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Vision in children with spectacle lenses designed to manage short-sightedness

Submission date
05/12/2023

Recruitment status
No longer recruiting

Registration date
12/12/2023

Overall study status
Completed

Last Edited
21/11/2024

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 short-sightedness, is a common refractive eye disorder. Later in life it can lead to eye diseases. Currently, there are spectacle lenses available to correct and manage myopia and its progression. In this study we are going to evaluate the speed of adaptation with myopia management spectacle lenses in children.

Who can participate?
Myopic (short-sighted) children aged 6-12 years old with good vision and healthy eyes.

What does the study involve?
Before child participants take part in the study, the investigators will explain the details of this study to the parents/ guardians and the child. Parents/ guardians will be invited to sign the consent form and the child participant will be asked to sign the assent form. Investigators will ask questions about the child's eye condition and eye history, and 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. The study consists of 5 visits to the Aston University Optometry Clinic in the Vision Sciences Building. The child will be provided with three new pairs of glasses, wearing each of them full-time for one week (7 days). Most measurements taken during the study are the same as those used by optometrists to conduct site tests.

1st Visit: Screening (approximately 90 mins)
At this visit the child will be asked 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 eyedrops are used as a standard part of children's eye examinations. Once these drops are administered, the investigators will measure the child's prescription.

2nd Visit: Baseline measures and spectacles collection (approximately 60 mins)
The child will be given your a pair of glasses to wear for 30 mins. The investigators will measure the thickness of the child's retina (a structure that is at the back of the eye) and the eye length

using non-invasive devices. Visual acuity will also be measured. No eyedrops will be used in this visit. After the measurements have been taken, the child will be given a pair of glasses to take home. Before they leave, the investigators will measure the visual acuity with these glasses whilst the child looks through both the lens centre and periphery under normal room light conditions and in dim light. The child is then required to wear these glasses as they would normally wear any spectacles for a period of 1 week.

3rd Visit: Repeat of baseline measures and second spectacle lens collection (approximately 60 mins)
After wearing the glasses full time for one week, the child will be invited to come to return to the clinic. The investigators will repeat the measurement for visual acuity, eye length and thickness of the retina. In addition, the investigators will give the child a short questionnaires to fill in to see how they felt about the glasses. The child will then be given a second new pair of glasses to take away and wear for a period of 1 week.

4th Visit: Repeat of baseline measures and third spectacle lens collection (approximately 60 mins)
Same as the 3rd visit, but the child will be given another new pair of glasses to take away and wear for a period of 1 week.

5th Visit: Repeat of baseline measures (approximately 60 mins)
Same as the 3rd and 4th visit, but the child will exit the study once all measures are taken.

What are the possible benefits and risks of participating?
Benefits- The parent/ guardian and child will gain more understanding and knowledge of how to manage the progression of myopia. The data obtained will help the investigators determine how children with short-sightedness adapt to myopia management spectacles lenses. The results will be shared and could be useful to short-sighted children, their parents/ guardians, optometrists and other eye care professionals. Risks- The risks associated with all procedures and devices in this study are extremely low. The side effects of eye drops that are used in this study are the same as those children experiences 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. So, the child’s eye will be more sensitive to light and their vision will be slightly blurred. 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 child eye exams and it is rare for children to have any adverse effects. The myopia management spectacles lenses used in this study are the same as those of commercially available spectacles lenses. The child may observe blurriness in the periphery of their vision. They may feel tired and may experience slight disorientation. The child may also experience increased glare (discomfort to vision) or halos (bright circles around lights) with bright lights. However, most of these symptoms would be temporary and breaks will be given whenever required.

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 2025

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

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

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
HLS21133

Study information

Scientific Title
Evaluation of the speed of adaptation with myopia management spectacle lenses in children

Study objectives
Diffusion Optics Technology (DOT) spectacle lenses for myopia management have no impact on visual behaviour versus standard single vision lenses & DOT lenses provide enhanced dynamic vision versus competitors.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/11/2023, 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: HLS21133

Study design
Prospective multi-visit double-blind three-way randomized crossover observational study

Primary study design
Interventional

Study type(s)
Other, Quality of life

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

Interventions
The aim of this dispensing study is to evaluate the speed of adaptation with myopia management spectacle lenses (DOT 0.2 and Miyosmart) in children. Standard single vision lenses will be used as a control. Data will be collected within the Optometry School at Aston University. Once recruited and informed consent is given, the children who fulfil the inclusion criteria will be enrolled on the study. It is a randomised crossover design study entailing a total of 5 visits. The participating children will be randomised into three test groups and data measures will be taken before and 1 week after they are dispensed with each of the following spectacle lenses:
1. Single vision lenses

2. Sight Glass Vision DOT 0.2 spectacle lenses
3. Hoya Miyosmart spectacle lenses

The five visits include:

Visit 1: Screening
Screening tests will be performed to determine if the children are eligible for this study.
1. 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.
2. 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.
3. Cycloplegic objective refractive error: 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 eye examination in order to achieve the 'true' refractive error of the eye (please refer to point 17 of this application form for the possible side effects of using this eyedrop). 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.
4. Best corrected visual acuity (VA) will be assessed monocularly using a crowded logMAR letter chart at distance (4 m; ETDRS) and near (33 cm; ETDRS). Letter-by-letter scoring (0.02 logMAR) will be employed.

Eligible participants will be randomised into three groups and the above lenses will be ordered in their prescription.

Visit 2: Baseline measurement
In this visit participants will be asked to perform a distance vision task: watch TV for a period of 30 minutes with single-vision lenses. The following measurements will then be taken as the baseline:
1. Subfoveal 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.
2. 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 at the internal red light. Five measurements will be taken and averaged
3. High and low contrast logMAR VA at 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 (randomly allocated) will be dispensed to the participant. High and low contrast VA at distant 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 them full time for 1 week (12 hours per day). Daily text messages will be sent to the parent from the

Aston Eye Clinic IT system to check their child's compliance and how well they are adapting to the dispensed spectacles.

Visit 3: Follow up 1 week after dispensing 1st pair of lenses
Participants and their parents will be invited to our clinic after wearing the spectacles for 1 week (± 2 days). High and low contrast logMAR VA at distant and near, ocular biometry and subfoveal 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.

A second pair of lenses will then be dispensed at this visit and high and low contrast VA will be measured with these lenses in place. Participants will then be asked to wear these spectacles full time for 1 week.

Visit 4: Follow up 1 week after dispensing 2nd pair of lenses
All measurements in this visit will be the same as Visit 3. A third pair of lenses will then be dispensed at this visit and high and low contrast VA will be measured with these lenses in place. Participants will then be asked to wear these spectacles full time for 1 week.

Visit 5: Follow up 1 week after dispensing 3rd pair of lenses
All measurements in this visit will be the same as Visit 3 and the child can keep their preferred pair of spectacles.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Diffusion Optics Technology (DOT) spectacle lenses, Defocus Incorporated Multiple Segments (DIMS) spectacle lenses, Single vision spectacle lenses

Primary outcome(s)
Visual acuity (VA) is measured under high- and low-contrast conditions using a logMAR visual acuity chart for each device after a 7-day wearing period

Key secondary outcome(s))
Sub-foveal choroidal thickness is measured under using a non-contact spectral domain optical coherence tomographer for each device after a 7-day wearing period

Completion date
13/03/2025

Eligibility

Key inclusion criteria
1. Age range: 6 to 12 years
2. Spectacle prescription: myopic (mean spherical equivalent [MSE] ≥-0.50 DS to <-8.00 DS) by cycloplegic autorefraction
3. Astigmatism <2.00 DC by cycloplegic autorefraction

4. Anisometropia ≤2.00 D (MSE) by cycloplegic autorefraction
5. Best corrected level of visual acuity of at least 0.00 logMAR

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
12 years

Sex
All

Total final enrolment
40

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
05/12/2023

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Aston University
The Aston Triangle
Birmingham
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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	Children version 3	20/11/2023	11/12/2023	No	Yes
Participant information sheet	Parent/Guardian version 3	20/11/2023	11/12/2023	No	Yes