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Contact lens performance comparison

Submission date 16/10/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 23/10/2024	**Overall study status** Completed	
Last Edited 23/10/2024	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
In routine clinical practice, the measurement of contact lens visual performance is carried out using standard Snellen charts that present high-contrast letters (black letters on a white background) under photopic light conditions (good daytime lighting). The methodology lacks sensitivity to identify differences in visual performance between contact lenses which achieve very different levels of satisfaction. This study aims to test whether the difference in visual performance can be detected between a water-surface contact lens and a non-water-surface contact lens under testing conditions applicable to routine practice (high contrast high luminance visual acuity). Other aspects of interest will be to explore the sensitivity of letter contrast sensitivity and in vivo de-wetting kinetics measurements at detecting differences between water gradient and non-water gradient contact lenses

Who can participate?
Healthy volunteers aged between 18 and 75 years old who are current soft contact lens wearers and have low levels of astigmatism

What does the study involve?
The participant attends an initial screening, and enrolment fitting visit, followed by two test visits using two different contact lens types, one at each test visit at most seven days apart.

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 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?
July 2023 to January 2025

Who is funding the study?
Alcon Research, LLC

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

Contact information

Type(s)
Public

Contact name
Miss 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
-
mguillon@otg.co.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
347931

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ID24-34

Study information

Scientific Title
Contact lens performance novel endpoints contact lens comparison

Study objectives
The hypotheses to be tested is that high luminance high contrast Visual acuity achieved with the test contact lens material is different to that achieved with the control contact lens material.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/09/2024, North East - Newcastle & North Tyneside 1 Research Ethics Committee (2nd Floor, 2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8384; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: 24/NE/0168

Study design
Double-masked prospective randomized cross-over study

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Contact lens wettability

Interventions
This study is a double-masked prospective randomized cross-over study involving three study visits, an initial screening, and an enrolment fitting visit, followed by two test visits using two different CE-marked soft contact lens types (water-surface contact lens and non-water-surface contact lens). Computerised balance randomisation is used. The washout period is a minimum of 1 day between each treatment.

Following a visit in which potential participants are screened, enrolled and familiarised with the testing procedures, participants will visit the clinic on two separate days within 7 days and will complete tests to evaluate their vision and eye wettability at fixed time points.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Water-surface contact lens, non-water-surface contact lens

Primary outcome(s)
Monocular static logMAR visual acuity high luminance (250 cd/m2), high contrast (>90%), distance (4 m) measured at each of the study visits

Key secondary outcome(s))
The following secondary outcome measures will be assessed at each of the study visits:
1. Contact lens comfort measured using a 100-point visual analog scale
2. Visual performance for distance, intermediate and near distances measured using the OTG-i Vision Suite Landolt ring high luminance (250 cd/m2), distance (4 m), monocular timed control monocular contrast sensitivity test (3, 6, 12, 18 cycles per degree)
3. Pre-contact lens tear film measured using a tearscope over 30 seconds interblink period

Completion date
31/01/2025

Eligibility

Key inclusion criteria
1. Aged from 18 to 75 years old
2. Current daily disposable hydrogel or silicone hydrogel spherical contact lens wearer to represent a normal contact lens-wearing population
3. Spectacle refraction: Distance: Sphere: -6.00D to + 2.00D; Astigmatism: 0.00D to -0.75
4. Best corrected visual acuity of at least 20/25 in each eye

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. Habitual wearer of one of either of the two study contact lenses
2. Acute and subacute inflammation or infection of the anterior chamber of the eye
3. Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids that would contraindicate contact lens wear
4. Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
5. Severe insufficiency of lacrimal secretion (dry eyes)
6. Any systemic disease that may affect the eye or may be exaggerated by wearing contact lenses (e.g. acne and eczema)
7. Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
8. Any active corneal infection (bacterial, fungal, protozoal or viral)

9. Newly prescribed (within the past 30 days) use of some systemic medications (such as antihistamines, decongestants, diuretics, muscle relaxants, tranquillizers, 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
10. Monocular participants (only one eye with functional vision) or participants fit with only one contact lens
11. 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
12. History of corneal refractive surgery
13. 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
02/10/2024

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ocular Technology Group Ltd
66 Buckingham Gate
London
United Kingdom
SW1E 6AU

Sponsor information

Organisation
Optometric Technology Group Ltd

Funder(s)

Funder type

Industry

Funder Name
Alcon Research, LLC

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