APPROVED BY SALUS IRB: 07 MAY 2024

TITLE:	Comparative Study of the DMM and Conventional Toric Marker
PROTOCOL NO:	IIT# 92162521
AMENDMENT NO:	Version 1.0
IRB:	Salus IRB 2111 West Braker Lane, Suite 100 Austin, TX 78758
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INVESTIGATOR:	Ganesha Ramana ‘Rom’ Kandavel MD Colvard-Kandavel Eye Center 5363 Balboa Blvd Suite 545 Encino, CA 91316 United States
STUDY-RELATED PHONE NUMBER:	818-906-2929 (During business hours) 818-446-2312 (24-Hour line)

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

You are being invited to take part in a research data collection study. A person who takes part in a research study is called a research subject, or research participant.

You were selected as a possible participant in this study because you have been diagnosed with cataract and are planning to proceed with femto-second laser assisted cataract surgery as recommended by your surgeon. In addition, your surgeon has determined that you have corneal astigmatism, recommending the Clareon monofocal Toric intraocular lens (IOL) to reduce dependence on glasses.

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The doctor performing your procedure will discuss the risks and benefits of femto-second laser assisted cataract surgery with implantation of a Toric IOL in a separate consent. The procedure is not part of the research data collection.

WHAT SHOULD I KNOW ABOUT THIS RESEARCH?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don’t understand, ask questions.
- Ask all the questions you want before you decide.
- The alternative is to not participate in this study.

WHY IS THIS RESEARCH BEING DONE?

Toric intraocular lenses (IOLs) are a type of lens used in cataract surgery for patients with high corneal astigmatism. They can potentially reduce the dependence on glasses after surgery. However, getting the alignment of these lenses just right is crucial for their effectiveness.

The purpose of this research study is to compare outcomes between the traditional manual marking technique and the newer digital method. Using the Digital Marking Method [DMM] may result in better lens alignment during surgery, leading to improved vision and less reliance on glasses afterwards. You are being asked to allow us to collect your surgery data (information from before, during and after your surgery) to compare the outcomes between manual marking and digital marking.

At least 20 subjects (a total of 40 eyes), ages 50-80 years, will take part in this research.

HOW LONG WILL I BE IN THE RESEARCH STUDY?

Participation will last for about 2 months. You will undergo pre-operative measurements during your initial surgical consult, proceed with cataract surgery as planned, and will have additional measurements taken 6 weeks following the surgery.

WHAT HAPPENS TO ME IF I AGREE TO TAKE PART IN THIS RESEARCH?

During your 6-week post-operative visit, your vision will be measured and your glasses prescription will be determined. Your physician will then perform a dilated eye examination to confirm the stability of the Toric IOL. Photographs of the IOL during the surgery and 6 weeks following surgery will be taken.

COULD BEING IN THIS RESEARCH HURT ME?

The collection of this data does not hold any additional risk or change the visual outcome of your surgery. There is a risk of loss of confidentiality. The data collection done as a part of this study will not pose additional risks to your routine surgical care.

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.

The principal investigator is being paid to conduct this study. This may pose a conflict of interest. If you have questions about it, please ask the person discussing this consent form with you.

WILL BEING IN THIS RESEARCH BENEFIT ME?

There is no benefit directly to you from your taking part in this research. However, the results of the research may benefit others by providing valuable data on the outcome of using digital marking methods for Toric IOL positioning during cataract surgery. This data may also assist with the treatment of future patients undergoing cataract surgery.

It is possible that the sponsor or the FDA could stop the study before it is over. If that happens, you will still get your usual post-operative care.

WILL I BE PAID TO BE IN THE RESEARCH STUDY?

You will not be paid for participating in the study.

WHAT OTHER CHOICES DO I HAVE BESIDES TAKING PART IN THIS RESEARCH?

You may continue to proceed with femto-second assisted cataract surgery with implantation of the Clareon monofocal Toric intraocular lens, as previously determined by your surgeon. However, if you decide not to participate in the study none of the data collection or other aspects of the research study will take place.

WHAT HAPPENS TO THE INFORMATION COLLECTED FOR THIS RESEARCH?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- The Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential. We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

WHO CAN ANSWER MY QUESTIONS ABOUT THIS RESEARCH?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page. This research is being overseen by Salus IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-300-0815 between 8:00 AM and 5:00 PM Central Time or salus@salusirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.

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- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

STATEMENT OF CONSENT FOR CLINICAL STUDY

My participation in this research study is completely voluntary and I may choose not to participate, or I may withdraw my participation at any time, without penalty or loss of benefits to which I am otherwise entitled. I consent to participating in a clinical research study at the Colvard-Kandavel Eye Center. The data collected from this visit may be used in clinical research in an anonymous fashion both for publication and for presentation. My data may be reviewed by the study sponsor, the US Food and Drug Administration, and the IRB overseeing this research. The collection of this data does not hold any additional risk or change the visual outcome of my surgery, I allow use of this data for the purpose of this research only.

Print name of Participant ____________________

Date ____________________

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Signature of Participant	Date
Print Name of person obtaining consent	Date
Signature of person obtaining consent	Date

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CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

These rights are the rights of every person who is asked to be in a research study. If you choose to take part in research, you have all of these rights.

1. I have the right to be told what the research is trying to find out.
2. I have the right to be told about all research procedures. If there are drugs or devices being used in the research, I have the right to know about them. I have the right to know if anything is different from standard practice.
3. I have the right to be told about any risks or discomforts that might reasonably happen because of the research.
4. I have the right to be told if I can reasonably expect to benefit from taking part in the research. If there are or might be benefits, I have the right to be told about them.
5. I have the right to be told about other choices I have and how they may be better or worse than taking part in the research. These choices may include other procedures, drugs, or devices.
6. I have the right to be told what kind of treatment will be available if the research causes any complications.
7. I have the right to ask any questions I have about the research. I can ask these questions before the research begins or at any time during the research.
8. I have the right to say yes or no to taking part in the research. If I take part, I have the right to withdraw (quit) at any time. My decision will not affect my care or my relationship with my doctor. It will not affect my legal rights.
9. I have the right to get a copy of the research consent form that I have signed and dated.
10. I have the right to be free of any pressure as I decide if I want to take part in the research.

AS REQUIRED BY CALIFORNIA STATE LAW, PLEASE SIGN AND DATE THIS DOCUMENT

____________________________________ ____________________
Signature of Participant Date