

Contact lens fitting characteristics study

Submission date 22/06/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/06/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/11/2020	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

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)

Who is the main contact?

Deborah Moore
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Contact information

Type(s)

Public

Contact name

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

281961

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

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 decentration (horizontal and vertical) from the centre of the pupil (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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

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

Sponsor information

Organisation
Cooper Vison Inc. (USA)

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 v0.3	27/10/2020	17/11/2020	No	No