LOVE Trial: Limits On Vaginal Intercourse After Mid-urEthral Sling

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Wake Forest®
School of Medicine

Female Pelvic Health of *Department of Urology*

Limits **O**n **V**aginal penetration after Midur**E**thral sling (**LOVE** Trial)
Informed Consent Form to Participate in Research
Catherine Matthews, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to understand how satisfied patients are with their postoperative recovery after a sling surgery. You are invited to be in this study because you are having a mid-urethral sling and are sexually active. Your participation in this research will involve 2 visits and last about 3 months.

Participation in this study will involve being randomly assigned to "early" or "standard" return to vaginal penetration/intercourse after surgery. All research studies involve some risks. A risk to this study that you should be aware of is that earlier return to vaginal penetration may increase wound complications, although the risk of this is small. 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. The person in charge of this study is Catherine Ann Matthews, MD. If you have questions, suggestions, concerns regarding this study, or if you ever you want to withdraw from the study, you may contact her 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 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 urinary incontinence and have decided to undergo a mid-urethral sling. 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 take this form with you to discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to understand if the "standard" 6-week restriction on vaginal penetration/intercourse after mid-urethral sling affects patient satisfaction. The standard 6-week restriction is not actually based on any scientific evidence. We know that wounds heal much faster than 6 weeks. Animal models have demonstrated that vaginal wounds heal as early as 24-48 hours and as late as 2 weeks after surgery. We would like to understand if women are more satisfied with their ability to return to vaginal penetration/intercourse if restrictions are lifted at 2 weeks rather than the "standard" 6 weeks. We would also like to know if women have similar wound healing and pain between "early" and "standard" return to use of the vagina.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 150 women at 4 research sites will take part in this study, including approximately 80 women at this research site. In order to identify the 150 subjects needed, we may need to screen as many as 500 because some women will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

After you complete your consent form, you will complete 2 questionnaires that assess your urinary symptoms and sexual function. You will not need any additional examination other than the standard pelvic exam already performed.

At the time of sling surgery, you will have a urine pregnancy test as indicated by standard protocol and will not be able to participate if you are pregnant. Following sling placement surgery, you will be discharged with the below instructions:

Activity	**Instructions**
Walking and stairs	You may walk and climb stairs right away after surgery.
Lifting, running, high-impact aerobic activities, sit-ups	You may resume these activities as soon as you feel able.
Sexual intercourse	You should not have anything in your vagina after your surgery other than vaginal estrogen cream (if applicable); this includes a penis, fingers, toys, tampons, douching, etc. You will be instructed at your 2 week visit when you are able to return to these activities.

If you have a normal pelvic examination at 2 weeks postoperatively, 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 an equal chance of being placed in either group.

The "early" group will be given instructions that allow them to return to vaginal penetration/intercourse after 2 weeks. The "standard" group will be given postoperative instructions that allow them to return to intercourse after 6 weeks. Both groups will be able to

return to other physical activities as they feel able. Below are the instructions:

Activity	Early Group	Standard Group
Walking and stairs	You may walk and climb stairs right away after surgery.	You may walk and climb stairs right away after surgery.
Lifting, running, high-impact aerobic activities, sit-ups	You may resume these activities as soon as you feel able.	You may resume these activities as soon as you feel able.
Sexual intercourse	You are being seen today for the two weeks post-surgery visit and you are now free to resume vaginal penetration immediately since it has been two weeks since the surgery. Please write down the date that you resume intercourse/penetration on the data collection form that is included in this packet. Please also keep track of the frequency of sexual activity.	You should not have anything in your vagina for **6 weeks** after your surgery other than vaginal estrogen cream (if applicable); this includes a penis, fingers, toys, tampons, douching, etc. After 6 weeks, you are free to resume vaginal penetration. You are being seen for the two weeks post-surgery visit. Since the restrictions in vaginal penetration are to continue for a total of 6 weeks, you may resume these activities in 4 weeks. Please write down the date that you resume intercourse/penetration on the data collection form that is included in this packet. Please also keep track of the frequency of sexual activity.

You will be asked to keep a log of sexual activity until the 3 month follow up visit- this will track the first date of sexual activity and the average weekly frequency of sexual activity.

You will return to the office for a standard postoperative visit at 3 months after surgery. At this visit, you will be asked questions regarding your satisfaction, urinary symptoms and sexual function. You will have a pelvic exam in which the pain at the incision and the healing is assessed. We will also check your bladder emptying with an ultrasound.

If you take part in this study, you will have the following tests and procedures (those for research purposes only are in **bold,** those not bolded are standard of care):
2 week postoperative visit:

- **Pelvic exam that involves checking for pain in the vagina**
- **Questions regarding urinary function**

12 week postoperative visit:

- Pelvic exam, **checking for pain in the vagina**
- Bladder scan
- **Questions regarding satisfaction, urinary function, sexual function and use of vaginal estrogen if applicable**
- **Collection of sexual activity log**

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 3 months after your surgery.

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. It will be important to have a follow up examination to make sure that the incision remains well healed.

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. Risks and side effects related to the postoperative instructions we are studying include: risk of wound complications. There is a possibility that returning to vaginal intercourse/penetration sooner could affect the healing of the vaginal incision. Impaired healing could result in pain, infection, excessive vaginal bleeding, excessive vaginal discharge, pain with intercourse and/or mesh exposure. If you developed mesh exposure, it is possible that you would need an outpatient vaginal surgery to remove the mesh. We plan to perform a pelvic exam at 2 weeks before any participant engages in sexual activity to help decrease this risk. Participants with poor healing at this point will not be randomized. The risk of mesh complication in the patients undergoing sling procedure is 2-6%. We plan to analyze our data after ¼ and ½ of participants have completed the 3 month follow up to make sure our rates of mesh exposure are similar to reported rates. If rates of mesh complication exceed a safe threshold, we will stop the study.

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 doctor 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.

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. We hope to improve satisfaction following mid-urethral sling surgery by allowing earlier return to vaginal penetration/intercourse in those who wish to be sexually active after sling placement.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. Instead of being in this study, you have the option to proceed with standard postoperative instructions.

WHAT ARE THE COSTS?

There is no cost to participating in the study.

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

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Department of Urology.

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 *Catherine Ann Matthews, MD at* [redacted].

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**:** age, weight, height, medical history, surgical history, social life style including tobacco and alcohol usage, operative reports, urinary symptoms, sexual symptoms, exam findings, sexual activity log and postoperative complications.

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. 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 can tell doctor Catherine Ann Matthews 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:

Catherine Ann Matthews, MD
[redacted]**:**

[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.

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.

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 your incision did not heal after surgery. 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, *Catherine Ann Matthews, MD at 3*[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