

Comprehensive intermediate and near vision testing with trifocal intraocular lenses

Submission date 04/03/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/03/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 10/03/2020	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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. The replacement lens known as 'Trifocal' lens has 'multiple focus'. People who get a trifocal intraocular lens (IOL) will be able to see well at all distances (far, intermediate and near) and do not require spectacles specifically for intermediate and near vision. The aim of this study is to evaluate the impact of different types of defocus on the intermediate and near visual performance of trifocal IOL and to measure intermediate and near vision with a comprehensive OTGi vision test system compared to a standard ETDRS vision test.

Who can participate?

People aged 18 years or older who had successful cataract surgery and both eyes implanted with trifocal IOL (at least 3 to 24 months)

What does the study involve?

The study comprises of one scheduled visit of approximately 4-5 hours. Participants will be given four different spectacle corrections in a random sequence and their intermediate and near vision will be measured with two different letter charts using high and low contrasts under standard room lighting. Participants will be asked to read out and identify the letters presented in the letter charts with both eyes. In total, 10 vision measurements (5 for intermediate vision and 5 for near vision) will be taken with each correction. Regular breaks will be provided. At the end of the visit the participant will be discharged from the study.

What are the possible benefits and risks of participating?

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 with their trifocal IOL. Due to the nature and duration of the study, the risks of participating are minimal. Participants will be reading letter charts from an intermediate (67 cm) and near (40 cm) position. All the assessments are safe, and none present any increased risk compared with a routine vision test.

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?
February 2019 to October 2019

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

Who is the main contact?
Kishan Patel
kpatel@otg.co.uk

Contact information

Type(s)
Scientific

Contact name
Mr Kishan Patel

Contact details
66 Buckingham Gate
London
United Kingdom
SW1E 6AU
+44 (0)20 7222 4224
kpatel@otg.co.uk

Type(s)
Scientific

Contact name
Ms Sylvie Franz

Contact details
Ocular Technology Group
66 Buckingham Gate
London
United Kingdom
SW1E 6AU
-
sfranz@otg.co.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)

254198

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

OTGi ID 18-52, IRAS 254198

Study information

Scientific Title

Technology validation and optimization for Trifocal Intra Ocular Lens visual performance quantification

Study objectives

The different types of defocus and contrast conditions will have an impact on the intermediate and near visual performance of pseudophakic subjects implanted with trifocal IOLs. Comprehensive intermediate and near vision testing will provide better discrimination compared to standard testing.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 30/10/2018, Yorkshire & The Humber - Leeds East Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne NE2 4NQ, UK; +44 (0)207 104 8081; nrescommittee.yorkandhumber-leedseast@nhs.net), ref: 18/YH/0430

Study design

Interventional randomized cross over trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Vision of pseudophakic patients implanted with trifocal IOLs

Interventions

Participants who have been implanted with trifocal 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, four different spectacle corrections will be worn in a random sequence and intermediate (67 cm) and near (40 cm) vision will be measured with two different letter charts (OTGi and ETDRS) using high and low contrasts and standard room lighting level. Participants will be asked to read out and identify the letters presented in the letter charts with both eyes. In total, 10 vision measurements (5 for

intermediate and 5 for near) 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 the 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)

Trifocal intraocular lens

Primary outcome(s)

Intermediate and near 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 ten vision testing conditions with two different contrasts (high and low) and timed:

1. Best distance correction
2. Best distance correction & +0.50D spherical refractive blur
3. Best distance correction & -0.50D spherical refractive blur
4. Best distance correction & -1.00D cylinder axis 45

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

31/10/2019

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® PanOptix (TFNT00) or RayOne Trifocal by Rayner or Fine Vision Trifocal by PhysiOL 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

01/02/2019

Date of final enrolment

30/10/2019

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 #IIT42375403

Alternative Name(s)

Funding Body Type

Government 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 testing 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