CONSENT FORM

Custom Anterior Surfacing of Scleral Lens for Vision Quality Improvement in Patients with Keratoconus

Principal Investigator: Tara C Vaz, OD

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

Key Information

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you are18 years of age or older; you have a condition called keratoconus; and you are currently wearing a BostonSight scleral contact lens in at least one eye.
- The purpose of this study is to investigate the effect of an advanced technique for designing custom scleral contact lenses to improve your vision.
- Your participation in this study will last between 4 to 9 ½ hours throughout 4-10 visits.
- Procedures will include fittings of new scleral lenses and measurements of your vision. Some measurements will be done while you are wearing a contact lens.
- There are risks from participating.
    - The most common risk is eye fatigue.
    - One of the more serious risks is the potential for corneal abrasions from frequent replacement of the scleral lens. See the "Risks of Participation" section in this consent form for more information. You should discuss these risks in detail with the study team.
- If you find that the test lens created during this trial provides you with better vision quality, then it will be provided to you free of charge. There are no other benefits from being in this study.

Purpose of Study

The purpose of this study is to investigate the effect of an advanced technique for designing scleral lenses to improve your vision.

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Description of Study Procedures

If you decide to take part in this study, you will be asked to undergo an optical screening visit as well as at least 3 study visits. Some of the communication regarding the scheduling of the study visit may be done over phone or email.

Screening Visit: The initial screening visit may be combined with your normal eye check-up procedure. This screening visit will take between 30-60 minutes. It is similar to a regular eye exam and will evaluate your ocular health to let us know if you qualify for participation in this study. Your vision and the fit of your scleral lens will be checked by the study optometrist.

Study Visit 1: After the screening we can begin the study visits. The first study visit will take between 1-2 hours. A new lens will have been created for you based on the Screening Visit. Your vision and the fit of the new lens will be checked. If an adjustment is needed for the new lens, then a new Study Visit 1 will be scheduled.
After determining that the lens is appropriate, your eye will be dilated with eye drops. You will be asked to wait around 20 minutes while the drops take effect. When your eye is fully dilated, you will be measured with a portable sensor that evaluates the surface of your eye. That measurement will conclude Study Visit 1. You will be asked to wear your original lens until Study Visit 2.

Study Visit 2: The second study visit will take about 30 minutes. A new customized scleral lens will have been made for you based on the measurements from Study Visit 1. Your vision and the fit of the lens will be assessed. If an adjustment is needed for the lens, then a new Study Visit 2 will be scheduled. Otherwise, Study Visit 3 will be scheduled .You will be asked to wear your original lens until Study Visit 3.

Study Visit 3: The third study visit will take between 2-3 hours. Your vision will be checked with a customized and non-customized lens that are created based on your previous visits. Once the fit of the lenses is assessed, your vision quality will be more fully evaluated using a series of common, non-invasive ocular tests similar to reading an eye chart. Neither you nor the study team member administering the ocular tests will know which lens is customized and which one is non-customized. This is done to ensure a non-biased evaluation of the two lenses. After these evaluations are complete, your eye will be dilated using eyedrops. You will be asked to wait around 20 minutes while the drops take effect. When your eye is fully dilated, you will be measured with each of the two lenses using a portable wavefront sensor. As part of the evaluation, you will be asked which of the two lenses you prefer. You will be allowed to keep whichever lens you prefer as your new regular lens.

Additional Information:
Information about your study participation and study results may be included in your electronic health record. If you have concerns about this or to obtain more detail, you should discuss this with the study team.

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Depending on the quality of the data collected during your visit, you may be asked to return for one additional visit to complete the task. Any additional visits will not be at a specific interval of time, but rather we will contact you to schedule so that they fit your schedule. You may be fitted with up to 10 lenses, if an adequate fit still cannot be achieved then you will be withdrawn from the study.

Number of Subjects
Up to 40 subjects will take part in this study.

Risks of Participation
Light Exposure Safety: You will be exposed to light flashes that are comparable in intensity or less than those they would encounter in a routine eye examination in an ophthalmologist's office. The laser light will shine into your eye briefly, and the light that bounces back through your cornea will be measured by the wavefront sensor. Exposure is more than 15 times less than the Maximum Permissible Exposure (MPE) specified by the American National Standard for the Safe use of Lasers (ANSI Z136.1-2000).

Scleral Lenses: The testing scleral lenses used in the study pose the same risks as the lenses you already wear. These risks include but are not limited to discomfort, pain, tearing, redness, burning, sensitivity to light, and blurred vision. More serious risks may include but are not limited to corneal abrasion, and corneal swelling or eye infection. Participation in the study requires you to undergo multiple new fittings which carry a slightly higher risk of corneal abrasion than you would have otherwise been exposed to. This is due to the more frequent application and removal of the scleral lenses during the fitting processes. If any of these or other concerning signs or symptoms occur, you should immediately contact a study team member. You will be referred to Flaum Eye Institute for treatment if needed. You will be monitored for these complications during all of your visits by the optometrist as part of this study.

Pupil Dilation: For this study we will use both phenylephrine (2.5%) and tropicamide (1%) to dilate the pupil of your eye. These eyedrop will dilate your pupils and cause blurred vision and sensitivity to light for at least 5-7 hours after they are applied. These are similar or identical to the dilation eyedrops used in a standard eye exam and carry the same risks. The dilation drops may cause mild discomfort and temporary redness in the eye. Sometimes people's eyes get red and sore after they have had dilating eye drops. This should get better when you stop using the drops. If your eyes are still uncomfortable after a couple of days, you can be treated with mild anti-inflammatory medications if needed. For some predisposed to the condition, an adverse reaction called acute angle-closure glaucoma may be triggered from the dilating drops. While every subject will be screened for risk of this reaction prior to dilation, the risk cannot be completed mitigated. This is extremely rare and treatable with immediate medical attention. Signs include redness, severe pain, nausea, and / or loss of vision. If this occurs after dilation,

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call our office immediately. The risk of angle closure is permanent loss of vision which is possible if the condition is not treated or does not respond to treatment.

Potential Loss of Confidentiality: The risk associated with this study also includes loss of privacy and confidentiality. Protected health data will be kept as confidential as it can be but complete confidentiality cannot be assured. Some protected health information will be shared with BostonSight for the purposes of manufacturing the scleral lenses. The data will be shared through a secure established computer system and will be limited to name, date of birth and lens parameters.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

The study team may be notified if you receive other health care services at URMC or its Affiliates (e.g., visit to the emergency room). In addition, the following individuals may know you participated in research and may see results of testing conducted for this study:

- Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
- Health care providers who are involved in your care at a facility that is not part of the University of Rochester Medical Center and its Affiliates and who have reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

Benefits of Participation

If you find that the test lens created during this trial provides you with better vision quality, then it will be provided to you free of charge. There are no other benefits from being in this study.

Compensation for Injury

If you are directly injured by medical procedures needed because of this study, and you receive medical care for the injury, you may need to pay for that care. You will be reimbursed for reasonable and necessary medical costs for such care, but you might not be reimbursed for care covered and paid for by a third party like your health insurance provider, or costs such as required co-payments or deductibles related to that coverage. No other funds have been set aside to pay for such things as lost wages or expenses due to a current underlying illness or condition.

If your research injury is paid for by the sponsor, Ovitz Corporation, we will collect your name, date of birth, gender, and Medicare Health Insurance Claim Number or Social Security Number to determine your Medicare status. This information will be used only in accordance with the law. If you are a Medicare beneficiary, information about the study you are in, and any payments

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made related to your injury, will be reported to the Centers for Medicare & Medicaid Services (CMS), in accordance with CMS requirements. This information will not be used for any other purpose.

Costs
There will be no cost to you to participate in this study. All the scleral lenses made during this study will be paid for by the study.

Payments
You will not be paid for taking part in this study.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes
The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will limit access to your information to study staff and will de-identify your information as much as possible. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:
- Research records
- Records about your study visits

Who may use and give out information about you?
- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:
- The Department of Health and Human Services
- The University of Rochester
- Ovitz Corporation
- BostonSight
- The U.S. Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been completed. In the event that this should occur, every effort will be made to keep identifying information about you private.

Why will this information be used and/or given to others?
- To do the research
- To study the results

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- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Sponsor Support
The University of Rochester is receiving payment from Ovitz Corporation for conducting this research study.

Contact Persons
For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact**:** Dr. Tara Vaz at 585-273-3937.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;

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- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

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Use of E-mail for Communication in Research

When using e-mail to communicate with you in this study, the researcher cannot guarantee, but will use reasonable means to maintain security and confidentiality of e-mail information sent and received. You and the researcher should understand the following conditions, instructions and risks of e-mail use:

Conditions for e-mail use:

a) E-mail is not appropriate for urgent or emergency situations. The researcher cannot guarantee that any particular e-mail will be read and responded to.
b) E-mail must be concise. You should schedule an appointment if the issue is too complex or sensitive to discuss via e-mail.
c) E-mail communications between you and the researcher will be filed in your research record.
d) Your messages may also be delegated to any member of the study team for response.
e) The researcher will not forward subject-identifiable e-mails outside of URMC and Affiliates without your prior written consent, except as authorized or required by law.
f) You should not use e-mail for communication regarding sensitive medical information.
g) It is your responsibility to follow up and/or schedule an appointment if warranted.

Instructions for e-mail use:

a) Avoid use of your employer's computer.
b) Put your name in the body of the e-mail.
c) Put the topic (e.g., study question) in the subject line.
d) Inform the researcher of changes in your e-mail address.
e) Take precautions to preserve the confidentiality of e-mail.
f) Contact the researcher's office via conventional communication methods (phone, fax, etc.) if you do not receive a reply within a reasonable period of time.

Risks of e-mail use:

Sending your information by e-mail has a number of risks that you should consider. These include, but are not limited to, the following:

a) E-mail can be circulated, forwarded, stored electronically and on paper, and broadcast to unintended recipients.
b) E-mail senders can easily misaddress an e-mail.
c) Backup copies of e-mail may exist even after the sender or the recipient has deleted his or her copy.
d) Employers and on-line services have a right to inspect e-mail transmitted through their systems.
e) E-mail can be intercepted, altered, forwarded, or used without authorization or detection.
f) E-mail can be used to introduce viruses into computer systems.

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SIGNATURES/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____
Subject Name (Printed by Subject)

_____ _____
Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____
Name and Title (Print)

_____ _____
Signature of Person Obtaining Consent Date

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