Department of Plastic & Reconstructive Surgery

# THE EFFECT OF NITROGLYCERIN OINTMENT, FLUORESCENT ANGIOGRAPHY, AND INCISIONAL NEGATIVE-PRESSURE WOUND THERAPY ON MASTECTOMY SKIN FLAP PERFUSION-RELATED PROBLEMS

Informed Consent Form to Participate in Research

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## 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 will be undergoing a mastectomy with possible immediate breast reconstruction. 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. Since researchers do not know which procedure/arm of the study will have the best outcome, it is possible that you could be assigned to the procedure that has a less favorable outcome than the others.

## WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to compare different ways of examining blood flow to the skin remaining after mastectomy as well as the effect of different ointments and dressings on breast skin after mastectomy. All of the examination techniques and treatments applied to the skin after mastectomy are well accepted techniques and may improve the outcome of your mastectomy and breast reconstruction. These therapies are contra-indicated in certain patients with pre-existing conditions and the doctor or study coordinator will speak with you more about these conditions.

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

One hundred sixty (160) people at Wake Forest Baptist Health will take part in the study. These people will be randomly assigned to one of eight groups detailed below.

## WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have a one in eight chance of being placed into any group. All of these groups are considered standard of care and not investigational/experimental.

If you take part in this study, you will be randomized to one of the following groups before your

surgery:

Group 1: Breast skin after mastectomy will be clinically examined by the surgeon to determine if there is adequate blood flow to the skin to allow safe coverage of the breast implant. No dye study, ointment, or vacuum dressing will be applied to the breast after implant placement.

Group 2 - Breast skin after mastectomy will be clinically examined by the surgeon, and nitroglycerin (NTG) cream will be applied to the breast skin after implant placement. This cream does not have systemic effects but may improve blood flow to the remnant breast skin after mastectomy.

Group 3 - Breast skin after mastectomy will be clinically examined by the surgeon and an incisional vacuum-assisted dressing (iVAC) will be placed over the breast incisions after implant placement, which may improve blood flow to the skin and help wound healing.

Group 4 - Breast skin after mastectomy will be clinically examined by the surgeon, and both NTG cream will be applied to the breast skin and an iVAC will be placed over the incisions after implant placement.

Group 5 - Blood flow to breast skin after mastectomy will be examined using a fluorescent dye study called fluorescent angiography (FA) to determine if there is adequate blood flow to the skin to allow safe coverage of the breast implant. No further intervention will be used after implant placement.

Group 6 - Blood flow to breast skin breast skin will be examined using FA. NTG cream will be applied to the skin after the implant is placed.

Group 7 - Blood flow to breast skin breast skin will be examined using FA. An iVAC will be placed over breast skin incisions after the implant is placed.

Group 8 - Blood flow to breast skin breast skin will be examined using FA. Both NTG cream and iVAC will be used as interventions after the implant is placed.

The assigned procedure will be performed at time of surgery. For research purposes, we are comparing the results of each of these groups. The decision of whether to insert a tissue expander or implant at the time of surgery will depend on the clinical appearance of the skin flaps and/or evidence of adequate blood flow to the skin through exam or intraoperative imaging (i.e. fluorescent angiography). If your skin flaps appear to be able to house a breast implant without negatively affecting blood flow, your surgeon may forego tissue expansion and place a final breast implant at the time of mastectomy ("Direct-to-implant" technique). Most frequently, however, tissue expansion is performed with an implant device that is filled with fluid through a port to gradually stretch the soft tissues.

As part of this research study, you will be photographed pre-operatively, intraoperatively and weekly during each follow-up. This is being done to follow your healing process post mastectomy with immediate breast reconstruction. You understand that you may request the

filming or recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the photograph/videotape/audiotape 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/videotape/audiotape used in this research study:

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

____ The photographs/videotapes/audiotapes 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 at least thirty (30) days to allow us time to see you after your surgery for your post-operative clinic visits. If you have a tissue expander placed at the time of your mastectomy, your first clinic visit will be approximately one week post-operatively. After that, weekly clinic visits will be necessary for filling the tissue expander(s) with a small amount of fluid each time, in order to stretch the tissues so that they may house a final breast implant in the future. These clinic visits are routine for this form of breast reconstruction, and are the standard of care.

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 study with the study staff. The following are some risks and side effects related to fluorescent angiography, nitroglycerin ointment, and the vacuum-assisted surgical dressing we are studying:

Risks associated with fluorescent angiography can include an allergic reaction that may result in hives or breathing problems. As a result, this therapy should not be used in people with allergies to iodine dye used for contrast.

Risks associated with the nitroglycerin ointment are: dizziness, light-headedness, blurred vision, fainting, increased risk of alcohol toxicity if consumed in conjunction with the ointment, headaches, severe allergic reactions (rash, hives, itching, difficulty breathing, tightness in chest, swelling of mouth, face, lips, throat or tongue), flushing, and red, swollen, blistered or peeling skin.

Risks associated with the vacuum-assisted closure dressing (“incisional VAC®”) include potential allergic reaction to one type of adhesive cover for the dressing (called Ioban®) in

people with allergies to iodine and potential for irritation or a skin reaction to the adhesive used in people who are sensitive to tape being used on their skin. There is also a risk of pain/discomfort with removal of the VAC.

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 in this study. There also may be other side effects that we cannot predict.

In addition, there is a slight risk of a breach of confidentiality. 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. We will do our best to protect your confidential information.

## Reproductive Risks and other Issues to Participating in Research

Pregnant women are excluded from participation in this study. If you are a sexually active woman of childbearing potential and have not been using a reliable method of birth control, two negative pregnancy tests performed 15 days apart are required to check for possible early pregnancy prior to starting treatment. Costs of pregnancy tests are not included in this research study.

## Will I Be Paid?

You will receive no payment or other compensation for taking part in this study.

## 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.

## WHAT OTHER CHOICES ARE THERE?

Your alternative is to not participate in this study.

## WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you, 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:
Date of Birth, Date of Surgery, Age, BMI, co morbidities, tobacco use, complications related to surgery, intraoperative appearance of mastectomy flap, medical record and name.

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. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research
2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center.

3)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 will be maintained in the research records. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. 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. Ivo A. Pestana 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:

**Dr. Ivo A. Pestana**
[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.

Laboratory test results and other 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 are obtained at NCBH as part of this study.

## WHAT ARE THE COSTS?

All of the arms of this study employ well accepted techniques, dressings, and medications and therefore are not considered experimental. Due to this, most costs associated with the interventions will be covered by your insurance, although some arms might require greater expense than other arms. Costs for your regular medical care, which are not related to this study

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00038262
Meeting Date Approved 6/17/2019
Version Valid Until: 6/16/2020

will be your own responsibility.

## WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Department of Plastic and Reconstructive Surgery. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

## 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 does 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. Ivo Pestana at [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 condition worsens, new information becomes available, you have an unexpected reaction, you fail to follow instructions, or because the entire study will be stopped.

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, Dr. Ivo Pestana at [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, 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]

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