Consent to Take Part in a Human Research Study

FULL PROTOCOL TITLE: Evaluating Contact Lens Optics

NCT05028790

October 16, 2020

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Title of research study: Evaluating Contact Lens Optics

Principal Investigator: David A Berntsen, OD PhD

Key Information:

The following focused information is being presented to assist you in understanding the key elements of this study, as well as the basic reasons why you may or may not wish to consider taking part. This section is only a summary; more detailed information, including how to contact the research team for additional information or questions, follows within the remainder of this document under the "Detailed Information" heading.

What should I know about a research study?

- Someone will explain this research study to you.
- Taking part in the research is voluntary; whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide, and can ask questions at any time during the study.

We invite you to take part in a research study about the optical and visual changes that happen when wearing multifocal soft contact lenses because you meet the following criteria;

- You can read and understand the informed consent document
- You are between 18 to 39 years of age (inclusive)
- You have best corrected visual acuity of 20/25 or better in the right eye
- You are myopic (nearsighted)

In general, your participation in the research involves a single study visit during which we will measure your prescription and the length of your eye. You will wear two different new and previously unworn FDA-approved soft contact lenses on your right eye. Your pupil will be dilated, and we will measure your eye pressure. Measurements include things that are involved in routine eye exams like how well you can see, where light focuses in the back of the eye, and the curvature of the front of your eye. Standard clinical instruments will be used for all measurements.

The primary risk to you in taking part is no different than for a routine eye exam in which your pupils are dilated and you are fitted with a soft contact lens. There is no personal benefit to you from participating, but possible benefit to society includes the development of a tool to improve the development of contact lenses for myopia control. Myopia is also known as nearsightedness.

Detailed Information:

The following is more detailed information about this study, in addition to the information listed above.

Why is this research being done?

Some soft contact lenses (called multifocal contact lenses) have a reading power and are usually used to help people read up close. Some of these lenses have been shown to help slow down the progression of nearsightedness, which we think is because the lenses change how light focuses on the back of the eye. These lenses can also change how clearly someone can see certain things in their environment.

We want to understand whether we can predict how different contact lens designs affect how light focuses on the back of the eye and how they change vision. This information may help us more easily design new lenses that are optimized for slowing the progression of nearsightedness while providing the best vision possible.

How long will the research last?

We expect that you will be in this research study for a single visit lasting about 2.5 hours.

How many people will be studied?

We expect to enroll no more than 25 people in this research study.

What happens if I say yes, I want to be in this research?

All testing in this study will be conducted by trained study personnel. One of the study personnel will determine whether you are eligible to participate in this study. You will be asked questions about your eyes and medical history to see if you are able to participate. The front of your eye will be examined. Your glasses prescription and how well you are able to see will also be determined.

Eye drops used during routine eye examinations will be used to dilate the pupil of your right eye. A clinical instrument will be used to measure the length of your eye and the thickness of structures in your eye. The instrument will not touch your eye. You will wear two different FDA-approved contact lenses in this study. Each contact lens you wear will be a new lens that has never been worn. You will only wear contact lenses on your right eye. After wearing each contact lens, clinical instruments will be used to measure the surface of the front of your eye and how the lens affects the focusing of light in various parts of your eye. You will also be asked to read letters on a screen and indicate whether or not you see targets on a screen. Some of these letters and targets will be very faint.

You will wear two different contact lenses in this study. The order in which you wear the contact lenses will be chosen by chance, like flipping a coin. You will not be told which contact lens you are wearing; however, your study doctor will know. At the end of the study, you will be told the order of the contact lenses that you wore. You will not receive a prescription for glasses or any of the contact lenses being evaluated in this study. If you wish to be fitted with any of the contact lenses tested in this study, you can make an appointment with your eye doctor to do so. The whole study visit is expected to last for about 2.5 hours.

While you are wearing the contact lens, we will take a picture of the contact lens on your eye to determine how well the contact lens fits your eye. You cannot be identified from this picture. If you do not agree to have a picture of the contact lens on your eye photographed, you cannot take part in the study.

What are my responsibilities if I take part in this research?

If you take part in this research, you will wear each of the contact lenses being evaluated in the study on your right eye. You should wear glasses (if you own a pair) to the visit.

What happens if I do not want to be in this research?

You can choose not to take part in the research, and it will not be held against you. Choosing not to take part will involve no penalty or loss of benefit to which you are otherwise entitled.

If you are a student, a decision to take part or not, or to withdraw from the research will have no effect on your grades or standing with the University of Houston. If you are an employee of the University of Houston, a decision to take part or not, or to withdraw from the research will have no effect on your employment with the University of Houston. If you are receiving clinical care at the University of Houston, a decision to take part or not will have no effect on what would be offered to you as part of routine care.

Participation in this study is voluntary, and the only alternative is non-participation.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. If you decide to leave the research study, the data collected up to the point of study exit may still be used. If you decide to leave the study, contact the investigator. If you stop being in the research, already collected data may not be removed from the study database.

Is there any way being in this study could be bad for me?

The risks to subjects from participation in the study are minimal. The procedures in the study (slit lamp exam, contact lens fitting, etc.) are commonly used clinical procedures in optometry and ophthalmology. The visual tests used in this study involve approved clinical instruments.

Dilation of your pupils may interfere with vision for the next few hours and make near work difficult. The eye drops may cause temporary stinging or burning and light sensitivity. Your eyes will be evaluated prior to receiving eye drops to ensure that there is no reason why your pupils should not be dilated.

Commercially available (FDA approved) contact lenses will be fit as part of this study. While most individuals wear contact lenses without problems, there are some risks associated with wearing contact lenses. Ulcerative keratitis (infection of the clear front part of the eye), is the most severe risk and can lead to loss of vision. Ulcerative keratitis is estimated to happen to about 1-2 out of 10,000 people who use daily wear daily disposable contact lenses. The risk in this study is no greater than the risk if your

eye care provider fit you in contact lenses. You will only wear the study contact lenses while at your study visits (you will not be sent home with any of the study contact lenses), which further minimizes this risk.

The following problems may also occur when wearing contact lenses:

- Other, less serious, infections or inflammation of the eye(s)
- Burning, stinging, itching, dryness or general irritation of the eye(s)
- Excessive watering, unusual eye secretions (such as mucus), or redness of the eye(s)
- Reduced or blurred vision (compared to glasses)
- Seeing rainbows or halos around bright lights (compared to glasses)

These are typically side effects that come with extended wear and many (e.g., ulcers) are extremely unlikely to occur in this study because you will wear the contact lenses only during the study visit.

In the event you experience signs or symptoms associated with one of the problems listed above, you should immediately contact Dr. Augustine N Nti or the study Principal Investigator, Dr. David A Berntsen.

Will I receive anything for being in this study?

If you are eligible to participate in the study, you will receive a $50 Amazon gift card after completing the study visit. You must complete the entire study visit to receive the $50 Amazon gift card. If we determine that you are not eligible to participate in the study, you will not receive a gift card.

A parking pass will be provided for the patient parking lot on the day of your visit.

Will being in this study help me in any way?

There are no known benefits to you from your taking part in this research. Your participation will help the investigators develop tools to aid in the design of new multifocal contact lenses.

What happens to the information collected for the research?

Efforts will be made to keep your personal information private, including research study and medical records, to people who have a need to review this information. Each subject's name will be paired with a code number, which will appear on all written study materials. The list pairing the subject's name to the code number will be kept separate from these materials. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the Institutional Review Board (IRB) and other representatives of this organization, as well as collaborating institutions and federal agencies that oversee our research.

This study collects private information with identifiers (such as name, birthdate, etc.). Following collection, researchers may choose to remove all identifying information from these data. Once identifiers are removed, this information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

We may share and/or publish the results of this research. However, unless otherwise detailed in this document, we will keep your name and other identifying information confidential.

Can I be removed from the research without my OK?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include if you do not attend the study visit or do not have acceptable vision or fit with the contact lenses. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. The University of Houston has no program to pay for medical care for research-related injury.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, you should talk to [Redacted] or [Redacted].

This research has been reviewed and approved by the University of Houston Institutional Review Board (IRB). You may also talk to them at (713) 743-9204 or cphs@central.uh.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website 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.

May we contact you regarding future research opportunities?

In the future, our research team may be interested in contacting you for other research studies we undertake, or to conduct a follow-up study to this one. There is never any obligation to take part in additional research. Do we have permission to contact you to provide additional information?

- ☐ Yes
- ☐ No

Signature Block for Capable Adult

Your signature documents your consent to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	