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Study to validate a new test to measure contrast vision

Submission date	Recruitment status	[X] Prospectively registered
25/01/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/01/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/01/2021	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A very important aspect of vision is to be able to detect differences in shades (contrast). This is tested by a range of tests called contrast sensitivity and these tests are used to measure vision in particular in older people because this function decreases with age. A new test has become available and needs to be validated. The key validation is to measure if the test is repeatable (e. g. if we carry out the test twice on the same person do we get the same result). The aim of this study is to compare the repeatability of the new test with that of two current commercial tests.

Who can participate?
People aged 40 to 50 with normal vision other than needing glasses or contact lenses to see clearly at a distance.

What does the study involve?
The participants will come to the clinic three times. At the first visit, the participant's suitability to take part will be assessed and their vision correction will be determined. If suitable to take part the participants will come to the clinic twice within 1 week each time; during the two visits their vision will be tested with three different contrast sensitivity tests (the new test and two commercial tests).

What are to possible benefits and risks of participating?
There may be no direct benefits, but the data collected will help to develop a new test to better measure the vision of older people. There are no anticipated risks associated with taking part the tests are vision tests similar to those at the optician but more in-depth and taking longer so visual fatigue could occur.

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

When is the study starting and how long it is expected to last?
October 2020 to November 2021

Who is funding the study?
Alcon LLC (USA)

Who is the main contact?
Deborah Moore
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Contact information

Type(s)
Public

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Integrated Research Application System (IRAS)
291587

Protocol serial number
ID20-65

Study information

Scientific Title
Letter contrast sensitivity testing in a young presbyopic phakic population

Study objectives
The hypothesis that will be tested in this test validation study is that the reliability of letter contrast sensitivity method is non-inferior to the repeatability of two commercially available sine grating contrast sensitivity test methods.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/01/2021, East of England - Cambridge South Research Ethics Committee (The Gonville Hotel, Gonville Place, Cambridge, CB1 1LY, UK; +44 (0)2071048104; cambridgesouth.rec@hra.nhs.uk), REC ref: 20/EE/0276

Primary study design
Interventional

Study design
Single-centre repeated-measures participant-masked randomized trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Evaluation of contrast sensitivity testing methods in a presbyopic phakic population

Interventions
Following a visit in which potential participants are screened, enrolled and familiarised with the testing procedures, participants will visit the clinic on two separate days within a 7-day period and will complete tests to evaluate their contrast sensitivity. Presentation of the test and two control tests will be randomised. Contrast sensitivity is measured at photopic (85 cd/m²) and mesopic (2.5 cd/m²) light levels using three different tests, one using letters of different contrasts and two using sinusoidal patterns of different contrasts:
1. OTG-i Vision Suite letter contrast sensitivity test
2. M&S Technologies linear sine wave grating test from the Clinical Trial Suite
3. Vector Vision standardized contrast sensitivity

Intervention Type
Other

Primary outcome(s)
Contrast sensitivity measured at photopic (85 cd/m²) and mesopic (2.5 cd/m²) light levels at up to five spatial frequencies: 18, 12, 6, 3 and 1.5 c/degree using:
1. OTG-i Vision Suite letter contrast sensitivity test
2. M&S Technologies linear sine wave grating test from the Clinical Trial Suite
3. Vector Vision standardized contrast sensitivity
Measured twice up to 1 week apart

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
01/11/2021

Eligibility

Key inclusion criteria
1. Aged 40-50 years
2. Spectacle refraction: Distance: Sphere: -6.00D to +4.00D, Astigmatism: 0.00D to -3.00D, Near Addition: +0.50D to +2.50D
3. Best corrected visual acuity of at least 20/20 in each eye
4. Spectacles or soft contact lenses habitual visual correction
5. Have normal eyes with the exception of a need for visual correction
6. Have read and understood the Participant Information Sheet in English

7. Have read, signed and dated the Informed Consent
8. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Ocular anterior segment infection, inflammation, abnormality or active disease that would contraindicate contact lens wear
2. Newly prescribed (within past 30 days) use of some systemic medications (such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilisers, stimulants, anti-depressants, anti-psychotics, oral contraceptives) or new prescription eye drops which is not rewetting eyedrops for which contact lens wear would be contraindicated as determined by the investigator
3. Monocular patients (only one eye with functional vision) or participants fit with only one lens
4. Any moderate or severe ocular condition observed during the slit-lamp examination at the enrollment visit
5. History of herpetic keratitis, ocular surgery or irregular cornea
6. Known pregnancy during the study period
7. Enrollment of the investigator or his/her staff, 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
01/02/2021

Date of final enrolment
31/07/2021

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
Ocular Technology Group - International

Funder(s)

Funder type
Industry

Funder Name
Alcon Research, LLC

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No