

Effect of eye astigmatism on multifocal contact lenses

Submission date 12/06/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/06/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/11/2020	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Multifocal contact lens wearers have varying low degrees of astigmatism which affect both visual performance and visual satisfaction. Astigmatism, along with short sight and long sight, is a common cause of blurry vision. It's usually corrected with glasses or contact lenses.

Astigmatism means your eye is shaped more like a rugby ball than a football, so light is focused at more than one place in the eye.

The aim of the study is to measure the effect of astigmatism on visual acuity and vision satisfaction when wearing multifocal contact lenses.

Who can participate?

Adults who are at least 40 years old, who have healthy eyes and wear multifocal contact lenses and have astigmatism from -0.50D to -1.00D in each eye.

What does the study involve?

The study involves a single visit during which the effect of various levels of astigmatism is being tested. The routine includes consenting the participant followed by screening to take part in the study and if they fulfil the inclusion criteria a series of various vision measurements will be carried out.

What are the possible benefits and risks of participating?

The participants are current multifocal contact lens wearers and they will use under approved application multifocal contact lenses which are CE marked. The risk to the participants are no greater than wearing their own contact lenses. The risks are further minimised by the fact that the contact lenses will only be worn in the clinic under the supervision of the investigators. The possible benefit to the participant who all have low level of astigmatism is for them to experience the effect of correcting their astigmatism on their vision.

Where is the study run from?

Ocular Technology Group - International (UK)

When is the study starting from and how long is it expected to run for?

July 2020 to December 2020

Who is funding the study?
CooperVision Inc. (USA)

Who is the main contact?
Deborah Moore, dmoore@otg.co.uk

Contact information

Type(s)
Public

Contact name
Mrs Deborah Moore

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
281917

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CV20-43 ID20-15, IRAS 281917

Study information

Scientific Title
The effect of astigmatism axis location on multifocal contact lens visual performance

Study objectives
The study is a pilot feasibility study so formal hypothesis testing involving a sample size to demonstrate superiority is not possible. However, the study will give guidance as to the benefits of correcting astigmatism on axis versus misalignment of 100 or 200 for multifocal contact lens correction.

The key aspect to be evaluated will be that at least one misalignment of the astigmatic correction will achieve a visual performance that is not inferior to the visual performance achieved with the optimal alignment of the astigmatic correction.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 19/05/20, London - City & East Research Ethics Committee (Bristol Research Ethics Committee Centre, Whitefriars, Level 3, Block B, Lewis Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8214; cityandeast.rec@hra.nhs.uk), ref: 20/LO/0633

Study design

Non dispensing prospective randomised (order of testing) cross over double-masked observational study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Other

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Presbyopia vision correction using multifocal contact lenses

Interventions

Multifocal contact lens wearers have various levels of astigmatism and it is important to understand how this astigmatism is effecting visual performance and visual satisfaction. In the study both will be measured when the astigmatism is fully corrected and for different levels of miscorrection.

The method used to measure visual performance will be time-limited logMAR visual acuity at distance, 4 metres, and near, 40cm.
Visual satisfaction will be recorded for similar conditions using 100 point visual analogue scales.

The participant will attend a single study visit of approximately 5 hours duration during which they will be screened and enrolled into the study and will wear one pair of contact lenses with different levels of astigmatic correction in spectacle form. Remaining at all times in the clinic. The participants visual acuity and visual satisfaction will be recorded with the different levels of astigmatic correction

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

MyDay Multifocal Daily Disposable Contact Lenses. Manufactured by CooperVision Inc (USA)

Primary outcome measure

Overall monocular binocular distance timed visual acuity measured using computerised test charts. The visual acuity is measured in logMAR at 4 m and 40 cm at the time of data collection.

Secondary outcome measures

Measured at a single timepoint:

1. Monocular and binocular distance timed controlled visual acuity for the individual lighting and contrast conditions measured using computerised test charts. The visual acuity is measured in logMAR.
2. Near binocular visual acuity under different contrast conditions. The visual acuity is measured in logMAR.
3. Visual satisfaction on 0 - 100 point visual analog scale.

Overall study start date

23/03/2020

Completion date

31/12/2020

Eligibility**Key inclusion criteria**

1. At least 40 years old
2. Have read and understood the participant information sheet in English
3. Have read, signed and dated the Informed Consent
4. Best corrected visual acuity of at least 20/25 in each eye
5. Have normal eyes with the exception of the need for visual correction
6. Current multifocal contact lens wearer
7. Spectacle refraction:
Distance: Sphere: -6.00D to + 4.00D
Astigmatism: -0.50DC to -1.00DC in each eye
Axis: 180° ± 20° or 90° ± 20°
Near Addition: +0.75D to +2.50D
7. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule.

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

30

Key exclusion criteria

1. Ocular anterior segment infection, inflammation, abnormality, or active disease that would contraindicate contact lens wear
2. 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 new prescription eyedrops which is not rewetting/lubricating eyedrops for which contact lens wear could be contraindicated as determined by the investigator
3. Monocular participants (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 enrolment visit
5. History of herpetic keratitis, ocular surgery or irregular cornea
6. Known pregnancy or lactation during the study period
7. Enrolment 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

01/07/2020

Date of final enrolment

30/09/2020

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Ocular Technology Group - International

66 Buckingham Gate

London

United Kingdom

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Sponsor information

Organisation

CooperVision (United States)

Sponsor details

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Sponsor type

Industry

Funder(s)

Funder type

Industry

Funder Name

Cooper Vision Inc. (USA)

Results and Publications

Publication and dissemination plan

There are no specific plans for publication or dissemination of the study results. However, an abstract for submission at an ophthalmic conference and/or peer reviewed publication may be generated.

Intention to publish date

30/03/2022

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results	version V0.2	27/10/2020	11/11/2020	No	No
HRA research summary			28/06/2023	No	No