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RECELL Following CO2 Laser Treatment in Cosmetic Patients

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Informed Consent

Department/Section of Plastic and Reconstructive Surgery

RECELL FOLLOWING CO2 LASER TREATMENT IN COSMETIC PATIENTS

Informed Consent Form to Participate in Research
Joseph Molnar, MD, PhD, Principal Investigator

SUMMARY
You are invited to participate in a research study. The purpose of this research is to determine if RECELL® regenerative epidermal harvesting device can accelerate wound healing in the setting of facial rejuvenation. The system works by processing a small sample of your healthy skin to create a Regenerative Epidermal Suspension (RES) graft that can be sprayed onto an area for treatment. You are invited to be in this study because you are planning to undergo a face lift combined with CO2 laser resurfacing. Participation in this study will involve you undergoing your planned face lift and CO2 laser resurfacing. Your participation in this research will involve 3-5 visits and last about 3 months.

At the time of the procedure, the surgeon will use tissue from your facelift procedure in the RECELL® regenerative epidermal harvesting process. The RECELL® Regenerative Epidermal Suspension (RES) will then be sprayed onto the skin around your mouth after the resurfacing with the CO2 laser. You will follow up with your surgeon as planned. During your follow up appointments, your wound healing will be documented via photographs and a patient survey. RECELL® is currently FDA approved for use in burn care, including direct application to acute partial-thickness thermal burn wounds or application with meshed autografting for acute full-thickness thermal burn wounds. All research studies involve some risks. Adverse effects associated with RECELL® use in burn care are typical of care and treatment of burns and include swelling, blistering, infection, pain, scarring, inflammation of hair follicles, skin irritation, redness, itching, and delayed healing. An additional risk to this study that you should be aware of is there may be an unequal rate of wound healing on your perioral region. You may or may not 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. 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. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator at [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 Atrium Health Wake Forest University School of Medicine Research Subject Advocate at [redacted].

Introduction

You are invited to be in a research study. Research studies help scientists learn new information that may help other people in the future. You are being asked to be in this study because you are electing to undergo face lift and CO2 laser resurfacing. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. 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?

The purpose of this research study is to determine if RECELL® regenerative epidermal harvesting can accelerate wound healing when applied following face lift and CO2 laser resurfacing.

RECELL® regenerative epidermal harvesting has been approved by the US Food and Drug Administration (FDA) for use in burn care, specifically for direct application to acute partial-thickness thermal burn wounds or application in combination with meshed autografting for acute full-thickness thermal burn wounds. However, it has not been approved for use following CO2 laser resurfacing.

In this study, RECELL® will be applied to the perioral region. A placebo will be used in the region that is not receiving RECELL®. A placebo is a substance that is not thought to have any effect on your disease or condition. Placebos are used in research studies to see if the drug being studied really does have an effect.

How Many People Will Take Part in the Study?

Ten people at one research site will take part in this study.

What Is Involved in the Study?

At your first study visit, standardized studio photographs and photos using the Quantificare LifeViz® Camera will be obtained.

You will be randomized into one of two study groups; (A) Right perioral area receives RECELL®/Left receives Placebo or (B) Left perioral area receives RECELL®/ Right receives Placebo . Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the investigator will know which area of your face will be receiving RECELL® (right perioral or left perioral). This is done so that a fair evaluation of results can be made. This

information is available to the researchers if needed in an emergency.

You will undergo your scheduled facelift and CO2 laser resurfacing as planned. During the procedure, the excised tissue from the facelift will be used as donor tissue for the RECELL® regenerative epidermal harvesting Device. Those in group A will be sprayed with RECELL® on the right perioral area and sprayed with placebo on the left side. Those in group B will be sprayed with RECELL® on the left perioral area and sprayed with placebo on the right side.

Intraoperatively, the patient will be photographed in CO2 treated areas with the Quantificare LifeViz® Camera and standardized photography.

Both the treatment and placebo sides will be dressed with a standard regenerative epidermal suspension post treatment dressing (Telfa Clear and Xeroform). Xeroform will be removed on postoperative day 1. Telfa clear will be removed on postoperative day 7. Patients will return to clinic for follow up at the following interval:

- Post Operation Day 1
- Post Operation Day 7
- Post Operation Day 14
- 1-month Post Operation
- 2-months Post Operation
- 3-months Post Operation

Postoperatively, patients will be evaluated at each visit via standardized photography, Quantificare LifeViz® Camera photos, a patient completed survey, and pain score (standard 1-10 pain scale).

As part of this research study, you will be photographed. This is being done in order to document wound healing. You understand that you may request the photography to stop at any time during the course of the research study. You can also withdraw your consent to use and disclose the photograph before it is used. You should also understand that you will not be able to inspect, review, or approve the photographs, videotapes, audiotapes or other media (including articles containing such) before they are used in this study.

Please choose one of the following regarding the use and disclosure of the photograph used in this research study:

_____ I would like the photographs of me to be destroyed once their use in this study is finished.

____ The photographs of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

How Long Will I Be in the Study?
You will be in the study for about 3 months.

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. However, there is no consequence for withdrawal from the study.

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 study with the study staff. The risks of facelift and laser resurfacing should be discussed with your physician.

RECELL® is currently FDA approved for use in burn care, including second degree burns and skin grafts for third degree burn wounds. Adverse effects associated with RECELL® use in burn care are typical of care and treatment of burns and include swelling, blistering, infection, pain, scarring, inflammation of hair follicles, skin irritation, redness, itching, and delayed healing.

The application of RECELL® following CO2 laser has not been studied, so there may be some 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. A potential risk that you assume by participating in this study is an unequal rate of wound healing between your right and left perioral areas.

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.

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. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may include faster healing in the area of your face that is sprayed with RECELL®. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

What Other Choices Are There?
You do not have to be in this study. Instead of being in this study, you can choose to proceed with facelift and CO2 laser resurfacing without RECELL®.

What Are the Costs?
All study costs, including any study products or 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.

The RECELL® device is provided by Avita Medical/AHWFB Department of Plastic and Reconstructive Surgery. Neither you nor your insurance company will be billed for the investigational device. You and/or your insurance company will not be billed for the cost of any surgical procedure(s) necessary to apply the RECELL® regenerative epidermal suspension.

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.

Your 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 not be paid for taking part in this research study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Department of Plastic and Reconstructive Surgery. The sponsor is providing the RECELL® Device to the researchers to help conduct this study. The researchers do not hold a direct financial interest in the sponsor or the product being studied.

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**:** Name, age, sex, medical and surgical history, medications, history of smoking, alcohol or drug use.

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 Atrium Health, Wake Forest University Health Sciences, and/or their respective affiliated entities. These results and reports will be kept secure in compliance with applicable laws, with permission to access this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A medical record will be created for all study participants seen on-site and if a medical record doesn't already exist. Information about your participation in the study will be placed in the medical record, along with any routine medical test results that were obtained as part of this study.

If this research study involves the diagnosis or treatment of a medical condition, then your

medical record will indicate that you are participating in this study and Protected Health Information collected from you 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. If you are not a patient at this Medical Center, a medical record will be created for you to ensure that this important information is available to doctors in case of an emergency. This part of the medical record will only be available to people who have authorized access to your medical record.

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 Protected Health Information or information that identifies you 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 your healthcare facility; 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 either be destroyed or it 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 Joseph Molnar, MD 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:

Joseph Molnar, 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.

What Happens If I Experience an Injury or Illness as a Result of Participating in this Study?

Wake Forest University Baptist Medical Center maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of injuries or illnesses to some participants in certain research studies. 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. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

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 Joseph Molnar MD at [redacted] or after hours [redacted].

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 it is in your best medical interest, your conditioned worsened, new information becomes available, you had an unexpected reaction, you failed to follow instruction, or because the entire study has been stopped. 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.

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 Web site at any time.

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 team at [redacted]. If after hours, call [redacted].

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