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Sensitivity of the front part of the eye and its association with dry eye

Submission date	Recruitment status	[_] Prospectively registered
06/09/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/09/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/03/2023	Eye Diseases	

Plain English summary of protocol

Background and study aims
Measurement of corneal sensitivity (how sensitive the front part of your eye is) has been a marker for contact lens performance for a long time. Recent technology developments have meant we have new instruments for measuring corneal sensitivity. Recent interest has been around corneal sensitivity in dry eye sufferers. To date, there is no corneal sensitivity data available for those with varying types and extents of dry eye and so this study aims to establish population norms.

Who can participate?
Individuals ages between 18 and 75 years old that are non-contact lens wearers can take part. You also can have no history of eye surgery or eye disease (except for dry eye).

What does the study involve?
The study involves a single clinic visit in which the extent of your dry eye will be assessed and your corneal sensitivity will be measured.

What are the possible benefits and risks of participating?
There may not be any direct benefits for participating in the study, however participants will be contributing to scientific research which can be used in the care of those suffering with dry eye. The measurements in the study, except for corneal sensitivity measurement, are routine clinical procedures and so present no more risk to patients than their own primary eye care. The measurement of corneal sensitivity is non-invasive using well-established technology. Participants will be under the care of the investigator while they are active in the study and the health of their eyes will be checked at the start and end of the study to ensure their vision and eye health is unchanged.

Where is the study run from?
Ocular Technology Group - International (UK)

When is the study starting and how long is it expected to run for?
March 2022 to December 2022

Who is funding the study?
CooperVision International Ltd. (UK)

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

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
318209

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ID22-25 CV-22-22, IRAS 318209

Study information

Scientific Title
Corneal sensitivity demographics and its association with dry eye

Study objectives
No formal hypotheses will be formulated for this study. But the following questions will be addressed separately:
i. What are the corneal sensitivity characteristics of symptomatic and asymptomatic patients?
ii. What are the corneal sensitivity characteristics of symptomatic patients with signs of aqueous deficient dry eyes?
iii. What are the corneal sensitivity characteristics of symptomatic patients with signs of evaporative dry eyes?

iv. What are the corneal sensitivity characteristics of symptomatic patients with signs of mixed dry eyes?
v. What are the corneal sensitivity characteristics of three categories of dry eye sufferers (i. asymptomatic with signs of dry eyes; ii. symptomatic without signs of dry eye and iii. symptomatic with signs of dry eyes)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/08/2022, West Midlands - South Birmingham Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 1048345; southnirmingham.rec@hra.nhs.uk), ref: 22/WM/0179

Study design
Single centre observational double masked single group study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Non contact lens wearers that suffer from dry eye

Interventions
Participants will complete a dry eye evaluation by a qualified optometrist and also answer some questions about their dry eye. They will then have their corneal sensitivity assessed using a device called an aesthesiometer.

Intervention Type
Other

Primary outcome(s)
Corneal sensitivity is measured by the point at which a participant detects a light puff of air on their cornea. There are no defined time points for the measurement.

Key secondary outcome(s))
Extent of ocular symptoms measured by an OSDI questionnaire.

Completion date
07/12/2022

Eligibility

Key inclusion criteria
1. Age 18 to 75 years;
2. No contact lens wear in the past 5 years.
3. Non-contact lens wearers divided into three groups based upon symptomatology:

3.1. Asymptomatic OSDI ≤ 9.0 points
3.2. Symptomatic slight to mild OSDI >9.0 points & ≤ 33.0 points
3.3. Symptomatic moderate to severe > 33 points
4. Best corrected visual acuity of at least 20/30 in each eye;
5. No history of eye surgery or ocular disease (except for dry eye)
6. No history of medical conditions which, in the investigator's opinion, could impact ocular symptoms or corneal sensitivity. Examples include diabetes and autoimmune diseases.
7. No history of systemic or topical medication (except for artificial tears) which, in the investigator's opinion, could impact symptoms or corneal sensitivity. Examples include acne medication, anti-inflammatory medication and/or dry eye medication;
8. Have read and understood the Participant Information Sheet in English;
9. Have read, signed and dated the Informed Consent.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Ocular anterior segment infection, inflammation, abnormality, or active disease;
2. Monocular participants (only one eye with functional vision);
3. Any moderate or severe ocular condition observed during the slit lamp examination at the enrolment visit;
4. History of herpetic keratitis, ocular surgery or irregular cornea;
5. Known pregnancy or lactation during the study period;
6. 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
01/08/2022

Date of final enrolment
04/12/2022

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
CooperVision International Ltd

Funder(s)

Funder type
Industry

Funder Name
CooperVision

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 1.0	07/03/2023	13/03/2023	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes