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Contact lenses comfort daily variation

Submission date 09/05/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/05/2024	**Overall study status** Completed	
Last Edited 27/02/2025	**Condition category** Eye Diseases	

Plain English summary of protocol
Background and study aims
Some clinical evidence suggests that eye discomfort with soft toric contact lenses is different to that experienced by spherical soft contact lens wearers. The aim of this study is to assess and compare eye discomfort during contact lens wear with spherical and toric soft contact lenses manufactured with the same material.

Who can participate?
Adults aged 18 to 35 years who are current soft contact lens wearers and have low levels of astigmatism (imperfection in the curvature of the eye)

What does the study involve?
Participants will attend the clinic on two separate occasions about 10 hours apart. At the first visit the participant will be fitted with the relevant study contact lenses MyDay spherical for the control group and MyDay toric for the test group. At visit 2 comfort will be assessed by the investigators.

What are the possible benefits and risks of participating?
Participants have the opportunity to try contact lenses to correct their astigmatism. Any contact lens wear comes at the risk of corneal infection, but the incidence 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?
December 2023 to October 2024

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
341662

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CV24-15 OTG-i ID 24-09, IRAS 341662

Study information

Scientific Title
Spherical and toric contact lenses' comfort and wettability diurnal variation

Study objectives
Whereas the study is an exploratory study the primary working hypothesis to be tested is that at the end of the wearing period comfort of a toric contact lens in a population of habitual toric

contact lens wearers is non-inferior to the comfort of a spherical contact lens made from the same material and manufacturing technology in a population of habitual spherical contact lens wearers.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/04/2024, London - Surrey Borders Research Ethics Committee (Equinox House City Link, Nottingham, NG2 4LA, United Kingdom; Not available; surreyborders.rec@hra.nhs.uk), ref: 24/PR/0373

Study design
Interventional open-label prospective investigator-masked parallel-group study

Primary study design
Interventional

Secondary study design
Open-label, prospective

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
Participants will attend the clinic for two study visits about 10 hours apart and complete a series of remote questionnaires while wearing the study contact lenses. At the first visit the participant will be fitted with the relevant study contact lenses MyDay spherical for the control group and MyDay toric for the test group. At visit 2 comfort will be assessed by the investigators.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase IV

Drug/device/biological/vaccine name(s)

MyDay Toric®, MyDay® spherical

Primary outcome measure
Contact lens comfort measured using a 100-point Visual Analogue Scale (VAS) at the end of the wearing period (10 hours)

Secondary outcome measures
1. Exposed contact lens surface area under the curve at selected timepoints post eye opening at insertion and at the end of the wearing period, measured from tear film digital video recording using the tearscope lighting system during the investigational visit
2. Contact lens decentration classification at the end of the wearing period measured using a four-point forced choice scale
3. Ease of contact lens insertion and removal measured using a 100-point visual analogue scale (VAS) during the visit

Overall study start date
23/12/2023

Completion date
31/10/2024

Eligibility

Key inclusion criteria
1. Age 18 to 35 years
2. Best corrected visual acuity in each eye of 20/25
3. Control population:
3.1. Current spherical contact lens wearer but not MyDay®
3.2. Spectacle refraction:
Sphere: -6.00D to + 2.00D
Astigmatism: 0.00D to -0.75D
4. Test population:
4.1. Current toric contact lens wearer but not MyDay® toric
4.2. Spectacle refraction:
Sphere: -6.00D to + 2.00D
Astigmatism: -0.75D to -1.25D

The prospective participants will be given a Participant Information Sheet to read and an Informed Consent Form to sign prior to any evaluation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit

35 Years

Sex
Both

Target number of participants
50

Total final enrolment
40

Key exclusion criteria
1. Acute and subacute inflammation or infection of the anterior chamber of the eye
2. Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids that would contraindicate contact lens wear;
3. Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
4. Severe insufficiency of lacrimal secretion (dry eyes)
5. Any systemic disease that may affect the eye or may be exaggerated by wearing contact lenses (e.g. acne and eczema)
6. Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
7. Any active corneal infection (bacterial, fungal, protozoal or viral)
8. 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
9. Monocular participants (only one eye with functional vision) or participants fit with only one contact lens
10. 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
11. History of corneal refractive surgery
12. Enrolment of the family members of the investigator, family members of the investigator's staff, or individuals living in the households of these individuals
13. Current wearer of the control contact lenses MyDay® spherical or the test contact lenses MyDay Toric®

Date of first enrolment
15/05/2024

Date of final enrolment
30/09/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Ocular Technology Group – International
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Sponsor information

Organisation
CooperVision International Limited

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Sponsor type
Industry

Website
https://coopervision.com

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

Publication and dissemination plan
There are no plans at this stage for publication or dissemination.

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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		25/11/2024	27/02/2025	No	No