

# Contact lenses comfort daily variation

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| <b>Submission date</b><br>09/05/2024   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>16/05/2024 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>27/02/2025       | <b>Condition category</b><br>Eye Diseases         | <input type="checkbox"/> Individual participant data  |

## 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?

Deborah Moore, [dmoore@otg.co.uk](mailto:dmoore@otg.co.uk)

## Contact information

**Type(s)**

Public

**Contact name**

Ms Deborah Moore

**Contact details**

66 Buckingham Gate  
London  
United Kingdom  
SW1E 6AU  
+44 (0)2072224224  
dmoore@otg.co.uk

**Type(s)**

Scientific, Principal investigator

**Contact name**

Dr Michel Guillon

**Contact details**

66 Buckingham Gate  
London  
United Kingdom  
SW1E 6AU  
+44 (0)2072224224  
mguillon@otg.co.uk

## Additional identifiers

**Integrated Research Application System (IRAS)**

341662

**Protocol serial number**

CV24-15 OTG-i ID 24-09

## 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**

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## **Ethics approval(s)**

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

## **Study design**

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

## **Primary study design**

Interventional

## **Study type(s)**

Other

## **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

## **Phase**

Phase IV

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

MyDay Toric®, MyDay® spherical

## **Primary outcome(s)**

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

## **Key secondary outcome(s)**

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

## **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

35 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**Ocular Technology Group – International**

66 Buckingham Gate

London

United Kingdom

SW1E6AU

## **Sponsor information**

**Organisation**

CooperVision International Limited

## **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**

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? |
|-------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Basic results</a> |         | 25/11/2024   | 27/02/2025 | No             | No              |