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Effect of eye astigmatism on multifocal contact lenses

Submission date
12/06/2020

Recruitment status
No longer recruiting

Registration date
22/06/2020

Overall study status
Completed

Last Edited
11/11/2020

Condition category
Eye Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 t 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
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
281917

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Diagnostic

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 Mutifocal Daily Disposable Contact Lenses. Manufactured by CooperVison Inc (USA)

Primary outcome(s)

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.

Key secondary outcome(s))
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 conditons. The visual acuity is measur3ed in logMAR.
3. Visual satisfaction on 0 - 100 point visual analog scale.

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: 180o ± 20o or 90o ± 20o
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

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 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
United Kingdom

England

Study participating centre
Ocular Technology Group - International
66 Buckingham Gate
London
United Kingdom
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Sponsor information

Organisation
CooperVision (United States)

Funder(s)

Funder type
Industry

Funder Name
Cooper Vision Inc. (USA)

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes