

# Contrast sensitivity measurement validation testing program

<b>Submission date</b> 29/07/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/07/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/07/2025	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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

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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 difference 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/m<sup>2</sup>) and mesopic (3cd/m<sup>2</sup>) 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/m<sup>2</sup>) 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

London

United Kingdom

SW1E 6AU

## 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