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Effect of contact lens replacement and manipulation on comfort

Submission date	Recruitment status	[_] Prospectively registered
20/01/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/02/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/03/2023	Eye Diseases	

Plain English summary of protocol

Background and study aims
Some people find wearing contact lenses can be uncomfortable, especially at the end of the day. At present, we do not know whether changes to the eye or to the contact lens are the most important factors in governing this discomfort. This project aims to improve our understanding in this area by assessing the effect of lens replacement and lens manipulation on the comfort of contact lenses.

Who can participate?
Adults who currently use daily disposable soft contact lenses and have used them for at least six months and have symptoms of discomfort at the end of the day

What does the study involve?
Volunteers will attend a clinic for six visits over four days. They will wear their habitual contact lenses during the course of the study. On day 1, volunteers will attend the clinic for an initial visit in which the investigator will confirm that they match the inclusion and exclusion criteria and will do an examination of the front surface of the eye. On days 2 and 3, volunteers will attend the clinic in the morning and 5 hours later. The investigator will randomly assign an intervention to each eye. In the morning, comfort scores will be collected before and after lens application. Volunteers will then leave the clinic and will be asked to wear their contact lenses in the normal way for at least 12 hours during which time they will provide comfort scores via SMS. Volunteers will return to the clinic 5 hours after lens application and the investigator will either replace the lens or manipulated the lens on-eye. The contact lens will not be manipulated in any way in the control group. Comfort scores will be collected at this time. Volunteers will then be asked to continue wearing their lenses and to provide comfort scores via SMS until they remove their lenses. On day 4, volunteers will attend the clinic for an exit visit in which they will receive an examination of the front surface of the eye and will then leave the study.

What are the possible benefits and risks of participating?
Benefits may include a thorough anterior eye examination and advice on contact lenses. All lens care products have the potential of causing serious injury to the eye. Due to the nature and duration of the study, the risks are judged to be similar to those of normal contact lens wear since subjects. It is possible that the following may occur with the use of contact lens products:

pain, abrasion of the eyes, sensations of itching, burning or stinging, excessive tear production, unusual secretions, redness, reduced sharpness of vision, blurred vision, sensitivity to light or dry eyes. In rare instances, corneal ulcers, scarring, the growth of blood vessels into the cornea, temporary or permanent decreased vision, iritis and infections of the eye requiring treatment might occur. Major side effects from the use of diagnostic dye sodium fluorescein are very rare, but there are three reports of anaphylaxis following topical instillation of fluorescein. Anaphylaxis can result in death but none of the reported cases to date has been fatal. Other rare side effects from the topical use of sodium fluorescein can include slight stinging on instillation and temporary blurred vision.

Where is the study run from?
Eurolens Research at the University of Manchester (UK)

When is the study starting and how long is it expected to run for?
From February 2013 to March 2014

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Miss Maria Navascues-Cornago

Contact information

Type(s)
Public

Contact name
Miss Maria Navascues-Cornago

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ER13-541

Study information

Scientific Title
Effect of three interventions on contact lens comfort in symptomatic wearers: a randomised single-blind study

Study objectives
To investigate the effect of replacing the lens with the same or with a new lens and performing a scleral swish part way through the day on comfort in symptomatic daily disposable soft contact lens wearers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Manchester Committee on the Ethics of Research on Human Beings, 07/06/2013, ref: 13009

Study design
Interventional randomised controlled single-blind single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Subjects will attend the clinic on two study days. On each day, subjects attended the clinic in the morning without any lenses in situ (and not having worn lenses beforehand on the day). A new pair of their habitual daily disposable lenses was applied directly from the packaging solution and worn for at least 12 hours. Comfort scores were recorded before lens application and 6 minutes post-application using the 0 to 100 grading scale. Automated short message service (SMS) text messages via mobile phone were sent to subjects every hour following lens application requesting a comfort score using the same scale. Five hours after lens application, the investigator performed one of three interventions on each eye together with a control:
1. Replacement of the existing lens with a new lens: the existing lens will be removed and a new, fresh contact lens will be re-applied directly from the packaging solution
2. Removal of the existing lens and re-application of the same lens: the existing lens will be

removed and placed in a lens case containing 0.9% sterile saline (Eye Care solutions, Crest Medical Ltd, Warrington, UK) and then re-applied
3. A scleral swish: the contact lens will be slid off the cornea onto the temporal conjunctiva; subjects will then be asked to fully blink five times, and then the lens will be slid back onto the cornea
4. No action (control): the contact lens will not be manipulated in any way

The interventions will be randomly assigned to each eye (i.e., each eye will receive a different intervention) and subjects will be masked to whether the re-applied lens is a new lens or the same lens. The investigator will generate the randomisation scheme using the web site Randomization.com (http://www.randomization.com), which creates random permutations of interventions for a situation where subjects are to receive all of the interventions in random order.

Intervention Type
Other

Primary outcome measure
1. Contact lens comfort score will be measured with an annotated vertical analogue comfort scale of 0 (causes pain, cannot be tolerated) and 100 (excellent, cannot be felt) and recorded on paper before lens application, 5 hours post-application, and 6 minutes post-intervention
2. Comfort scores at 6 minutes post-application and at every hour following lens application will be collected through SMS messaging using the same scale; only SMS comfort scores received within 30 minutes from the target time will be included in the analysis

Secondary outcome measures
None

Overall study start date
04/02/2013

Completion date
05/03/2014

Eligibility

Key inclusion criteria
1. At least 18 years old and capacity to volunteer
2. Understand rights as a research subject
3. Willing and able to sign a statement of informed consent
4. Willing and able to follow the protocol
5. Agree not to participate in other clinical research for the duration of this study
6. Wear daily disposable soft contact lenses and have worn them for at least 6 months
7. Symptomatic according to method by Young et al (Characterizing contact lens-related dryness symptoms in a cross-section of UK soft lens wearers. Contact Lens and Anterior Eye 2011; 34: 64–70)
8. Willing to wear contact lenses for at least 12 hours a day
9. Having a mobile phone

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Systemic or ocular disorder that might affect ocular health
2. Grade 2 or greater of any anterior ocular clinical signs
3. Use of any topical medication, such as eye drops or ointment
4. Previous cataract or corneal refractive surgery
5. Corneal distortion resulting from previous hard or rigid lens wear or keratoconus
6. Pregnant or lactating
7. Diabetes
8. Infectious disease (e.g., hepatitis)
9. Immunosuppressive disease (e.g., HIV)
10. History of severe allergic reaction or anaphylaxis (a serious form of hypersensitivity that can, in rare cases, result in death)
11. Unacceptable lens fit (grade –2 or +2 on a –2 to +2 grading scale)
12. Participation in other clinical trial or research within 2 weeks before starting this study

Date of first enrolment
21/08/2013

Date of final enrolment
17/02/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Eurolens Research, University of Manchester
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester

Sponsor details
Oxford Road
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Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The results of this study are intended to be published in a scientific journal in the near future (to be confirmed at a later date)

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/08/2015		Yes	No

Protocol (other)	07/03/2023	No	No