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Single vision vs toric contact lens centration on the eye study

Submission date	Recruitment status	[_] Prospectively registered
05/07/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/07/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/09/2021	Eye Diseases	

Plain English summary of protocol

Background and study aims
The quality of vision produced by multifocal contact lenses (contact lenses that correct both distance and near vision in presbyopic patients) depends on how well the contact lenses centre on the eye in particular the pupil (the central black part). The centration of standard contact lenses (spherical) is well know, however, to develop new design of contact lenses is is necessary to use more complex contact lens designs which stabilise better (toric) and the centration of this type of contact lenses is not known. The aim of the study is therefore to compare the centration of the two types of contact lenses on the same eye to see if the information we have on the spherical contact lenses can be used or if new studies are necessary to precisely determine the centration of toric contact lenses.

Who can participate?
Adults who are at least 40 years old, who have healthy eyes, who wear contact lenses and are start to need reading glasses (near addition +0.75 to +1.25).

What does the study involve?
A single visit to the study clinic when the participants will wear two different pairs of contact lenses (one spherical & one toric) and have some video recordings the movement of the contact lenses on their eyes.

What are the possible benefits and risks of participating?
The participants will be current contact lens wearers and they will use under the control of the investigator the two currently marketed contact lenses. The risks to the participant are no greater than wearing their own contact lenses. The risks will be further decreased 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 2021 to October 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
300441

Protocol serial number
CV21-38 ID21-33 IRAS ID: 300441

Study information

Scientific Title
MyDay® single vision vs MyDay® toric non-dispensing centration pilot study

Study objectives
1. Lens centration in primary and downgaze of toric contact lenses is not significantly different from that of spherical contact lenses;
2. Fitting characteristics (lens centration and movement) of toric contact lenses will not be significantly different from that of spherical contact lenses.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 29/06/2021, East of England - Cambridge South Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8084; cambridgesouth.rec@hra.nhs.uk), REC ref: 21/EE/0149

Study design
Non-dispensing single-centre interventional double-blinded randomized crossover trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Each participant wears the two contact lenses in a random order for a half-hour period, after which the contact lens fitting measurements and comfort measurements are carried out.

1. Measurement of contact lens decantation (horizontal and vertical) from the centre of the pull (mm). The measurement is performed in primary gaze and reading gaze
2. Lens centration and lens movement classification on a five-point scale
3. Contact lens comfort rating on Likert scale

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MyDay Single Vision Contact Lens, MyDay Toric Contact Lens

Primary outcome(s)
Contact lens decentration measured from a high-speed video taken after 0.5 hours of wear

Key secondary outcome(s))
1. Lens centration measured on a four-point scale by investigator using a slit lamp biomicroscope after 0.5 hours of wear
2. Lens movement measured on a five-point scale by investigator using a slit lamp biomicroscope after 0.5 hours of wear
2. Comfort rating measured by participant using a computer-based six-point Likert scale after 0.5 hours of wear

Completion date
29/10/2021

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. 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 + 4.00DS
Astigmatism: -0.50DC to -1.25DC in each eye
Near Addition: +0.75D to +2.50D
8. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
21

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
05/07/2021

Date of final enrolment
15/10/2021

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
CooperVision International Limited

Funder(s)

Funder type
Industry

Funder Name
CooperVision International Limited

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current are unknown at this stage 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		29/09/2021	29/09/2021	No	No
HRA research summary			28/06/2023	No	No