CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research: Maximizing the Initial Experience of a Neophyte Scleral Lens Wearer

UAB IRB Protocol #: IRB-300006015

Principal Investigator: Andrew D. Pucker, OD, PhD

Sponsor: Department of Optometry and Vision Science

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purposes of the study are to evaluate the initial scleral lens wearing experience and to understand the best way to apply scleral lenses.
Duration & Visits	You will be in this study for up to 6 months, and there will be a minimum of 3 visits, which would otherwise be part of your standard contact lens care.
Overview of Procedures	This study will include eye tests, eye photos, surveys, and a scleral lens fitting. All of this will be integrated into your normal contact lens care.
Risks	The risks of the study do not exceed that of a normal contact lens exam. All contact lens wear comes with a risk of eye infection that could potentially result in permeant blindness; however, this risk is very rare.
Benefits	You will benefit from participating this study by being able to try all of the common methods for applying scleral lenses. We do not anticipate any additional benefits beyond your standard contact lens care.
Alternatives	The only alternative to this study is to not take part in this study and to continue with your regular eye care.

Purpose of the Research Study

We are asking you to take part in a research study that plans to evaluate the initial scleral lens wearing experience. The purpose of this research is to investigate which scleral lens application method is the most effective for new scleral lens wearers. Scleral lenses are FDA-approved, large dimeter, hard contact lenses that are commonly used to correct advanced glasses prescriptions and to provide eye protection from the environment. Since scleral lenses are rigid and larger than the typical soft contact lens, most patients find it beneficial to use an application device when putting on their contact lenses each day. The most commonly used application methods include the use of a DMV inserter with or without an end, the three fingers method, the o-ring method, and the tea light candle method. We would like you to try all five of these methods, and we would like you to tell us about your experience with these methods at the initial training visit and after you have completed your scleral lens fitting. We plan to enroll 30 participants in this study.

Study Participation & Procedures

Baseline Visit

- **Subject History, Eligibility, Informed Consent:** You will be asked to complete a screening survey to verify that you are still eligible for the study. We will also fully explain this study to you and let you decide if you would like to participate.

- **Contact Lens Questionnaire:** We will ask you to complete an investigator-designed questionnaire that asks about your contact lenses and your contact lens experience.

- **Standardized Patient Evaluation of** Eye **Dryness (SPEED):** You will be asked to complete the SPEED questionnaire because it is a validated dry eye symptoms questionnaire that asks about the most common dry eye symptoms.

- **Contact Lens Dry Eye Questionnaire (CLDEQ)-8:** You will be asked to complete the CLDEQ-8 because it is a validated instrument that asks about contact lens comfort and coping mechanisms.

- **Orthokeratology and Contact Lens Quality of Life Questionnaire (OCL-QoL):** You will be asked to complete the OCL-QoL because it assesses the patient's visual quality of life.

- **Visual Acuity:** We will evaluate your ability to read the eye chart will be evaluated.

- **Manifest Refraction:** Your glasses prescription will be determined because it helps determine your contact lens power and visual potential.

- **Slit-Lamp Biomicroscopy:** We will use a slit-lamp biomicroscope to document your eye health.

- **Topography:** We will determine your eye shape with topography to help us select the best contact lenses for your eyes.

- **Scleral Lens Fitting:** You will be fitted with the Europa scleral lens based upon the manufacturer's guidelines. You will try on different scleral lenses, and we will measure the fit of these lenses with a slit-lamp biomicroscope. Sodium fluorescein will also be placed on your eye to help better visualize your contact lens. After obtaining these measurements, we will order your contact lens and schedule you for your follow up visit.

Dispense Visit

- **Visual Acuity:** We will evaluate your ability to read the eye chart will be evaluated.

- **Slit-Lamp Biomicroscopy:** We will use a slit-lamp biomicroscope to document your eye health.

- **Scleral Lens Dispense:** The investigator will help you try on your new lenses, and they will evaluate them with a slit-lamp biomicroscope, sodium fluorescein, and an optical coherence tomography (OCT) after your contact lenses have settled on your eyes for 30 minutes. If the lenses fit acceptably, we will teach you how to apply and remove your contact lenses. If the lenses do not fit acceptably, new lenses will be ordered, and we will schedule you for a follow up visit to try on these new lenses. If this happens, you will need to repeat the dispense visit.

- **Randomization:** We will have you try out the five different lens application methods: *DMV inserter with (A) or without an end (B), three fingers (C), o-ring (D), and tea light candle (E)*. We will then have you rank these methods from easiest to hardest.

- **Scleral Lens Release:** After you complete your training, we will give you everything you need to start wear the lenses (e.g., care product, non-preserved saline, application devices), and we will then have you try out the lenses at home for about one week. You will be allowed to use your favorite application method.

- **Scleral Lens Adaptation Form:** We will ask you to complete a take-home diary daily during your first week of wear, and we will ask you questions about your wearing experience.

Outcome Visit

- **Contact Lens Questionnaire:** We will ask you to complete an investigator-designed questionnaire that asks about your contact lenses and your contact lens experience.

- **Standardized Patient Evaluation of** Eye **Dryness (SPEED):** You will be asked to complete the SPEED questionnaire because it is a validated dry eye symptoms questionnaire that asks about the most common dry eye symptoms.

- **Contact Lens Dry Eye Questionnaire (CLDEQ)-8:** You will be asked to complete the CLDEQ-8 because it is a validated instrument that asks about contact lens comfort and coping mechanisms.

- **Orthokeratology and Contact Lens Quality of Life Questionnaire (OCL-QoL):** You will be asked to complete the OCL-QoL) because it assesses the patient's visual quality of life.

- **Visual Acuity:** We will evaluate your ability to read the eye chart will be evaluated.

- **Scleral Lens Evaluation:** We will evaluate your scleral lenses with a slit-lamp biomicroscope, sodium fluorescein, and an optical coherence tomography (OCT). We will finalize your contact lens prescription if the lenses fit acceptably. If the lenses do not fit acceptably, new lenses will be ordered, and we will be scheduled for a follow up visit for after your lenses arrive. If this happens, you will need to repeat the outcome visit.

- **Study Completion:** You will be compensated, and you will be exited from the study.

Risks and Discomforts

This study does not involve any inherent discomforts. If you find any of the eye tests uncomfortable, you will be allowed to stop participation in the study. There is also a small risk of eye infection associated with wearing contact lenses. If you develop an eye infection, you will be removed from the study and sent back to your eye care provider for treatment and all follow up care. There is also a risk of breach of confidentiality. The order that you will try each application method will be assigned by chance; however, you will have the opportunity to try all of the different application methods being offered by this study.

Benefits

You may not benefit directly from taking part in this study. However, you will have the opportunity to try all of the common scleral lens application methods. Also, knowledge gained from this research will help the medical community better the initial scleral lens wearing experience.

Alternatives

Your alternative is to not participate in this study.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?
All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

Who may use and give out this information?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?
All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the billing offices of *UAB and UAB Health Systems affiliates and/or Children's of Alabama* and its billing agents
- University of Alabama at Birmingham School of Optometry

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution. However, you should return to see the study doctor for safety reasons so you can be taken off the study drug and referred for follow-up care. Contact the study doctor if you want to withdraw from the study.

You may be removed from the study without your consent if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

You are responsible for the cost of the scleral lenses and all fees associated with being fit in scleral lenses. These materials and services may or may not be covered by your insurance, and reimbursement rates vary by

insurance company. We will help you determine your final out-of-pocket costs before you agree to move forward with being fit with scleral lenses and before you agree to participate in this study. If you have any questions about cost, please ask the study investigator.

Payment for Participation

You will be paid $50 via a Greenphire Clincard at the completion of this study to compensate you for the extra time that you devoted to this study. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

Payment for Research-Related Injuries

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

New Findings

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study doctor. You may contact Dr. Andrew D. Pucker at (205) 975-9938 or after hours by emailing him at apucker@uab.edu.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

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Signature of Participant Date

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Signature of Person Obtaining Consent Date