RESEARCH SUBJECT CONSENT FORM

TITLE:	Assessment of Wound Closure Comparing Synthetic Hybrid-Scale Fiber Matrix with Standard of Care in Treating Diabetic Foot Ulcer
PROTOCOL NO.:	21-RES-002 IRB Protocol #20211790
SPONSOR:	Acera Surgical, Inc.
INVESTIGATOR:	Dr. Khalid Husain, DPM Midwest Foot & Ankle Clinics 2260 W. Higgins Rd. #101 Hoffman Estates, IL 60169 United States
STUDY-RELATED PHONE NUMBER(S):	Phone Number: 847-398-8637 Phone Number: 847-312-5719 (24 hours)

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details. You will receive a signed copy of this form.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

We expect that you taking part in this research will last up to approximately 17 weeks. Your doctor may also decide to remove you from the study if he/she determines you require treatment outside of the study procedures.

Why is this research being done?

The primary purpose of this research is to study Synthetic Hybrid-Scale Fiber Matrix (Restrata® manufactured by Acera Surgical, Inc., United States), a therapy for treating chronic wounds.

Synthetic Hybrid-Scale Fiber Matrix acts as a protective covering for wound defects, providing a moist environment for the body's natural healing process to occur. It is made of small synthetic fibers that are designed to be similar to the structure of human skin. Synthetic Hybrid-Scale Fiber Matrix will be compared with Standard of Care treatment. The Standard of Care treatment include weekly debridement and daily dressing (foam or alginate) change. None of these products are experimental as they have all been cleared by FDA.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include:

- A two-week screening period to determine if you will be enrolled in the study. Screening assessments include a blood test, and an assessment of blood flow by completing a blood pressure assessment, oxygen measurement or ultrasound assessment.
- If you complete the two-week screening period and meet all requirements to be enrolled in the study, then you will begin treatment with one of the study products. You and the study doctor will know which product you will receive.
    - You will be randomly assigned to be treated with either Synthetic Hybrid-Scale Fiber Matrix or Standard of Care. Half of the patients will receive Synthetic Hybrid-Scale Fiber Matrix and the other half will receive Standard of Care.
    - If you have more than one ulcer, then your study doctor may choose to treat the additional ulcer(s) with the study product if the additional ulcer(s) meet study requirements.
- If you are randomly assigned to receive Synthetic Hybrid-Scale Fiber Matrix, your study doctor will apply the product weekly (or as needed based on the clinician discretion and ongoing wound assessment) until all of your wounds treated for the study are closed or up to 12 weeks (whichever occurs first). You will have weekly visits up until this time for the doctor to examine your wound and take an image.
- If you are randomly assigned to receive Standard of Care, your study doctor will debride the wound and apply the wound dressing weekly until all of your wounds treated for the study are closed or up to 12 weeks (whichever occurs first). You will have weekly visits up until this time for the doctor to examine your wound and take an image.
- You will be asked to complete a questionnaire on the first and last day of treatment.
- If your wound closes completely during the treatment period, then you will be asked to return for an additional visit two weeks later so that the study doctor can examine the closed wound.

Could being in this clinical study hurt me?

Risks include:

- pain
- infection
- chronic inflammation
- excessive redness, pain, swelling, or blistering
- failure of the ulcer to heal
- allergic reaction to the study product
- need for additional wound care procedures that are not part of the study procedures
- rare but possible transmission of infectious diseases that are unknown including fungi, bacteria, and viruses

Will being in this clinical study benefit me?

Your ulcer may heal more quickly and more fully than if you only received standard treatment outside the study. However, it is not known how likely you are to receive this benefit. Your participation will help your doctor and the developer of this wound care product understand whether Synthetic Hybrid-Scale Fiber Matrix is as effective as Standard of Care. This study will provide information to determine if benefits and coverage from various insurance companies can be provided for this type of wound care product. The research may also benefit people who have chronic wounds in the future.

What other choices do I have besides taking part in this research?

Instead of being in this research, your choices may include:

- Treatment with one of the study products without participating in the study
- Treatment without the study products
- Treatment with other types of skin substitute products

DETAILED RESEARCH CONSENT AND AUTHORIZATION TO USE HEALTH INFORMATION

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

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.

Why is this research being done?

The primary purpose of this research is to study Synthetic Hybrid-Scale Fiber Matrix (Restrata® manufactured by Acera Surgical, Inc., United States), a therapy for treating chronic wounds.

Synthetic Hybrid-Scale Fiber Matrix acts as a protective covering for wound defects, providing a moist environment for the body's natural healing process to occur. It is made of small synthetic fibers that are designed to be similar to the structure of human skin. Synthetic Hybrid-Scale Fiber Matrix will be compared with Standard of Care. The Standard of Care treatment include weekly debridement and daily dressing (foam or alginate) change. None of these products are experimental as they have all been cleared by FDA.

Additional purposes of this research include the collection of data to be used in future publications, at conferences and in marketing materials.

About 48 subjects with diabetic foot ulcers will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last up to approximately 17 weeks.

What is the process for me if I agree to take part in this research?

Two-Week Screening Period
If you decide to participate in this study, there will be a two-week screening period to determine if you will be enrolled in the study. If you have more than one ulcer, then your study doctor may choose to screen the additional ulcer(s) to determine if they can be enrolled in the study. During your first visit at the start of the screening period, your study doctor will collect information about your demographics and medical history. The following tests will also be completed:

- Your study doctor will examine your wound(s) and take an image.
- You may have one of the following noninvasive blood circulation tests depending on when you had your last test:
    - Blood pressure measurements on your arms, ankles, and/or toes
    - A test that uses sensors attached to your skin on your leg and/or foot to measure the level of oxygen
    - Ultrasound of your leg(s). Ultrasound is a procedure that uses sound waves to "see" inside your body so that your doctor can examine your blood circulation.
- You may have a blood test depending on when your HbA1C (hemoglobin A1C) was last tested.

If your study doctor confirms you meet all study requirements after the first visit, then you will have a second screening visit one week later. During this visit your study doctor will examine your wound(s) and take an image. If you do not continue to meet all study requirements, then you will not participate in the study.

Treatment Period (Up to 12 Weeks)

If your study doctor confirms you continue to meet all study requirements after your second visit, then you will have a third visit one week afterwards. During this visit your study doctor will examine your wound(s) and take an image. If you do not continue to meet all study requirements, then you will not continue participating in the study. If you have more than one ulcer that is screened, it is possible that only one or some of the ulcers will continue to meet study requirements. You study doctor will provide standard treatment for ulcers that do not meet study requirements.

If you continue to meet all requirements to be enrolled in the study, then you will begin treatment with one of the study products.

- You will be randomly assigned to be treated with either Synthetic Hybrid-Scale Fiber Matrix or Standard of Care. Half of the patients will receive Synthetic Hybrid-Scale Fiber Matrix and the other half will receive Standard of Care.

You will be put into a study group by chance (like a coin toss or drawing straws). You have a 1 out of 2 chance of being placed in each group. You cannot choose your study group. Once you are assigned to a group, the treatment period will begin. If you have more than one ulcer that meets study requirements, then all ulcers will be put in the same group and receive the same study product.

If you are randomly assigned to receive Synthetic Hybrid-Scale Fiber Matrix, your study doctor will apply the product weekly (or as needed based on the clinician discretion and ongoing wound assessment) until all of your wounds treated for the study are closed or up to 12 weeks (whichever occurs first). You will have weekly visits up until this time for the doctor to examine your wound and take an image. Your study doctor will provide you with an off-loading device for your foot and instruct you how to use it during the treatment period. An off-loading device reduces the weight you place on your foot.

If you are randomly assigned to receive Standard of Care, your study doctor will debride the wound and apply the wound dressing weekly until all of your wounds treated for the study are closed or up to 12 weeks (whichever occurs first). You will have weekly visits up until this time for the doctor to examine your wound and take an image. Your study doctor will provide you with an off-loading device for your foot and instruct you how to use it during the treatment period. An off-loading device reduces the weight you place on your foot.

On the first and last day of the treatment period you will be asked to rate your pain from your wound and complete an SF-36 questionnaire, which asks questions about your quality of life.

Follow-Up Period (Two weeks)
If your wound(s) closes completely during the treatment period, then you will be asked to return for an additional visit two weeks after your wound closes so that the study doctor can examine the closed wound.

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

If you take part in this research, you are responsible to:

- Follow all wound care instructions from your study doctor and the research staff. These include:
    - Wearing compression stockings or an offloading device as directed and if necessary
    - Changing wound dressings as directed
- Notify your study doctor if you do not follow all instructions correctly
- You may not participate in this study if you are pregnant, breastfeeding or planning to become pregnant over the next 6 months. Immediately notify your study doctor if you become pregnant during the study.
- Confirm with your study doctor before taking any medications containing steroids.
- Notify your study doctor if you have an allergy or sensitivity to suture materials, fish, fish materials, bovine (cow) materials or agarose shipping materials.

Could being in this clinical study hurt me?

Known risks and discomforts of Synthetic Hybrid-Scale Fiber Matrix include:

- Pain
- Failure of the ulcer to heal
- Allergic reaction or sensitivity
- Infection
- Chronic inflammation
- Need for additional wound care procedures that are not part of the study procedures

Known risks and discomforts of Standard of Care include:

- Pain
- Failure of the ulcer to heal
- Allergic reaction or sensitivity
- Infection
- Chronic inflammation
- Excessive redness, pain, swelling, or blistering
- Need for additional wound care procedures that are not part of the study procedures

Drawing blood may cause pain, bruising, lightheadedness, or, on rare occasions, infection.

Depending on the type of blood circulation test you take, you may experience discomfort from the blood pressure measurements, skin irritation from the sensor adhesives, or discomfort from the ultrasound probe.

Risks of wound debridement include pain and bleeding.

If you don't follow the instructions from your study doctor about changing wound dressings, wearing compression stockings and/or using an offloading device, then the wound(s) may take longer to heal.

Because data is being collected about your treatment, there is the risk of loss of some confidentiality related to your medical records. However, identifying data such are your name, address and medical record identification number will not be collected as part of this research study.

In addition to these risks, taking part in this research may harm you in unknown ways.

Taking part in this study may hurt a pregnancy or fetus in unknown ways. These may be minor or so severe as to cause death. Immediately notify your study doctor if you become pregnant during the study.

Will it cost me money to take part in this research?

There will be no cost to you or your insurance for any tests or procedures done only for the purpose of this research. You or your insurance company may be responsible the cost of your standard care.

Taking part in this research may lead to added costs to you. In some cases, insurance does not pay for services ordinarily covered as part of your treatment because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay. The sponsor will assist in confirming benefits and coverage through a Reimbursement Support Hotline at no charge to you.

Will being in this clinical study benefit me?

We cannot promise any benefits to you or others from your taking part in this research.

Your ulcer may heal more quickly and more fully than if you only received standard treatment outside the study. However, it is not known how likely you are to receive this benefit. Your participation will help your doctor and the developer of this wound care product understand whether Synthetic Hybrid-Scale Fiber Matrix is as effective as Standard of Care. This study will provide information to determine if benefits and coverage from various insurance companies can be provided for this type of wound care product. The research may also benefit people who have chronic wounds in the future.

What other choices do I have besides taking part in this research?

You do not have to be part of this study to receive treatment for your condition. Instead of being in this research, your choices may include:

- Treatment with one of the study products without participating in the study
- Treatment without one of the study products
- Treatment with other types of skin substitute products

What happens to the information collected for this research?

As a part of this research, the study doctor will collect and use records that contain information and/or data about you and your health. These records may identify you and will be kept as confidential as possible. This is required by law.

Under the privacy laws, you have the right to decide who can use your personal health information (called PHI).

When you sign this form, you are saying that you will allow the study doctor to use your personal health information for the purpose of the study.

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

- Name, address, telephone number, and email
- Birth date
- Race and Ethnicity
- Sex
- Social security number
- Insurance information for use in verification of benefit coverage
- Medical history
- Family medical history
- Allergies
- Medications you take (current and past)
- Information from the physical examinations done by the study doctor
- Results of study tests and study procedures including:
    - 3-dimensional photos of your wound(s)
    - Blood tests
    - Blood flow test
- Study Questionnaires
- Other information from other doctor's offices, clinics, and hospitals that is needed for the study

Information collected about you by the study doctor and research staff for the study will be kept in a research file. The study team will know your identity; however, they may label your records with your initials or a code that is randomly assigned to you. The study doctor and research staff are authorized to disclose data to other organizations involved with and overseeing the 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 including study monitors and auditors of your medical records, research records, and wound photos
- Government agencies, such as the U.S. Food and Drug Administration may review your research records
- The Institutional Review Board (IRB) that reviewed this research
- Other doctors and health care professionals who are involved in the study

The study doctor will release your study information to the groups listed above as needed. If your study information is reviewed by these people, they may also need to review your entire medical record. Once information is released, it may be redisclosed and no longer protected by U.S. privacy laws.

We may publish the results of this research or present results at conferences. However, we will keep your name and other identifying information confidential.

We will protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

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.

Data collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically.

This permission will be good until December 31, 2070.

There is no expiration date for your permission (also called an authorization) to use your information that will be collected for this research.

You have a right to see your study records. You may also take away (or withdraw) your permission for us to use your health information at any time. If you choose to withdraw your permission, you must notify the study doctor in writing. The study doctor and groups identified in the list above will still be able to use the health information collected about you before you withdrew your permission.

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

You do not have to sign this form in order to receive one of the products in this study because you can receive the same treatment without participating in research. However, you will not be able to participate in this study without signing this form.

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 WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.comif:

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

Financial Disclosure
The study investigator, Dr. Kahlid Husain, has received consulting fees from the sponsor during the last year. Please ask any questions you may have about this.

What if I am injured because of taking part in this research?

If you are injured or get sick because of being in this research, call the study doctor immediately: Dr. Khalid Husain (847-398-8637). The study doctor will provide emergency medical treatment. Your insurance may be billed for this treatment.

In the event of any physical injury, costs for the treatment of injuries will be charged to your insurance carrier or to you. If for any reason these costs are not covered by your insurance, they will be billed to you. You will also be responsible for any deductible, co-insurance, and/or co-pay.

No financial payments or other forms of compensation (such as lost wages, physical therapy or other recovery needs, other loss of income or pain or suffering or discomfort) will be offered to you for injuries.

You will not lose any legal rights by signing this form.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- You become pregnant
- The research is canceled by the sponsor or IRB
- You are unable to keep your scheduled appointments
- You do not follow the instructions from your study doctor and research staff
- All or part of your study limb is amputated

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

What happens if I agree to be in this research, but I change my mind later?

If you decide to leave this research, contact the research team. Your study doctor may ask you to return to examine your wound and discuss future treatment options.

Will I be paid for taking part in this research?

You will receive a payment of $25.00 for each follow-up visit you attend.

Important Reminders and Statement of Consent:

As a reminder:

- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.
- You will be notified of any significant new information during your participation in the study.
- You will not waive any of your legal rights by signing this document.

You will receive a signed copy of this form.

Your signature documents your permission for you or the individual named below to take part in this research.

Signature of subject capable of consent	Date
Printed name of subject (not required if subject personally provided consent)	Date
Signature of person obtaining consent	Date