University of Illinois at Chicago (UIC) and/or
University of Illinois Hospital & Health Sciences System (UI Health)
Research Information and Consent for Participation in Biomedical Research

Initial Correction Keratoconus: Scleral vs Corneal Gas Permeable Lenses

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About this research study

You are being asked to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

Taking part in this study is voluntary

Your participation in this research study is voluntary. You may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with the University of Illinois Hospital and Health Sciences System (UI Health) and/or University of Illinois at Chicago (UIC).

This consent form will give you information about the research study to help you decide whether you want to participate. Please read this form and ask any questions you have before agreeing to be in the study.

You are being asked to participate in this research study because you are 18 or older with a diagnosis of keratoconus that was found during routine clinical exams at the Illinois Eye and Ear Infirmary.

Each clinic will enroll up to 25 participants with a maximum of 125 participants for this study.

Important Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

WHY IS THIS STUDY BEING DONE?	Keratoconus is a condition in which the cornea or clear front surface of the eye steepens and thins. It is a non-inflammatory, progressive disease in which corneal irregularity increases and thickness decreases. Keratoconus can decreased vision. We hypothesize that patient-reported quality of life may vary depending upon the prescribed form of contact lens correction. Your physician has considered treatment options for your keratoconus. Participation in this study and receipt of either lens #1 or lens #2 is one of your treatment options. In this study, you will be fit with both small diameter corneal and large diameter scleral lenses according to standard clinical practice. Both lenses are considered standard of care for patients with keratoconus. This study will compare satisfaction with vision and lens handling between corneal gas permeable and scleral lenses for patients with keratoconus.
WHAT WILL I BE ASKED TO DO DURING THE STUDY?	• You will be asked to provide consent or agreement to enter the study, • At the 1st study visit, you will be fit with corneal gas permeable and scleral lenses in both eyes. You will also be asked to complete two dry eye questionnaires (Ocular Surface Disease Index (OSDI) and Contact Lens Dry Eye Questionnaire (CLDEQ)). • You will return for routine follow up visits to improve lens fit and vision. • At the 2nd study visit, you will be randomized to receive lens application and removal training with lens type #1. You will begin daily wear of lens type #1. • At the 3rd study visit (2-4 weeks after dispensing of lens #1), we will measure your vision and ask you about comfort and handling with lens #1. The OSDI and CLDEQ questionnaires will be repeated. • You will be trained in lens application and removal with lens #2. Lens #1 will be returned to the study clinician unless you refuse (thus ending the study). You will begin using lens #2 immediately with no need to wait after stopping using lens #1. There is no known risk for switching from lens #1 to lens #2. • At the 4th study visit (2-4 weeks after dispensing lens #2), we will measure your vision and ask you about comfort and handling with lens #2. The OSDI and CLDEQ questionnaires will be repeated. You will be asked to select

	your final lens of choice between lens #1 and lens #2. If you are unable to return for a study visit, a member of the study team will contact you via phone to complete the surveys and to share your final lens preference. For more information, please see the "What Procedures Are Involved?" section below.
HOW MUCH TIME WILL I SPEND ON THE STUDY?	The study will consist of 4 visits after being consented and enrolled during routine clinical visits. Study Visit #1 will take about 45-90 minutes. Study Visit #2 will take about 30 – 60 minutes. Study Visit #3 will take about 45 – 75 minutes. Study visit #4 will take about 15- 45 minutes.
ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?	Being in this study will not help you directly. We hope that your participation in the study may benefit other people in the future by helping us learn more about keratoconus.
WHAT ARE THE MAIN RISKS OF THE STUDY?	For this study, the potential risks to know about are: • Eye pain • An abrasion or scratch on the front surface of the eye • Infection • Scarring on the front surface of the eye • New blood vessels growing on the front surface of the eye These issues are not specific to the study but with wearing/using new contact lens in general.
DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?	You have the option to not participate in this study.
QUESTIONS ABOUT THE STUDY?	For questions, concerns, or complaints about the study, please contact Ellen Shorter, OD at 312-996-5410 or email at eshorter@uic.edu. If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu. If you have questions or concerns regarding your privacy rights under HIPAA, you should contact the University of Illinois HIPAA Privacy Office at (844) 341-2201 or hipaa@uillinois.edu.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research. Please also feel free to ask the study team questions at any time.

What procedures are involved?

This research will be performed at 1855 W. Taylor Street, Chicago, IL 60612.

If you agree to be in the study, you will be asked to do the following procedures:

- **Screening eligibility**
  - .1 Patients age 18 or older with a diagnosis of keratoconus will be recruited during routine clinical exams at the Illinois Eye and Ear Infirmary.
  - .2 Available baseline corneal topography and pachymetry.
  - .3 Willingness to return for 4 study visits.
- Informed consent will be obtained by the principal investigator or co-investigators.

Study visit number 1 (estimated 45-90 minutes)

Standard medical history and eye exam.

Dry eye symptoms and contact lens comfort assessed using the validated 12-item OSDI and CLDEQ questionnaire.

Both eyes will be fit with small diameter corneal and large diameter scleral lenses using the RoseK 2 corneal gas permeable and Synergeyes VS scleral lenses.

Subjective comfort with lens use rated on comfort scale of 0 (not comfortable) to 10 (very comfortable).

- Routine Follow up visits with standard medical history and eye exam.

  Meibography [standard of care] - if already performed and present in the patient's medical record, the data will be gathered. However, it will not be completed solely for the purpose of this study.

Study visit number 2 (estimated 30-60 minutes)

You will randomly be decided to be given either lens 1 or lens 2. You will be trained on safe application and removal of the lens. You will be asked to rate your comfort with the lens.

Study visit number 3- wearing lens #1 between 2-4 weeks for minimum of 3 hours (estimated 45-75 minutes)

Standard medical history and eye exam. We will ask you general questions about lens wear time but will not ask you to keep a written log. We will ask you to rate your comfort with lens use. In addition, we will have you complete the OSDI and CLDEQ dry eye questionnaires. We will train you on safe application and removal of lens #2. We will ask you to rate your comfort with lens #2.

Study visit number 4- wearing lens #2 between 2-4 weeks for minimum of 3 hours (estimated 15-45 minutes)

- Standard medical history and eye exam. We will ask you general questions about lens wear time but will not ask you to keep a written log. We will ask you to rate your comfort with lens use. In addition, we will have you complete the OSDI and CLDEQ dry eye questionnaires. We will train you on safe application and removal of lens #2. We will ask you to rate your comfort with lens #2. We will ask you which lens you prefer (lens #1 or lens #2). We will then inform you of the annual self pay cost of the lenses and ask you again which is your lens of choice (lens #1 or lens #2).

During this study, Dr. Ellen Shorter and her research team will collect information about you for the purposes of this research. Dr. Shorter and her team will review your medial history and collect personal demographics such as age, race, age diagnosed with keratoconus. They will also collect answers to questionnaires during visits.

What will happen with my information used in this study?

De-identified data will be shared among the sites listed in this document. Your identifiable private information collected for this research study may be used for future research studies and/or shared with other researchers for future research but the information which could identify you will be removed before any information is shared. Once the identifying information is removed, the information and samples cannot be withdrawn from further use. You will not be asked for additional consent.

Will I receive the results (including any psychological or health results) from the study?

We will not share results of the study with you.

What are the potential risks and discomforts of the study?

Side effects, risks, and/or discomforts from participation in this study include problems due to contact lens wear including:

- Eye Pain
- An abrasion or scratch on the front surface of the eye
- Infection
- Scarring on the front surface of the eye
- New blood vessels growing on the front surface of the eye

There may be risks from the study that are not known at this time.

A risk of this research is a loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others to whom you have not given permission to see this information).

What about privacy and confidentiality?

Efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. In general, information about you, or provided by you, during the research study, will not be disclosed to others without your written permission. However, laws and university rules might require us to tell certain people about you. For example, study information which identifies you and the consent form signed by you may be looked at and/or copied for quality assurance and data analysis include:

- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- Government Regulatory Agencies, such as the Office for Human Research Protections (OHRP).

A possible risk of the study is that your participation in the study or information about you and your health might become known to individuals outside the study. Your personal information, research data, and research records will be maintained by the principal investigator in a locked file cabinet of locked office to prevent access by unauthorized personnel.

Your individual data will be stripped of all direct and indirect identifiers and destroyed after the analysis of the data.

When the results of the study are published or discussed in conferences, no one will know that you were in the study.

What if I am injured as a result of my participation?

If you get ill or injured from being in the study, UIC will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Ellen Shorter, OD at 312-996-5410.

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proven that your injury or illness is directly caused by the negligence of UIC.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

What are the costs for participating in this research study?
The procedures/services listed as standard of care will be billed to your insurance. You will not have any costs for contact lens materials/lenses. There will no charge to you for the non-standard of care portions of the visit.

Will I be reimbursed for any of my expenses or paid for my participation in this research study?
You will receive $40 (Visa gift cards) for each of the four study visits at the completion of the study. If you do not finish the study, you will be compensated for the visits you have completed. If you complete the study, you will receive a total of $160. You will receive your payment at the completion of the 4 visits. Visa gifts cards will be given in person. We may need to collect your social security number or Taxpayer Identification Number (TIN) in order to issue your compensation and for tax reporting purposes to the United States Internal Revenue Service (IRS).

Your participation in this research study may contribute to the development of commercial products from which the Sponsor company or others may derive economic benefit. There are no plans to compensate you for any of these developments.

Will I be told about new information that may affect my decision to participate?
During the course of the study, you will be informed of any significant new research findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

Can I withdraw or be removed from the study?
If you decide to participate, you have the right to withdraw your consent and leave the study at any time without penalty.
The researchers also have the right to stop your participation in this study without your consent if they believe it is in your best interests.

If you choose to no longer be in the study, you must inform the researchers in writing at the address on the first page. The researchers may use your information that was collected prior to your written notice.

Will health information about you be created, used or shared with others during this study?

State and federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect your health information. This section of this form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information in this research study. By signing this form you are authorizing Ellen Shorter, OD and his/her research team to create, get, use, store, and share protected health information that identifies you for the purposes of this research.

The health information includes all information created and/or collected during the research as described within this consent form and/or any health information in your medical record that is needed for the research and that specifically includes:

- Personal identifiers (your name, address, phone number, date of birth, social security number, medical record number), dates of service, and demographic information (race, gender, ethnicity, age)
- Results of physical examinations
- Medical history
- blood tests, x-rays and other diagnostic and medical procedures (being as specific and detailed as is necessary)
- certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study devices

During the conduct of the research, the researchers may use or share your health information:

- With each other and with other researchers involved with the study.
- With law enforcement or other agencies, when required by law.
- With non-UIC collaborators of the research study

Jennifer Fogt, OD, MS at Ohio State University College of Optometry

- De-identified data will be shared with non-UIC sites

Muriel Schornack, OD and Cherie Nau at Mayo Clinic

- De-identified data will be shared with non-UIC sites

Jennifer Harthan, OD at Illinois College of Optometry

- De-identified data will be shared with non-UIC sites

- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- United States Government Regulatory Agencies, including but not limited to the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA).

If all information that identifies you is removed from the research data, the remaining information is no longer subject to the limits of this Authorization or to the HIPAA privacy laws. Therefore, the de-identified information may be used and released by the researchers (as permitted by law) for other purposes, such as other research projects.

During your participation in this research, you will not have access to the research records or information that is not usually kept in your medical record. However, this information is available to your doctor in the case of an emergency. The researcher may provide you with access to the research records or information related to this research once the study is done.

How will your health information be protected?

The researchers agree to protect your health information and will only share this information as described within this research consent/authorization form.

When your health information is given to people outside of the research study, those agencies that receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it. They may also share your information with others without your permission, unless permitted by laws that they have to follow.

Your Authorization for release of health information for this research study expires at the end of this study, but can be canceled sooner if you decide to withdraw your permission.

You may change your mind and cancel this Authorization at any time. To cancel this Authorization, you must write to:

Ellen Shorter, MD
1855 West Taylor Street, Room 2186C, M/C 648
Chicago, IL 60612

If you cancel this Authorization, you may no longer be allowed to take part in the research study. Even if you cancel this Authorization, the researchers may still use and disclose health information they have already obtained as necessary to maintain the integrity and reliability of the research and to report any adverse (bad) effects that may have happened to you.

Right to Refuse to Sign this Authorization

You do not have to sign this Consent/Authorization. However, because your health information is required for research participation, you cannot be in this research study if you do not sign this form. If you decide not to sign this Consent/Authorization form, it will only mean you cannot take part in this research. Not signing this form will not affect your non-research related treatment, payment or enrollment in any health plans or your eligibility for other medical benefits.

Remember:

Your participation in this research study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University or IEEI. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Signature of Subject

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research study. I will be given a copy of this form.

If you have not already received a copy of the Notice of Privacy Practices, you should ask for one.

Your signature below indicates that you are providing both consent to participate in the research study and authorization for the researcher to use and share your health information for the research.

_____ _____

Signature Date

_____

Printed Name

_____ _____

Signature of Person Obtaining Consent Date (must be same as subject's)

_____

Printed Name of Person Obtaining Consent