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Clinical evaluation of prototype scleral contact lenses

Submission date	Recruitment status	[_] Prospectively registered
20/11/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/11/2024	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/10/2026	Eye Diseases	

Plain English summary of protocol

Background and study aims
A pre-presbyopic crystalline lens changes dioptric power (focus) by changing its shape due to its elasticity. The main optical function of the crystalline lens is to transmit light, focusing it on the retina offering clear vision at all distances. When presbyopia occurs the crystalline lens can no longer change power effectively which is caused by loss of elasticity of the contact lens of the eye, occurring typically in middle and old age and different corrections are needed for distance and near vision.

The current study is the first study of the initial proof of concept phase utilising a novel optic to demonstrate that this new optic does not affect adversely the visual performance of the contact lens.

The rationale is to measure the effect of a novel optic scleral contact lenses compared with the same scleral contact lens design without the novel optic.

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 two visits. during each they were fitted with control or test contact lens selected randomly. The study contact lenses were worn for 30 minutes. At the end of end of the wearing period the visual performance, ocular comfort, vision satisfaction were evaluated.

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?
04 September 2024 until 29 October 2024

Who is funding the study?
CooperVision International Limited

Who is the main contact?
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Contact information

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Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
342156

Protocol serial number
ID23-37 CV23-38

Study information

Scientific Title
Non-dispensing clinical evaluation of prototype scleral contact lenses with novel optics

Study objectives
The primary objective was to measure high contrast ETDRS monocular visual acuity under photopic condition.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/06/2024, South East Scotland Research Ethics Committee 02 (2nd Floor, Waverley Gate 2-4 Waterloo Place, Edinburgh, EH1 3EG, United Kingdom; +44 131 5369000; ruth.fraser4@nhslothian.scot.nhs.uk), ref: 24/SS/0049

Primary study design
Interventional

Study design
Non dispensing bilateral randomized study

Study type(s)
Other

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

Interventions
The participants attended the clinic for two visits. during each they were fitted with control or test contact lens selected randomly. The study contact lenses were worn for 30 minutes. At the end of end of the wearing period the visual performance, ocular comfort, vision satisfaction were evaluated.

Intervention Type
Device

Phase
Phase I

Drug/device/biological/vaccine name(s)
Test : Prototype scleral contact lenses with Novel Optics / Control : OneFit MED scleral contact lenses

Primary outcome(s)
Measurement of high contrast ETDRS monocular visual acuity under photopic condition.

Key secondary outcome(s)

Completion date
29/10/2024

Eligibility

Key inclusion criteria
1. 40 or more years of age
2. Contact lens wearer
3. Spectacle refraction:
3.1. Distance: Sphere: -6.00D to + 4.00D
3.2. Astigmatism: 0.00D to -1.00D
3.3. Near Addition: +1.25D to +2.50D
4. Best corrected visual acuity of at least 20/25 in each eye
5. Total wearing time of prototype contact lenses in previous implementations of less than 22 hours
6. 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)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
40 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
11

Key exclusion criteria
1. Acute or subacute 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)
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. Any eye disease which affects the cornea or conjunctiva
8. Insufficiency of lacrimal secretion or dry eye
9. Corneal hypoesthesia (reduced corneal sensitivity)
10. Any systemic disease which may affect the eye or be exacerbated by contact lens wear

11. Allergic reactions to ocular surfaces or adnexa which may be induced or exaggerated by the wearing of contact lenses and/or contact lens care solutions
12. Herpes simplex cornea, hepatitis; human immunodeficiency virus (HIV), Adenovirus
13. 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
04/09/2024

Date of final enrolment
24/10/2024

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
CooperVision 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	version 1.0	30/09/2026	21/10/2026	No	No