Myopia control with spectacle lenses with aspherical lenslets: a 2-year randomized clinical trial

Author Block: *Jinhua Bao[1,2] , Yingying Huang[1,2] , XUE LI[1,2] , Adeline Yang[3,2] , Ee Woon Lim[3,2] , Daniel Spiegel[3,2] , Bjorn Drobe[3,2] , Hao Chen[1,2]*
[1] Eye Hospital and School of Ophthalmology and Optometry of Wenzhou Medical University, China; [2] Wenzhou Medical University–Essilor International Research Center (WEIRC), China; [3] R&D AMERA, Essilor International, Singapore

Disclosure Block: Jinhua Bao, R&D AMERA, Essilor International (Code F (Financial Support)); Yingying Huang, R&D AMERA, Essilor International, (Code F (Financial Support)); XUE LI, R&D AMERA, Essilor International, (Code F (Financial Support)); Adeline Yang, R&D AMERA, Essilor International, (Code E (Employment)); Ee Woon Lim, R&D AMERA, Essilor International, (Code E (Employment)); Daniel Spiegel, R&D AMERA, Essilor International, (Code E (Employment)); Bjorn Drobe, R&D AMERA, Essilor International, (Code E (Employment)); Hao Chen, R&D AMERA, Essilor International, (Code F (Financial Support))

Purpose: To investigate the myopia control efficacy of two new designs of spectacle lenses with concentric rings of contiguous aspherical lenslets in a 2-year clinical trial.

Methods: One hundred and seventy Chinese children (aged 8 to 13 years old, myopia between -0.75D and -4.75D) with myopia were randomly assigned to wear one of the three spectacle lenses: spectacle lenses with highly aspherical lenslets (HAL), spectacle lenses with slightly aspherical lenslets (SAL), or control single-vision lenses (SVL) for 2 years. Spherical equivalent of cycloplegic autorefraction (SER) and axial length (AL) were measured on a six-monthly basis. Wearing time was assessed using a questionnaire at each visit.

Results:A total of 157 children completed the 2-year study, of which, 54, 53, and 50 were in the HAL group, SAL group, and SVL group, respectively. After 2 years, the mean SER and AL (± SEM) of the SVL control group increased by -1.46 ± 0.60 D and 0.69 ± 0.26 mm, respectively. Compared with SVL, spectacle lenses with aspherical lenslets significantly slowed myopia progression (HAL, -0.66 ± 0.08 D, difference 0.80 D; SAL, -1.04 ± 0.06 D, difference 0.42 D) and axial elongation (HAL, 0.34 ± 0.03 mm, difference 0.35 mm; SAL, 0.51 ± 0.03 mm, difference 0.18 mm; all $p<0.001$). In children who wore their lenses every day for at least 12 hours per day, the reduction in SER and AL, compared to SVL group, was greater at 0.99 D ($p<0.001$) and 0.41 mm ($p=0.03$) for HAL ($n=32$) and at 0.57 D ($p=0.04$) and 0.26 mm ($p=0.02$) for SAL ($n=28$), respectively.

Conclusions: Spectacle lenses with aspherical lenslets were effective in slowing myopia progression and axial elongation in children over a two-year period, compared with SVL. Myopia control efficacy was higher in children who wore their lenses full-time (≥12 hours/day) and spectacle lenses with highly aspherical lenslets

Myopia Control with spectacle lenses with Aspherical Lenslets: a 2-year randomized clinical trial

***Jinhua Bao*[1,2], Yingying Huang[1,2], Xue Li[1,2], Adeline Yang[2,3], Ee Woon Lim[2,3], Daniel P. Spiegel[2,3], Björn Drobe[2,3], Hao Chen[1]**

1 Eye Hospital, Wenzhou Medical University, Wenzhou, Zhejiang Province, China
2 Wenzhou Medical University–Essilor International Research Center (WEIRC), Wenzhou, Zhejiang Province, China
3 R&D AMERA, Essilor International, Singapore, Singapore

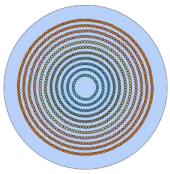
Conflict of interest

Jinhua Bao is an Associate Director of Wenzhou Medical University–Essilor International Research Centre. Adeline Yang, Ee Woon Lim, Daniel P. Spiegel and Björn Drobe are employees of Essilor International, the company that supplied the study device and holds the following patent applications related to this work: WO2019166653 WO2019166654 WO2019166655.

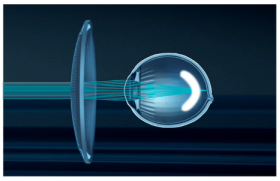
No conflicts of interest exist for the rest of the authors.

Test lenses

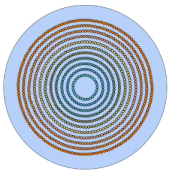
HAL



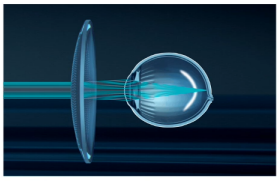
Spectacle lenses with
Highly ***A***spherical
Lenslets

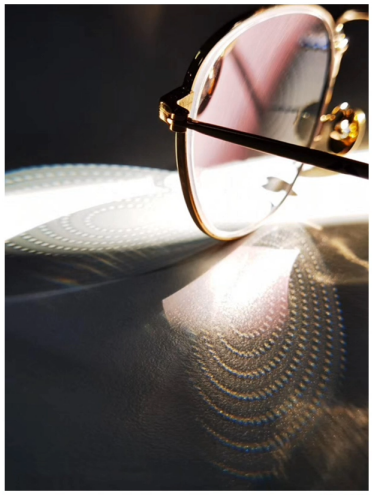


SAL



Spectacle lenses with
Slightly ***A***spherical
Lenslets





Objectives of the MyCAL clinical trial

溫州醫科大學附屬眼視光醫院
溫州醫科大學眼視光學院
浙江省眼科醫院
Eye Hospital, WMU
School of Ophthalmology & Optometry, WMU
Zhejiang Eye Hospital

Based on new spectacle lenses with Aspherical Lenslets:

- *To evaluate the myopia control efficacy of spectacle lenses with Aspherical Lenslets*
- *To evaluate a possible dose-dependent effect of Lenslet Asphericity, i.e., is a higher asphericity more effective in slowing myopia progression than lower asphericity?*

Protocol

Summary

Prospective, Randomized, Double Masked clinical trial

Location: Eye Hospital, Wenzhou Medical University, Wenzhou, China

Duration: 2 years

3 parallel arms:

- ***HAL**: Spectacle lenses with Highly Aspherical Lenslets*
- ***SAL**: Spectacle lenses with Slightly Aspherical Lenslets*
- ***SVL**: Single Vision Lens (control)*

All lenses fitted as SVLs

Primary outcomes:

Cycloplegic autorefraction (SER) in D

Axial length (AL) in mm

Inclusion criteria

Age: 8-13 years

Myopia: -0.75D to -4.75D

Astigmatism: ≤1.50D

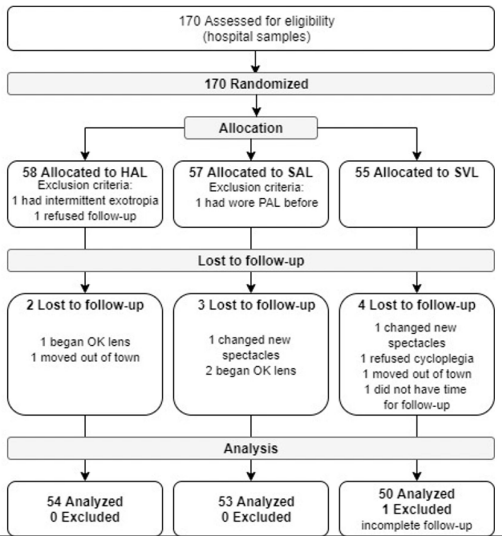
Anisometropia: ≤1.00D

Normal vision

No history of myopia control

WEIRC

Subject randomization & Follow-up



Lost to follow-up @ 24 months

- 9 out of 167 (5.4%)
- No lens related discontinuation

Impact of Covid-19

- Delay of 18M visit by 3 weeks
- 1 child excluded from analysis (did not come for 18M visit)

WEIRC

Baseline characteristics

Baseline demographic data, mean (SD)	HAL (n=54)	SAL (n=53)	SVL (n=50)	P value
Age (years)	10.65 ± 1.15	10.21 ± 1.22	10.36 ± 1.26	0.15
Gender				0.03*
Male, %(n)	48 (26)	32 (17)	58 (29)	
Female, %(n)	52 (28)	68 (36)	42 (21)	
Cycloplegic SER (D)	-2.70 ± 1.02	-2.28 ± 0.95	-2.44 ± 0.87	0.08
Axial length (mm)	24.76 ± 0.68	24.44 ± 0.75	24.77 ± 0.66	0.02*
Age Myopia Onset (years)	9.33 ± 1.4	9.36 ± 1.5	9.34 ± 1.5	0.996
Near Phoria (Δ)	-1.86 ± 6.76	-2.36 ± 6.49	-2.17 ± 6.51	0.92
Acc. Lag at 33 cm (D)	0.94 ± 0.38	1.09 ± 0.28	1.04 ± 0.36	0.06
Myopic parents, %(n)				0.66
0	33 (18)	23 (12)	24 (12)	
1	37 (20)	42 (22)	36 (18)	
2	30 (16)	36 (19)	40 (20)	

Analysis will be adjusted for age, gender, baseline SER, baseline AL, age of myopia onset, number of myopic parents

Adaptation and adherence

Adaptation

No difference in adaption time between groups (p=0.07):

- all children adapted in less than 1 week
- >90% adapted in less than 3 days

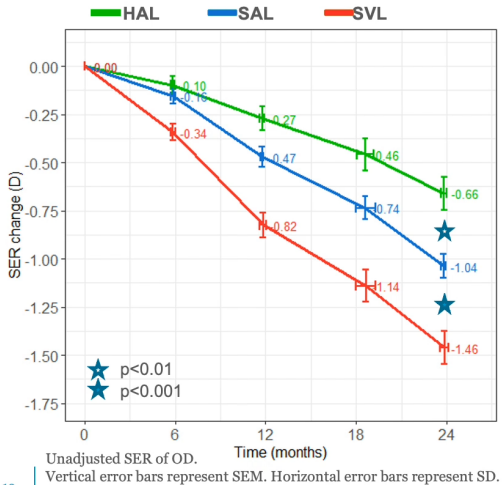
Adherence

No difference in daily wearing time between groups (p=0.37):

- HAL: 13.4 ± 2.2 hours/day
- SAL: 13.5 ± 1.8 hours/day
- SVL: 13.9 ± 1.7 hours/day

Myopia progression

Mean change in Spherical Equivalent Refraction (D) - unadjusted



Unadjusted SER of OD.
Vertical error bars represent SEM. Horizontal error bars represent SD.

Children in SVL progressed fast: ***1.46D*** over 2 years

HAL slowed myopia progression by ***0.80D*** (55%)

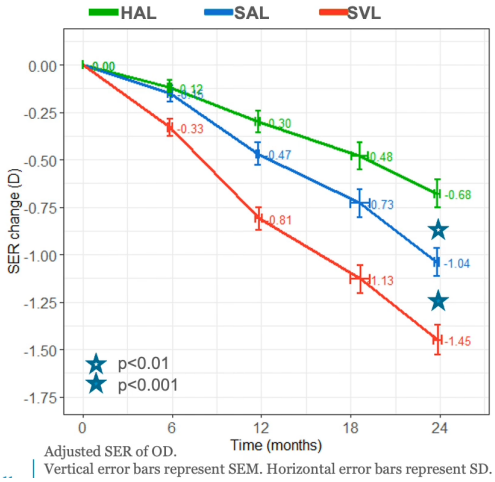
SAL slowed myopia progression by ***0.42D*** (29%)

Larger treatment effect for lenses with higher lenslet asphericity

2x2 p values correspond to Bonferroni post-hoc test for a 1-way ANOVA $F(2,154)=26.09$, $p<0.0001$.

Myopia progression (adjusted)

Mean change in Spherical Equivalent Refraction (D) - adjusted



Adjusted SER of OD.
Vertical error bars represent SEM. Horizontal error bars represent SD.

Comparable results with adjusted* values:

HAL slowed myopia progression by ***0.77D*** (53%)

SAL slowed myopia progression by ***0.41D*** (29%)

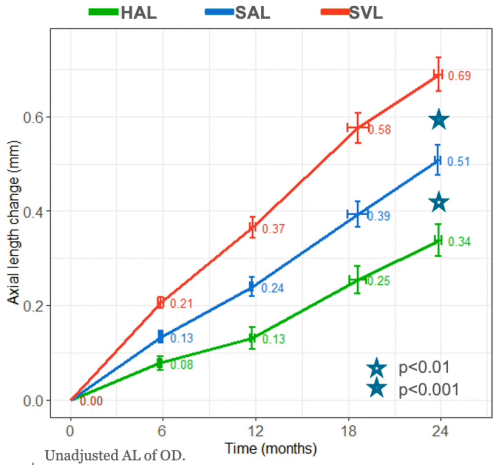
Larger treatment effect for lenses with higher lenslet asphericity

*adjusted for age, gender, baseline SER, baseline AL, age of myopia onset, number of myopic parents

2x2 p values correspond to Bonferroni post-hoc test for a 1-way ANOVA $F(2, 146.8) = 22.31$, $p<0.001$.

Axial elongation

Mean change in Axial Length (mm) - unadjusted



Children in SVL progressed fast: ***0.69mm*** over 2 years

HAL slowed axial elongation by ***0.35mm*** (51%)

SAL slowed axial elongation by ***0.18mm*** (26%)

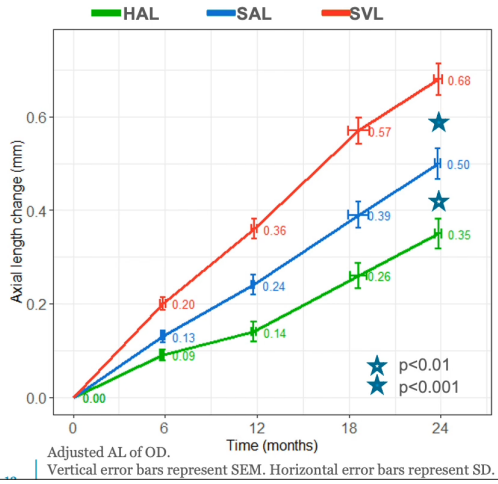
Larger treatment effect for lenses with higher lenslet asphericity

Unadjusted AL of OD.
Vertical error bars represent SEM. Horizontal error bars represent SD.

2x2 p values correspond to Bonferroni post-hoc test for a 1-way ANOVA $F(2,154)=26.36$, $p<0.0001$.

Axial elongation (adjusted)

Mean change in Axial Length (mm) - adjusted



Comparable results with adjusted* values:

HAL slowed axial elongation by ***0.34mm*** (50%)

SAL slowed axial elongation by ***0.18mm*** (26%)

Larger treatment effect for lenses with higher lenslet asphericity

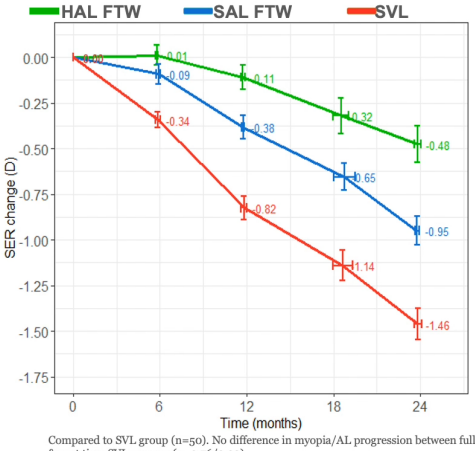
*adjusted for age, gender, baseline SER, baseline AL, age of myopia onset, number of myopic parents (SPSS)

Adjusted AL of OD.
Vertical error bars represent SEM. Horizontal error bars represent SD.

2x2 p values correspond to Bonferroni post-hoc test for a 1-way ANOVA $F(2, 142.0)= 30.76$, $p<0.0001$.

Wearing time

Full-time wearing of spectacles



Compared to SVL group (n=50). No difference in myopia/AL progression between full & part time SVL wearers (p=0.76/0.92).
Significant effect of wearing time in myopia/AL progression between full & part time SAL (n=28, p=0.04/0.02) and HAL (n=32, p<0.01/p=0.03) wearers.

Full-time wearer (FTW): ≥12 h/day, every day*

More than half of children wore their lenses full time

Myopia control increased significantly for full time wearers:

	SER	*AL*
HAL (FTW)	***0.99 D*** (67%)	***0.41 mm*** (60%)
SAL (FTW)	***0.57 D*** (39%)	***0.26 mm*** (38%)

Difference between full-time treatment wearers and control

*Calculated on the first 12 months

Conclusion

MyCAL 2-year Clinical Trial

Adaptation and adherence was comparable between HAL , SAL and SVL

Spectacle lenses with aspherical lenslets slow myopia progression over 2 years

Increased treatment effect with asphericity of lenslets for all children

SER: 0.80D (HAL) vs. 0.42D (SAL)
AL: 0.35mm (HAL) vs. 0.18mm (SAL)

Increased treatment effect with wearing time (HAL)

SER (full time): 0.99D (67%)
AL (full time): 0.41mm (60%)

Thank you
谢 谢

Vision for *Vision*
有"眼力"才会有"远见"
Eye for 爱 ai
小眼睛里有大爱

温州医科大学附属眼视光医院
温州医科大学眼视光学院
浙江省眼科医院
Eye Hospital, WMU
School of Ophthalmology & Optometry, WMU
Zhejiang Eye Hospital

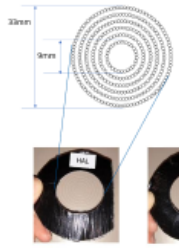
ESSILOR
RESEARCH & DEVELOPMENT

Impact of myopia control spectacle lenses with aspherical lenslets on peripheral vision

Yi GAO, Ee Woon LIM, Adeline YANG, Björn DROBE
R&D AMERA, Essilor International, Singapore

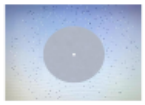
Introduction

Spectacles with peripheral lenslets have shown promising myopia control effect[1,2]. How do these lenslets affect the peripheral vision?

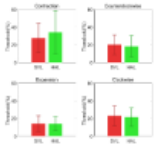


Tested lenses:
1. Spectacle lenses with highly aspherical lenslets (HAL)
2. Spectacle lenses with slightly aspherical lenslets (SAL)
3. Single vision lens (SVL)

Peripheral Global Motion

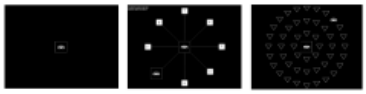


- Adults, N = 8, mix of myopes, emmetropes, hyperopes
- Only tested HAL and SVL
- Global motion task, discriminate between 4 motion directions, to measure the minimum proportion of coherent dots
- Speed 4 °/s, contrast 100%, size 6° of arc

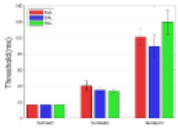


✓ Significant main effect of direction of the coherent motion
✓ HAL did not affect peripheral global motion coherent threshold

Useful Field of View (UFOV)

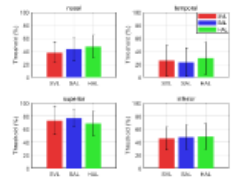


- Adults, N = 8
- Mix of myopes, emmetropes, hyperopes
- Three subtests, identify the location of the peripheral target at 10° eccentricity, measure the shortest presentation time



✓ HAL and SAL did not affect UFOV

Peripheral Motion Detection



- Adults, N = 10
- Mix of myopes, emmetropes, hyperopes
- 4-alternative forced choice task, detect the location of the phase shifting gabor, staircases
- Eccentricity 20°, SF 2 c/°, speed 4 °/s, size 4°, 600 ms
- 42 cm, 10 lux

✓ Significant main effect of location in the visual field
✓ HAL and SAL did not affect peripheral motion contrast detection threshold

Summary

Test	Peripheral Motion Detection	Peripheral Global Motion	UFOV
HAL vs SVL	No impact	No impact	No impact
SAL vs SVL	No impact	Not tested	No impact

Financial disclosure:
All authors are employees of Essilor International.

Reference:
1. Bao J, Yang A, Huang Y, et al. One-year myopia control efficacy of spectacle lenses with aspherical lenslets. *British Journal of Ophthalmology* Published Online First: 02 April 2021. doi: 10.1136/bjophthalmol-2020-318367
2. Bao J, Yang A, Huang Y, et al. Myopia control with spectacle lenses with aspherical lenslets: a 2-year randomized clinical trial. *ARVO* 2021, May 07 2021

Effect of Myopia Control Spectacle Lenses with Aspherical Lenslets on Choroidal Thickness in Myopic Children: 1-Year Results

WEIRC

Yingying Huang[1,2], Xue Li[1,2], Adeline Yang[2,3], Daniel P. Spiegel[2,3], Björn Drobe[2,3], Hao Chen[1,2], Jinhua Bao[1,2]

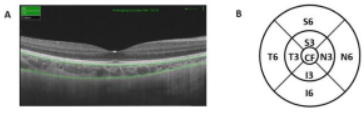
1 - School of Optometry and Ophthalmology, Wenzhou Medical University, Wenzhou, China.
2 - WEIRC, WMU-Essilor International Research Centre, Wenzhou, China..
3 - R&D Vision Sciences AMERA, Essilor International, Singapore

Purpose

This study aimed to assess changes in choroidal thickness (ChT) in Chinese children wearing two new types of myopia control spectacle lenses with concentric rings of contiguous aspherical lenslets over a period of one year.

Material & Methods

Within a randomized, controlled, double-masked clinical trial, 160 children (age 8 to 13 years, myopia between -0.75 D and -4.75 D) wore either spectacles lenses with highly aspherical lenslets (HAL), slightly aspherical lenslets (SAL) or single-vision lenses (SVL)[1]. We acquired ChT form central 6 mm radial OCT scans (Topcon Triton) at the baseline, 6 months, and 12 months. The changes from the baseline were compared between groups at foveal locations according to the Early Treatment Diabetic Retinopathy Study (ETDRS) areas.

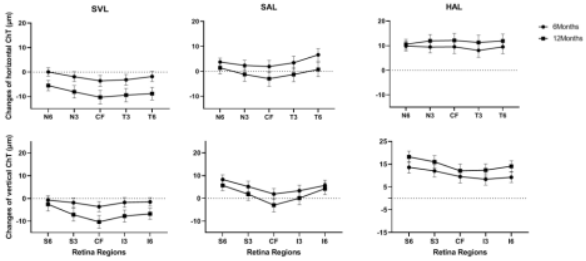


Conclusion

The expected choroidal thinning associated with myopia progression in the SVL group was observed . Wearing SAL lenses reduced this effect and wearing HAL lenses reversed this effect. These results are in agreement with the superior myopia control effect of the HAL lenses.

Results

After one year, the ChT decreased at all regions in the SVL group by up to -10.29 ± 20.11 µm in the central fovea. This trend was significantly less pronounced in all regions in the SAL group ($p < 0.05$) that showed a maximal thinning of -2.94 ± 21.78 µm also in the central fovea. Most remarkably, the HAL group exhibited an increase in choroidal thickness in all regions by up to 18.24 ± 18.22 µm in the superior regions and this effect was significantly different from both SVL and SAL ($p < 0.05$).



1. Bao J, Yang A, Huang Y, et al. Br J Ophthalmol Epub ahead of print: doi:10.1136/bjophthalmol-2020-318367

Influence of Lenslets Configuration for Short-Term Visual Performance in Myopia Control Spectacle Lenses

Xue Li[1,2,3], Chenglu Ding[1,2], Yuhao Li[1,2], Ee Woon Lim[3,4], Yi Gao[3,4], Bruno Fermigier[5], Adeline Yang[3,4], Hao Chen[1,2,3], Jinhua Bao[1,2,3]

1 Eye Hospital and School of Ophthalmology and Optometry, Wenzhou Medical University, Wenzhou, Zhejiang Province, China Email: 809288497@qq.com

2 National Clinical Research Center for Ocular Diseases, Wenzhou, Zhejiang Province, China 3 Wenzhou Medical University–Essilor International Research Center (WEIRC), Wenzhou, Zhejiang Province, China

4 R&D AMERA, Essilor International, Singapore, Singapore 5 R&D Essilor International, Créteil, France

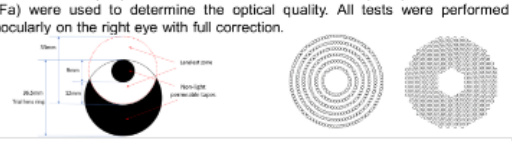
3527732

Introduction & Purpose

Spectacle lenses with lenslets face similar visual performance issues like multifocal contact lenses used for myopia control, especially in the peripheral part of the visual field. In normal, straight viewing conditions, using spectacle lenses with lenslets have no impact on visual acuity. However, eye-movements and possible position shifts of the spectacle frame make it possible that the visual axis passes through the peripheral zone with lenslets. Thus this study aimed to evaluate the optical quality and visual performance through various lenslets configurations and compare them with single-vision lenses (SVL) in children.

Material & Methods

Distance visual acuity (VA) was measured in 50 myopic children; contrast sensitivity (CS) was measured in 36 myopic children. For each test, four spectacle lenses were evaluated in random order: single vision lens (SVL), lens with concentric rings of highly aspherical lenslets (HAL), lens with concentric rings of slightly aspherical lenslets (SAL)[1] and lens with honeycomb configuration of spherical lenslets (HC)[2]. The modulation transfer function (MTF) and MTF area (MTFa) were used to determine the optical quality. All tests were performed monocularly on the right eye with full correction.



Conclusion

Short-term visual performance was minimally impaired by looking through the lenslets structure of myopia control spectacle lenses. Concentric rings with aspherical lenslets had a significantly lower impact on both VA and CS than honeycomb configuration with spherical lenslets.

Reference

1. Jinhua Bao, et al. One-year myopia control efficacy of spectacle lenses with aspherical lenslets. *Br J Ophthalmol*. 2021
2. Lam, C. S. Y., et al. Defocus Incorporated Multiple Segments (DIMS) spectacle lenses slow myopia progression: A 2-year randomised clinical trial. *Br J Ophthalmol* 2019.
3. Xue Li, et al. Influence of Lenslets Configuration for Short-Term Visual Performance in Myopia Control Spectacle Lenses. *Front*

Results

HAL and SAL had larger MTFa than HC (Fig.1). VA in lenses with lenslets was significantly reduced compared to SVL (all $p < 0.01$). The reduction in VA was worse with HC than with SAL ($p = 0.02$) and HAL ($p = 0.03$) (Fig.2); no effect of lenslets asphericity was found ($p > 0.05$). VA changes induced by lenslets did not show any correlation with spherical equivalent refraction (all $p > 0.05$) but had a weak positive association with age for SAL ($r = 0.36$, $p = 0.01$) and HC ($r = 0.31$, $p = 0.03$), but not for HAL ($p = 0.30$). The area under the log contrast sensitivity function (AULCSF) decreased with HAL and HC (all $p < 0.001$) in all illumination levels, and AULCSF with HAL were higher than with HC in photopic condition (1.17 ± 0.10 vs 1.10 ± 0.13, $p = 0.0004$). The presence of lenslets did not affect CS at 3 cpd ($p = 0.80$). At 6 to 18 cpd, CS was significantly reduced by HAL and HC (all $p < 0.05$), not by SAL ($p > 0.05$) compared to SVL. At high spatial frequencies (>12 cpd) both SAL and HAL reduced CS significantly less than HC (all $p < 0.01$) (Fig.3)[2].

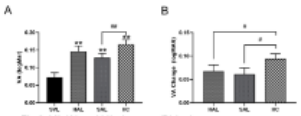


Fig 2. VA (A) and VA changes (B) by lenses
(A) Mean VA with standard errors of four lenses (SVL for single vision lens, HAL for spectacle lenses with concentric rings of highly aspherical lenslets, SAL for spectacle lenses with concentric rings of slightly aspherical lenslets, HC for lenses with spherical lenslets in honeycomb configuration) and (B) relative VA changes from SVL of three lenses with lenslets in logMAR unit. N = 50

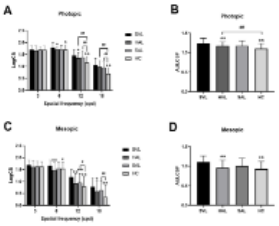
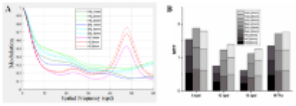
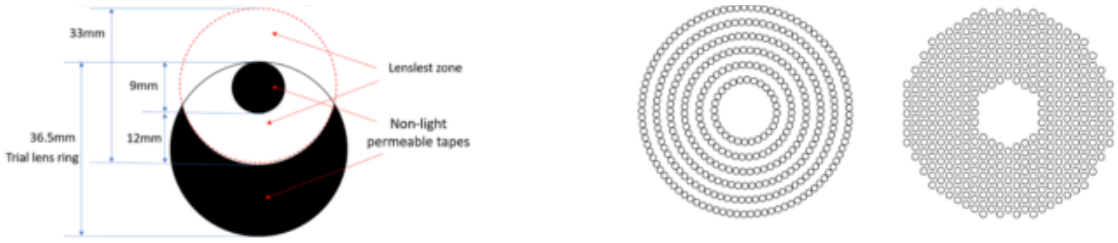


Fig3. CSF (A, C) and AULCSF (B, D) of lenses
Mean log contrast sensitivity and area under the log contrast sensitivity function (AULCSF) with standard deviations of four tested spectacle lenses (SVL for single vision lens, HAL for spectacle lenses with concentric rings of highly aspherical lenslets, SAL for spectacle lenses with concentric rings of slightly aspherical lenslets, HC for lenses with spherical lenslets in honeycomb configuration) in photopic and mesopic conditions, with and without glare. N=36. * and # represent significance in the Bonferroni post hoc test following the repeated measures ANOVA. * $p < 0.05$, ** $p < 0.01$, data compared with SVL; # $p < 0.05$, ## $p < 0.01$, data compared between pairs of spectacle lenses with lenslets.



➢ Fig1. MTF (A) and MTFa (B) of lenses
For lenses of HC, SAL and HAL, MTFs were computed for three pupil apertures of 4mm, 6mm and 8mm (A). MTFs at 5 cpd, 10 cpd and 15 cpd, and MTFs from 0 up to 15 cpd at the three pupil apertures were shown in (B).



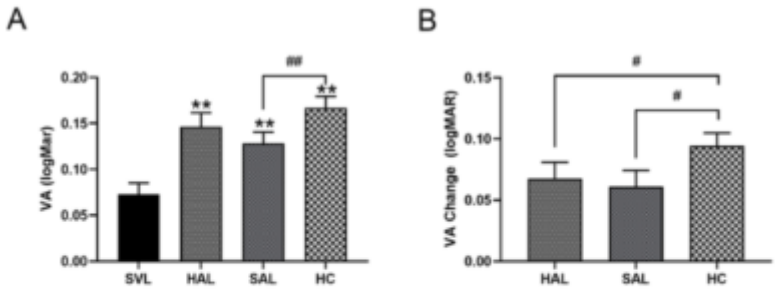


Fig 2. VA (A) and VA changes (B) by lenses

(A) Mean VA with standard errors of four lenses (SVL for single vision lens, HAL for spectacle lenses with concentric rings of highly aspherical lenslets, SAL for spectacle lenses with concentric rings of slightly aspherical lenslets, HC for lenses with spherical lenslets in honeycomb configuration) and (B) relative VA changes from SVL of three lenses with lenslets in logMAR unit. N = 50

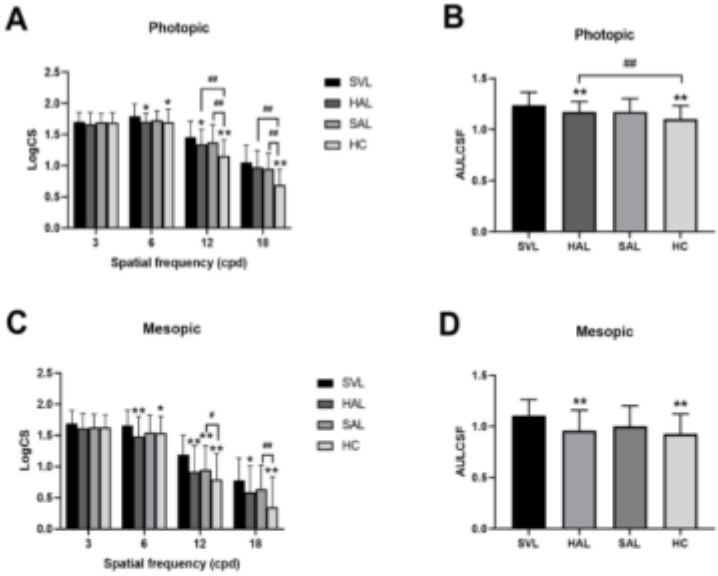


Fig3. CSF (A, C) and AULCSF (B, D) of lenses

Mean log contrast sensitivity and area under the log contrast sensitivity function (AULCSF) with standard deviations of four tested spectacle lenses (SVL for single vision lens, HAL for spectacle lenses with concentric rings of highly aspherical lenslets, SAL for spectacle lenses with concentric rings of slightly aspherical lenslets, HC for lenses with spherical lenslets in honeycomb configuration) in photopic and mesopic conditions, with and without glare. N=36. * and # represent significance in the Bonferroni post hoc test following the repeated measures ANOVA. * $p < 0.05$, ** $p < 0.01$, data compared with SVL; # $p < 0.05$, ## $p < 0.01$, data compared between pairs of spectacle lenses with lenslets.