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Comprehensive distance vision testing with monofocal intraocular lenses

Submission date	Recruitment status	[ ] Prospectively registered
25/02/2020	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/03/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/03/2020	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
As people get older, sometimes the lens of the eye becomes cloudy leading to loss of vision. The cloudy lens is known as a 'cataract'. The cataract can be removed and a replacement lens put in its place. Usually the replacement lens has one 'point of focus'. This means that a person's vision after cataract surgery is either good for distance vision (driving, watching television) or good for near vision (reading, sewing) but not good for both. This standard lens is known as a 'monofocal' lens. People who get a monofocal intraocular lens (IOL) will need to use spectacles for either distance or, more usually, for near vision.
The aim of the study is to evaluate the impact of different types of defocus on the visual performance of monofocal IOL and to measure distance vision with a comprehensive OTGi vision test system compared to a standard ETDRS vision test.

Who can participate?
People who had successful cataract surgery and both eyes implanted with monofocal IOL (at least 3 to 24 months) and who are aged 18 years or older.

What does the study involve?
The study comprises of one scheduled visit of approximately 4-5 hours. Participants will be given 4 different spectacle corrections in a random sequence and their distance vision will be measured with 2 different letter charts using high and low contrasts and under 2 lighting levels (similar to daytime and nighttime). Participants will be asked to read out and identify the letters presented in the letter charts with both eyes. In total, 9 vision measurements will be taken with each correction. Regular breaks will be provided. At the end of the visit participant will be discharged from the study.

What are the possible benefits and risks of participating?
Due to the nature and duration of the study, the risks of participating are minimal. Participants will be reading letter charts from a distance. All the assessments are safe, and none present any increased risk compared with routine vision test. The potential benefit will be that the vision testing will be provided at no cost and may be beneficial in understanding how well the participants can see in different settings.

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

When is the study starting and how long is it expected to run for?
January 2019 to August 2019

Who is funding the study?
Ocular Technology Group – International with Alcon Research Investigator Initiated Study Grant #IIT42375343

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
253925

Protocol serial number
OTGi ID 18-42, IRAS 253925

Study information

Scientific Title
Technology validation and optimization for Monofocal Intra Ocular Lens visual performance quantification.

Study objectives

The different types of defocus and environmental (luminance and contrast) conditions will have an impact on the visual performance of pseudophakic subjects implanted with monofocal IOLs. Comprehensive vision testing will provide better discrimination compared to standard testing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
09/11/2018, South Central - Oxford A Ethics Committee (Level 3, Block B Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8041;nrescommittee.southcentral-oxforda@nhs.net), ref: 18/SC/0539

Study design
Single-arm noninterventional vision testing prospective randomized order of correction with investigator and participant masking

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Vision of pseudophakics subjects implanted with monofocal IOLs

Interventions
Participants who have been implanted with monofocal IOLs will be wearing four different spectacle corrections at the clinic only (one study visit of approximately 4-5 hours). The investigator will examine the eyes, check the vision, spectacle prescription. After that, 4 different spectacle corrections will be worn in a random sequence and distance vision will be measured with 2 different letter charts (OTGi and ETDRS) using high and low contrasts and under 2 lighting levels (similar to daytime and nighttime). Participants will be asked to read out and identify the letters presented in the letter charts with both eyes. In total, 9 vision measurements will be taken with each correction. Participants will be given regular breaks in between measurements. All study participants will undergo the same series of vision tests and tasks. At the end of the visit participant will be discharged from the study.

The computer-generated randomization sequence will be applied to the order of the four spectacle corrections worn. For example: ID#1 order will be Spec 2, 4, 3, 1. ID#2 will be 1, 4, 2, 3 etc.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Monofocal intra ocular lens

Primary outcome(s)
Visual acuities in letters will be measured once using ETDRS charts (control) and OTGi vision suite (test) recorded in LogMAR
with four corrections under the nine vision testing conditions with varying luminance (bright and dim), time and contrast (high and low)
1. Best distance correction
2. Best distance correction & +0.50D spherical refractive blur
3. Best distance correction & +1.00D spherical refractive blur
4. Best distance correction & -1.00D cylinder axis 45

Key secondary outcome(s))
None

Completion date
01/08/2019

Eligibility

Key inclusion criteria
1. At least 18 years of age
2. Have read and understood the Participant Information Sheet and gave Informed Consent
3. Pseudophakic successfully implanted with AcrySof® IQ Monofocal IOLs bilaterally for at least 3 months but no longer than 24 months
4. Best-corrected visual acuity of at least +0.20 logMAR (20/32) in each eye
5. 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

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Ocular anterior segment infection, inflammation, abnormality, or active disease that would contraindicate study participation
2. History of any ocular surgical procedures or surgeries other than cataract surgery including but not limited to limbal relaxing incision (LRI),astigmatic keratotomy, laser-assisted in situ keratomileusis (LASIK), and retinal laser treatment
3. Use of systemic or ocular medications that could be contraindicated as determined by the investigator

4. Any moderate or severe ocular condition observed during the slit-lamp examination prior to study vision measurements
5. Known pregnancy or lactation during the study period

Date of first enrolment
04/01/2019

Date of final enrolment
30/07/2019

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 Investigator Initiated Study Grant #IIT42375343

Funder Name
Alcon Research Institute

Alternative Name(s)
ARI

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. This is an early feasibility study conducted by Ocular Technology Group in order to gain insights into vision testings protocol. Data will be held at the site.

IPD sharing plan summary
Not expected to be made available

Study outputs

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