# Clinical evaluation of scleral contact lenses

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
22/06/2022		Protocol		
Registration date	Overall study status	Statistical analysis plan		
07/07/2022	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
25/04/2023	Eye Diseases			

### Plain English summary of protocol

Background and study aims

The aim of this study is to find out whether changing to a different type of scleral contact lens (different overall sagittal height) affects contact lens centration.

### Who can participate?

Adults who are least 40 years old, who have healthy eyes and who wear multifocal contact lenses.

### What does the study involve?

Phase 1 involves two study visits in which participants will be fitted with two different pairs of contact lenses at each visit. Each pair will be worn for about an hour and a half and in this time, video recordings and photos of the lens fit will be taken by a member of the study staff. The second visit will be at least 3 days after the first visit.

Phase 2 will involve participants returning to the clinic to wear a fifth pair of contact lenses and the same routine will be followed - they will wear the contact lenses for about an hour and a half and in this time, video recordings and photos of the lens fit will be taken by a member of the study staff.

# What are the possible benefits and risks of participating?

The participants are current contact lens wearers and they will use three currently marketed contact lenses under the control of the investigator. 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? June 2022 to March 2023

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

# Contact information

# Type(s)

**Public** 

#### Contact name

Ms Deborah Moore

#### Contact details

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# Additional identifiers

### **EudraCT/CTIS** number

Nil known

#### **IRAS** number

315747

# ClinicalTrials.gov number

Nil known

# Secondary identifying numbers

CV22-19 ID22-21, IRAS 315747

# Study information

#### Scientific Title

Non-dispensing clinical evaluation of customised OneFit MED scleral contact lenses

# Study objectives

The primary hypothesis to be tested will be that changing the scleral contact lens overall sagittal height will affect contact lens centration.

# Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 23/05/2022, South Central - Oxford A Research Ethics Committee (Ground Floor, Temple Quay House, 2 the Square, Bristol, BS1 6PN, UK; +44 (0)2071048290; oxforda.rec@hra.nhs.uk), ref: 22/SC/0171

### Study design

Single-centre non-randomized sequential study

### Primary study design

Interventional

### Secondary study design

Non randomised study

## Study setting(s)

Other

# Study type(s)

Treatment

### Participant information sheet

Not available in web formar, please use contact details to request a participant information sheet.

# Health condition(s) or problem(s) studied

Presbyopia

#### **Interventions**

Each participant will wear all the study contact lenses in a sequential fashion for about 1 hour and a half each. During each period of wear, contact lens fitting video recordings and photos will be taken. These will then be analysed post hoc.

## Intervention Type

Device

#### Phase

Not Applicable

# Drug/device/biological/vaccine name(s)

OneFit MED Scleral Lens

#### Primary outcome measure

Contact lens centration in primary and down gaze measured in mm after 40 minutes of wear

## Secondary outcome measures

Corneal clearance measured in mm after 40 minutes of wear

# Overall study start date

01/06/2022

### Completion date

01/03/2023

# Eligibility

### Key inclusion criteria

- 1. 40 or more years of age
- 2. Have read and understood the Participant Information Sheet in English
- 3. Have read, signed and dated the Informed Consent
- 4. Current multifocal contact lens wearer
- 5. Spectacle refraction:
- 5.1. Distance: Sphere: -6.00D to + 4.00DS
- 5.2. Astigmatism: -0.00DC to -1.50DC in each eye
- 5.3. Near Addition: +0.75D to +2.50D
- 6. Best corrected visual acuity of at least 20/25 in each eye
- 7. Have normal eyes with the exception of the need for visual correction
- 8. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

### Participant type(s)

Patient

### Age group

Adult

#### Sex

Both

### Target number of participants

30

#### 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

06/07/2022

#### Date of final enrolment

01/12/2022

# Locations

### Countries of recruitment

England

**United Kingdom** 

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

# Sponsor information

### Organisation

CooperVision International Limited

# Sponsor details

Delta Park
Concorde Way
Segensworth North
Fareham
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United Kingdom
SW1E 6AU
+1 (0)925 251 6682
PLazon@coopervision.com

## Sponsor type

Industry

#### Website

http://coopervision.com

# Funder(s)

### Funder type

Industry

#### **Funder Name**

# **Results and Publications**

# Publication and dissemination plan

There are no plans at this stage for publication or dissemination of the study results.

# Intention to publish date

# 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	<b>Details</b> version 1.0	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		24/04/2023	25/04/2023	No	No
HRA research summary			28/06/2023	No	No