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Performance and acceptance of spherical vs toric multifocal contact lenses

Submission date
17/03/2021

Recruitment status
No longer recruiting

Registration date
18/03/2021

Overall study status
Completed

Last Edited
22/09/2021

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
Presbyopia is the gradual loss of the eyes' ability to focus on nearby objects. It's a natural, often annoying part of ageing. Presbyopia usually becomes noticeable in the early to mid-40s and continues to worsen until around age 65.
Multifocal contact lenses (contact lenses that correct both distance and near vision for people who need reading glasses) come in very different designs, some giving better vision at near or at distance. In order to improve this type of contact lenses it is important to compare how well different designs are tolerated by patient and correct vision.
The study compares the level of vision satisfaction and the visual acuity achieved by two different contact lenses types currently available for people with presbyopia (needing distance and near vision correction) with astigmatism (a common vision problem caused by an error in the shape of the cornea).

Who can participate
Adults who are at least 40 years old, have healthy eyes, are current multifocal contact lens wearers, and have an astigmatism

What does the study involve?
Each participant attends the clinic on four occasions. At the first visit after being screened and enrolled in the study, their eyes are examined and the study contact lenses are ordered to the research clinic in both types of study contact lens. The second visit takes place once the study contact lenses have arrived at the clinic and are ready to be dispensed. Contact lenses are dispensed in a randomly assigned order. Visit 3 takes place about 1 week later and the contact lenses which the participant wore are assessed. Then, the participant is dispensed with the other contact lens pair, which they wear for 1 week. At the fourth and final visit, the contact lenses that have been worn are assessed and the participant is discharged from the study.

What are the possible benefits and risks of participating?
The participants will have the opportunity to try two different types of multifocal contact lenses which they may prefer to their own multifocal contact lenses and at a later date may decide to opt for these lenses. The two contact lens types are CE marked and therefore the risks are no different to them wearing their own contact lenses.

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

When is the study starting from and how long is it expected to run for?
August 2020 to December 2021

Who is funding the study?
CooperVision International Limited (UK)

Who is the main contact?
Deborah Moore
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
294068

Protocol serial number
CV20-97 ID20-77

Study information

Scientific Title
Performance and acceptance of spherical vs toric multifocal contact lenses in a low astigmatic population - proof of concept study

Acronym
Harlequin

Study objectives
Overall vision satisfaction will not be inferior with toric clariti® multifocal contact lenses than with spherical clariti® 1-day multifocal contact lenses but will trend towards better vision.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/03/2021, East of England - Essex Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)2071048106; essex.rec@hra.nhs.uk), REC ref: 21/EE/0034

Primary study design
Interventional

Study design
Single-centre interventional randomized crossover double-masked trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Presbyopia and astigmatism

Interventions
Multifocal contact lenses are prescribed to provide wearers with good vision satisfaction and visual performance using the manufactures prescribing routine. It is important to compare this feature for a new contact lens with established contact lenses.

The study is a cross over study, the participants wear both contact lens types (Biofinity and Pluto daily disposable multifocal contact lenses) for 1 week each, the randomisation is limited to the order of testing, the randomisation process is a computer-based randomisation selection process.

Each participant attends the clinic on four occasions. At the first visit after being screened and enrolled in the study, their eyes are examined and the study contact lenses are ordered to the research clinic in both types of study contact lens. The second visit takes place once the study contact lenses have arrived at the clinic and are ready to be dispensed. Contact lenses are dispensed in a randomly assigned order. Visit 3 takes place about 1 week later and the contact lenses which the participant wore are assessed. Then, the participant is dispensed with the other contact lens pair, which they wear for 1 week. At the fourth and final visit, the contact lenses that have been worn are assessed and the participant is discharged from the study.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Visual satisfaction measured on a 100-point visual analogue scale after 1 week of wear

Key secondary outcome(s)
1. Visual performance measured using LogMAR at distance, intermediate and near and monocularly after 1 week of wear

2. Lens centration measured using a 4-point forced-choice scale at Visits 3 and 4
3. Lens movement measured using a 5-point forced-choice scale at Visits 3 and 4
4. Intention to purchase measured using a 5-point forced-choice scale at Visits 3 and 4
5. Overall preference measured using a forced-choice scale with two alternatives at Visits 3 and 4

Completion date
31/12/2021

Eligibility

Key inclusion criteria
There are no requirements as to participant race or gender. In order to be enrolled, each participant shall meet the following criteria:
1. 40 or more years of age
2. Current multifocal contact lens wearer
3. Spectacle refraction:
Distance: Sphere: -6.00 D to + 4.00 D
Astigmatism
Power: -0.50 D to -1.25 D
Axis; 180o ± 20o & 90o ± 20o
Near addition: at 40 cm: +0.75 D to +2.50 D in three groups:
- Emerging presbyopes: +0.75 D to +1.25 D
- Established presbyopes: +1.50 D and +1.75 D
- Advanced presbyopes: +2.00 D to +2.50 D
4. Best corrected visual acuity of at least 20/25 in each eye

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
24

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 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
19/03/2021

Date of final enrolment
31/07/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Optometric Technology Group - International
66 Buckingham Gate
London
United Kingdom
SW1E 6AU

Sponsor information

Organisation
CooperVision International Ltd

Funder(s)

Funder type
Industry

Funder Name

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?
Basic results	version 0.1	13/09/2021	22/09/2021	No	No
HRA research summary			28/06/2023	No	No