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Comparative performance and acceptance validation study of CVI new multifocal contact lenses

Submission date	Recruitment status	[_] Prospectively registered
10/02/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/02/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/09/2020	Eye Diseases	

Plain English summary of protocol

Background and study aims
Presbyopia is a condition associated with ageing in which the eye's ability to focus on near objects gradually becomes more difficult. Multifocal contact lenses can be used to help individuals with presbyopia to see objects both in the distance and up close; however, how well these contact lenses perform depends on the wearer's prescription, the activities that they are conducting and the lighting conditions. The aim of this study is to measure and compare the visual performance and visual satisfaction achieved with two pairs of multifocal contact lenses which are designed to correct distance, intermediate and near vision.

Who can participate?
Adults who are at least 40 years old and who have healthy eyes other than for needing a near vision correction

What does the study involve?
Participants' eyes will be examined by the investigator and they will be fitted with a pair of the first type of multifocal contact lenses. They will be provided with a supply of these lenses to be worn on a daily disposable basis (wearing one pair each day and discarding it at the end of the day) and asked to return after a period of 7 to 10 days. At this time they will be asked to complete a short questionnaire about the lenses and then the investigator will measure their vision with the lenses. They will be asked to read letters of different sizes on both a computer screen and on smaller electronic tablets under bright, normal and dim lighting conditions. They will then remove the lenses and their eyes will once again be examined by the investigator before they are fitted with a pair of the second type of multifocal lenses. They will be provided with a supply of these lenses to be worn on a daily disposable basis to return after a further period of 7 to 10 days. At this time they will be asked to complete a short questionnaire about the lenses and then the investigator will measure their vision with these lenses. They will then remove the lenses and their eyes will once again be examined by the investigator before they are discharged from the study. All study participants will undergo the same series of vision tests and tasks.

What are the possible benefits and risks of participating?
The possibility exists that participants may not directly benefit from participation in this study. Their participation, however, is contributing scientific research information that may be used in the development of new, perhaps more successful, contact lenses. The examination and assessments of the front part of the eye are at no cost to the participants and can be considered beneficial by documenting their current health status. All contact lenses have the potential of causing serious injury to the eye. Due to the nature and duration of the study, the risks of participating in this study are considered to be similar to those of normal contact lens wear. It is possible that the following problems may occur with the use of contact lenses: eyes stinging, burning, itching (irritation) or other eye pain; comfort is less than when lens was first placed on the eye; feeling that something is in the eye such as a foreign body or scratched area; excessive watering (tearing) of the eye; unusual eye secretions; redness of the eye; reduced sharpness of vision (poor visual acuity); blurred vision, rainbows, or halos around objects; sensitivity to light (photophobia); or dry eyes. If participants experience any of these, they should let the investigator know as soon as possible. In rare instances, corneal ulcers, scarring, the growth of blood vessels into the cornea, temporary or permanent decreased vision, iritis and infections of the eye requiring treatment might occur.

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

When is study starting and how long is it expected to run for?
January 2018 to August 2018

Who is funding the study?
CooperVision Inc (USA)

Who is the main contact?
Ms Trisha Patel
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Contact information

Type(s)
Public

Contact name
Mr Kishan Patel

Contact details
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
241098

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CV 17-81/OTGi 17-88, IRAS 241098

Study information

Scientific Title
Comparative performance and acceptance validation study of CooperVision new multifocal contact lenses vs. 1-Day Acuvue® moist contact lenses

Study objectives
This is an initial verification study, therefore there is no formal hypothesis. The intent is to assess if a trend is present, to show that the overall visual satisfaction and the number of lenses used to attain the optimal lens with CVI MF is equivalent to 1DAVM.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/02/2018, London - Harrow Research Ethics Committee (Level 3, Block B Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; Tel: +44 (0)207 104 8057; Email: nrescommittee.london-harrow@nhs.net), ref: 18/LO/0162

Study design
Interventional randomized cross over trial with investigator and participant masking

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Treatment

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

Interventions
Participants will be wearing two different MF CL (Test - CVI MF, Control - 1DAVM). Their eyes will be examined by the investigator and they will be fitted with a pair of the first type of multifocal contact lenses. They will be provided with a supply of these lenses to be worn on a daily disposable basis (wearing one pair each day and discarding it at the end of the day) and asked to return after a period of 7 to 10 days. At this time they will be asked to complete a short questionnaire about the lenses and then the investigator will measure their vision with the lenses. They will be asked to read letters of different sizes on both a computer screen and on smaller electronic tablets under bright, normal and dim lighting conditions. They will then remove the lenses and their eyes will once again be examined by the investigator before they are fitted with a pair of the second type of multifocal lenses. They will be provided with a supply of these lenses to be worn on a daily disposable basis to return after a further period of 7 to 10 days. At this time they will be asked to complete a short questionnaire about the lenses and then the investigator will measure their vision with these lenses. They will then remove the lenses and their eyes will once again be examined by the investigator before they are discharged from the study. All study participants will undergo the same series of vision tests and tasks.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
1. Subjective overall visual satisfaction measured using the Visual Analog Scale (VAS) at baseline and after 1-week wear with each contact lens type
2. The number of contact lenses needed (count) for fitting per eye prior to dispensing is recorded for each contact lens type

Secondary outcome measures
Binocular visual performance (LogMAR visual acuity) measured using letter charts at baseline and after 1-week wear with each contact lens type

Overall study start date
10/01/2018

Completion date
01/08/2018

Eligibility

Key inclusion criteria
1. At least 40 years old
2. Have read and understood the Participant Information Sheet
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: 0.00D to -0.75D
Near Addition: +0.75D to +2.50D

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Up to a total of 60 participants

Key exclusion criteria
1. Ocular anterior segment infection, inflammation, abnormality, or active disease that would contraindicate contact lens wear
2. Use of systemic or ocular medications 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
01/02/2018

Date of final enrolment
01/06/2018

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre

Ocular Technology Group - International
66 Buckingham Gate
London
United Kingdom
SW1E 6AU

Study participating centre
Peter Ivins Eye Care
72 Drymen Road, Bearsden
Glasgow
United Kingdom
G61 2RH

Sponsor information

Organisation
CooperVision (United States)

Sponsor details
5870 Stoneridge Drive, Suite 1
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Sponsor type
Industry

Website
http://www.coopervision.com

Funder(s)

Funder type
Industry

Funder Name
CooperVision

Results and Publications

Publication and dissemination plan

1. Study documents (such as study protocol, informed consent, participant information sheet) can be requested by writing to the Principal Investigator and will be made available based on Study Sponsor approval
2. Conference presentation, journal publication

Intention to publish date

01/02/2021

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

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			15/04/2020	No	No
Basic results		08/09/2020	17/09/2020	No	No
HRA research summary			28/06/2023	No	No