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Assessment of optical quality of myopia control spectacle lenses

Submission date 03/11/2026	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 10/11/2026	**Overall study status** Ongoing	
Last Edited 10/11/2026	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title
Objective and subjective assessment of optical quality and light scattering induced by myopia-control spectacle lens treatment zones

Study objectives
To quantify the optical and perceptual impact of central and treatment-zone designs in myopia-control spectacle lenses.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/09/2026, Ethics Committee of the Department of Mathematics and Physics at the University of Salento (Piazza Tancredi, 7, Lecce, 73100, Italy; +39 (0)377 182 5055; maurizio.martino@unisalento.it), ref: ECDMP-2026-09-0016

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Crossover

Purpose
Treatment

Study type(s)

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

Interventions
A within-subject, repeated-measures design will be used, with each participant undergoing all test-lens conditions. The order of lens designs, including the single-vision control lens, will be randomized for each participant using a computer-generated sequence. For myopia-control lenses, the order of central optical-zone and treatment-zone testing will also be randomized. Only one eye per participant will be included. The dominant eye will be selected as the study eye; if ocular dominance cannot be established, the study eye will be randomly selected.

This study compares several eyeglass lenses designed to help manage myopia with a standard single-vision lens:
1. Defocus segments
2. Aspheric lenslets
3. Cylindrical Annular Refractive Element
4. Micro Optical Variable Elements
5. Diffusion Optics Technology

Duration: Two visits, each visit will last approximately 1 hour.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Myopia control spectacle lenses

Primary outcome(s)
1. Objective visual quality measured using HD Analyzer at 2 months

Key secondary outcome(s)

Completion date
01/07/2027

Eligibility

Key inclusion criteria
1. Age between 18 and 22 years, inclusive
2. Manifest spherical equivalent refraction between –0.50 and 0.00 D, inclusive, in the study eye
3. Refractive astigmatism of less than 0.50 D in magnitude in the study eye
4. Best-corrected high-contrast visual acuity better than 0.00 logMAR in the study eye
5. Ability to understand and complete the study procedures and provide written informed consent

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
22 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Failure to meet any of the inclusion criteria
2. Any ocular disease or abnormality that could affect visual acuity, optical quality, or intraocular straylight
3. Previous ocular surgery or ocular trauma that could influence the study measurements

4. Use of ocular or systemic medications that could affect visual function, pupil size, or the ocular surface
5. Inability to complete the measurements reliably or comply with the study procedures

Date of first enrolment
20/10/2026

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Italy

Sponsor information

Organisation
SightGlass Vision, Inc. (United States)

ROR
https://ror.org/0578t2977

Funder(s)

Funder type

Funder Name
SightGlass Vision

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available