Official Title: Pilot Study of Early Postoperative Fractional Ablative Laser Treatment of Skin Grafts for Burns
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Wake Forest®
School of Medicine

Department General Surgery

PILOT STUDY OF EARLY POSTOPERATIVE FRACTIONAL ABLATIVE LASER TREATMENT OF SKIN GRAFTS FOR BURNS

Informed Consent Form to Participate in Research
J. Kevin Bailey, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to determine the effects of early use of fractional ablative laser on skin grafts within 6-10 days of split-thickness skin graft surgery. Fractional ablative laser is currently used on skin grafts after they are more mature to assist with improving the overall appearance of the scar and help make it less restrictive. The laser used in this study will allow your doctor to precisely target and effectively treat your skin graft scars at the surface, middle and deep layers. The laser uses a small beam of light to make a checkerboard pattern on your scar that goes to the bottom layer of your skin. You are invited to be in this study because you have a burn that will require skin grafting. Your participation in this research will involve approximately 5 visits and last about one year.

Participation in this study will involve post-operative examination and measurement of your scars, 3 post-operative laser treatments and post-operative clinic visits, and filling out a survey about your scars. All research studies involve some risks. A risk to this study that you should be aware of is pain, possible fever, lightening of the skin, rash or blistering. There is the possibility that you may benefit from participation in this study.

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. Some other choices may include not participating in the study. 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 if you need help deciding whether to join the study. The person in charge of this study is:

J. Kevin Bailey, MD
[redacted]

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have a burn that will require grafting. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

Doctors and patients refer to all areas of skin changes from burn injury as burn scars. However, different areas of scars from burns can be treated differently. The burn scars that come from skin grafting surgery might be improved with laser treatment. The purpose of this study is to see if treating your burn skin graft scars with a laser could make it better.
Fractional Ablative Laser has been approved by the US Food and Drug Administration (FDA), but it has not been approved for use in the early stages of scar maturation and is considered investigational for this study.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

This is a study with a total of 15 burn patients participating from our institution.

WHAT IS INVOLVED IN THE STUDY?

If you decide to be a part of this study, you will first sign this Informed Consent. After you have agreed and signed this form, we will examine and measure your scars. If there is one single scar, it will be divided into two different areas. If you have two different areas of skin grafts, each area will be a site. Sites will be called A and B. This is a randomized study, which means one site (A or B) will be assigned by chance (like flipping a coin) to receive the laser treatment, while the other one will be assigned to no laser treatment. We will trace out each site and then select three locations inside each site. These will be the locations we measure each time you come for a study visit, and we will ask you to really focus on these three locations when you answer questions about how you think your scars are doing. Each time you visit, measurements will be done before the laser treatment. We understand how valuable your time is, so the three laser treatments will be completed at weeks 1(6-10 days after skin grafting), week 5 and 9, and measurement sets done at weeks 1, 5, 9, 12 and 24. Although it sounds like a lot of visits, it is typical for us to follow burn patients for at least a year to help them get the best results.

Before using the laser on your skin graft's scar, both sites will be covered with a numbing medication cream, which will be left on the area for approximately 30 to 45 minutes. We have to put it on the non-laser side to make sure the only thing we do different is the laser treatment. Because skin grafts are placed over areas of third-degree burn, there are very few nerves – so patients have less feeling in these areas of surgery. The use of numbing cream will also help to decrease the discomfort even more. After the numbing cream has set, the area will be cleaned, and the laser treatment will be completed by your surgeon associated with the study. Each time the switch is turned on, the laser shines a very small beam of focused infrared light. The beam is thinner than a common sewing needle and the beam creates a checkerboard of 64 holes on the bottom layer of your skin. You will then have a prescription-strength solution of steroid (similar to the hydrocortisone steroid cream used for rashes of the skin) applied to both site A and B.

After the treatment is completed, you will be asked to care for your grafts as your doctors and nurses have shown you (so the skin grafts are treated the same).
In addition to the laser treatment, the other important part of this study is to make very exact measurements of your two scar sites**.** We will take measurements (trace the outline of your burn scar) before each of the three laser treatments and then two times after that. . Because the skin graft is fragile at first, we will only take pictures and trace the outline of your skin graft scars the first two times (7-10 days and at about 5 weeks from your skin graft surgery).
At the next three visits (9 weeks, 12 weeks, and 10-12 months after your skin graft surgery) we will ask you to fill out a survey where you tell us about what you think about each of the two sites–this is the patient portion of the Patient and Observer Scar Assessment Scale (POSAS). We will fill out a survey as well – the observer portion of the POSAS and the Vancouver Scar Scale (VSS). In addition, we will make three additional specialized measurements. The BTC-2000 is a machine that applies a gentle amount of suction into a tube placed against your skin. It measures how much the skin might move up into the tube (because of the gentle suction). The Mexameter is an instrument that is gently pressed onto your skin and it takes a picture to give a number of the amount of redness and brown color in a small area. Finally, we will take an impression of the scar using the same material a dentist might use to take a mold of your teeth. We use this to make a model of your scar to measure how high it is.

HOW LONG WILL I BE IN THE STUDY?

You will be receiving active treatment for a total of 12 weeks from the moment you sign informed consent, and the final measurement will be about one year after your skin grafting. Burn patients typically have frequent visits during their first few months, and usually follow up in the burn clinic for a year or more after skin grafting. We will make the measurements and treat with the laser when you are coming to the clinic for your routine care to avoid extra visits. You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this with the study staff. Risks and side effects related to the procedures we are studying include:

- Pain (similar to a mild sunburn), experienced by 19% of the patients treated with laser therapy. We will try to reduce this pain by applying a numbing cream before we start the procedure.
- Subjective fever, experienced by 4.8% of patients. This can be easily treated with over the counter ibuprofen or acetaminophen.
- Lightening of dark skin (4.8%), rash (2.4%), and blistering (2.4%). Changes in the skin tone and rash are not uncommon side effects on skin grafts even without laser treatment.

The measurements (BTC-2000, Mexameter, and dental molding materials) are painless. Because we are delaying treatment until the graft is well healed, we do not expect any damage to the skin grafts. We know that some burn scars can be more sensitive than others. Although unlikely, there may be a chance of discomfort from some of the testing (tapping, twisting and suction on your scar), but any discomfort will be minimal and would last less than five minutes. The discomfort will be minimized by making sure that there is time between trials for the skin to return to normal before collecting the next measurement. In addition, if the patient feels any discomfort during a particular measurement, this measurement can be stopped and not performed again.

Finally, we will ask you if the area we want to study is especially sensitive. If it is a sensitive area, we will try to see if another area can be tested. Mechanical tests will be performed using a BTC-2000™. The BTC-2000™ sticks a probe onto the skin using double-sided tape and applies a slight suction to the area. The skin changes shape in response to the suction and this change is used to calculate the properties of the skin. It would feel like a small suction cup being applied to the skin, and may result in temporary redness at the site.

We hope that the skin grafts treated with the laser may not shrink as much. If this happens, you could notice that the areas not being treated with the laser feel “tighter” or do not look as good. .

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe. A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study.

Reproductive Risks and other Issues to Participating in Research

Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, OrthoEvra patch, NuvaRing, intrauterine devices (IUD), Nexplanon implant, DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a diaphragm with spermicide with Plan B used for any noticed condom or diaphragm failures. We encourage you to discuss this issue further with your physicians if you have any questions.

Pregnant women are excluded from participation in this study. Before your original surgery (skin grafting) you will have been tested for pregnancy. If you are not using a reliable method of birth control (listed in paragraph above), please let the research team know.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. Potential Benefits:

- With laser treatment, we are hopeful we can demonstrate less contraction ("shrinkage" of your skin graft) and an increase in the elasticity of your skin, and have you regain some of the mobility you had in the affected area prior to your injury.
- There is the potential you can avoid the need for future reconstructive surgeries when treated with laser.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options:
Proceed with normal healing without the use of Fractional Ablative Laser

WHAT ARE THE COSTS?

All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will be receive a $25 gift card for each of the completed scheduled study visits, for a total of $100.00 if first visit is while still in the hospital, $125.00 if first visit is completed in clinic after hospital discharge. If you withdraw for any reason from the study before completion you will not receive any further compensation beyond those visits that have been completed at the time of withdrawal. To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

WHO IS SPONSORING THIS STUDY?

This study is being conducted by Dr. John Kevin Bailey at Wake Forest Baptist Medical Center.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted]

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. J. Kevin Bailey at [redacted] or [redacted] after hours.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:**
Your name, age, medical record number and thickness of burn, burn scar measurements and photographs of your burn scars.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations. We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will be de-identified.. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. J. Kevin Bailey that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

J. Kevin Bailey, MD
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because of you not following study instructions, intolerance to laser treatment or new information becomes available that requires your doctor to withdrawal you from the study, or that the study is stopped permanently. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, call Dr. J. Kevin Bailey at [redacted] or [redacted] after hours.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted]

YOU WILL BE GIVEN A COPY OF THIS SIGNED CONSENT FORM.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

Legally Authorized Representative Name (Print):_____

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Relationship to the Subject:_____

Legal Representative Signature: _____ Date:_____ Time:_____ am pm