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Contrast sensitivity measurement validation testing program

Submission date 29/07/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 29/07/2025	**Overall study status** Completed	
Last Edited 29/07/2025	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
Presbyopia is the gradual loss of the eye's ability to focus on nearby objects due to natural aging. Visual performance measurement is traditionally based upon visual acuity measurement and occasionally on the measurement of contrast sensitivity. The latter method, considered to be more sensitive at detecting differences in performance between different optical designs than visual acuity, uses linear or circular sinusoidal contrast target.
The study aim is to determine the sensitivity of two contrast sensitivity tests in detecting changes in contrast sensitivity associated with refractive defocus.

Who can participate?
Presbyopes aged between 40 to 50 years old.

What does the study involve?
Part 1 involves attending the clinic for nine study visits.
Part 2 involves attending the clinic for five study visits

What are the possible benefits and risks?
The study results will contribute to collect additional information about visual performance variability under different contrast conditions.

Where is the study running from?
Ocular Technology Group - International (OTG-i) (UK)

When is the study starting and how long is it expected to run for?
July 2025 to October 2025

Who is funding the study?
Alcon Research, LLC (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
359150

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Contrast sensitivity measurement validation testing program - phase 1 - test resolution determination

Study objectives
Part 1: determination of the sensitivity of the test in detecting change in contrast sensitivity associated with refractive defocus.
Part 2: determination of the test ability to measure binocular summation via the measurement of contrast sensitivity through focus curve.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/07/2025, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 1224558458; gram.nosres@nhs.scot), ref: 25/NS/0063

Study design
Part 1: Exploratory part following a clinic based prospective randomized cross-over study design
Part 2: Clinic based prospective single group study design

Primary study design
Interventional

Study type(s)
Efficacy

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

Interventions
Part 1 will be an exploratory part following a clinic based, prospective, randomized cross-over study design testing the sensitivity to defocus of both linear sinusoidal contrast sensitivity and letter contrast sensitivity. Part 1 will involve 9 study visits.
The rationale for including sinusoidal contrast sensitivity measurements only in this part is that the repeatability of the technique has been shown to be poorer than the repeatability of letter contrast sensitivity , therefore it is not anticipated that sensitivity to refractive blur will be as good which trend should be demonstrated with only a small study population. The objective of the two part approach is minimizing participants burden due to the large different in the repeatability of the two methods.

Part 2 will follow a clinic based, prospective single group study design testing only letter contrast sensitivity. Part 2 will involve 5 visits.

Intervention Type
Other

Primary outcome(s)
Measurement of Contrast sensitivity at photopic (85cd/m²) and mesopic (3cd/m²) luminance using timed controlled contrast sensitivity visual acuity with the OTGi vision suite and M&S Technology between four and nine times during the study visit

Key secondary outcome(s))

Measurement of high contrast timed logMAR visual acuity at photopic (85 cd/m²) luminance using timed controlled visual acuity using OTGi vision suite 9 times during the first study visit

Completion date
30/10/2025

Eligibility

Key inclusion criteria
1. Age 40 to 50 years
2. Spectacle refraction:
Distance: Sphere: -6.00D to + 2.00D
Astigmatism: 0.00D to -0.75D
Near Add +0.50 to +2.50D
3. Spectacles or soft contact lenses habitual vision correction
4. Best corrected visual acuity of at least 20/25 in each eye

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
50 years

Sex
All

Key exclusion criteria
1. Any history of eye disease, injury or abnormality that affects any part of the eye that affects vision
2. Any active eye disease that affects any part of the eye that affects vision
3. Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
4. Newly prescribed (within the past 30 days) use of some systemic medications (such as antihistamines, decongestants, diuretics,
muscle relaxants, tranquilizers, stimulants, anti-depressants, anti-psychotics, oral contraceptives) or ocular medication that may affect vision and its stability as determined by the investigator
5. Enrolment of the family members of the investigator, family members of the investigator’s staff, or individuals living in the households of these individuals

Date of first enrolment
17/05/2025

Date of final enrolment
30/10/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ocular Technology Group International
66 Buckingham Gate
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Sponsor information

Organisation
Optometric Technology Group Ltd

Funder(s)

Funder type
Industry

Funder Name
Alcon Research LLC

Results and Publications

Individual participant data (IPD) sharing plan
Not expected to be made available

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes