

Additive Effect of Highly Aspherical Lenslet Target Spectacles to Children Inadequately Controlled by Atropine Monotherapy

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Purpose: Myopia progression in children, especially in East Asia, is a significant public health concern. This study evaluated the efficacy of combining myopia control spectacle lenses with Highly Aspherical Lenslet Target (HALT) technology and atropine in children who continued to progress on low-dose atropine (LDA).

Design: Prospective cohort.

Subjects: Children aged 6–11 years with ≥ 0.5 diopters (D) myopia progression over 6 months on LDA (0.01% or 0.025%) were recruited.

Methods: All participants used HALT (Essilor Stellest) spectacle lenses while maintaining their LDA dose. The changes in spherical equivalent (SE) and axial length (AL) were tracked for 6 months before and 6–12 months after starting combination treatment.

Main Outcome Measures: Progression of SE and AL.

Results: Fifty children (mean age 8.9 ± 1.1 years) were separated into group A (on 0.01% atropine daily, n20) and group B (on 0.01% atropine twice daily, n5 and 0.025% atropine nightly, n25). Most (86%) were ethnic Chinese. The baseline SE and AL showed no significant intergroup differences, with prior myopia progression (0.60D/0.24 mm) over 6 months. After adding HALT lenses, progression slowed to $-0.06\text{D}/0.06$ mm at 6 months and $-0.15\text{D}/0.14$ mm at 12 months. A hyperopic shift in AL was seen in 11 children (24%). However, the progression of $>0.5\text{D}$ was noted in 20%, with 18% and 40% progressing by >0.3 mm and >0.15 mm, respectively. Univariate analysis suggested that children who progressed >0.10 mm over 6 months were more likely to be younger, whereas multivariate analysis suggested that change in AL was associated with smaller pupil size (possibly from poor compliance or absorption of atropine) at 6 months and younger age at 12 months, after controlling for sex, race, and baseline SE and AL. There were no complaints of glare, near, or peripheral blur in children after starting combination treatment.

Conclusions: The addition of HALT spectacle lenses significantly reduced myopia progression in children, aged 6–11 years, who were poorly controlled on LDA alone demonstrating a potential synergistic effect with LDA. These findings supported combination therapy for managing challenging myopia cases.

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Myopia is a rapidly growing public health concern, particularly among children in East Asia. Currently, the prevalence rates in young adults in countries such as Singapore, Taiwan, and Hong Kong are $>80\%$, of which 20%–30% may be highly myopic.^{1–4} This can lead to serious ocular complications later in life, including retinal detachment, glaucoma, and myopic macular degeneration.

The strategy to manage myopia is to prevent or delay myopia onset if possible and to slow progression once myopia occurs. Current interventions for myopia control include low-dose atropine (LDA) eye drops,^{5–9} myopia control peripheral lenslets spectacle lenses such as the Highly Aspherical Lenslet Target (HALT),^{10,11} or defocus

incorporated multiple segments (DIMS) spectacle lenses,^{12,13} night-time wear orthokeratology contact lenses, or day-time wear defocus contact lens.^{14–17}

Atropine eye drops have been used since the 1970s for childhood myopia control.^{9,18,19} It is a nonselective muscarinic acetylcholine antagonist, with as yet uncertain mechanism of action. A dose-related response with higher doses showing better efficacy has been illustrated in multiple studies with a trade-off of higher side effects such as pupil dilation and loss of accommodation.^{20,21} More recently, LDA has been preferred because it can provide a good balance between efficacy, without side effects (such as glare and near blur).^{5,6}

Essilor Stellest lenses were developed in the late 2010s and use the HALT technology, which consists of 1021 high plus lenslets spread over 11 rings. It is believed that this creates a “volume of myopic defocus” that helps slow down the progression of myopia by defocusing light in the mid-peripheral retina.^{10,11}

Individually, HALT spectacle lenses and LDA eye drops are effective in controlling myopia progression in children. However, response to treatment is variable, with some children still progressing on mono-treatment. In this study, we aim to assess the efficacy of combining the Essilor Stellest (HALT) spectacle lens with atropine eye drops in children still progressing on LDA monotherapy. We hypothesized that the synergistic combination of these 2 interventions may be more effective in controlling myopia progression than atropine alone.

Methods

Children aged 6 to 11 years old who were still progressing by ≥ 0.5 diopters (D) over the past 6 months while on LDA (0.01% or 0.025%) were invited to take part in this study. Children had to have been compliant to atropine treatment at recruitment and agreed to be compliant throughout the study period (through a questionnaire), have a myopic spherical equivalent (SE) between -1.50 and -6.00 D in both eyes, an astigmatism of less than -2.00 D. Children with ocular diseases besides myopia (e.g., strabismus and amblyopia) and previously on other forms of myopia control treatment such as contact lenses were excluded from the study. Consent and assent were taken from the parents and patients, respectively. The study was conducted in accordance with the tenets of the Declaration of Helsinki, and ethics approval was obtained from the SingHealth Institutional Review Board.

Data collected at baseline included age, sex, race, and dose of atropine. Refractive error (both noncycloplegic and cycloplegic) and axial length (AL) from the previous 6 to 12 months were documented. Spherical equivalent, sphere plus half cylinder power, was calculated. The change of SE and AL over 6 months before the study was calculated as D or mm change over time measured multiplied by 6 months.

Children were divided into group A: those using atropine 0.01% every night and group B: those using atropine 0.01% 2 times per day or atropine 0.025% every night. All children were started on Essilor Stellest (HALT) spectacle lenses and informed to continue their atropine eye drops at the usual dose.

Cycloplegic refraction and autorefractometry, AL, and pupil size were assessed at baseline, 6 and 12 months. Cycloplegic autorefractometry was also measured ≥ 30 minutes after administration of 2 drops of cyclopentolate 1% (Alcon) given 10 minutes apart at baseline, using a table-mounted autorefractor (CKR2, Topcon Corporation). Five readings, each less than 0.25D apart, were averaged. Axial length was measured using the IOLMaster 500 (Carl Zeiss AG). Five readings, each less than 0.10 mm apart, were averaged.

The changes in SE and AL in the 6 months prior to starting HALT lenses and the first and second 6 months after starting HALT lenses were compared, with differences between groups also analyzed. Children were divided into 2 groups. Children previously on atropine 0.01% daily were included in group A. Children on atropine 0.01% twice daily and atropine 0.025% daily were included in group B because only a small number of children were on the atropine 0.01% twice daily and cumulative daily concentration was more similar to atropine 0.025% daily.

Multivariate analyses adjusted (generalized estimated equations) for both eyes was conducted to assess the effect of age, ethnicity, sex, and pupil size on change in SE and AL. Statistical significance was set at 0.05 level, and all analyses were conducted with STATA/IC 11.2 (StataCorp) and SPSS Statistics for Windows, Version 29.0.2.0 (IBM Corp).

Results

Fifty children (mean age 8.9 ± 1.1 years) were recruited, of whom 20 were on atropine 0.01% daily (group A) and 5 were on 0.01% twice daily and 25 on atropine 0.025% daily (group B).

The majority of children were ethnic Chinese (86%), with 8% Indian, 4% Malay, and 2% Eurasian (Table 1). There was no significant difference in age, sex, race, and pupil size between the 2 treatment groups. However, children in group A were less myopic than those in group B.

Follow-up data were available from all children at 6 months. However, 2 children, both from group B, failed to return for follow-up at 12 months.

In the 6 to 12 months before the study, SE and AL were available in 42 children. In these children, the estimated progression of SE and AL over 6 months while children were on atropine monotherapy was -0.60 ± 0.38 D and 0.24 ± 0.10 mm. There was also no significant difference in progression between 2 treatment groups (Table 1).

After the addition of HALT lenses, the myopia progression was significantly reduced at -0.06 ± 0.38 D ($P < 0.001$) and 0.06 ± 0.10 mm ($P < 0.001$) in the first 6 months and -0.15 ± 0.21 D ($P < 0.001$) and AL 0.14 ± 0.09 mm ($P < 0.001$) in the second 6 months. There was no significant difference in progression between change in SE ($P = 0.177$) and AL ($P = 0.687$) between the first and second 6 months and within the 2 treatment groups (Fig 1).

A hyperopic shift in AL was seen in 18 subjects (36%) at 6 months and 11 subjects (22%) at 12 months. However, 20% of subjects showed a progression of >0.5 D over 12 months, whereas 18% showed a progression of >0.3 mm and 40% >0.15 mm over 12 months (Fig 2). A positive effect seemed to present in all ages, including children as young as 7 years old. Children whose progression ≥ 0.1 mm over 6 months tended to be younger at baseline (Table 2).

Multivariate analysis showed that change in AL over 6 months was greater in those with smaller baseline pupil size, whereas change over 12 months was greater in younger children, after controlling for sex, race, age, and treatment group and adjusting for 2 eyes (Table 3). A similar analysis looking at the change of SE over 6 months showed no association with any variables.

There was no complaint of glare, near, or peripheral blur in children after starting combination treatment.

Discussion

Children on combination therapy demonstrated much less progression in the first 6 months (-0.03 D or 0.06 mm) compared with the estimated progression in the prior 6

Table 1. Baseline Characteristics

	Total (n50)	Group (n20)	Group B (n30)	P Value
Age at baseline (yrs)	8.98 (1.15)	9.15 (1.12)	8.87 (1.16)	0.234
Male (%)	19 (37%)	8 (40%)	11 (35%)	0.645
Chinese (%)	43 (84%)	18 (90%)	25 (80%)	0.204
Parental myopia: none:1:2	4:7:39	2:5:13	1:2:27	0.018
Baseline cycloplegic SE (D)	-4.63 (1.22)	-4.32 (1.07)	-4.82 (1.28)	0.048
Baseline AL (mm)	25.01 (0.74)	24.72 (0.64)	25.19 (0.75)	0.001
Pupil size (mm)				
Baseline	5.7 (1.7)	6.0 (1.7)	5.5 (1.8)	0.206
6 mos	4.9 (1.2)	4.4 (1.0)	5.4 (1.1)	0.001
12 mos	5.4 (2.4)	5.4 (3.5)	5.3 (1.1)	0.876
Change in cycloplegic SE (D)				
Prior 6 mos	-0.60 (0.38)	-0.62 (0.31)	-0.59 (0.43)	0.743
First 6 mos	-0.03 (0.28)	0.02 (0.20)	-0.07 (0.32)	0.084
Second 6 mos	0.00 (0.66)	0.07 (0.08)	-0.04 (0.28)	0.710
Over 12 mos	-0.07 (0.28)	0.05 (0.30)	-0.09 (0.53)	0.607
Change in AL (mm)				
Prior 6 mos	0.24 (0.12)	0.24 (0.11)	0.24 (0.13)	0.952
First 6 mos	0.06 (0.10)	0.05 (0.10)	0.07 (0.10)	0.257
Second 6 mos	0.07 (0.07)	0.06 (0.08)	0.08 (0.07)	0.238
Over 12 mos	0.13 (0.14)	0.11 (0.11)	0.15 (0.16)	0.231

Group A: atropine 0.01% daily.

Group B: atropine 0.01% twice daily or atropine 0.025% nightly.

AL = axial length; SE = spherical equivalent.

months (-0.60D or 0.024 mm) (Table 1). Progression in the second 6 months was similar to the first 6 months (Fig 1). The overall progression of -0.07D or 0.13 mm over 12 months was a good clinical outcome with little or no adverse effect, suggesting that the combination of HALT to LDA was clinically beneficial, efficacious, and well-tolerated over the first 12 months.

Notably, our study population is unique and included children for whom LDA monotherapy had proved insufficient. Options then included increasing the atropine dose, which may be associated with more side effects (such as glare and near blur), or adding an optical treatment. These

children may intrinsically be children who require more treatment than others. Direct comparison with studies including treatment-naïve eyes is difficult, especially when there are also differences in age, race, and doses.

There are several randomized studies involving LDA in treatment-naïve Asian children (Table 4).^{5,10,11,22,23} The mean progression with atropine dose of 0.01% to 0.025%, in the Atropine for the Treatment of Myopia, Low-Concentration Atropine for Myopia Progression, and Atropine in the Prevention of Myopia Progression and Lower-dose Evaluation studies, ranges from -0.40D to -0.59D and 0.20 to 0.32 mm over a 12-month period.^{5,21,24} The 2 most

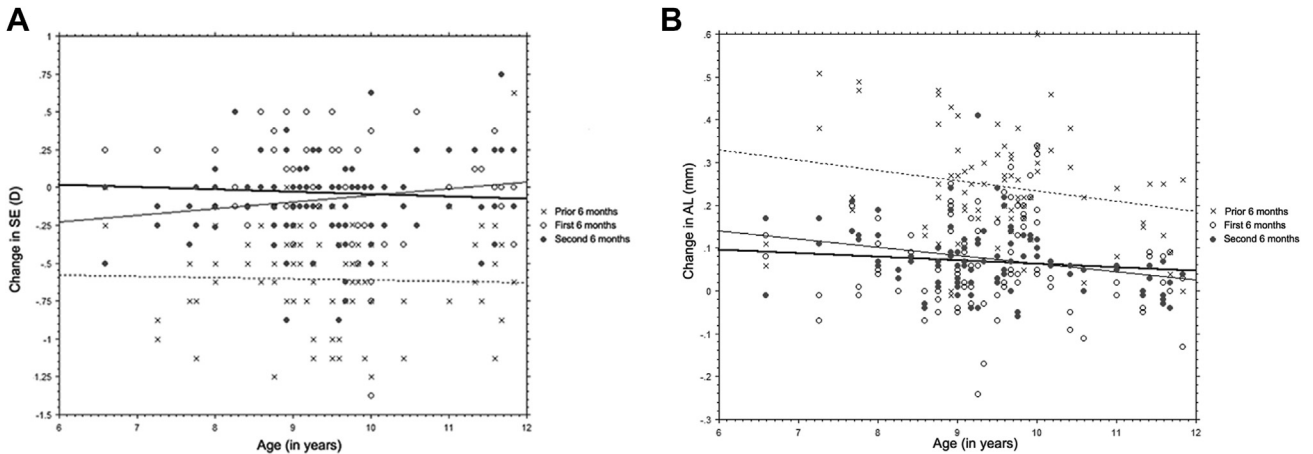


Figure 1. **A**, Change in spherical equivalent (SE) versus age. Scatterplot depicting change in SE versus age. Regression lines: dotted (prior 6 months), light line (first 6 months), and dark line (second 6 months). **B**, Change in axial length (AL) versus age. Scatterplot depicting change in AL versus age. Regression lines: dotted (prior 6 months), light line (first 6 months), and dark line (second 6 months). D = diopters.

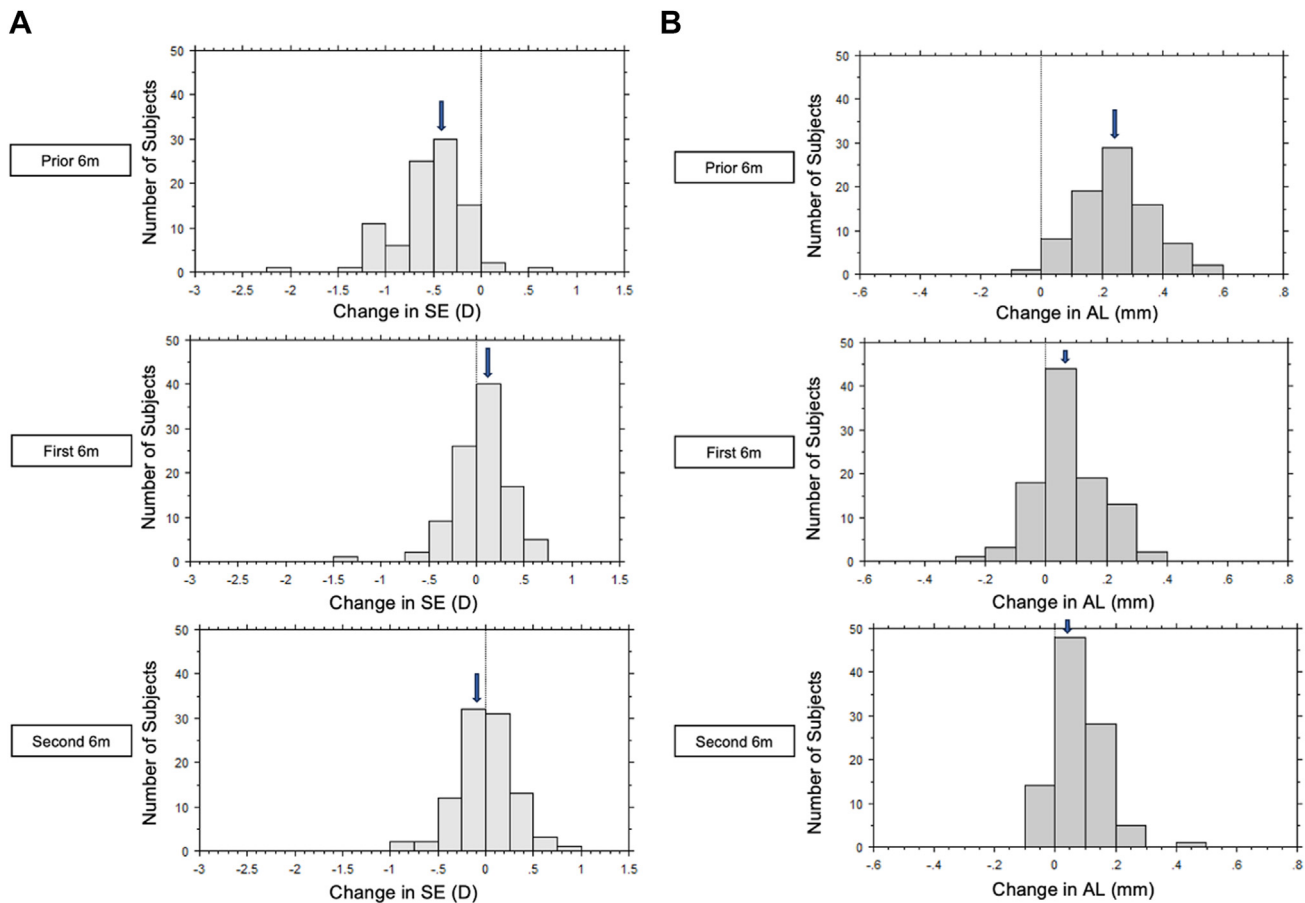


Figure 2. A, Change in spherical equivalent (SE) in prior 6 months, first 6 months, and second 6 months on the addition of HALT lenses. Histogram depicting change in SE at prior 6 months, first 6 months, and second 6 months on the addition of HALT lenses. Black arrow indicates mean. B, Change in axial length (AL) in prior 6 months, first 6 months, and second 6 months on the addition of HALT lenses. Histogram depicting change in AL at prior 6 months, first 6 months, and second 6 months on the addition of HALT lenses. Black arrow indicates mean. D = diopters; HALT = Highly Aspherical Lenslet Target.

established myopia control glasses options include the HALT and DIMS glasses. Bao et al¹⁰ in the first randomized controlled trial using HALT glasses, including 170 Chinese

children aged 8–13 years, found a progression of -0.27D or 0.13 mm over 12 months, compared with -0.81D or 0.36 mm in their control eyes. Progression in DIMS glasses, in a randomized controlled trial of a Chinese population of 183 children, suggests progression of -0.17D or 0.11 mm over 12 months, compared with -0.55D or 0.32 mm in the control arm.¹²

There are currently few studies on combination myopia control glasses with atropine eye drops. Huang et al²² in a retrospective study of 107 Chinese children, aged 7 to 12 years, showed a progression of -0.49D or 0.28 mm in the combination DIMS + atropine 0.01% ; which is much less than that noted in the DIMS (-0.79D or 0.41 mm) or control group (-1.07D or 0.52 mm). By contrast, Nucci et al²³ in a prospective cohort of 146 European children, aged 6 to 18 years old, noted a much lower progression in their DIMS + atropine 0.01% group (-0.30D or 0.05 mm) and control groups (-0.71D or 0.17 mm). However, differences in inclusion and exclusion criteria, study design, study populations, and background factors limit the direct comparability of results across various combination studies (Table 4).

Table 2. Change in AL at 6 Months

	AL <0.10 mm (n34)	AL ≥0.10 mm (n16)	P Value
Age (yrs)	9.23 (1.15)	8.50 (1.03)	0.035
Male	11 (32%)	7 (43%)	0.433
Chinese	30 (88%)	13 (81%)	0.292
Parental myopia none:1:2	3:4:27	1:2:13	0.951
Group A:	15 (44%)	5 (31%)	0.676
Group B:	19 (66%)	11 (69%)	
Baseline SE (D)	-4.18 (1.21)	-4.84 (1.35)	0.089
Baseline AL (mm)	24.94 (0.80)	25.28 (0.55)	0.129
Baseline PS (mm)	5.9 (1.6)	4.9 (1.5)	0.055
6 month PS (mm)	5.0 (1.0)	4.9 (1.3)	0.854
Change SE prior 6 m	-0.53 (0.36)	-0.77 (0.60)	0.099
Change AL prior 6 m	0.24 (0.10)	0.21 (0.15)	0.523

Group A: atropine 0.01% daily.

Group B: atropine 0.01% twice daily or atropine 0.025% nightly.

AL = axial length; PS = pupil size; SE = spherical equivalent.

Table 3. Multivariate Analysis: Associations of Change of AL over 6 and 12 Months Compared with Sex, Ethnicity, Age, Treatment Group, and Pupil Size, Adjusted for Use of Both Eyes

	Change in AL over 6 mos			Change in AL over 12 mos		
	Coeff	95% CI	P	Coeff	95% CI	P
Male	−0.005	−0.052 to 0.412	0.817	+0.002	−0.073 to 0.076	0.961
Chinese	−0.026	−0.092 to 0.038	0.417	−0.044	−0.160 to 0.073	0.461
Age	−0.003	−0.023 to 0.016	0.732	−0.025	−0.049 to 0.000	0.047
Group A (ref)						
Group B	0.012	−0.031 to 0.056	0.561	0.025	−0.044 to 0.095	0.475
Pupil size	−0.016	−0.030 to −0.003	0.016	−0.019	−0.041 to 0.004	0.100

Group A: atropine 0.01% daily.
Group B: atropine 0.01% twice daily or atropine 0.025% nightly.
CI = confidence interval.

In this study, the progression of SE was much less than in both monotherapy and DIMS+atropine studies. The AL progression was also much less than in the Asian-based studies but equivalent to the DIMS+atropine results in European eyes. It is known that LDA may affect SE more than AL, while the DIMS and HALT glasses seem to benefit both SE and AL. It is possible that the combination of both resulted in both a better SE and AL result. The benefit of this may be a better stabilization of both parameters, which also result in the DIMS and HALT glasses being able to “last” longer without needing to be changed.

Children on atropine 0.01% daily (group A) were analyzed separately from those on a higher dose (i.e., atropine 0.01% twice daily or atropine 0.025% daily, group B) because it was possible that those on a higher dose may have a stronger response. Interestingly, there was no significant difference in SE and AL progression both before and after the addition of HALT glasses (Table 1). This suggests that any additional benefit of combination treatment may be more determined by prior progression than on atropine dose.

That said, although some children did well with up to 24% experiencing a hyperopic shift at 12 months. A poor response (myopia progression >0.5D or >0.3 mm) was noted in almost 20%. This variety of response means that some children will likely need even more aggressive treatment.

There are many factors that have been associated with myopia progression including younger age, previous rapid progression, family history, and lifestyle factors.^{25,26} In this study, after multivariate analysis, AL progression at 6 months was associated with smaller pupil size at baseline. This could be a reflection of poor compliance or poor absorption or reaction to atropine eye drops. At 12 months, however, an increase in AL seemed to be more associated with younger age.

Overall, our study results showed that the combination of HALT lenses with LDA yielded significantly superior results compared with both LDA monotherapy and HALT monotherapy studies in terms of SE progression and AL elongation. The effect seems to be present across a wide age range, including children as young as 7 years (Fig 2).

Table 4. Comparison with Studies with LDA or Atropine-DIMS/HALT Combination Studies

Study	Intervention	Change 6 m	Change 12 m
This study, Singapore	Prospective cohort, N50, mean age 8.9 yrs mean SE −4.83 D	HALT+ATP HALT+A0.01% A0.025% Placebo	−0.03 D/0.06 mm 0.02 D/0.05 mm Change 4m −0.20 D/0.12 mm −0.34 D/0.16 mm −0.14 D/0.12 mm
Yam et al, ⁵ Hong Kong. LAMP	RCT, N438, mean age 8.5 yrs, mean SE −3.9 D		−0.07 D/0.13 mm 0.05 D/0.11 mm −0.46 D/0.29 mm −0.81 D/0.41 mm
SNEC audit, Singapore (unpublished)	Retrospective, N81, mean age 8.3 yrs, mean SE −4.01 D	A0.025%	−0.22 D/0.24 mm
Bao et al, ¹⁰ China	RCT, N157 8-13YO, mean age 10.4 yrs, mean SE −2.50 to −2.55 D	HALT Placebo	−0.10 D/0.08 mm −0.27 D/0.13 mm −0.34 D/0.20 mm −0.81 D/0.36 mm
Sankaridurg et al, ¹¹ Vietnam	RCT, N119 7-13 yrs, mean age 11 yrs, mean SE −3.42 D	HALT Placebo	−0.20 D/0.05 mm −0.33 D/0.14 mm
Huang et al, ²² China	Retrospective, N107, 7-12 yrs 1-5 D mean age 9.06 yrs, mean SE −2.59 D	DIMS+A0.01% DIMS Placebo	−0.49 D/0.28 mm −0.79 D/0.41 mm −1.07 D/0.52 mm
Nucci et al, ²³ Europe	Prospective cohort, N146, 6-18 yrs Mean SE −1.5 to −2	DIMS+A0.01% Placebo	−0.30 D/0.05 mm −0.71 D/0.17 mm

A = atropine; DIMS = defocus incorporated multiple segments; HALT = Highly Aspherical Lenslet Target; LAMP = Low-Concentration Atropine for Myopia Progression; RCT = randomized controlled trial; SNEC = Singapore National Eye Centre.

However, given the differences in inclusion and exclusion criteria, study design, study populations, and background factors, this may limit the direct comparability of results across various combination studies. Hence, these conclusions should be treated as preliminary until further evidence is available.

This study builds on existing literature by providing evidence that combination therapy may offer superior control of myopia compared with atropine monotherapy, especially in those who fare poorly at monotherapy. This has great significance in optimizing myopia control treatment, not only in terms of efficacy but also in reducing side effects risks from the potential alternative of increasing atropine dose.

The strengths of this study include being able to answer a common clinical question and provide preliminary evidence that children still progressing on LDA may benefit from combination therapy with HALT lenses. Study limitations include a small sample size, absence of a monotherapy control group, reliance on historical or past data as comparison, and a short study duration of 12 months. In this prospective single-arm, noncontrolled cohort study, children were invited to take part in the study, but clinician's advice on management and parental or child's choice may lead to selection and sampling biases. Estimating myopia

progression in the 6 months prior using a time-based formulae may result in some over- and underestimation of SE and AL progression. Compliance to atropine eye drops and HALT lenses wear could potentially be variable (subject to recall and reporting bias). It is possible that reductions in myopia progression after the addition of HALT lenses could be partially due to the natural age-related deceleration in myopia progression. The small sample size may reduce the statistical power of this study and introduce bias especially when interpreting the multivariate analysis. Given the small sample size and potential confounders, our conclusion that HALT glasses benefit children who continue to progress on LDA remains preliminary and requires validation through a larger randomized control study.

Conclusions

In a multiethnic Singaporean population, the addition of HALT lenses was effective in slowing down myopia progression in children still progressing on LDA alone. These findings suggest that dual approaches targeting both optical and pharmacologic pathways offer enhanced control of myopia progression. Future research should explore longer-term outcomes and the sustainability of these interventions for different myopia progression profiles.

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HUMAN SUBJECTS: Human subjects were included in this study. Consent and assent was taken from the parent and patient, respectively. The study was conducted in accordance with the tenets of the Declaration of Helsinki, and ethics approval was obtained from the SingHealth Institutional Review Board.

No animal subjects were used in this study.

Author Contributions:

Conception and design: Sim B., Loh, Chia

Data collection: Sim B., Loh, Htoon, Balakrishnan, Chan, Sim R., Lam, Chia

Analysis and interpretation: Sim B., Loh, Htoon, Sim R., Chia

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Overall responsibility: Sim B., Loh, Chia

Abbreviations and Acronyms:

AL = axial length; **D** = diopters; **DIMS** = defocus incorporated multiple segments; **HALT** = Highly Aspherical Lenslet Target; **LDA** = low-dose atropine; **SE** = spherical equivalent.

Keywords:

Atropine, Highly Aspherical Lenslet Target (HALT), Myopia control spectacles, Optical intervention, Pediatric Ophthalmology, Stelvest.

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