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Toric multifocal contact lens development

Submission date 25/01/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/01/2024	**Overall study status** Completed	
Last Edited 21/10/2026	**Condition category** Other	

Plain English summary of protocol

Background and study aims
MyDay® Multifocal contact lenses with spherical distance vision correction are CE marked for the correction of presbyopia in patients with no or low levels of astigmatism. MyDay® Toric contact lenses are CE marked for the correction of astigmatism. Population demographics revealed that 40% of the adult population is also affected by astigmatism requiring correction to achieve good vision, hence, requiring to be fitted with multifocal contact lenses with astigmatic correction.
CooperVision is expanding the MyDay® contact lens portfolio to develop a new toric multifocal daily disposable silicone hydrogel contact lens to correct both presbyopia and astigmatism
The purpose for this non-dispensing clinical study is to confirm that the fitting guide for Investigational Toric Multifocal contact lens is not different from MyDay® Toric and MyDay® Multifocal.

Who can participate?
Adults who are current soft contact lens wearers, age 40 years and older with astigmatism and presbyopia

What does the study involve?
The participants attended the clinic for one study visit. They were fitted with the study contact. Up to three fit attempts were allowed to achieve the optimal study contact lens fit. The visual satisfaction and vision performances were evaluated with optimal study contact lens.

What are the possible benefits and risks of participating?
Participants have the opportunity to try contact lenses to correct their presbyopia and astigmatism
Any contact lens wear comes at the risk of corneal infection, but the incidence rate is very low

Where is the study run from?
Ocular Technology Group - international (OTG-i).

When is the study starting and how long is it expected to run for?
May 2024 to October 2024.

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

Who is the main contact?
Deborah Moore
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Contact information

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Scientific, Principal investigator

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Public

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Additional identifiers

Integrated Research Application System (IRAS)
327300

Protocol serial number
CV23-08

Study information

Scientific Title

Toric multifocal contact lens development phase 2 non-dispensing prescribing methodology validation

Study objectives
The primary objective was to confirm the fitting guide for ERIS Toric Multifocal test contact lens. The secondary objectives of the study was to measure overall visual performance.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/05/2023, South East Scotland Research Ethics Committee 2 (2nd Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, United Kingdom; +44 (0)131 536 9000; ruth.fraser4@nhslothian.sct.nhs.uk), ref: 23/SS/0052

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Historical

Assignment
Single

Purpose
to confirm that the fitting guide for Investigational Toric Multifocal contact lens is not different from MyDay® Toric and MyDay® Multifocal

Study type(s)
Other

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

Interventions
The participants were fitted with the study contact. Up to three fit attempt were allowed to achieve the optimal study contact lens fit. The visual satisfaction and vision performances were evaluated with optimal study contact lens.

Intervention Type
Device

Phase

Phase I

Drug/device/biological/vaccine name(s)
ERIS toric multifocal

Primary outcome(s)
The prevalence of first pair successful fit to arrive to the dispensed contact lenses

Key secondary outcome(s)
Combined binocular distance and near time controlled logMAR visual acuities

Completion date
30/10/2024

Eligibility

Key inclusion criteria
1. Aged 40 years or older to match the target population for the test product
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. Normal eyes, with the exception of the need for visual correction
6. Current contact lens wearer
7. Spectacle refraction meeting the following criteria: 7.1. Distance sphere: -9.00 D to +3.00 D 7.2. Astigmatism: -0.75 D to -2.25 D 7.3. Axis: within 10° of the study contact lens axes 7.4. Near addition: +0.75 D to +2.50 D
8. Willing and able to adhere to the instructions set out in the clinical protocol and maintain the appointment schedule
9. Healthy volunteers are allowed

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
31

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 fitted 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. The investigator or their staff, family members of the investigator, family members of the investigator's staff, or individuals living in the households of any of these individuals

Date of first enrolment
08/05/2024

Date of final enrolment
30/10/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ocular Technology Group International
66 Buckingham Gate
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England
SW1E 6AU

Sponsor information

Organisation
CooperVision International Ltd

Funder(s)

Funder type
Industry

Funder Name
CooperVision

Alternative Name(s)
CooperVision, Inc., CooperVision Inc, CooperVision Inc., CooperVision, Inc

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results	version 1.0	29/09/2026	21/10/2026	No	No