Title of research study: Evaluation of Software Generated Customized Foot Orthoses

Investigator: Eric Giza, MD

California Experimental Subjects Bill of Rights

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any drug or device to be used.
- Any common or important discomforts and risks.
- Any benefits you might expect.
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document.

Key Information about This Research Study

The purpose of this study is to assess whether custom-made foot orthotics help alleviate your foot/ankle pain. You are invited to be in this study because you are experiencing foot/ankle pain. Your participation in this research will involve at least 1 visit and will last about 12 months. We expect about 60 people at UC Davis will join to participate in this research.

Participation in this study will involve routine visits, filling out surveys, and having your data collected. All research studies involve some risk. These risks are described in detail later in this document. You may or may not benefit from your participation in this study. One of the ways we can monitor your outcomes is through surveys.

Here are some reasons you may not want to participate in this research: unwilling or unable to complete the follow ups and surveys.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. You can still receive normal standard of care. Some other choices may include normal standard of care. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions you need to help decide whether or not to join this study.

Information to help you understand research is online at
http://www.research.ucdavis.edu/policiescompliance/irb-admin/for-research-participants.

What if I have Questions?

The person in charge of this study is Dr. Eric Giza. If you have questions or concerns about this study, please contact the Lead Researcher, at (916)-734-6805.

For non-emergency issues you can call the UCDMC Hospital Operator (916-734-2011), tell the Operator you are participating in a research study and you wish to talk to Orthopaedic Surgery resident on-call. In the case of an emergency, dial 911 from any phone.

If you have any questions about your rights as a research subject or have complaints about the research study or study team, you may talk to a team member at the Institutional Review Board (IRB) at (916) 703-9151, hs-irbadmin@ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817. The IRB is a group of people who oversee research.

How is this research funded?

This research is being funded/sponsored by Soleit, a UC Davis-associated startup. Sponsors may change or be added.

Why is this research being done?

The purpose of this study is to assess whether custom-made foot orthotics help alleviate foot/ankle pain. We have the possibility of designing foot orthoses tailored to each person's foot, which generates support and impacts absorption according to the shape of one's foot. The potential benefits of software generated custom-made orthopedic foot orthotics are decrease in foot/ankle pain and an increase in comfort and quality of life.

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

If you decide to participate in this research study, the researchers will ask you to do the following:

- A 30-minute evaluation for the creation of your foot orthotics, which will be sent to you about 2 weeks later.

The following activities are for research purposes:

Collecting data. These occur the day you begin to use your foot orthotics and then 7, 30, 120, and 360 days afterward. The collected data may include:

- Demographic information
- How the orthotics are affecting your pain, comfort, and quality of life
- Other notable information

How is being in this study different from my regular health care?

If you take part in this study, the main difference between your regular care and the study is completing surveys.

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

If you take part in this research, you will be responsible for filling out surveys.

Do I have to be in this study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. You can choose to be in the study or not be in the study. If you decide to be in the study, you can choose to leave the study at any time.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UC Davis Health or any services you receive from them. No matter what you decide, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Please let the researchers know if you choose to leave the study.

Instead of being in this research study, your choice includes normal standard of care.

If you stop being in the research, data that has already been collected will not be removed from the study database. You will be asked whether the investigator can collect data from your future routine medical care. If you agree, this data will be handled the same as research data.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

Can I be removed from the research without my OK?

The researchers may take you out of the study, even if you want to continue, if:

- your health changes and staying on the study is no longer in your best interest;
- you do not follow the study rules or you no longer meet the requirements to be in the study; or
- the study is stopped by the sponsor or researchers.

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

There are risks to participating in this research. The study doctor and study team will monitor you to see if you are experiencing any harm related to your participation. If you experience any pain or discomfort, you must inform the study team as soon as possible.

- **Device-Related Risks:**
    - Discomfort: A conceived risk is that the foot orthotics cause discomfort. This will be controlled in two ways. The first is that the use of the orthotics will be done progressively. This means that you should use the orthotics for 1 hour on the first day, then increase use by 1 hour each day until reaching 4 consecutive hours at which time the foot orthoses can be worn continuously.
    - Blisters: Another conceived risk is the generation of blisters due to friction. Inspect the bottom of your feet when you finish any type of physical activity and check for any areas of redness
- **Data integrity and Patient Privacy Risks:** Any time information is collected, there is a potential risk of loss of confidentiality. Every effort will be made to keep patient information confidential; however, this cannot be guaranteed. To minimize these risks, data will be stored securely under your study identification number. All clinical data and images will be de-identified prior to any in-house or public presentation of data or images. Coded data will only be released to those listed as study investigators or support staff. Paper data records will be stored in locked file cabinets in a locked office. All electronic research data will be stored on the PI computer that is password protected and encrypted.

- **Other Risks:** There may possibly be other risks or side effects that are unknown at this time. Patients concerned about other, unknown side effects, should discuss this with the researchers.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include a decrease in your foot/ankle pain. Also, your participation in the study may benefit other people in the future by helping us learn more about the efficacy of foot orthotics in alleviating foot/ankle pain.

Will being in this study cost me anything?

There will be no cost to you for any of the study activities or procedures.

You will have to pay for basic expenses like any childcare, food, parking, or transportation related to study activities.

You or your insurance company will have to pay for all costs for medical care related to participation in this study, including co-payments and deductibles. You will have to pay for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may have to pay, you should contact your insurance company. If you do not have health insurance, you will have to pay all the costs for your medical care just as you would if you did not take part in this study.

If you need treatment for side effects while you are on the study, you or your insurance will need to pay for this treatment.

For more information about possible costs, please contact the research team. The research team can follow UC Davis Uninsured Non-Emergency Estimate Policy (Policy ID 1883) to work with their department and Decision Support Services to get you a cost estimate.

Will I be paid or receive anything for being in this study?

Participants will receive custom-made foot orthoses free of charge. No additional compensation will be received.

What happens if I am injured or get sick because of this study?

If you are injured as a result of being in this study, the University of California will provide the necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by the University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about compensation, you may contact the IRB Administration at (916) 703-9151 or HS-IRBAdmin@ucdavis.edu.

If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

What happens to the information collected for the research?

We will do our best to limit the use or disclosure of your personal information, including information from this research study and from your medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Some organizations may be required to inspect and copy your information including the IRB and other University of California representatives responsible for the management or oversight of this study.

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will maintain your study data on encrypted computers and access to the information will be limited to only members of the research team who need the access to properly conduct the study.

While this study does not involve banking the data we collect with your identifiable information (e.g., your name, medical record number, or date of birth) for future use, we may still use your data to answer additional research questions or share them with other investigators for additional research. If we do so, we will remove all identifiable information before use or sharing. Once identifiers have been removed, we will not ask your consent for the use of sharing of your data or specimens in additional research.

However, we cannot promise complete confidentiality. If you agree to be in this study, Federal or state laws may permit or require us to show information to university or government officials and to study sponsors responsible for monitoring this study. We may also show your medical records to study monitors, auditors, the IRB, and the FDA. These groups are obligated to maintain your confidentiality. The following is a list of individuals who may access your records:

• Members of the research team

• Offices and committees responsible for the oversight of research

• Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study

• The U.S. Food and Drug Administration (FDA)

• The study sponsor, Soleit

We will access protected health information (e.g., your medical record) for this study and you will be asked to sign a separate form, commonly referred to as a HIPAA authorization, to give your permission. Your medical records may become part of the research record. If that happens, your medical records may be looked at by the sponsor of this study and government agencies or other groups associated with the study. They may not copy or take your personal health information from your medical records unless permitted or required by law.

If you agree to participate in this research study, a signed copy of this consent document and the privacy authorization form may be filed in your electronic medical record (EMR) and your study participation may be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment. Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your EMR until the study is complete to ensure that the study remains unbiased. If necessary for your care, this information will be provided to you or your physician.

Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/legal/privacy/) and in an attached document.

Will I receive any results from this research?

Since the surveys are self-reported, you will know what you report. However, the data analysis results will not be shared.

Do not write below this line. For IRB stamp and version date only.

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
1771535	December 16, 2021

Signature Block for Capable Adult

Your signature documents your permission 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	

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date
Printed name of person witnessing consent process	

Do not write below this line. For IRB stamp and version date only.

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