ISRCTN17860990 https://doi.org/10.1186/ISRCTN17860990

Contrast sensitivity evaluation using different glare levels

Submission date	Recruitment status	[_] Prospectively registered
26/11/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/11/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
26/11/2025	Eye Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims:
As per the ISO the glare produced by intraocular lenses can be evaluated using the glare level that produces a contrast loss of 0.1 log contrast at 6 cycles per degree spatial frequency. This study aims to determine the glare level required by the ISO using three different contrast sensitivity systems as follows:
1. M & S Technologies linear sine wave gratings contrast sensitivity test at mesopic light level (2.5 to 3 cd/2) under four glare conditions: no glare, glare level 1, glare level 2, glare level 3
2. M & S Technologies sinusoidal bulls eye contrast sensitivity test at mesopic light level (2.5 to 3 cd/2) under four glare conditions: no glare, glare level 1, glare level 2, glare level 3
3. OTG-i Vision Suite timed letter contrast sensitivity test at mesopic light level (2.5 to 3 cd/2) under four glare conditions: no glare, glare level 1, glare level 2, glare level 3

Who can participate?
Participants aged between 45 and 55 years old

What does the study involve?
The study involves attending the clinic for two study visits:
Visit 1: Screening/enrollment/study test familiarization
Visit2: Study tests/discharge. The following tests will be carried out in random order and for each test no glare will be tested first, and the order of testing of the three glare levels will be randomized:
1. M & S Technologies sinusoidal linear contrast sensitivity test
2. M & S Technologies sinusoidal bulls eye contrast sensitivity test
3. OTG-i timed letter contrast sensitivity test

What are the possible benefits and risks of participating?
The study will collect information to test the disability glare produced by intraocular lenses.

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

When is the study starting and how long is it expected to run for?
November 2025 to June 2026

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

Who is the main contact?
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Contact information

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Principal investigator, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
362627

Study information

Scientific Title
Method optimization for evaluating contrast sensitivity using different glare levels

Study objectives

The objective of the pilot study will be to determine the light outputs producing a contrast sensitivity loss of 0.1 log contrast or closest for the M & S Technologies linear sine wave gratings contrast sensitivity, M & S sinusoidal bulls eye contrast sensitivity and OTG-i letter contrast sensitivity tests at 2.5 to 3 cd/m2 for both the overall study population.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/11/2025, London - Riverside Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8150; riverside.rec@hra.nhs.uk), ref: 25/LO/0724

Primary study design
Observational

Secondary study design
Randomized (order of testing) cross-over study design

Study type(s)

Health condition(s) or problem(s) studied
Glare produced by intraocular lenses

Interventions
Up to 50 potential participants will attend the research clinic for their first visit to initially obtain their informed consent and to screen them for their suitability to take part in the investigation Then the participants will be familiarized with the study tests.

At Visit 2 the following tests will be carried out in random order and for each test no glare will be tested first, and the order of testing of the three glare levels will be randomized:
1. M & S Technologies sinusoidal linear contrast sensitivity test
2. M & S Technologies sinusoidal bulls eye contrast sensitivity test
3. OTG-i timed letter contrast sensitivity test

Intervention Type
Other

Primary outcome(s)
1. Linear sine wave gratings contrast sensitivity threshold measurement at 6 cycles per degree at 2.5 to 3 cd/m2 measured using M & S Technologies linear sine wave gratings contrast sensitivity test at mesopic light level (2.5 to 3cd/2) under four glare conditions: no glare, glare level 1, glare level 2, glare level 3 at Visit 2

2. Sinusoidal bulls eye contrast sensitivity distance vision (400 cm) threshold measurements at 6 cycles per degree at 2.5 to 3 cd/m2 measured using M & S Technologies sinusoidal bulls eye contrast sensitivity test at mesopic light level (2.5 to 3 cd/2) under four glare conditions: no glare, glare level 1, glare level 2, glare level 3 at Visit 2

3. Timed letter contrast sensitivity distance vision (400 cm) threshold measurements at 6 cycles per degree at 2.5 to 3 cd/m2 measured using OTG-i Vision Suite timed letter contrast sensitivity

test at mesopic light level (2.5 to 3 cd/2) under four glare conditions: no glare, glare level 1, glare level 2, glare level 3 at Visit 2

Key secondary outcome(s)

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Age 45 to 55 years
2. Spectacle refraction:
Distance: Sphere: -4.00D to + 2.00D
Astigmatism: 0.00D to -0.75
3. Best corrected distance visual acuity of at least 20/20 in each eye
4. Clear media
5. No ocular comorbidity

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
45 Years

Upper age limit
55 Years

Sex
All

Total final enrolment
40

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

21/11/2025

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ocular Technology Group International
66 Buckingham Gate
London
England
SW1E 6AU

Sponsor information

Organisation
Ocular Technology Group Ltd

Funder(s)

Funder type

Funder Name
Alcon Research LLC

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available