EYE AND VISION RESEARCH WITH PLYMOUTH UNIVERSITY

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BIOMECHANICAL PROPERTIES OF THE ANTERIOR SURFACE OF KERATOCONIC EYES PRE AND POST COLLAGEN CROSSLINKING

# INFORMATION AND CONSENT LETTER

*Professor Nabil Habib and Daniela Oehring* are the lead investigator of this study and will work with other Plymouth University, School of Optometry and Royal Eye Infirmary, Derriford Hospital clinical investigators. This is an educational research project and will form part of Daniela Oehrings PhD thesis. They will take the study measures and answer any questions you have. Dr *Hetal Buckhurst* (Study Director) and Dr *Phillip Buckhurst* are overseeing this study.

## INFORMATION RELATED TO YOUR PARTICIPATION

### 1. What is this study about?

In keratoconus (KC) the structure of the cornea (a layer of tissue at the front of the eye) is changed and its strength is reduced. These structural changes alter the shape of the cornea, which in turn can cause myopia (short-sightedness) and irregular astigmatism (irregular shape of the cornea), affecting vision. Corneal-collagen-crosslinking is a relatively new technique, which aims to increase the biomechanical strength of the cornea and hence stopping these unwanted shape changes. Despite strong evidence showing that corneal-collagen-crosslinking leads to increased biomechanical strength of human corneas, there is a significant need for accurate measures of these biomechanical changes before and after this procedure. Until recently technical limitations have restricted our ability to assess the effectiveness of the technique.
Utilising the latest imaging techniques this study aims to better understand the biomechanical strength of the eye before and after corneal-collagen-crosslinking.

### 2. Who may participate in this study?

This study will involve up to 35 participants. To be eligible for this study, you must be at least 18 years old and enrolled for collagen crosslinking treatment. Please let us know if you are currently participating in any other research study.

### 3. What is the time commitment for this study?

This study involves two study visits, one before your corneal collagen crosslinking treatment and one 3-6 months following your treatment. Each of these visits will take up to 120 minutes but please consider that this time frame can be different between each participant.

*Visit 1 Pre-corneal collagen crosslinking treatment investigation (120 mins)*: A series of measurements will be taken (see section 4 for a description of all study measurements) before you undergo collagen crosslinking treatment.

*Visit 2 3-6 months post corneal-collagen cross-linking treatment investigation (120 mins)*: The measurements conducted for the study will be taken (see section 4 for a description of all study measurements) after 3-6 months after having collagen crosslinking treatment.

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## 4. What is expected of me at these visits?

The following is a description of measurements that do not require any instrument to touch your eye. All instruments will be sanitized with alcohol swabs between study participants.

*Subjective symptoms and ratings:* Your personal details and medical history will be asked. Furthermore, you will be asked to describe any symptoms you may be having with your eyes and rate the dryness of your eyes.

*Visual acuity:* To assess how well you are seeing at distance and near you will be asked to look at a chart and read the lowest line you can see. Lenses with different power will be shown to see if your vision can be improved. This procedure will be done for far and near distance. This test is normally conducted during routine eye examinations.

*Tear film assessment:* We will assess the quality of your tears by performing a simple test requiring you to blink and stare at a target for as long as possible. You will be asked to sit at an instrument, place your chin on the chin rest and head against the headrest, and to focus on a target. Before each measurement you will be asked to blink three times and then hold your eyes open for as long as possible (i.e., a few seconds).

*Biometrical data:* As part of the study we will need to take some measurements to assess the length and curvature of your eyes. As part of the test you will be asked to sit at different non-contact instruments, placing your chin on the chin rest and head against the headrest, and to focus on a target. Before each measurement you will be asked to blink a few times and then hold your eyes open and then a scan will be taken. With each device the measurement will be repeated three times. Each measurement will take only few seconds.

*Biomechanical properties:* To examine the strength of the tissues at the front of the eye we will perform a test similar to the procedure conducted to assess the pressures of your eyes during a routine eye examination. The test entails a gentle puff of air being blown onto the eye. As part of the procedure you will be asked to sit at two different instruments, placing your chin on the chin rest and head against the headrest, and to focus on a target. The target will be presented in nine different positions and a puff of air will be blown onto the eye in each of the nine positions. Before each measurement you will be asked to blink a few times and then hold your eyes open for as long as possible. Each measurement will only take a few seconds. With each device the measurement will be repeated consecutively three times. The instrument will not touch the eye at any time.

Prescription of the eyes: A device called an auto-refractor will be used to measure your distance prescription. It will be necessary to put drops (Tropicaminde 1%) into your eyes in order to relax the focusing power of the eye and to obtain the most accurate measure of the eye's prescription. The drops will temporarily make your pupils big (dilated) and it will be hard for you to focus at near distances. The drops take about 15 to 30 minutes to work and the effect may last for up to six hours. Occasionally the effect may last until the next day. Before the drops are put in we will check that your eyes are safe to be dilated. After instilling the drops you will be asked to sit at an instruments, placing your chin on the chin rest and head against the headrest, and to focus on a target. This device will automatically measure your refractive error.

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*Slit-lamp examination:* As part of the study will be need to check the health of the front of your eyes and lids/lashes with a device called a slit lamp. You will be asked to be seated at an instrument, placing your chin on the chin rest and head against the headrest. As part of the test you will be asked to look up and out (away from your nose) and your lids will be gently pressed to assess the secretions from the glands on the lid margins. The investigator will view and evaluate these secretions while applying pressure for approximately 10-15 seconds. The hand-held instrument will be cleaned with alcohol swabs between participants.

## 5. Are any risks associated with this study?

We do not anticipate any risks associated with this study. You may feel some eye irritation during or after some of the study procedures. This irritation is temporary in most cases; repeated blinking will alleviate this irritation in a short period of time. Please advise the investigator if you experience any irritation.

The drops (Tropicamide 1%) that we are using to assess the prescription of your eyes and dilate your pupils are the same drops used in hospitals and by optometrists to make your pupil larger. After receiving the drops there is a very slight risk of them causing pressure to build up in your eye. We will check that this does not happen by measuring the pressure before and after the measurements. However if the pressure does increase significantly we will ensure that you receive treatment at an eye hospital immediately.

Due to the dilating drops instilled in your eyes you will find that your vision may be blurred for a period of 6 hours (especially for reading) and that you are more sensitive to bright light such as sunlight. Because of this it is necessary that **you do not drive, cycle** or operate heavy or moving machinery while your vision is affected. General care with your environment and bright sunlight especially (i.e. it may be useful to wear sunglasses) is also advised. If after the examination you find that you are experiencing any pain or discomfort with your eyes please contact your local eye department or any of the individuals listed below.

## 6. What are the benefits of participation?

This study is not likely to benefit you directly, but it will help researchers at Plymouth University to evaluate the biomechanical properties of keratoconic eyes in different locations of the cornea before and after corneal collagen cross-linking treatment.
You will have a detailed assessment of the biomechanics of the eye pre- and post- corneal crosslinking. It is possible that this additional information regarding the structure and biomechanics of your cornea may inform any future corneal treatment that you may have. In addition the visits will help increase your awareness and understanding of the corneal cross-linking procedure and outcomes.

## 7. Is there remuneration for participation?

£20 of travel expenses will be provided to get to and from the study visits.

## 8. Can I withdraw from the study? Can my involvement be discontinued?

You are free to decide whether or not to participate in this study. Your decision will not influence the eye care available to you or you will receive at either the Nuffield Health Plymouth Private Hospital

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and the Royal Eye Infirmary (Derriford Hospital). The chief investigator may remove you from the study if the investigator believes it to be in your best interest.

## 9. Informing your General Practitioner (GP)

As part of the study we would like to keep your GP informed of your participation in this study. You will be asked to consent to us contacting your GP before we contact them when you consent to the study.

## 10. Confidentiality and security of data

All information you provide as a participant and any data we collect as a result of your participation in this study will remain confidential. You will be assigned an identification number, which will appear on all study records in place of your name. All members of the study are clinically qualified and registered Optometrists or Ophthalmologists who are bound by a code of conduct and data protection. All data will be anonymised and stored on a password protected university computer and backed up on encrypted files, on CDROMs, locked in a cabinet in a locked office. Any data collected in this investigation may be submitted for publication or used in presentations. Neither your name nor information disclosing your identity will be released or published without your explicit consent to the disclosure. Records from this study will be retained for a minimum of 10 years. After 10 years, records will be confidentially disposed of in accordance with the guidelines laid out by the Plymouth University.

## 11. Other important issues

If you have any questions regarding the study procedures, please contact the School of Optometry at (0) 1752 588886

## 12. Questions or concerns about participation in the study

This study has been reviewed and received ethics clearance through the NHS ethics committee. If you have any concerns or questions about your participation in this study, you may contact Dr Hetal Buckhurst on 01752 588886 or Professor Nabil Habib on 01752 704255.

## 13. Is there an independent contact point where I can get general advice about taking part in research studies?

Yes, the NHS Patient Advisory Liason Service is able to provide general advice about participation in research. The contact details for this service are:

NHS Patient Advisory Liason Service, Level 7, Derriford Hospital
Email: pals@phnt.swest.nhs.net
Tel: 01752 439884

## 14. Can I find out the results from the study?

Following the completion of the study we would be delighted to share our findings with you. If you would like to receive a copy of the study results then please email Dr Hetal Buckhurst on hetal.buckhurst@plymouth.ac.uk who will send you a summary of the findings once the study is complete.