have contributed to this minute difference.[28,29]

In the HAL3 group, SER and AL changes in the 3rd year were -0.33 (0.06) D and 0.14 (0.02) mm, significantly less than those in the previous year (-0.67 [0.05] D and 0.34 [0.02] mm), and also less than those in the nSVL group (-0.56 [0.05] D and 0.28 [0.02] mm), indicating that HAL is efficacious in slowing myopia progression and axial elongation in older children (10 to 15 years) wearing HAL for the first time. In contrast, the myopia control efficacy of the switchover group in the LAMP study (from placebo to 0.05% Atropine) showed more dramatic (1st year vs 2nd year, -0.82 D vs -0.18 D; 0.43 mm vs 0.15 mm).[22] We found that the control groups in both studies had inconsistent myopia progression in the year prior to switching (-0.67 D, our study vs -0.82 D, LAMP), possibly due to an over 2-year age difference.[30]

No differences among the 3 HAL treatment groups were found in the 3rd year. This result was similar to previous reports from Chamberlain and associates[31] and Lam and associates.[32] In Chamberlain and associates' study, children from the single-vision contact lens group who switched to wearing dual-focus soft contact lenses (DFCL) for 3 years showed a similar treatment effect to those who continued wearing DFCL. Lam and associates[32] found similar results for children switching to wearing defocus-incorporated multiple segment spectacles for 1 year after SVL. In this study, the myopia control efficacy of HAL was not affected by previous optical correction methods (SVL or SAL). Whether the myopia control efficacy of HAL is affected by previous use of other myopia control treatments, such as low-concentration atropine, needs to be further investigated.

There were some limitations to this study. First, the control group that was used to evaluate the long-term myopia efficacy of HAL over 3 years was formed by combining the initial SVL and new SVL groups. After the 2-year RCT, the initial SVL group switched to wearing HAL lenses. Thus, a new SVL group was recruited as the control group in the third year, and this extension 1-year study was non blinded. However, the myopia progression of average 12 years was comparable to another two studies from mainland China.[33,34] And the predicted AL elongation in year 3 could be 0.289 mm based on a 15% decrease in AL elongation per year by Shamp et al.,[30] which is very comparable with the observed 0.28 mm in the current study. Second, this study was not designed to observe any possible rebound effect as found in atropine studies.[17,35,36] However, a recent cross-over trial has shown that there was no rebound of myopia with HAL, as the rate of progression observed in Vietnamese children (7-11 years) who ceased wearing HAL and switched to SVL was similar to that of the comparative control group wearing SVL.[37]

In conclusion, in Chinese myopic children, wearing HAL effectively slows myopia progression and axial elongation compared with SVL over 3 years. Similarly, when myopic children switched to HAL in the third year after two years of wearing SVL, myopia progression and axial elongation decreased significantly. The myopic children who have been wearing HAL for three years will be followed for two more years to determine the long-term efficacy of HAL lenses over a 5-year period.

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Abbreviations: AL: Axial length; D: Diopter; OK: Orthokeratology; HAL: Spectacle lenses with highly aspherical lenslets; SAL: Spectacle lenses with slightly aspherical lenslets; SVL: Single-vision spectacle lenses.
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Acquisition, analysis, or interpretation of data: Li, Huang, Yin, Liu, Zhang.
Drafting of the manuscript: Li
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