The LASER Pilot Project: Laser Therapy in Amputee Skin Care to Enhance Rehabilitation. A Preliminary Investigation

A4110-P NCT05966636

Informed Consent Version Date: 8/18/25

CIRB Approval Date: 8/26/25

Participant Name: _____ IRBNet ID:

Title of Study: ____ The LASER Pilot Project: Laser Therapy in Amputee Skin Care to Enhance Rehabilitation. A Preliminary Investigation _____

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: Dr. Jeffrey Heckman, MD

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in ***The LASER Pilot Project: Laser therapy in Amputee Skin Care to Enhance Rehabilitation*** that is being funded VA Rehabilitation Research and Development (RR&D) Service. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?
Fractionated CO_2 laser treatment is sometimes used for scar treatment in non-amputee patients, such as those with limb salvage or burns. The purpose of this research study is to determine if fractionated CO_2 laser therapy may potentially improve outcomes in Veterans who use prostheses and who have limitations due to problematic scars. Fractional Laser Therapy is used for routine care for scars. However, it has not been studied on scars and amputated residual limbs.

The research will be done at the Tampa VA and the Miami VA with support from the University of South Florida. Dermatologic evaluation and laser therapy intervention will be provided at the local VA sites or at our clinical dermatology partners in the community.

Why are you being asked to take part?
We are asking you to take part in this research study because you have lower limb amputation, you are using a prosthesis and you are affected by problematic scarring.

How many other people will take part?
About 20 people will take part in this study. The entire research study is expected to take about 2 years. Your individual participation will be about 7 hours over 7 months.

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PI/SC Approval Date: 8/26/25

LSI Approval Date: N/A

LSI Verification Date: N/A

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There may be no direct benefit to you. However, you may benefit from laser therapy as it could improve scar thickness and texture and/or pain and therefore, prosthetic wear and use may be more comfortable for you and your movement and function may improve. For a complete description of benefits, refer to the Detailed Information section of this consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

If you do not choose to volunteer for this study, you can continue using your prosthesis as you have in the past. You may wish not to volunteer due to concern of developing new scars or worsening of existing scars, discoloration of the skin and possible infection. For a complete description of risks, refer to the Detailed Information section of this consent.

If you choose not to participate, you may talk with your doctor about other treatments for skin problems. Current treatments for skin problems include manual scar mobilization and massage, stretching, desensitization techniques, pain medication, prosthetic adjustment, steroid injection, scar excision and others.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you chose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is _____ [Local Site Principal Investigator's name]. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: [Local Site phone number and email address].

After you read this form, you can:

- Take your time to think about the information that has been provided to you.
- Have a friend or family member go over the form with you.
- Talk it over with another health care provider.

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DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research project, we hope to learn if the fractionated CO_2 laser will improve skin issues and therefore improve mobility and function with lower limb amputees' prosthetic use. Our goal is to try find better ways to provide treatments for lower limb amputees with problematic scarring. To do this, we are asking for the assistance of people with lower limb amputations (transfemoral/transtibial) to take part in our study.

HOW LONG WILL I BE IN THE STUDY?

The entire research study is expected to take about two years. Your individual participation will last up to 7 months and you will be asked to complete up to 9 visits. Follow-up visits may be required at the discretion of the dermatologist to ensure your safety.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Study Procedures

- Visit 1 will occur at [name of VA facility] at [location].

- For the laser treatment visits (Visits 2-6), you will be seen for about 60-90 minutes at the [name of community dermatology clinic] located [location] which is about [distance] from your local VA. You may have up to 5 laser treatments. A few different CO_2 fractional laser systems are available and will be used in the study and the treatment will be performed by the licensed dermatologists. Each laser treatment will be performed by the study dermatologist who has completed specialized training of the laser devices. Follow-up visits may be required at the discretion of the dermatologist. You will not receive a gift card during follow-up visits.

- For Visits 7-9, photographs of the residual limb, performance tests and survey completion will occur at your VA clinic and are expected to take up to 2 hours.

- You will receive reminder calls for appointments. Details related to each visit are described below.

Visit Number	What will happen?	Performed by:	Estimated time	Location
1	Review consent and study information	Study Member	30-45 minutes	Local VA [Name and location]
1-Baseline	Demographic data collection	Study Member	2 hours	Local VA [Name and location]
	Physical outcomes			
	Wearing IMU			
	Photos			
	Questionnaires			
2	Laser #1	Dermatologists	60-90 minutes	Dermatology Clinic [name and location]
	Questionnaire			
3	Laser #2	Dermatologists	60-90 minutes	Dermatology Clinic [name and location]
	Questionnaire			
4	Laser #3	Dermatologists	60-90 minutes	Dermatology Clinic [name and location]
	Questionnaire			
5	Laser #4	Dermatologists	60-90 minutes	Dermatology Clinic [name and location]
	Questionnaire			
6	Laser #5	Dermatologists	60-90 minutes	Dermatology Clinic [name and location]
	Questionnaire			

Visit Number	What will happen?	Performed by:	Estimated time	Location
7 6 weeks after final laser	Physical outcomes Wearing IMU Photos Questionnaire	Study Member	2 hours	Local VA [Name and location]
8 3 months after final laser	Physical outcomes Wearing IMU Photos Questionnaires	Study Member	2 hours	Local VA [Name and location]
9 Final 6 months after final laser	Physical Outcomes Wearing IMU Photos Questionnaires	Study Member	2 hours	Local VA [Name and location]

Visit 1: A study member will review the consent and study information with you. You may ask questions at any time, and you will be given sufficient time to review before deciding to participate in the study. You may also discuss with others such as family, provider, etc. before deciding. Once you sign the informed consent, you will be enrolled in the study and can begin baseline testing. All study visits will be scheduled after you sign the informed consent. The informed consent and baseline will be completed at the VA site and can take up to 30-45 minutes (consent) and 2 hour for performance tests/surveys. If time permits, you can continue to

complete the baseline performance tests. If you are unable to complete in one visit, you may schedule another time to return to complete Visit 1.

Baseline: Demographic information such as age, gender, amputee and prosthetic history will be collected. Physical outcomes such as your range of motion, strength, mobility, residual limb measures, gait and balance tests will be collected by the study clinician. While performing balance and gait tests, you will wear wrist- watch size wireless sensors called Inertial Measurement Units (IMU), this captures and stores acceleration movement. Sensors will be placed on the lower limbs including one in your low back area.

Photographs of your residual limb will be taken and during the follow up visits (7-9). Photographs are taken to show outcomes and for educational purposes. However, you may opt-out if you do want the photos of your residual limb taken. This will not affect your participation in the study. Faces and or special markings such as tattoos will be blurred.

You will be asked to complete self-report paper questionnaires about your prosthetic use. This will include socket comfort, a prosthesis evaluation questionnaire, and a Prosthetic Limb Users Survey of Mobility (PLUS-M, 12 item short form). You may ask as many questions as you like, and you may skip questions you do not want to answer.

- **Visit 2**: Depending upon the dermatologist's schedule, you will visit (name of Dermatology clinic). You will be seen for your initial laser treatment session which will last up to 90 minutes. After the laser treatment, you will be asked to fill out a dermatologic questionnaire.

You may be asked to complete the following visits depending on your reaction to the laser and the dermatologist's discretion. The dermatologists will schedule your laser visits with you and notify the VA study coordinator of when your last laser visit will occur. Follow-up visits may be required at the discretion of the dermatologist to ensure your safety. During follow-up visits, you may not receive laser treatment. You will not be eligible to receive a payment for dermatology visits where laser treatment is not performed.

- **Visit 3:** You will be seen at the dermatology clinic to complete a laser treatment session and repeat the dermatologic questionnaire. This visit can be 60-90 minutes.

- **Visit 4:** You will be seen at the dermatology clinic to complete a laser treatment session and repeat the dermatologic questionnaire. This visit can be 60-90 minutes.

- **Visit 5**: You will be seen at the dermatology clinic to complete a laser treatment session and repeat the dermatologic questionnaires. This visit can be 60-90 minutes.

- **Visit 6:** You will be seen at the dermatology clinic to complete the final laser treatment session and repeat the dermatologic questionnaires. This visit can be 60-90 minutes.

There will be 3 follow-up visits after your final laser treatment session. For follow-up visits, you will be seen at [name of VA facility].

- **Visit 7:** 6 weeks after your final laser treatment, you will repeat the performance tests and prosthetic use surveys that were completed in visit 2. This visit may last up to 2 hours.

- **Visit 8:** 3 months after your final laser treatment, you will repeat the performance tests and prosthetic use surveys. This visit may last up to 2 hours.

- **Visit 9:** 6 months after your final laser treatment, you will repeat the performance tests and prosthetic use surveys. This visit may last up to 2 hours. This will be the final tests and surveys and will conclude your participation in the study.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

Participating in this study will not impact your medical treatment(s). You will keep seeing your regular doctor and continue with your regular medical treatments. However, you should tell the study doctor about all the medicines you take and about any planned surgery you may have scheduled.

Responsibilities and expectations

While participating in the study, you are expected to follow the guidelines below:

- Please follow the instructions from the PI or other study member to reduce your chances of experiencing side effects.
- Please notify the study doctor or other study members right away if you experience any side effects or discomforts.
- Keep your study appointments. Please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- For participants with childbearing potential, if you think you may be pregnant at any time during the study, tell the study staff right away.
- Complete your questionnaires as instructed, in which you are free to skip any questions that you would prefer not to answer.
- Ask questions as you think of them.
- While participating in this research study, do not take part in any other research projects or scar treatments without approval from the investigators. This is to protect you from possible injury or potential reactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

You may have problems because of the laser treatments used in this study. These problems are called side effects. Some side effects are just a bother and others could harm you. Everyone taking part in the study will be monitored for any side effects. There may be some side effects that we don't know about yet. We will tell you as soon as we can if we find out more information about possible side effects.

Throughout the study, the researchers may notify you (via telephone or in person at a scheduled visit) of any new information that may become available, and which might affect your decision to remain in the study.

Though the study staff will take steps to prevent risks and discomfort, the following risks may occur:

Laser Treatment:

- Infection
- Infection which may require hospitalization
- Development of new scarring or worsening of existing scars. Also, they may not look the way you want them to.
- Symptoms may not be relieved.
- Rash
- Reaction to the medicines given during or after treatments
- Pain or discomfort
- Swelling
- Discoloration of the skin
- Increased itching

Physical Performance Tests:

- There is a risk of falling during and or after tests
- Muscle Soreness/Fatigue

Survey/Questionnaires:

- A breach of confidentiality is always a risk.
- Some questions may be uncomfortable

Pain will be minimal during the laser treatments and will be controlled by anesthetics (topical, local or ProNox). The topical analgesic used is a numbing cream that is applied to the skin, the local anesthesia is an injection of lidocaine 1% with epinephrine 1:100,000 and ProNox is a safe, patient administered analgesic gas delivery (fixed 50%/50% blend of oxygen and nitrous oxide). With the ProNox, you will hold a mouthpiece in your mouth and breathe in and out of it until you feel extremely relaxed.

The side effects of ProNox include feeling extremely relaxed, you may notice a slight deepening of voice after initial administration and in rare cases, you may feel light-headed. The effects of the ProNox should diminish about 10-15 minutes. The dermatologists will monitor subjects during and

after treatment sessions.

The dermatologists may apply a corticosteroid ointment known as Triamcinolone that helps to soften scar tissue. Side effects from this medication are rare and may include itchy, red skin which may be a sign of an allergic reaction. Please notify your doctor if this occurs.

Post-laser treatment care

After laser treatment, if you experience pain or swelling, you may need to rest from using your prosthesis for about 2-3 days for skin recovery. You may return to wearing your prosthesis immediately after laser treatment if you do not experience any issues.

The dermatologists may prescribe oral medications at their discretion for laser treatments. Oral pain medication options and their possible side effects will be discussed with them before they are prescribed. If you choose to take over-the-counter pain medications, that is at your discretion.

It is possible that you may experience some post treatment discomfort; however, this is rare and is usually managed through elevation of the treated area and cool compresses. Post-treatment discomfort may include:

- Some patients describe intermittent itching for several days after the procedure.
- Rare side effects could potentially include prolonged redness, post procedure discomfort, skin peeling, and skin discoloration.
- Infection is a primary concern when applying fractional laser however the infection rate appears to be significantly less than 1%.
- Exceedingly rare reports of new scarring or worsening of scarring do exist.

Please be sure to follow all of the post procedure instructions provided by the dermatologist. Failure to do so may increase risk of post-treatment infection and/or delay healing.

The study principal investigator [PI's name] and treating dermatologists will stay in contact with you to monitor and intervene if necessary.

Physical performance tests

You may feel fatigued or have some muscle soreness after performing the performance tests. This can be reduced by following the study members instructions while you are in the study. Also, you can take as many rest breaks as needed during the gait and balance tests. You will be supervised by a licensed physical therapist and will use a gait belt for safety. Outcomes will be assessed by a physical therapist, so risks are comparable to a routine therapy session.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

For more information about risks and side effects, ask your study doctor.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There may be no direct benefit to you. However, you may benefit from this investigational laser therapy. This clinical study will help determine if laser therapy can improve scar thickness, skin texture and decrease pain for Veterans with lower limb amputations with problematic scarring. If so, it could be the case that prosthetic wear and use are more comfortable for you and that your movement and function may improve.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

If you do not want to join the study, you may talk with your doctor about other available scar treatments. Current treatments for skin problems include manual scar mobilization and massage, stretching, desensitization techniques, pain medication, prosthetic adjustment, steroid injection, scar excision and others.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. All data collected will be used strictly for this study and data that identifies you will not be leaving the_____ [local study site location]. Only research personnel affiliated with this research project will have access to the electronic data, which will

be stored in a secured, firewall/password protected location. Paper copies that include your private information will be locked in a cabinet, which will be locked in the PI's office and or study member's office. The electronic data collected will be stored in a secure drive in an encrypted folder located behind the VA firewall. This information will be kept confidential with all the other study information. Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.

The information collected for this study will be kept confidential. We will include information about your study participation in your medical record. There are times when we might have to show your records to other people for the purpose of monitoring or managing the conduct of this study. For example, someone from the Office of Human Research Protections (OHRP), the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight (ORO), the VA Central Institutional Review Board (IRB), the local VA medical facility Human Research Protections Program (HRPP), our local Research and Development Committee, University of South Florida (USF), Food and Drug Administration, Office (FDA), and the Government Accountability (GAO) and other study monitors may review portions of records that identify you.

Photos of your residual limb may be taken during the assessment sessions for us to evaluate the process and ensure consistency of testing procedures. Photos will be shared with the University of South Florida statistical center for analysis and may be used in educational presentations and publications. Your face and any special markings such as tattoos will be blurred.

We will include information about your study participation in your medical record.
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 website will include a summary of the results. You can search this website at any time.

Health Insurance Portability and Accountability Act (HIPAA)

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There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule. The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, medical conditions, age, use of prosthetic use and care.

The research team may also need to disclose the information to others as part of the study progress. For example, someone from the Office of Human Research Protections (OHRP), the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight (ORO), the VA Central Institutional Review Board (IRB), the local VA medical facility Human Research Protections Program (HRPP), our local Research and Development Committee, University of South Florida (USF), Food and Drug Administration, Office (FDA), and the Government Accountability (GAO), and other study monitors may look at or copy portions of records that identify you.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient. While this study is being conducted, you will have access to your research related health records. This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility, or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, [Local Site Investigator's name] and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You or your insurance will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

Will you be paid for taking part in this study?

We will pay you for the time you volunteer while being in this study. For study payment, you will receive $40 in the form of a VA approved payment methodfor each full study visit that you complete, up to $360.

You may be eligible to receive travel pay if you are driving more than 50 miles or more to and from the clinic/hospital. You will be the responsible to claim travel pay for these visits.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you or your insurance unless the injury is due to non-compliance with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution. No other form on compensation is available.

If you need emergency care:

- Go to your nearest hospital or VA emergency room right away. Call 911 for help or go to your nearest hospital. It is important that you tell the doctors at the hospital or emergency room that you are participating in a research study. If possible, take a copy of this consent form with you when you go.
- Call the study doctor as soon as you can. He will need to know that you are hurt or ill. Call [PI's name] at [PI's phone number]

If you do NOT need emergency care:

- Go to your regular doctor. It is important that you tell your regular doctor that you are participating in a research study. If possible, take a copy of the consent form with you. Please notify the study team of any non-emergency issues that may affect your participation in the study.

If you should have a medical concern or get hurt or sick because of taking part in this study, call the person below:

DURING THE DAY:
DR: [site investigator's name]_____
Telephone number: [study site clinic's number]_____

AFTER HOURS:
[study site's local emergency dept.]_____
Telephone number: [study site's local emergency dept.'s number]_____

Emergency and ongoing medical treatment will be provided as needed.
You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

DO I HAVE TO TAKE PART IN THE STUDY?
You do not have to participate in this study.
Participation in this study is voluntary. It is up to you to decide whether to take part in this study.

- If you decide to take part, you may still withdraw at any time.
- If you do not wish to be in this study or if you decide to leave the study early, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.
- If you don't take part, you can still receive all usual care that is available to you.
- Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

There may be certain circumstances that the team may need to terminate you from the study, which includes safety issues, poor skin integrity, non-compliance with your medical regime or not coming to your study visits as scheduled. If the principal investigator decides to terminate your participation or if you decided to withdraw early, we will try to collect study information (survey and tests) relative to the nearest timepoint if possible and if safe (i.e., no physical testing will be performed if there are safety concerns).

You will be advised to continue following up with your clinical MD or prosthetist as you normally did prior to the study. If needed, the Principal Investigator [PI's name] will be in contact with your local clinician/prosthetist regarding any relevant clinical issues such as skin breakdown or other injury related to the laser. The study personnel will document the reason for termination and what procedures occurred following termination.

You may withdraw from the research at any time.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions, concerns or complaints about this study, you may call_____ [study site investigator's name] at _____ [study site investigator's phone number].

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms._____ _____*[name of the local site investigator/study coordinator]* has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

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LSI Approval Date: N/A

LSI Verification Date: N/A

Participant Name: _____ IRBNet ID:

Title of Study: ____ The LASER Pilot Project: Laser Therapy in Amputee Skin Care to Enhance Rehabilitation. A Preliminary Investigation _____

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: _Dr. Jeffrey Heckman, MD_____

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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