PARTICIPANT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

STUDY TITLE: The Impact of Physiologic Cataract Surgery on Patient Comfort and Medication Usage

PROTOCOL NO: IIT 98621123

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SPONSOR: Alcon Research, LLC

WHY AM I BEING ASKED TO VOLUNTEER?

You are being asked to participate in a research study based on an initial examination of overall ocular health. Before you decide whether to participate, it is important for you to know why the research is being done, and what it will involve. Please take the time to read the following information carefully, and please ask the study doctor to explain anything that is not clear or if you would like more information. If you agree to take part in this study, you will need to sign this consent form. Your signature on this form means that you have been told about and understand the purpose of the study, procedures to be followed, and any benefits or risks. Your signature on this form also means that you want to take part in this study if you meet the criteria. You will be provided with a copy of this signed and dated form for your records.

DO I HAVE TO TAKE PART?

Taking part in this study is entirely voluntary, and you may refuse to participate or withdraw from the study at any time without influencing your regular medical treatment and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. There will not be any penalty or loss of benefits to which you are otherwise entitled if you withdraw early or decide not to participate. Regardless of your decision, you will still be treated for your medical condition.

WHAT IS THE PURPOSE OF THIS STUDY?

Phacoemulsification and intracapsular lens implantation is the most performed eye surgery to restore vision loss for patients with cataracts. During phacoemulsification, an eye surgeon makes a small incision in the clear outer layer at the front of the eye, then uses a handheld probe that uses ultrasound waves to break up the lens. The eye surgeon then uses a suction to remove the remnants of the lens. This procedure may lead to side effects, including structure and functional changes in the eye.

Phacoemulsification is usually performed while temporarily increasing the pressure inside the eye. The purpose of this study is to see if lowering the pressure inside the eye (intraocular pressure or IOP) during this procedure results in fewer side effects and better vision shortly after the surgery. Cataract surgery will be performed using the Centurion® Vision System with Active Sentry® at a traditionally high IOP setting in one eye and using Unity VCS/CS with Intelligent Fluidics at a low IOP setting in the other eye. These devices are approved by the U.S. Food and Drug Administration (FDA). It is expected that operating at a low IOP setting during cataract surgery will result in significantly less discomfort and less medication use than operating at a high IOP setting.

Alcon Research, LLC is providing funding to the study doctor to conduct this study. This financial support is not impacted by the results of the study.

HOW MANY PEOPLE WILL TAKE PART IN THIS RESEARCH STUDY?

Eighty-five (85) people aged 60 and older will be enrolled in this study.

WHAT HAPPENS IF I AGREE TO BE IN THIS RESEARCH STUDY?

The study doctor will determine if you meet all of the study entry criteria. You will be asked questions about your past and current health, including allergies, illnesses, conditions, treatments, operations, etc., and your age, gender, and race. You will also be asked about your eyes and vision. It is very important that you are honest with your study doctor about all diseases you have, both past and present.

If you qualify for the study, the study doctor will perform cataract surgery on one of your eyes using Centurion® Vision System with Active Sentry® at a traditionally high IOP setting and on the other eye using Unity VCS/CS with Intelligent Fluidics at a low IOP setting. The device used on each eye will be assigned by chance (like the flip of a coin) at your first study visit.

You will receive the standard pre-procedure, day of surgery, and post-procedure experience as all patients receiving standard of care cataract surgery. In addition, you will receive identical antibiotic (topical moxifloxacin) and anti-inflammatory (topical prednisolone acetate) eye drops. All patients included in the study will have cataract surgery with an anesthesia professional providing Monitored Anesthesia Care (MAC). With this form of sedation, the anesthesia team may provide either relaxing medication (midazolam) or pain medication (fentanyl) through a small, thin tube called an intravenous catheter or IV. You will receive topical lidocaine to numb the eye.

The goal of MAC anesthesia is not for complete sleepiness or sedation but rather to keep you comfortable. All cataract surgery patients are different; therefore, some patients require higher amounts of anesthesia to control anxiousness. Should too much anesthesia be required to initiate the surgery, you will be removed from study participation for that eye.

The Operating Room (OR) team will be recording the time of medication delivery, type of anesthesia administered, and amount received during your surgery. This information will be collected for the study.

The following measurements will be recorded during your surgeries for study purposes:

- Blood pressure and heart rate – Two of the vital signs always recorded during cataract surgery
- Surgeon Experience on Patient Cooperation.
- Surgeon Assessment on Overall Experience.
- Your response to a Visual Analogue Scale (VAS) measuring pain intensity on a sliding scale (0 [“no pain”] to 10 [“pain as bad as it possibly could be”])

You will receive a survey one day after each surgery that will ask about your experience during surgery. After the second surgery you will receive an additional survey that asks about which surgery you preferred and which eye was more comfortable.

HOW LONG WILL I BE IN THIS RESEARCH STUDY?

Your participation in the study will last up to 13 months. This timeframe includes:

- Your initial evaluation for cataract surgery (Visit #1) including a discussion about the study. You will review and sign this consent form at this visit.
- Your first eye cataract surgery (Visit #2).
- Your second eye cataract surgery (Visit #3).
- You will also receive 1-day post-operative phone call from study staff who will conduct surveys based on experience and preference after each surgery.

After Visit #3 and the 1-day post op survey is completed, you will have completed this study. All recommended scheduled follow up visits with local eye doctors after cataract surgery are still expected to occur.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

Your participation in this study is voluntary. You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are otherwise entitled and will not affect your access to health care. If you do decide to stop your participation in the study, you should talk to your study doctor immediately, so he/she can advise you of any additional treatment that may be needed for your long-term ocular health.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you
- If the complexity of your surgery falls outside of study guidelines
- If you fail to follow directions for participating in the study
- If it is discovered that you do not meet the study requirements
- If the study is canceled; or
- For administrative reasons.

WHAT ARE THE RISKS OF THE STUDY?

The risks of the study are identical to those involved with standard cataract surgery. Your study doctor will review these with you, and you will sign a separate consent form for surgery. These include but are not limited to infection, pain, bleeding, and loss of vision.

There are no additional risks that have been identified, but there may be risks to your participation in the study that are currently unforeseeable or unknown.

ARE THERE BENEFITS TO TAKING PART IN THIS RESEARCH STUDY?

There may be no direct benefit to you by participating in this study. The information collected for this study may add to the knowledge about how IOP setting during surgery impacts cataract surgery experiences and outcomes for both surgeons and future patients.

NEW FINDINGS

Any important new information that is discovered during the study that may influence your willingness to continue participation in the study will be provided to you.

WILL I NEED TO PAY FOR THE TESTS AND PROCEDURES?

Participation in this study will be of no additional cost to you. Insurance will still be responsible for the payment of your pre-operative evaluation and standard cataract surgery. The additional data monitoring needed will be provided at no cost to you.

WILL I BE PAID TO TAKE PART?

For the additional time required to educate you on the study during the consent process and for the completion of the study, you will be compensated $150.00. You will be mailed a check at the completion of the study.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

Cataract surgery inherently has risks. In the event there is a complication associated with cataract surgery, you will be provided with appropriate medical care. The costs for treatment of an injury or complication associated with the surgery will be billed to you and/or your medical insurance.

By signing this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS RESEARCH STUDY?

You have the right to refuse to sign this consent. Taking part in this research study does not take away any other rights or benefits you might have if you did not take part in the study. Taking part in this study does not give you any special privileges. You will not be penalized in any way if you decide not to take part or if you stop after you start the study. Specifically, you do not have to be in this study to receive or continue to receive medical care from your study doctor. If you stop the study, you will still receive medical care.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?

If you choose not to take part in this study, you will still receive standard care at the study site.

WHAT ABOUT CONFIDENTIALITY?

The personal information obtained about you during the study will remain confidential. When recording the results of the study you will be referred to only by a unique subject identifier code number (like a medical record number). Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records.

By agreeing to participate in this research study, you agree to give representatives of the following entities access to your research-related medical records to ensure the proper conduct of the research, to verify the accuracy of the collected data or for other reasons that are allowed under the law.

- The study sponsor
- People who work with the sponsor on the study
- Clinical monitors
- Auditors
- Sterling Institutional Review Board (IRB) who reviewed this research.

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 Web site at any time.

AUTHORIZATION TO COLLECT, USE AND DISCLOSE YOUR MEDICAL INFORMATION

As a part of this research, records that contain information or data about you and your health may be collected and used. These records may identify you and will be kept as confidential as possible. To the extent permitted by applicable laws and regulations, the records identifying you will not be made publicly available.

Under the privacy laws, you have the rights to decide who can use your protected health information (called PHI). When you sign this form, you are saying that you will allow the use of your protected health information for this study.

The information that will be collected about you as a part of this research includes:

- Name
- Address
- Telephone number
- Birth date
- Race
- Sex
- Family medical history
- Allergies
- Medications you take (current and past)
- Information collected during surgery
- Survey responses
- Other information from other doctors' offices, clinics, and/or hospitals that is needed for the study

Information collected about you for the study will be kept in a research file that is separate from your medical chart.

The following groups may review and use your study information. They may review your study information to make sure that it is correct. They may also review your information to make sure that the study is being conducted properly.

- The study sponsor (or sponsor representatives such as monitors and/or auditors)
- The U.S. Food and Drug Administration (FDA)
- Sterling Institutional Review Board (IRB)
- The Department of Health and Human Service (DHHS)
- Other government agencies in other countries
- Other doctors, health care professionals or research staff who are involved in the study

Your study information may be released to the groups listed above. If your study information is reviewed by these people, they may need to see your entire medical record; it is possible that your Social Security number may be included in the records reviewed. Because of this, it cannot be assured that your confidentiality will always be protected. It is possible that your information will be shared (re-disclosed) in a way that it would no longer be protected. However, this access to your records will be granted without violating your confidentiality to the extent permitted by applicable laws and regulations. By signing this form, you are authorizing this access to your records.

The results of the study, including your information, may also be presented at meetings or in articles written about the study (publications). If the results of the study (including your research or health information) are published, your identity will remain confidential.

This permission (also called an authorization) will have no end date.

You have a right to see your study records; however, you will not be able to see your study records until after the study has ended.

You may also take away (or withdraw) your permission for the use of your protected health information at any time. If you choose to withdraw your permission, you must write your study doctor a letter.

The study doctor's mailing address is Wolfe Eye Clinic, 6200 Westown Pkwy, West Des Moines, IA 50266. The study doctor will still be able to use the health information collected about you before you withdrew your permission. Information that has already been sent to the sponsor of the study cannot be taken back.

If you withdraw your permission after you have entered the study, you cannot continue participating in the study. If you refuse to give permission or withdraw your permission, your medical care and your relationship with the health care providers at the study center will not be affected.

PARTICIPANT STATEMENT AND AUTHORIZATION

I have read the Participant Informed Consent Form and Authorization to Use and Disclose Medical Information and I agree to participate voluntarily in this study. I give my permission to the study doctor to use and disclose my protected health information as described in this consent form.

- I will receive a signed copy of this form.
- All my questions have been answered.
- I have not waived any of my legal rights by signing this document.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Conducting the Consent Discussion

_____ _____
Signature of Person Conducting the Consent Discussion Date