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Contact lens fitting characteristics study

Submission date	Recruitment status	[X] Prospectively registered
22/06/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/06/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/11/2020	Eye Diseases	

Plain English summary of protocol

Background and study aims
The shape of the edge of the contact lens influences the way the lens fits on the eye and its comfort. Different contact lenses have got different edges. The aim of the study is to compare how the lens fits on the eye along with its comfort for different multifocal contact lenses with different edge designs.

Who can participate?
Adults who are least 40 years old, who have healthy eyes, who wear contact lenses and are starting to get longsightedness (near addition +0.75 to +1.25).

What does the study involve?
A single visit during which the participant will use the 3 study contact lenses each for 2 hours.

What are the possible benefits and risks of participating?
The participants are current contact lens wearers and they will use under the control of the investigator the 3 currently marketed contact lenses. The risks to the participant are no greater than wearing their own contact lenses. The risks will be 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 will be to try different contact lenses with different levels of comfort that they could eventually purchase from their own practitioner.

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?
May 2020 to December 2020

Who is funding the study?
Cooper Vision Inc (USA)

Whi is the main contact?
Deborah Moore
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
281961

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CV20-42 ID20-17, IRAS 281961

Study information

Scientific Title
The effect of contact lens parameters and material on fitting characteristics - pilot study

Study objectives
Mechanical performance of contact lenses with a feather edge design is not inferior to that with a chisel edge design.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/05/2020, North West - Preston Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8056; preston.rec@hra.nhs.uk), ref: 20/NW/020

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

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

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 multifocal contact lens fitting

Interventions
Each participant uses all 3 contact lenses in a random order for a 2 hour period, after which the contact lens fitting measurement and comfort measurement are being carried out.

1. Measurement of contact lens decantation (horizontal and vertical) from the centre of the pull (mm). The measurement to be performed in primary gaze and reading gaze.
2. Lens centration and lens movement classification on 5 point scale.
3. Contact lens comfort rating on 100 point VAS scale.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Clariti 1 day single vision contact lens Clariti 1 day multifocal low addition contact lens MyDay multifocal low addition contact lens

Primary outcome measure
Contact lens decentration is measured from high speed video taken after 2 h of wear

Secondary outcome measures
Measured after 2 h of wear:
1. Lens centration rating on a 5 point scale by investigator using a slit lamp biomicroscope
2. Lens movement rating on a 5 point scale by investigator using a slit lamp biomicroscope
2. Comfort rating by participant using a computer based 100 point VAS scale

Overall study start date
25/05/2020

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 contact lens wearer
7. Spectacle refraction:
Distance: Sphere: -6.00D to + 4.00D
Astigmatism: 0.00DC to -0.75DC
Near Addition: +0.75D to +1.25D
8. 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

Sex
Both

Target number of participants
20

Total final enrolment
15

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
29/07/2020

Date of final enrolment
01/12/2020

Locations

Countries of recruitment
England

United Kingdom

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

Organisation
Cooper Vison Inc. (USA)

Sponsor details
6150 Stoneridge Mall Road
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name

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 a peer-reviewed publication may be generated.

Intention to publish date

31/12/2021

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

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results	version v0.3	27/10/2020	17/11/2020	No	No