Supplementary Content

Title: One-year myopia control efficacy of spectacle lenses with aspherical lenslets

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1. SUPPLEMENTARY METHODS (Secondary Outcome)

1.1 Near Horizontal Phoria

Near horizontal phoria was measured three times using the modified Thorington technique at 33 cm with the intervention, and the results were averaged.

1.2 Lag of Accommodation

The accommodative response of the left eye was measured using an open-field infrared autorefractor (WAM-5500, Grand Seiko Co. Ltd., Hiroshima, Japan) at 33 cm under binocular viewing conditions with the intervention. During the measurement, the subjects were asked to fixate on a black single Chinese character (equivalent to 0.2 logMAR) on a white background presented on a computer screen with 80 cd/m^2 screen luminance and keep the target in focus. The accommodative response was recorded as the average of 3 measurements. The accommodative stimulus (AS) and accommodative response (AR) were calculated using the equations listed below. The AR was subtracted from the AS to obtain the lag of accommodation.

$$\text{AS} = \left\{\frac{1}{\left[\frac{1}{\left(\frac{1}{dle - dte}\right) + \text{ordser}}\right] - dle}\right\} - \text{subser}$$

$$\text{AR} = \left(\frac{1}{\left\{\frac{1}{\left[\frac{1}{\left(\frac{1}{gksker}\right) + dle}\right] + \text{ordser}}\right\} - dle}\right) - \text{subser}$$

AS: accommodative stimulus

AR: accommodative response

ordser: lens power of the prescribed intervention (spherical equivalent)

subser: subjective spherical equivalent at corneal plane

gskser: spherical equivalent of average readings from Grand Seiko at the corneal plane

dte: viewing distance = 0.33 m

dle: vertex distance = 0.013 m

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1.3 Distance BCVA

BCVA was measured using a multi-functional VA tester (MFVA-100, BriteEye Medical Tech Co. Ltd., Shenzhen, China) that continuously measures distant VA (5.5 m). The optotype was a single tumbling E presented on a calibrated LCD computer monitor with brightness of 80 cd/m^2 and its open direction was randomly selected from four directions (left, right, up and down) by the computer. The subject's task was to report the open direction to the examiner and the response was entered into the computer by the examiner. The test/staircase procedure had a starting point of 0.5 logMAR and stopped after at least five reversals were reached. The size of the tumbling E was determined according to the subject's response to the previous stimuli, with up or down for a correct or incorrect response. A Weibull function was fit to the response data across all trials. The VA was defined as the threshold corresponding to 75% correct responses.

1.4 Near BCVA

Near BCVA was measured using the 100% contrast EDTRS (Precision Vision Inc., USA) near chart at a distance of 40 cm in a brightly lit room at 200 Lux. Subjects start at the 0.5 logMAR line, and then read from left to right. Reading pace was controlled by the examiner such that it did not exceed a letter per second. When the reading place is lost, subject was asked to go back to the last letter that was identified. Upon the first error, the subject must start the line all over again; allowing 15-20 seconds per letter identification from that moment onwards. The testing endpoint was 3 or more mistakes on a line.

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1.5 Phone Interview

eTable 1. Phone interview questionnaire after dispensing

A phone interview was conducted 3 days after dispensing to ask the following questions:
Q1. Do you feel comfortable with your current pair of lenses? If No, please state the reasons. (As whether they have any signs and symptoms of any discomfort such as vomiting, giddiness, headache and/or eye fatigue while using the lenses.)
Q2. Do the glasses help you see clearly? If No, please state the reasons.
Q3. Have you been wearing the glasses for the past 2 days? If No, please state the reasons.
Q4. Have you been wearing the glasses for the entire day (at least 7 hours/day)? If No, please state the reasons.
The phone interview was repeated at 2 weeks for subjects who were unable to adapt within 3 days.

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1.6 Six-month self-response questionnaires

Six-month self-response questionnaires were administered by study examiners during the 6-month follow-up visit to understand the subjects' daily usage, such as wearing hours for the 6-month period and adaptation (eTable 2).

eTable 2. Examples of 6-month self-response questionnaires on daily usage and adaptation

How many hours do you wear your glasses each day? (0-24 hours) Monday [ ] Tuesday [ ] Wednesday [ ] Thursday [ ] Friday [ ] Saturday [ ] Sunday [ ] *Average daily wearing hours were calculated by averaging the total weekly wearing hours for six- and twelve-month questionnaires, then dividing by seven days in one week.*
How long did you need to get used to the lenses? ❑ hours ❑ 1 day ❑ Days ❑ More than 1week
Since wearing the lenses have you experienced: ❑ Vomiting ❑ Headaches ❑ Dizziness ❑ Tired eyes
Any other remarks or comments: (Free text)

1.7 Definition of Adverse Events

An adverse event is any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons.

NOTE 1: Adverse events include events related to test and reference lenses.

NOTE 2: Adverse events include events related to the procedures involved (any procedure in the investigation plan).

NOTE 3: For users or other persons, adverse events are restricted to events related to the investigational medical device.

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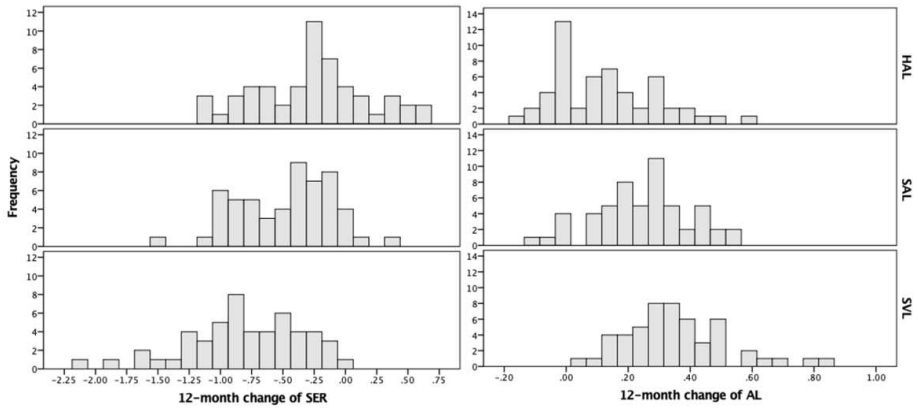
2. SUPPLEMENTARY RESULTS



eFigure 1. Distribution of changes in SER (left panel) and AL (right panel) among treatment groups at 1 year. (AL, axial length; HAL, spectacle lenses with highly aspherical lenslets; SAL, spectacle lenses with slightly aspherical lenslets; SER, spherical equivalent refraction; SVL, single-vision spectacle lenses)