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The acceptance of spectacle lenses designed to manage short-sightedness in children with unequal spectacle prescriptions

Submission date
19/06/2024

Recruitment status
Stopped

Registration date
25/06/2024

Overall study status
Stopped

Last Edited
06/03/2025

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Myopia (also called shortsightedness) is a common refractive eye disorder. The prevalence of myopia is alarmingly high in many Asian countries such as Hong Kong and Singapore where as many as 80% of young adults are myopic. There is a trend of increasing prevalence of myopia and increasing severity of myopia in the last decade. Furthermore, myopic eyes are prone to several ocular diseases, such as retinal degeneration and glaucoma, which can lead to severe visual impairment.
This dispensing study aims to evaluate the clinical acceptance of myopia management spectacle lenses in anisometropic children. (Anisometropia is when there is a difference in refractive power (spectacle prescription) between the 2 eyes.) Anisometropia is commonly found and this study will evaluate whether having a difference in prescription between the two eyes has any significant impact on myopia progression with myopia management spectacle lenses.

Who can participate?
Children aged between 6 to 12 years old with a spectacle prescription indicating myopia, ranging from ≥-0.50 DS to ≤-2.00 DS mean spherical equivalent (MSE) in one eye and near plano (+0.50 to -0.50 DS) in the contralateral eye, as determined by cycloplegic autorefraction. Additionally, the child should have astigmatism of less than 1.00 DC by cycloplegic autorefraction and a best-corrected level of visual acuity of at least 0.1 logMAR.

What does the study involve?
Before the child takes part in the study, the investigators will explain the details of this study. Parents/ guardians will be invited to sign the consent form and the child will need to sign the assent form. Questions about the child's eye condition and eye history will be asked. Investigators will take some eye and vision measurements to see if the child is eligible to take part. These are called the 'screening tests'. If the results of the screening tests tell the investigators that the child is eligible for the study, they will be enrolled into the study. The study consists of up to 5 visits over one year. Investigators will provide the child with a new pair

of glasses. The child will wear the spectacles full-time for the year. Investigators will take a series of measurements and most of these measurements will use the same instruments that the child is familiar with from regular optometrist examinations.

1st Visit: Screening and baseline measures
At this visit, Investigators will ask the child about their eye health and spectacle wear history. Investigators will measure how well they see letters on a chart (visual acuity) with glasses in place. Investigators will assess the eye coordination (any squint) and the eye health of the child. Investigators will use eye drops to make the child's pupils larger and to relax the eye's focusing muscles. These eye drops are used as a standard part of children's eye examinations. Once these drops are in, Investigators can measure the child's prescription and the eye length.

2nd Visit: Spectacles collection
The child will attend the clinic to collect the spectacles. Investigators will check the fit and comfort of the new glasses. Investigators will measure visual acuity with high and low-contrast letters with the new spectacles on. No eye drops will be used in this visit. The child is required to wear these glasses as they would normally wear any spectacles. They should wear the spectacles and engage in their usual everyday activities. A diary will be given for recording daily wearing time.

3rd, 4th and 5th Visit: Repeat of baseline measures
At 3, 6 and up to 12 months after wearing the glasses full time, the child will be invited to come to the clinic. Investigators will measure the visual acuity with high and low-contrast letters. Investigators will also measure your child's prescription and the eye length using the eye drops. In addition, Investigators will give the child a questionnaire to fill in to see how they felt about the glasses. Investigators will also give parents/ guardians a questionnaire to ask about their child's wearing schedule and comfort.

What are the possible benefits and risks of participating?
The child will benefit from gaining more understanding and knowledge of how to manage the progression of myopia. The data obtained will help the investigators to determine how children with different levels of short-sightedness in each eye adapt to the myopia management spectacles lenses. The results will be shared and could be useful to short-sighted children, their parents, optometrists and other eye care professionals.

The side effects of eye drops are the same as those experienced during a routine eye exam. The eye drop is called 'cyclopentolate' (1.0%) which is used to dilate pupils and relax the focusing muscles of the eye. The cyclopentolate drops take up to 30 minutes to work. For most people, it takes around 3-4 hours for their focusing ability to return to normal. The pupils may stay dilated for up to 36-48 hours. Sunglasses are advisable on a bright day and care should be taken until the effects of the drops have subsided. However, these eye drops are commonly used in optometric practices for children's eye exams and it is rare for children to have any adverse effects.

Where is the study run from?
The Eye Clinics at Aston University, Birmingham, UK.

When is the study starting and how long is it expected to run for?
June 2022 to March 2026

Who is funding the study?
SightGlass Vision Inc. (USA)

Who is the main contact?
Professor Leon Davies, l.n.davies@aston.ac.uk

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Study information

Scientific Title
Evaluation of the clinical acceptance of novel myopia management spectacle lenses in anisometropic children

Study objectives
Demonstration of no detriment/no significant change (beyond expected growth) for test eyes with Plano spectacle lenses in axial length, SER and VA during the study period.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/04/2024, College of Health and Life Sciences Research Ethics Committee (Aston University, Birmingham, B4 7ET, United Kingdom; +44 (0)121 204 3000; hls_ethics@aston.ac.uk), ref: HLS21155

Primary study design
Observational

Study design
Prospective multi-visit masked observational study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Myopia

Interventions
This dispensing study aims to investigate the clinical acceptance and long-term impact of myopia management spectacle lenses (DOT 0.2) on axial length and choroidal thickness in anisometropic children (6-12 years old).

Data will be collected within the Optometry School at Aston University. Once recruited and informed consent is given, the participants who fulfil the inclusion criteria will be enrolled on the study. It is a prospective, masked study entailing a total of 5 visits. The participant will be dispensed with a near plano Sight Glass Vision DOT 0.2 spectacle lens in their near plano eye and a prescription DOT 0.2 spectacle lens in their myopic eye. The lens material is Trivex and will have an anti-reflective coating. Correcting children's vision with such a refractive error of this material is standard practice, except for the use of DOT lenses, which have been shown to provide the same functional vision.

The 5 visits include:

Visit 1: Screening
Screening tests will be performed to determine if the participant is eligible for the study. Tests include:
a) Ocular history- a brief ocular history will be taken from the participant including questions eliciting previous spectacle wear, any myopia control interventions used, history of ocular disease or injury and related treatments.
b) Binocular vision and ocular health assessment- Measurements will be taken to see how well the two eyes are working together. The health of the back of the eye will also be assessed.
c) Subjective Refraction- The participant's refractive error in each eye will be determined by performing a subjective refraction. This test checks the participant's spectacle prescription while relying on their subjective responses (rather than the use of an objective measure of refractive error with an automated machine - an autorefractor). A subjective refraction is routinely carried out in eye examinations in practice.
d) Cyclopegic refraction- Cycloplegia will be achieved by instilling one drop of 1% cyclopentolate HCL in each eye. Cyclopentolate is an eye drop commonly used in optometric practices during an eye examination to achieve the 'true' refractive error of the eye. The cycloplegic objective refractive error will then be measured using an open-field autorefractor (e.g., Shin-Nippon NVision-K or Grand Seiko WAM) using standard operating procedures. A Maltese cross-fixation target will be placed 4 m from the machine. The vertex distance of the autorefractor will be set to 12 mm. The participant places their chin on the chin rest and their forehead against the forehead bar. The participant is instructed to view the centre of the fixation target through the "wide view" window. Five measurements will be taken for each eye.
e) Best corrected visual acuity (VA) will be assessed monocularly using a crowded logMAR letter chart at a distance (4 m; ETDRS) and near (40 cm; ETDRS). Letter-by-letter scoring (0.02 logMAR) will be employed.

Eligible participants will be booked in for visit 2.

Visit 2: Baseline
In this visit, the participants' refractive error will be corrected using trial lenses. They will then have a 30-minute washout period where they will perform a distance vision task. They will watch a programme on a TV screen for the duration of 30 minutes. After this time, baseline measurements will be taken from both eyes for the following standard clinical measurements with CE-marked instrumentation:
a) Choroidal thickness measured with a non-contact spectral domain optical coherence tomographer (SD-OCT; SPECTRALIS, Heidelberg). Participants are set up as per 'Patient Good Practices' in the instrument's operator manual. Using the macular cube/ volume scan or radial scan, the participant is asked to focus on the internal fixation target whilst the instrument is aligned with the participant's fovea and the scan is taken.
b) Ocular Biometry- Axial length (length of the eye) will be measured with non-contact biometry

(IOLMaster 500/700) using standard operating procedures. Participants place their chin on the chin rest and their forehead against the forehead bar and fixate on the internal red light. Five measurements will be taken and averaged.
c) High and low contrast logMAR VA at a distance and near-acuity will be assessed using a crowded logMAR letter chart at distance (4 m; EDTRS) and near (33 cm; crowded logMAR letter chart) at both high (96%) and low (10%) Michelson contrast levels. Letter-by-letter scoring (0.02 logMAR) will be employed.
After finishing the baseline measurements, a pair of spectacles with DOT 2.0 lenses will be dispensed to the participant. High and low contrast VA at distance and near will then be measured whilst looking through both the lens centre and periphery and under photopic (high illumination) and mesopic conditions (low illumination). Participants are required to wear the spectacles full-time (12 hours per day). Weekly text messages will be sent to the parents from the Aston Eye Clinic IT system to check their child's compliance and how well they are adapting to the dispensed spectacles.
d) Parent and child questionnaires will be provided to elicit information regarding initial visual satisfaction/comfort through the DOT 2.0 lenses.
e) Spectacle appliance compliance with participant diary- participants will be provided with a diary to promote compliance of spectacle wear.

The participant will then be booked in for visit 3.

Visit 3- Follow up 3 months after dispensing spectacles:
Participants and their parents will be invited to our clinic after wearing the spectacles for 3 months. All the procedures/ tests from Visit 2 will be repeated at Visit 3. High and low contrast logMAR VA at distant and near, ocular biometry and choroidal thickness will be measured again. In addition, short questionnaires will be completed by the participants and parents to determine the visual comfort and wearing schedule of the dispensed spectacles.

The participant will then be booked in for visit 4.

Visit 4- Follow up 6 months after dispensing spectacles:
After 6-months following the dispense of the DOT 2.0 spectacles, all the same procedures/ tests from visit 3 will be repeated at visit 4.

The participant will then be booked in for visit 5.

Visit 5- Follow up 12 months after dispensing spectacles:
After 12 months from the dispense of the DOT 2.0 spectacles, all the same procedures/ tests will be repeated at visit 5.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Diffusion Optics Technology (DOT) spectacle lenses

Primary outcome(s)

Visual acuity (VA) measured using high- and low-contrast conditions using a logMAR visual acuity chart at screening (visit 1), baseline (visit 2), and at follow-ups at 3, 6 and 12 months (visits 3, 4, and 5)

Key secondary outcome(s)
1. Axial length (length of the eye) will be measured using non-contact biometry (IOLMaster 500 /700) using standard operating procedures at baseline (visit 2), and at follow-ups at 3, 6 and 12 months (visits 3, 4, and 5)
2. Choroidal thickness measured using a non-contact spectral domain optical coherence tomography at baseline (visit 2), and at follow-ups at 3, 6 and 12 months (visits 3, 4, and 5)

Completion date
31/03/2026

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Children aged between 6 to 12 years old
2. Spectacle prescription: Myopic (≥-0.50 DS to ≤-2.00 DS Mean spherical equivalent (MSE) in one eye and near Plano (+0.50 to -0.50 DS) in the contralateral eye by cycloplegic autorefraction
3. Astigmatism <1.00 DC by cycloplegic autorefraction
4. Best corrected level of visual acuity of at least 0.1 logMAR

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Years

Upper age limit
12 Years

Sex
All

Key exclusion criteria
1. Aphakic or pseudophakic
2. Binocular vision problems (e.g. amblyopia, strabismus, nystagmus etc.)
3. Any current or evolving ocular pathology
4. Any previous ocular surgery

5. Any systemic condition which might have an influence on vision or visual function
6. Any medical treatment or medication which might have an influence on vision or visual function
7. Is/ has received any myopia management treatment

Date of first enrolment
24/06/2024

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Aston University Optometry
Aston University
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B4 7ET

Sponsor information

Organisation
Aston University

ROR
https://ror.org/05j0ve876

Funder(s)

Funder type
Industry

Funder Name
SightGlass Vision Inc.

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/ or analysed during the current study will be stored in a non-publicly available repository (i.e. Box).

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	15/04/2004	20/06/2024	No	Yes
Participant information sheet	version 2	15/04/2004	20/06/2024	No	Yes