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Testing two new methods to detect differences between contact lens materials

Submission date 28/11/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/11/2023	**Overall study status** Completed	
Last Edited 04/07/2024	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims

Differences in modern contact lens acceptance, mainly differences in comfort and quality of vision, have been reported in many studies. It is thought to be due to differences in the characteristics of the different contact lens materials. However, studies using standard clinical techniques do not reveal any differences between the different materials. OTGi has developed advanced clinical techniques that may be more sensitive to detect differences between materials.

The aim of this study is to determine the precision of two OTG-i proprietary methodologies that could detect differences between contact lens materials, called in vivo de-wetting kinetics and Landolt ring timed controlled contrast sensitivity. The results of the study will make it possible to calculate future study sample sizes to measure the performance of different contact lenses.

Who can participate?

Adults aged 18 to 35 years who are current soft contact lens wearers and have low levels of astigmatism

What does the study involve?

There are three study visits, each at most 1 week apart. During the study visits, the participant will be fitted with one type of study contact lens, a set of visual measurements will be carried out and a video recording of the tear film will be made.

What are the possible benefits and risks of participating?

There might not be direct benefits to the participants in this study. However, in taking part in the study, the participants will have the opportunity to try a different contact lens type than their own contact lenses. Further, their participation in the study may contribute to scientific research information that may be used in the development of better clinical testing and/or better contact lenses.

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 May 2024

Who is funding the study?
Alcon Research, LLC (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Public

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Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
335090

Protocol serial number
OTG-i ID23-50

Study information

Scientific Title

Contact lens performance novel endpoints validation

Study objectives
The objective of the study will be to determine the repeatability of the two methodologies; hence, no specific hypotheses will be tested.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/11/2023, West Midlands - Edgbaston Research Ethics Committee (2 Redman Place, Stratford, E20 1JQ, United Kingdom; +44 (0)2071048357; edgbaston.rec@hra.nhs.uk), ref: 23/PR/1219

Primary study design
Interventional

Study design
Prospective interventional test-re-test study

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Determination of the repeatability of OTG-i Vision Suite, Landolt ring contrast sensitivity and In vivo de-wetting kinetics

Interventions
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 a 7-day period and will complete tests to evaluate their contrast sensitivity at 85 cd/m² and eye wettability at fixed timepoints.

Intervention Type
Other

Primary outcome(s)
1. Post hoc analysis of tearscope digital video recording using scale percentage exposure per second, performed during visit 2 and visit 3
2. Timed letter contrast sensitivity using OTGi vision suite, the scale is in Log of contrast percentage, performed during visit 2 and visit 3

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
01/05/2024

Eligibility

Key inclusion criteria
There are no requirements as to participant race or gender.
1. Age 18 to 35 years
2. Current daily disposable hydrogel or silicone hydrogel spherical contact lens wearer
3. Normal contact lens wearing characteristics as per Young modified questionnaire
4. Spectacle refraction:
4.1. Sphere: -6.00D to + 2.00D
4.2. Astigmatism: 0.00D to -0.75
5. Best corrected visual acuity of at least 20/25 in each eye
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

Key exclusion criteria
To be eligible as a participant, each candidate shall be free of any ocular or medical condition that may affect the results of this study.
The following are specific criteria that exclude a candidate from enrolment in this study:
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

Date of first enrolment
14/11/2023

Date of final enrolment
30/12/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ocular Technology Group – International (OTG-i)
66 Buckingham Gate
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Sponsor information

Organisation
Ocular Technology Group-International (OTG-i)

Funder(s)

Funder type
Industry

Funder Name
Alcon

Alternative Name(s)

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?
Basic results	version 0.3	19/04/2024	04/07/2024	No	No