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Title: Randomized Trial Comparing Anchorsure® Suture Anchoring System and the Capiotm Slim Suture Capturing Device for Sacrospinous Ligament Suspension

## Randomized Trial Comparing Anchorsure® Suture Anchoring System and the Capio™ Slim Suture Capturing Device for Sacrospinous Ligament Suspension.

Informed Consent Form to Participate in Research  
Principal Investigator: Catherine Matthews, MD

### INTRODUCTION

You are invited to participate in a research study. Research studies are designed to gain scientific knowledge that may help participants or other people in the future. You are being asked to take part in this study because you have chosen to undergo surgery for pelvic organ prolapse (one or more of your pelvic organs has dropped and is pressing down on the vagina). You also meet the criteria for our study. There are different ways of treating pelvic organ prolapse including non-surgical and surgical management. Each of these ways has its own set of risks and benefits. Of the surgical options, attachment of the vagina or uterus to one or both sacrospinous ligaments is a common one and is regularly used for pelvic organ prolapse.

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 wish to discuss the study with your friends and family.

### WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to see how much pain you have after surgery in the buttock or the back of your thigh related to sacrospinous ligament fixation devices (devices used to repair your pelvic organ prolapse). The sacrospinous ligaments are two short bands of tough, flexible tissue that attach to the bones that support your abdominal organs and the lowest part of your spine. They help provide support to pelvic organs. Attachment of the vagina or uterus to these ligaments is performed regularly with devices like the Capio™ Slim Suture Capturing Device. The device uses stitches to attach the vagina or uterus to the sacrospinous ligaments. This device is good at correcting pelvic organ prolapse but has a high rate of pain right after surgery in the buttocks and back of the thigh located on the same side of the device attachment to the sacrospinous ligament(s). Doctors believe this to be due to injury to or near the nerves in the pelvis next to the sacrospinous ligament. There is a newer generation of devices that use a human-made attachment instead of a stitching device to attach to the sacrospinous ligaments. The goal of our study is to assess if one of these devices, the Anchorsure® System, will result in lower rates of this pain after surgery in your buttock and back of the thigh. In order to assess for this pain, we will randomize you to either receive the sacrospinous ligament stitch device the Capio™ Slim Suture Capturing Device or the human-made attachment-based system (Anchorsure® System). We will have you fill out questionnaires before your surgery, during your hospital stay, and at a follow up appointment in the office.

You will be assigned a study identification number. Your questionnaires will be stored de-identified and attached to your study ID number. All written information will be held in a locked cabinet at Wake Forest Baptist Health and all electronic information will be stored on password-encrypted devices. Information we gather from such a study will be useful in helping us better assess the risks and benefits of available sacrospinous ligament stitch devices. This will help us in our goal of providing the most effective and appropriate management for pelvic organ prolapse with the least risk to a patient's health.

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

We aim to enroll 60 patients into the study, and Wake Forest Baptist Medical Center will be the only research site.

## WHAT IS INVOLVED IN THE STUDY?

You are undergoing reconstructive surgery for pelvic organ prolapse and a sacrospinous ligament fixation has been deemed as an appropriate surgery and the chosen surgery for your condition by your physician and yourself. You will be randomized to have this fixation performed with either our standard device (the Capiro™ Slim Suture Capturing Device) or the anchor-based fixation system (Anchorsure® System).

Your medical records will be reviewed to make sure that you meet all of the study criteria. For all participants: Pregnant women are excluded from participation in this study. Because some methods of birth control are not 100% reliable, as part of your normal pre-operative work up, a pregnancy test will be administered preoperatively if you are sexually active woman of childbearing potential. If positive, you will not be included in the study as you will likely NOT undergo the procedure.

You will be asked to complete questionnaires at various time points up to at least one year following your procedure. You may be called at home to ensure that you have been able to complete certain questionnaires at home. Otherwise, your involvement in the study will not be different from the care you would normally receive.

You have participated in this randomized study, and completed six weeks of follow-up after your surgery. We further ask your participation to complete the survey/questionnaires at least by one year (greater or equal to 12 months) time from your surgery with intent to evaluate long-term outcome.

Your questionnaire responses will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA

Privacy Rules. The unique identifier will be an assigned number and only the principal investigator will have access to the code that links the unique identifier to you. Your name, address,

social security number, etc., will never be disclosed to future researchers. If you decide to at any time that you no longer want to have your questionnaire information included in the study, just contact the study investigator Dr. Catherine Matthews @ [REDACTED], or if she is not available then contact our office @ [REDACTED] and let them know and your information will no longer be used for research.

## HOW LONG WILL I BE IN THE STUDY?

You will be in the study from the time that you fill out the questionnaires before your surgery until your at least one year follow up questionnaires and clinic appointment are completed. You may be contacted for future follow up. You can stop participating at any time.

## HOW DO THE DEVICES WORK AND WHAT ARE THE DIFFERENCES BETWEEN THE TWO DEVICES?

Both the Anchorsure® and Capiro Slim™ devices are FDA approved and are used in surgical practice for sacrospinous ligament fixation for pelvic organ prolapse. We may refer to the Capiro Slim™ as the “standard device” according to the fact that the Anchorsure® device is newer, has fewer published studies relating to its use, and our department has a longer history of use of the Capiro Slim™ device. Both the Anchorsure® and Capiro Slim™ attach tissue to a ligament in the pelvis called the sacrospinous ligament. There is a sacrospinous ligament on both sides of the pelvis and they attach one part of the pelvic bone to the lower part of the spine. The ligaments are sturdy structures that can provide support to prolapsed pelvic organs. The Capiro Slim™ device attaches to a sacrospinous ligament via a mechanism of administering and retrieving a suture with a metal tip on the end instead of a full suture needle. This process relies on the ability for the surgeon to appropriately feel the sacrospinous ligament to ensure proper placement without directly watching the suture go in. The suture can always be taken out and the process can be tried again. The Capiro Slim™ metal tip is removed from the body and only the suture remains at the end of the procedure. The Anchorsure® device attaches to the sacrospinous ligament via the release of a human-made anchoring piece into the ligament. This process also relies the ability for the surgeon to appropriately feel the sacrospinous ligament to ensure proper placement without directly watching the suture go in. The Anchorsure® anchoring piece can be removed but is more difficult to remove than the Capiro Slim™ suture. The Anchorsure® anchoring piece is able to have a suture attached to it. The Anchorsure® anchoring piece is intended to stay in the body after the procedure as it is holds the surgical repair together. Both devices have their remaining suture ends attached to the back of the vagina or to the cervix in order to correct pelvic organ prolapse stop organs from falling on the vagina. Sometimes the back of the vagina needs to be attached to the sacrospinous ligament on both sides of the pelvis. It is believed that the act of releasing the Anchorsure® anchor may reduce the risk of nerve-injury pain associated with sacrospinous ligament fixation compared to the Capiro Slim™ metal tip and suture.

## WHAT ARE THE RISKS OF THE STUDY?

The risks for both surgical devices include the risks of injury to blood vessels or nerves near the sacrospinous ligament which are known risks of any sacrospinous ligament surgery. There are no current human studies to assess if this risk is higher or lower for anchor systems like Anchorsure® compared to our standard stitch devices. As with any surgery there is a risk with both devices of pain, bleeding, infection, and damage to nearby organs (including bowel, bladder, ureters, blood vessels, and nerves). There is also a risk of the surgery not correcting anything. And it may not prevent pelvic organ prolapse. There is a small metal piece of the Capiro Slim™ device (the suture tip) that can potentially break off and fall into the pelvis. This would then need to be removed from the body so that it doesn't become infected or damage surrounding organs; this complication is very rare. The Anchorsure® does not contain a similar metal piece, however it does contain an anchoring piece that is intended to remain in the body after the surgery. It is possible for any surgical piece left in the body to get infected or cause pain. If this happens to you, you may need medical or surgical treatment which may include removal of the anchoring piece. Taking part in this research study may mean giving information that you feel is 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 used to keep your information safe. This study is comparing two approved methods for treating your condition. You will be randomly assigned to one of the two groups. It is possible that one treatment group may have a better response than the other. Therefore there is a risk that you may be assigned to a group that does not perform as well as its comparison.

## ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you are randomized to the Anchorsure® group of the study you may or may not experience a difference in pain after surgery from those who are in the Capiro™ group. Your participation might help identify the best surgical device for sacrospinous ligament fixation for future patients with pelvic organ prolapse. Outcome data from this study may lead to reduced surgical complications relating to sacrospinous ligament surgery for patients in the future.

## WHAT OTHER CHOICES ARE THERE?

Your alternative is to not participate in the study and proceed with a sacrospinous ligament fixation using the standard Capiro™ Slim Device.

## 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, but is not limited to: your name, address, telephone number, and date of birth. Your personal health information includes all information about you which is collected or created during the study for

research purposes. It also includes your personal health information that is related to this study and that is maintained in your medical records at this institution and at other places such as other hospitals and clinics where you may have received medical care. Examples of your PHI include your health history, your family health history, how you respond to study activities or procedures, laboratory and other test results, medical images, and information from study visits, phone calls, surveys, and physical examinations. Your personal health information and 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. People, agencies and businesses that may receive and use your health information are research sponsors; representatives of sponsors 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), 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. If this research study involves the treatment or diagnosis of a medical condition, then information collected or created as part of the study may be placed in your medical record and discussed with individuals caring for you who are not part of the study. This will help in providing you with appropriate medical care. In addition, all or part of your research related health information may be used or disclosed for treatment, payment, or healthcare operations purposes related to providing you with medical care. 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. When you sign this consent and authorization form you authorize or give permission for the use of your health information as described in the consent form. This authorization does not have an expiration date. You can revoke or take away your authorization to use and disclose your health information at any time. You do this by sending a written notice to the investigator in charge of the study at the following address: Catherine Matthews, MD @ [REDACTED]

[REDACTED] If you withdraw your authorization you will not be able to be in this study. If you withdraw your authorization, no new health information that identifies you will be gathered after that date. Your health information that has already been gathered may still be used and disclosed to others. This would be done if it were necessary for the research to be reliable. You will not have access to your health information specific to this study until the end of 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 website at any time.

#### WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The purpose of this research study is to obtain data or information on the safety and/or effectiveness of the Anchorsure® device; the results will be provided to the sponsor, the Food and Drug Administration, and other federal and 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. 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. Every effort will be made to maintain participant privacy. Participants will be given a unique study identification number. This number will be used to record participant study information. Participants will never be tracked through the study by name, medical record number, or other personal identifier. A log of participants' names, ID numbers, and personal information (such as home address, telephone number, and emergency contact information) will be maintained in a locked area at the clinical site. All study data will be sent to the Data Coordinating Center (DCC) by secured electronic transfer. Only authorized members of the research study will have permission to see these data. Only authorized researchers will have access to use this data for future research.

Researchers who plan to use participant data or specimens for future scientific study will be required to request all of the necessary approvals or waivers before using participant data. Data will only be released to scientists who are qualified and prepared to conduct a research study. If publications or presentations result from this research, participants will not be identified by name or any other personal identifier.

#### WHAT ARE THE COSTS?

There are no additional costs to you for taking part in this study. All study administrative costs 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 YOU BE PAID FOR PARTICIPATING?

A \$50 gift certificate will be paid for complete participation in this study. The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.



## WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Adler Instruments. 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 contact Dr. Catherine Matthews @ [REDACTED] or call our office @ [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, new information becomes available that nullifies the purpose of the study or that significantly increases the anticipated risks of participation, your inability to follow the instructions of the study prevents further inclusion in the study, the supply of either of the devices to our surgical team has stopped, or the entire study has 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.

### 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. Catherine Matthews @ [REDACTED] or call our office @ [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]. 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.

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