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Effect of spectacle lenses with aspherical lenslets on choroidal thickness in myopic children: a 2-year randomised clinical trial

Yingying Huang ,^{1,2} Xue Li,^{1,2} Junqian Wu,¹ Jiawen Huo,¹ Fengchao Zhou,¹ Jiali Zhang,¹ Adeline Yang,^{2,3} Daniel P Spiegel,^{2,3} Hao Chen ,¹ Jinhua Bao ^{1,2}

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For numbered affiliations see end of article.

Correspondence to

Dr Jinhua Bao, Eye Hospital and School of Ophthalmology and Optometry, Wenzhou Medical University, Wenzhou, Zhejiang, China; baojessie@163.com and Professor Hao Chen, Eye Hospital and School of Ophthalmology and Optometry, Wenzhou Medical University, Wenzhou, China; chenhao@mail.eye.ac.cn

YH and XL contributed equally. HC and JB contributed equally.

YH and XL are joint first authors.

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ABSTRACT

Objective Spectacle lenses with highly aspherical lenslets (HAL) and slightly aspherical lenslets (SAL) showed effective myopia control. This study was to investigate their effects on macular choroidal thickness (ChT) in myopic children.

Methods Exploratory analysis from a 2-year, double-masked, randomised trial. 170 children aged 8–13 years with myopia between -0.75 D and -4.75 D, astigmatism of 1.50D or less, and anisometropia of 1.00D or less were recruited. Participants were randomly assigned in a 1:1:1 ratio to receive HAL, SAL or single vision spectacle lenses (SVL). The subfoveal, parafoveal and perifoveal ChT were evaluated every 6 months.

Results 154 participants completed all examinations. The ChT showed significant changes over time in all three groups in all regions (all $p < 0.05$). The ChTs continuously decreased in the SVL group (ranging from -20.75 (SD 22.34) μm to -12.18 (22.57) μm after 2 years in different regions). Compared with the SVL group, ChT in the SAL group decreased less (ranging from -16.49 (21.27) μm to -5.29 (18.15) μm). In the HAL group, ChT increased in the first year and then decreased in the second year (ranging from -0.30 (27.54) μm to 8.92 (23.97) μm after two years). The perifoveal ChT decreased less than the parafoveal ChT, and the superior region decreased the least.

Conclusions The ChT of the macula decreased after 2 years of myopia progression with SVL. Wearing spectacle lenses with aspherical lenslets reduced or abolished the ChT thinning and HAL had a more pronounced effect.

Trial registration number ChiCTR1800017683.

INTRODUCTION

The highly vascular choroid, located between the retinal pigment epithelium and the sclera, supplies oxygen and nutrients to the outer retina and plays an essential role in vision-guided eye growth. The choroid is hypothesised to influence visually guided eye growth via two mechanisms. The first is a change in choroidal thickness (ChT) that pushes the retina close to the focal plane.^{1,2} The second is a change in choroidal blood flow, which can initiate a cascade of signalling molecules or growth factors from the retina to the sclera and induce remodelling of the extracellular matrix resulting in alterations in eye growth.^{1,2}

The placement of positive or negative lenses in front of the eyes to induce myopic or hyperopic defocus is a commonly used method to induce

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The introduction of myopic defocus in the myopic children for a short time resulted in a significant thickening of choroid thickness and shortening of axial length, but the changes restored after removal of defocus.

WHAT THIS STUDY ADDS

⇒ Wearing spectacle lenses with aspherical lenslets for 2 years can inhibit the thinning of the choroid and slow down axial length elongation with a dose-dependent effect.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Changes of choroid thickness can be used as a short-term indicator to reflect the long-term effectiveness of myopia control lenses.

experimental hyperopia or myopia in animal models. Notably, axial elongation with the visual-guided pattern generated by defocus lenses has been significantly correlated with changes in ChT.^{3–7} Previous animal studies showed rapid, temporary and reversible changes in ChT and axial length (AL) after inducing hyperopic or myopic defocus in chicks,^{3–6} guinea pigs,⁹ marmosets,¹⁰ and macaque monkeys.¹¹ Wildsoet and Wallman also found that a higher defocus magnitude (± 15 diopters (D) vs ± 6 D) induced more significant changes in ChT and AL in chicks.⁵

Similar observations have been reported in humans. For young myopic and emmetropic human adults, a +2 D myopic defocus significantly increased the ChT in as little as 10 min (reverse changes in 30 min for -2 D hyperopic defocus) and sustained it for the entire defocus time.¹² Two hours of defocus induced by +3 D and -3 D lenses increase and decrease subfoveal ChT (SF ChT) in myopic children, respectively. These changes gradually revert after removing the lenses.¹³ Many recent studies in humans focused on short-term defocus on ChT (such as 2 hours) and found that the ChT reverted to baseline value once the defocus was removed.^{12,13} Therefore, long-term observation to determine the real impact of defocus on ChT and its relationship with axial elongation is needed.

Recent studies on myopia control based on myopic defocus have involved orthokeratology

(OK),¹⁴ bifocal and multifocal soft contact lenses,¹⁵ and specially designed spectacles.¹⁶ OK lens wearing for 1 week caused a rapid increase in the ChT¹⁷ that was sustained for the entire wearing period.^{7,18} However, after the cessation of lens wearing, the ChT quickly reverted to the baseline thickness.¹⁹ In those wearing bifocal soft contact lenses, the ChT showed no significant changes after lens wearing for 30 min.²⁰ Few studies have reported the effects of long-term wearing of specific spectacles with myopic defocus on ChT in children.

We have recently investigated the efficacy of two new myopia control spectacle lenses with lenslets with different asphericity and found that both spectacle lenses with highly aspherical lenslets (HAL) and spectacle lenses with slightly aspherical lenslets (SAL) effectively reduced the rate of myopia progression and axial elongation compared with single vision spectacle lenses (SVL) over 2 years, with the highest efficacy for HAL.²¹ At each study visit, we also collected optical coherence tomography (OCT) images (see the Method section for further details), and the purpose of this paper is to evaluate the effects of spectacle lenses with aspherical lenslets on ChT. We hypothesised that the changes in ChT would be related to the myopia control efficacy of the test lenses, and HAL would have a stronger effect.

METHODS

Study design

This 2-year, double-blind, randomised clinical trial was conducted at the Eye Hospital of Wenzhou Medical University. Participants were followed every 6 months for 2 years. The details of the study have been published previously,^{21,22} and the changes in ChT were an exploratory outcome in the study. 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. The inclusion criteria were age 8–13 years, spherical equivalent refraction between -0.75 D and -4.75 D, astigmatism of not more than 1.50 D, anisometropia of not more than 1.00 D, no strabismus or other ocular disease, and no myopia control history. Participants were randomised in a 1:1:1 ratio to receive HAL, SAL or SVL.^{21,22}

Measurements

To exclude the effects of accommodation on refraction, cycloplegia was performed with two drops of 1% cyclopentolate, with an interval of 5 min between drops; measurements were performed at least 30 min after administration of the second drop. AL was measured by Lenstar ocular biometry (LS900, Haag-Streit International, Koeniz, Switzerland). Five individual measurements with no more than 0.02 mm differences were obtained and averaged.

All participating children underwent macular scans using swept-source OCT (Topcon Corporation, Tokyo, Japan). The instrument's follow-up mode was activated, and built-in software was used to segment layers and construct topographic maps. The 'follow-up' mode means that the machine defines the first image as the benchmark, and all the subsequent shots of the same subject are positioned according to the features in the first image, therefore, the images can be captured at the same position in the fundus in all visits. The SF ChT was measured three times with a 9 mm line scan composed of 128 single A-scans. Twelve-line radial scans centred on the fovea, 6 mm in length and separated by 15°, were obtained three times. Each radial OCT image was constructed from an average of 16 scans. A central 6×6 mm circular region was partitioned automatically

according to the Early Treatment Diabetic Retinopathy Study (ETDRS).²³ The nine regions were classified as the central foveal, 3 mm nasal (N3), 3 mm superior (S3), 3 mm temporal (T3), 3 mm inferior (I3), 6 mm nasal (N6), 6 mm superior (S6), 6 mm temporal (T6) and 6 mm inferior (I6) regions. The scan length was adjusted by the instrument based on AL and refractive error of the individual participants at each visit. The ChT was determined as the thickness between the outer retinal pigment epithelium and the inner choroidoscleral interface. The average ChT of each region was calculated by integrated software. To avoid the influence of variability in anatomical features on automatic techniques, manual corrections for boundaries (retinal-choroidal and choroidal-scleral interfaces) were conducted by two masked and well-trained independent observers. The two observers made manual correction in all OCT images in every participant. The images were reanalysed if the differences between the results of the two observers were more than 10 µm. The repeatability of the ChT measurements of all visits in different regions between two observers was shown in online supplemental figure 1; they showed good repeatability with mean differences from -0.99 µm to 1.19 µm, the smallest 95% limits of agreement -8.59 to 6.60 µm were at SF ChT, and the largest 95% limits of agreement -9.89 to 10.49 µm were at T6 ChT. The results of the three measurements obtained by two observers were averaged.

Statistical analysis

IBM SPSS Statistics for Windows, V.24.0 (IBM, Released 2016,) was used for data analysis. Only right-eye data were included in the analysis. Repeated-measures analysis of variance was computed to assess the impact of time (5 visits), region (SF and 9 ETDRS regions, 10 regions in total) and group (3 groups) on the ChT. The relationship between the change in AL and baseline SF ChT or between the change in AL and the change in SF ChT was tested using Pearson correlation analysis. Values $p < 0.05$ were considered to be statistically significant difference.

RESULTS

This study initially included 170 participants, but 3 discontinued at baseline and 9 were lost to follow-up, due to changes in spectacles or OK lenses use ($n=4$), relocation ($n=2$), follow-up refusal ($n=3$), cycloplegia refusal ($n=1$), intermittent exotropia ($n=1$) and history of progressive addition lenses use ($n=1$). In addition, one participant missed the 18-month visit but came back for the 24-month visit. Of the 157 participants who attended the complete 2-year visit, 3 participants did not have complete OCT data. Consequently, 154 participants were included in the analysis (figure 1). The 18-month follow-up was scheduled for February 2020, during the COVID-19 epidemic in China. Therefore, the 18-month follow-up was delayed to March to April 2020, resulting in delays of 17 (SD 19) days, the same in the three groups ($F_{2,151} = 0.90$, $p=0.91$). In the meantime, participants experienced home-school courses, which involved near-work without outdoor activities.

There was significant sex ($p=0.03$) and baseline AL ($p=0.03$) differences among the groups (table 1). The SAL group contained more girls and had a shorter AL than the other two groups. There were no differences in baseline SF ChT or ChT values in the ETDRS regions among the three groups before and after adjustment for sex and AL (all $p > 0.05$, table 2).

Significant interaction was found between time and group ($p < 0.001$), and between time and region ($p < 0.001$), but not between group and region ($p > 0.99$). The ChT showed significant changes over time in all three group in all regions (figures 2

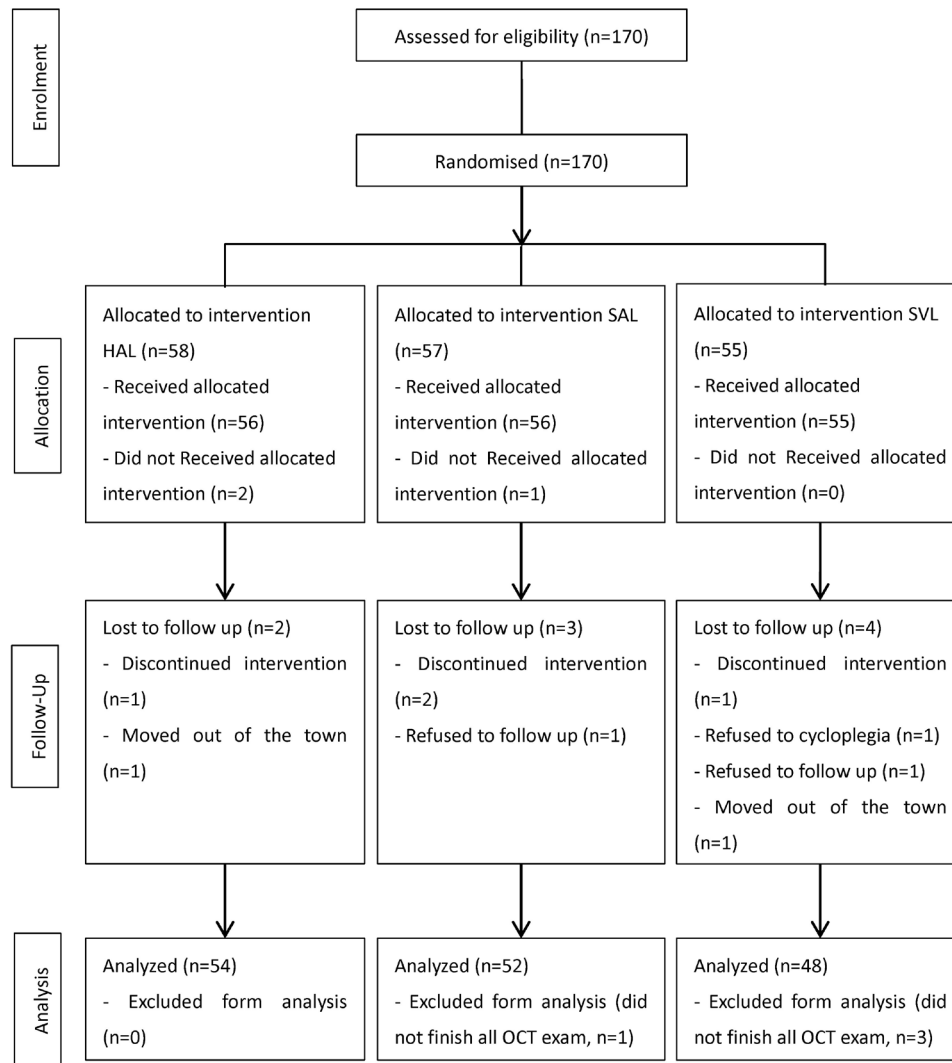


Figure 1 Consolidated Standards of Reporting Trials flow diagram of the study. HAL, highly aspherical lenslets; OCT, optical coherence tomography; SAL, slightly aspherical lenslets; SVL, single vision spectacle lenses.

and 3, table 2). The SVL group showed the largest consistent decrease ChT in all regions (all $p < 0.05$, figure 2C,F). The ChT in the SAL group increased during the first 6 months and then decreased until the end of follow-up ($p < 0.05$ in all regions, figure 2B,E). The ChT in the HAL group increased in the first year and decrease in the second year ($p < 0.05$ in all regions, figure 2A,D). The ChTs of the outer regions decreased less than the inner regions, and the ChTs of the superior regions decreased the least in the parafovea and perifovea in all three groups (all

$p < 0.05$). This ChT change pattern of different regions did not differ between the three groups as there was no significant interaction between group and region.

Two-year AL elongation was significantly different among groups ($F_{2,151} = 25.64$, $p < 0.001$, table 1), occurred significantly faster in the SVL group than in the HAL ($p < 0.001$) and SAL ($p = 0.001$) groups, and participants in the SAL group exhibited a faster elongation than those in the HAL group ($p = 0.002$). Changes in the SF ChT were negatively correlated with changes in AL in all groups ($r = -0.53$, $p < 0.001$ in the HAL group; $r = -0.48$, $p < 0.001$ in the SAL group; $r = -0.36$, $p = 0.01$ in the SVL group, figure 3). The 2-year change in AL was not correlated with baseline SF ChTs in any group ($r = -0.15$, $p = 0.29$ in the HAL group; $r = 0.22$, $p = 0.12$ in the SAL group; $r = 0.02$, $p = 0.92$ in the SVL group).

DISCUSSION

The main purpose of this study was to determine the long-term influence of spectacle lenses with aspherical lenslets on macular ChT. The ChT was decreased in the control SVL group, while the ChT in the HAL group did not decrease despite AL elongation after 2 years; the ChT in the SAL group also decreased, but to a lesser degree than that in the SVL group. There were

Table 1 Baseline characteristics and al elongation of participants

Parameters	HAL (n=54)	SAL (n=52)	SVL (n=48)
Age	10.65 (1.15)	10.25 (1.19)	10.38 (1.21)
Gender (M/F)	26/28	17/35	28/20
SER (D)	-2.70 (1.02)	-2.28 (0.96)	-2.46 (0.90)
AL (mm)	24.76 (0.68)	24.44 (0.76)	24.77 (0.67)
2 year AL elongation (mm)	0.34 (0.25)	0.50 (0.23)	0.68 (0.24)

Data are expressed as the mean (SD).

AL, axial length; D, dioptres; F, female; HAL, spectacle lenses with highly aspherical lenslets; M, male; SAL, spectacle lenses with slightly aspherical lenslets; SER, spherical equivalent of refraction; SVL, single-vision spectacle lenses.

Table 2 Choroidal thickness over time

Regions	Baseline			6 Months			12 Months			18 Months			24 Months		
	HAL	SAL	SVL	HAL	SAL	SVL	HAL	SAL	SVL	HAL	SAL	SVL	HAL	SAL	SVL
SF ChT	223 (59)	239 (64)	220 (47)	227 (62)	236 (67)	212 (43)	230 (61)	230 (61)	204 (46)	224 (63)	223 (60)	197 (47)	230 (64)	228 (57)	205 (46)
C ChT	231 (57)	248 (64)	228 (44)	241 (61)	250 (65)	224 (43)	244 (61)	245 (60)	217 (46)	236 (62)	235 (60)	208 (45)	232 (63)	231 (57)	207 (47)
N3 ChT	205 (53)	221 (60)	202 (45)	215 (57)	224 (60)	200 (43)	217 (56)	220 (56)	193 (45)	210 (58)	212 (56)	186 (45)	208 (57)	210 (53)	187 (47)
S3 ChT	237 (58)	252 (58)	233 (44)	249 (63)	258 (59)	231 (43)	253 (62)	254 (55)	225 (45)	246 (63)	246 (54)	216 (44)	242 (63)	241 (50)	216 (46)
T3 ChT	246 (56)	261 (61)	242 (43)	254 (61)	265 (63)	239 (43)	258 (58)	259 (57)	232 (46)	251 (61)	250 (58)	223 (45)	246 (62)	245 (55)	222 (48)
I3 ChT	233 (54)	254 (62)	231 (47)	242 (56)	258 (65)	230 (48)	246 (56)	254 (58)	223 (51)	239 (57)	246 (61)	215 (50)	234 (57)	240 (57)	214 (52)
N6 ChT	167 (45)	181 (53)	165 (42)	177 (49)	185 (52)	165 (40)	177 (48)	183 (50)	159 (42)	168 (50)	172 (49)	150 (41)	167 (50)	172 (47)	152 (44)
S6 ChT	238 (54)	249 (52)	235 (46)	252 (59)	258 (52)	234 (45)	256 (57)	256 (49)	231 (49)	249 (58)	247 (48)	222 (48)	247 (59)	244 (46)	223 (49)
T6 ChT	252 (52)	264 (55)	248 (42)	261 (56)	272 (56)	247 (43)	264 (54)	265 (49)	239 (44)	255 (53)	257 (52)	229 (44)	253 (57)	253 (50)	229 (46)
I6 ChT	226 (50)	249 (57)	226 (46)	235 (53)	256 (60)	225 (47)	240 (53)	254 (54)	219 (49)	232 (53)	244 (57)	210 (49)	229 (53)	239 (53)	210 (50)

Data are expressed as mean (SD).

AL, axial length; C, Central 1 mm; ChT, choroidal thickness; HAL, spectacle lenses with highly aspherical lenslets; I3, 3 mm inferior; I6, 6 mm inferior; N3, 3 mm nasal; N6, 6 mm nasal; N6, 6 mm superior; S3, 3 mm superior; S6, 6 mm superior; SAL, spectacle lenses with slightly aspherical lenslets; SF, subfoveal; SVL, single vision spectacle lenses; T3, 3 mm temporal; T6, 6 mm temporal.

significant negative correlations between the changes in AL and SF ChT in all groups.

Previous animal and clinical studies showed that short-term myopic defocus increased ChT in a transient and reversible way. Our study detected long-term changes in ChT and showed similar results. Over 2 years of lens wearing, SAL had little effect on increasing the ChT; furthermore, the choroid started to thin after the 6-month visit. Therefore, lenslets with slight asphericity may not be sufficient to prevent thinning of the ChT caused by axial elongation in the long term, and there may be a minimum lenslet asphericity required to prevent thinning. Lenslets with higher asphericity had a greater effect on preventing the ChT thinning. Among participants wearing HAL for 1 year, the ChT increased more than 10 μm (range: 11–16 μm) in all regions. However, in the second year, all the regions started to thin and finally showed no difference from the values at baseline. We assume that the retina gradually adapted and became less

sensitive to defocus signals; therefore, the effect on choroidal thickening and myopia control reduced with time.

There were significant differences in the changes in the ChTs among the different regions. The lack of a significant interaction for group and region means the concentric rings design of lenslets had a similar influence on different regions of the choroid. The trend of change among regions was consistent across all three groups. The outer regions decreased less than the inner regions, and the superior regions showed the smallest decreases. Previous studies showed that when compared with emmetropic or hyperopic children, myopic children had the fewest changes in the superior region of the choroid.^{24 25} Studies on myopia progression also showed that the smallest decrease in ChT occurred in the superior regions.^{25 26} The reasons for this minor change in the superior ChT during myopia development and progression remain unknown. The sensitivities of different choroidal regions to myopic or hyperopic defocus can be further

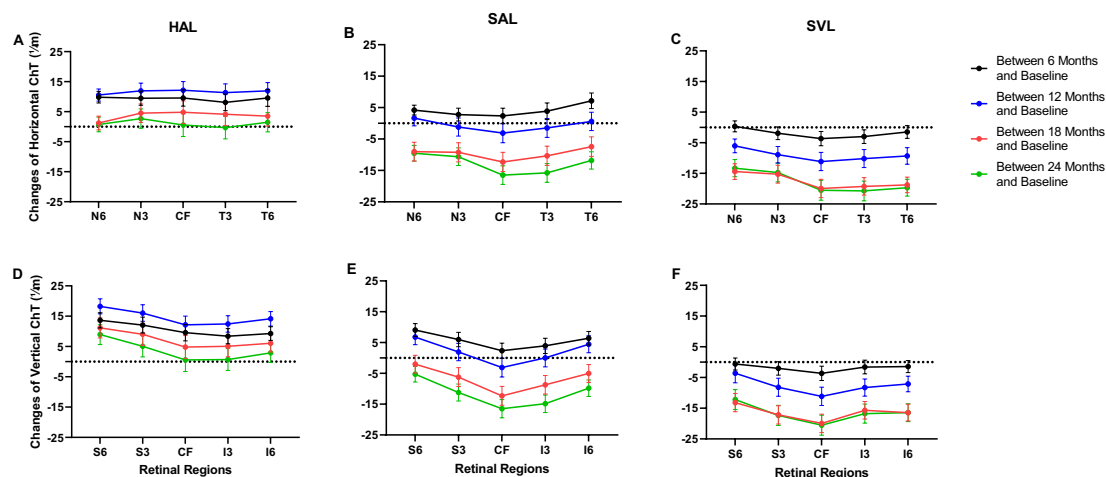


Figure 2 ChT changes in horizontal (A–C) and vertical (D–F) regions in the three groups. Changes in ChT between baseline and 6 months are shown in black, changes between 6 months and 12 months are in blue, changes between 12 months and 18 months are in red, changes between 18 months and 24 months are in green. Error bars represent one SE of the mean. CF, central foveal; ChT, choroidal thickness; HAL, spectacle lenses with highly aspherical lenslets; I3, 3 mm inferior region; I6, 6 mm inferior region; N3, 3 mm nasal region; N6, 6 mm nasal region; S3, 3 mm superior region; S6, 6 mm superior region; SAL, spectacle lenses with slightly aspherical lenslets; SVL, single vision spectacle lenses; T3, 3 mm temporal region; T6, 6 mm temporal region.

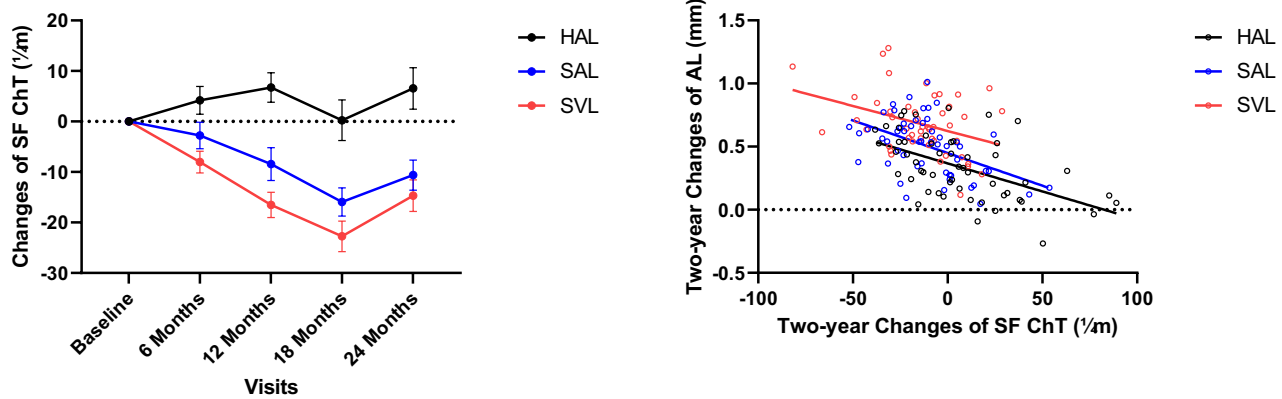


Figure 3 Changes in subfoveal ChT (A) and correlation with axial length (AL) in the three groups (B). Changes in ChT and correlation with AL are shown in black for the HAL group, in blue for SAL group and in red for SVL group. Error bars represent one SE of the mean. ChT, choroidal thickness; HAL, spectacle lenses with highly aspherical lenslets; SAL, spectacle lenses with slightly aspherical lenslets; SF, subfoveal; SVL, single vision spectacle lenses.

tested to determine the reasons for this phenomenon in the superior ChT.

The changes in the ChT at 18 months and 24 months were not consistent with those in the first year. The ChT revealed more decrease between the 12-month and the 18-month visits than in the first year, but less decrease between the 18-month and the 24-month visits (figure 2). One reason for this inconsistent change was a relatively long period of 18-month visit (7 months) and a shorter period of 24-month visit (5 months) because of COVID-19. Another hypothesis is that 1 month of near-work without outdoor activities before the 18-month visit led to transient but reversible thinning. Ghosh *et al*²⁷ and Woodman *et al*²⁸ found a decrease in the ChT with short-term accommodation that quickly reversed after relaxation of the accommodation. One month of near-work in our study (homeschooling from February to the date of visit²⁹) may have induced additional thinning of ChT besides myopia progression at the 18-month visit, but this additional thinning may have reversed after participants stopped homeschooling (the end of May 2020,²⁹ so the degree of thinning at the 24-month follow-up was less than other visits). The AL also showed the most elongation between 12 months and 18 months compared with other periods (0.12 mm, 0.15 mm, 0.21 mm between 12 months and 18 months, 0.34 mm, 0.50 mm, 0.68 mm for 2 years in the HAL, SAL and SVL group, respectively).

Both two test lenses in our study showed effective myopia control. Interestingly, after 2 years, the AL of three participants in the HAL group was shortened (−0.04 mm, −0.09 mm and −0.27 mm). Short-term myopic defocus induced by positive lenses worn for 1 hour significantly shortened the AL by approximately 10 µm, equal to the changes in ChT.³⁰ In our study, after accounting for the changes in the ChT and the central corneal thickness, three participants still had AL shortening of more than 0.02 mm, which was more than the measurement error range and diurnal fluctuations. It indicates that the changes in ChT cannot fully explain the effect of HAL and SAL on myopia control.

The OCT examinations were done after two drops of cyclopentolate in this study, while previous studies showed this cycloplegic agent would alter ChT. Bahar *et al*³¹ found that ChT decreased by 1 µm after 1% cyclopentolate. Ye *et al*³² also found cyclopentolate caused a 3 µm decrease in ChT. We did

not explore the influence of cycloplegia on the ChT, but all OCT exams were done at least 30 min after that last drop of cyclopentolate in all visits. On the other hand, participants were randomly assigned to three groups, and ChT had no difference among groups at baseline. We believe cycloplegia had the same impact on each ChT measurement and did not affect the results.

A limitation of this study is that the ChT measurement times were inconsistent between the visits. The times varied between 9:00 and 16:00 hours, and therefore, there is a possibility of diurnal fluctuations on ChT ($\pm 10 \mu\text{m}$).³³ As this study is a randomised and long-term follow-up design, we consider this limitation has little impact on the overall results and conclusions.

CONCLUSIONS

The macular ChT in myopic children had a lower degree of thinning or an increase after the use of spectacle lenses with aspherical lenslets for 2 years compared with the use of SVL, and the HAL had a better effect. For all groups, the outer regions experienced less thinning than the inner regions, and the superior choroidal regions had the most significant increases (HAL) or most minor decreases (SAL and SVL) in thickness compared with all other regions. More attention should be given to the properties of the superior choroid in the clinic rather than only the SF choroid. One month of homeschooling during the COVID-19 epidemic led to transient but reversible thinning of the choroid, and associations of near-work with ChT and myopia progression should be further explored.

Author affiliations

¹Eye Hospital and School of Ophthalmology and Optometry, Wenzhou Medical University, Wenzhou, Zhejiang, China

²Wenzhou Medical University–Essilor International Research Center (WEIRC), Wenzhou Medical University, Wenzhou, China

³Essilor International SA, Singapore

Contributors JB and HC are guarantors. YH and XL share cofirst authorship.

Concept and design: JB and HC. Acquisition, analysis, or interpretation of data: YH, XL, JW, JH, FZ, JZ, JB and HC. Drafting of the manuscript: YH. Critical revision of the manuscript for important intellectual content: Huang, XL, JW, JH, FZ, JZ, AY, DPS, HC and JB. Statistical analysis: YH, XL, JB. Obtained funding: YH, JB and HC. Administrative, technical or material support: JB, YH, XL and YH. Supervision: JB and HC.

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Competing interests AY and DPS are employees of Essilor International. This company supplied the study devices.

Patient consent for publication Consent obtained directly from patient(s).

Ethics approval This study involves human participants and was approved by Ethics Committee of the Eye Hospital of Wenzhou Medical University approved this study (Y2018-054). Participants gave informed consent to participate in the study before taking part.

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ORCID iDs

Yingying Huang <http://orcid.org/0000-0001-7694-513X>

Hao Chen <http://orcid.org/0000-0002-8594-5630>

Jinhua Bao <http://orcid.org/0000-0002-2103-8345>

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