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Contrast sensitivity evaluation of DOT spectacle lenses

Submission date	Recruitment status	[_] Prospectively registered
02/01/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/01/2023	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/02/2024	Eye Diseases	

Plain English summary of protocol

Background and study aims
Novel spectacle Diffusion Optic Technology (DOT) lenses from SightGlass Vision (SGV) have shown the ability to control the progression of myopia in children. These lenses contain contrast-reducing segments in the peripheral area of the lens as a signal to halt eye growth. The purpose of this non-dispensing vision study is to compare the contrast sensitivity (the ability to see low contrast images), of adult subjects wearing 2 DOT spectacle lenses compared to clear single vision spectacle lenses and +0.50DS single vision spectacle lenses.

Who can participate?
Adults aged 18 years and older who have healthy eyes

What does the study involve?
This study involves one visit lasting approximately 4 hours or 2 visits lasting 2 hours each. Each participant will be reading letter charts from a distance while seeing through the different study spectacles in a randomized order.

What are the possible benefits and risks of participating?
You will not personally benefit from your participation, other than having your eyes examined. Even if there is no personal benefit to you, information from this research will provide insight into current and future product development aimed at improving spectacle lenses. Spectacle lenses are classified as a non-significant risk device. The lenses have a CE mark and are commercially available outside the USA. Due to the nature (non-dispensing, vision testing) and the short duration of the study, the risks of participating are minimal.

Where is the study run from?
Indiana University – School of Optometry, Bloomington (USA)

When is the study starting and how long is it expected to run for?
June 2022 to January 2023

Who is funding the study?
SightGlassVision (USA)

Who is the main contact?
Sylvie Franz, sfranz@sightglassvision.com (USA)

Contact information

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Additional identifiers

Protocol serial number
SGV_IU 01

Study information

Scientific Title

Contrast sensitivity evaluation of Diffusion Optics Technology (DOT) spectacle lenses

Study objectives
Contrast sensitivity measurements of the subjects wearing DOT spectacle lenses will be comparable to control (single vision and single vision +0.50DS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/07/2022, Sterling IRB (6300 Powers Ferry Road, Suite 600-351, Atlanta, GA 30339, USA; +1 770-690-9491; account_relations@sterlingirb.com), ref: 10203

Primary study design
Interventional

Study design
Prospective randomized controlled subject-masked single- and multiple-day repeated measure study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Myopia management using contrast management spectacle lenses

Interventions
Novel spectacle Diffusion Optic Technology (DOT) lenses from SightGlass Vision (SGV) have shown the ability to control the progression of myopia in children. These lenses contain contrast-reducing segments in the peripheral area of the lens as a signal to halt eye growth. This study investigates the contrast sensitivity measurements with DOT spectacle lenses compared with control SingleVision (SV) and SV +0.50DS.

This study is a non-dispensing, cross-over design so all participants will see through all spectacle lenses tested. The order of the spectacle lenses will be randomized in the repeated measures experimental design. FrACT contrast sensitivity (CS) threshold at a 4m distance will be measured at 3, 6, 12 and 18 cycles per degree (cpd) while subjects view through the central and a peripheral portion (>4.5mm temporal of lens center) of all the spectacle lenses.

Intervention Type
Device

Phase
Phase III/IV

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

Primary outcome(s)
Contrast sensitivity measured using the FrACT test at a 4m distance at 8, 12, 6 and 3 cycles per degree under photopic (85cd/m2) conditions with each spectacle lens at one timepoint

Key secondary outcome(s)
Visual acuities measured using a standard letter chart at a 4m distance under photopic (85cd /m2) conditions with each spectacle lens at one timepoint

Completion date
05/01/2023

Eligibility

Key inclusion criteria
1. Has had a self-reported oculo-visual examination in the last two years
2. Is at least 18 years of age and has full legal capacity to volunteer
3. Has read and understood the informed consent letter
4. Is willing and able to follow instructions and maintain the appointment schedule
5. Is correctable to a visual acuity of 20/40 or better (in each eye) with their habitual vision correction or 20/20 best-corrected
6. Is willing and able to wear contact lenses in the office for testing
7. Spectacle cylinder less than -0.75DC
8. Has clear corneas and no active ocular disease
9. Can tolerate having one eye covered and study procedures

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
10

Key exclusion criteria
1. Has any systemic disease affecting their ocular health
2. Is using any systemic or topical medications that will affect their ocular health
3. Has any ocular pathology or severe insufficiency of lacrimal secretion (moderate to severe dry eyes) that would affect clear vision when wearing spectacle lenses
4. Is aphakic

Date of first enrolment
01/08/2022

Date of final enrolment
31/10/2022

Locations

Countries of recruitment
United States of America

Study participating centre
Indiana University - School of Optometry
800 E Atwater Ave
Bloomington
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Sponsor information

Organisation
SightGlass Vision

Funder(s)

Funder type
Industry

Funder Name
SightGlass Vision

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be published as a supplements to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		23/04/2023	16/02/2024	No	No