ISRCTN90702227 https://doi.org/10.1186/ISRCTN90702227

ERIS toric multifocal contact lens development

Submission date 07/08/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/08/2023	**Overall study status** Completed	
Last Edited 26/10/2026	**Condition category** Eye Diseases	

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, a requirement 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

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

What does the study involve?
The participants attended the clinic for one study visit. The participants were fitted with three pairs of study contact lenses at random order. Each contact lens was worn for 20 to 30 minutes. The ocular comfort and contact lens fit were evaluated after 5 and 15 minutes of wear.

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) (UK)

When is the study starting and how long is it expected to run for?
July 2023 to August 2023

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

Who is the main contact?
Deborah Moore, dmoore@otg.co.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Michel Guillon

Contact details
66 Buckingham Gate
London
United Kingdom
SW1E 6AU
+44 (0)20-7222-4224
MGuillon@otg.co.uk

Type(s)
Public

Contact name
Ms Deborah Moore

Contact details
66 Buckingham Gate
London
United Kingdom
SW1E 6AU
+44 (0)20-7222-4224
DMoore@otg.co.uk

Additional identifiers

Integrated Research Application System (IRAS)
326886

Protocol serial number
ID23-11A CV23-07

Study information

Scientific Title
ERIS toric multifocal contact lens development Phase I non-dispensing fitting method comparison

Study objectives

The objectives of the study were as follows:
1. The primary objective was to compare the fitting characteristics of ERIS Toric Multifocal contact lenses to the fitting characteristics of MyDay® Toric contact lenses
2. The secondary objective was to compare short-term comfort achieved with ERIS Toric Multifocal contact lenses to the short-term comfort achieved with MyDay® Toric contact lenses

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/05/2023, South East Scotland Research Ethics Committee 02 (2nd Floor, Waverley Gate 2-4 Waterloo Place, Edinburgh, EH1 3EG, United Kingdom; +44 (0)1315369000; ruth.fraser4@nhslothian.scot.nhs.uk), ref: 23/SS/0051

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Uncontrolled

Assignment
Contralateral

Purpose
Treatment

Study type(s)
Other

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

Interventions
The study participants were fitted with three pairs of contact lenses; The contact lenses were fitted in a random sequence and worn for 20 and 30 minutes with a break of 10 minutes not wearing contact lenses between each worn pair. The ocular comfort and contact lens fit were evaluated after 5 and 15 minutes of wear.

Intervention Type
Device

Phase
Phase I

Drug/device/biological/vaccine name(s)

MyDay® Toric , ERIS toric multifocal

Primary outcome(s)
Fitting characteristics assessed using high magnification video recording of the contact lens fit in primary gaze using an iPhone 13 attached to the slit lamp biomicroscope during the visit

Key secondary outcome(s)
Ocular comfort measured using a 100-point visual analog scale during the visit

Completion date
03/08/2023

Eligibility

Key inclusion criteria
1. Age 40 years or greater 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. Have normal eyes with the exception of the need for visual correction
6. Current contact lens wearer
7. Spectacle refraction:
Distance: Sphere: -9.00D to + 3.00D
Astigmatism: -0.75D to -2.25D
Axis: 20o to 160o & 70o to 110o
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)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
40 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
20

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 contact lens
4. Subjects with slit lamp findings greater than grade 1 (e.g. edema, infiltrates, corneal neovascularization, corneal staining, tarsal abnormalities, conjunctival, anterior segment inflammation) as per ISO 11980, any previous history or signs of a contact lens related corneal inflammatory event (past corneal ulcers), or any other ocular abnormality that may contraindicate contact lens wear at the enrolment visit
5. History of herpetic keratitis, ocular surgery or irregular cornea
6. Enrolment of the 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
10/07/2023

Date of final enrolment
03/08/2023

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
CooperVision International Limited

Funder(s)

Funder type
Industry

Funder Name
Cooper Vision International Ltd

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		29/06/2026	26/10/2026	No	No