Official Title: Barbed Suture Versus Non-Barbed Suture for Posterior Colporrhaphy: A Randomized Controlled Trial
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ATRIUM HEALTH
CONSENT TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor / Study Title:	**Atrium Health Department of OB/GYN / "Barbed Suture versus Non-Barbed Suture for Posterior Colporrhaphy: A Randomized Controlled Trial"**
Atrium Health IRB Number:	**04-20-01**
Principal Investigator: (Study Doctor)	**Amanda Merriman, MD, MPH**
Telephone:	[redacted] **(24 hours)**
Address:	**Atrium Health** **Women's Center for Pelvic Health-Mercy** **2001 Vail Avenue, Suite 360** **Charlotte, NC 28207** **Atrium Health** **Women's Center for Pelvic Health-Cabarrus** **200 Medical Park Drive, Suite 250** **Concord, NC 28025**

Please read this form carefully. Take time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign and date your name at the end of this form. You cannot take part in this research study until you sign and date this form.

INTRODUCTION

Pelvic organ prolapse (POP) is a growing concern for the aging female population, and symptomatic women often require surgical intervention. Approximately 200,000 surgical procedures for POP are performed annually in the United States. This number is anticipated to increase with the growth in the aging population. Surgical prolapse repairs are often categorized into either mesh augmented or native tissue repairs.

Women can have significant post-operative pain with native tissue posterior colporrhaphy. Native tissue posterior repairs are performed to address symptomatic prolapse or a widened vaginal opening. This type of repair may improve obstructed defecatory dysfunction and bulge symptoms, but can be associated with postoperative pelvic pain and pain with intercourse. Suture used for the posterior repair may contribute to postoperative pain at the time of posterior colporrhaphy. To date, there is no standardized suture material used for this type of repair and there are only a few studies evaluating suture in the posterior compartment. Barbed delayed absorbable suture has unique properties that allows the suture to remain in place without tying surgical knots. These properties may decrease postoperative pain by decreasing suture knot burden. Barbed suture has been successfully applied to gynecologic procedures and can reduce operative times. To date, there are no clinical trials that have evaluated the impact of barbed suture on postoperative pain or surgical time after posterior colporrhaphy.

STUDY PURPOSE

- To describe an innovative suturing technique for posterior repair using barbed suture.
- To compare the use of barbed suture to non-barbed suture at the time of posterior colporrhaphy.

HOW THE STUDY WORKS

Screening

- You will be screened at your preoperative visit to see if you meet eligibility for the study. The study doctor to determine your eligibility for participation in the study.
- Exclusion criteria for this study are listed below:
    - Documented allergy or contraindication to use of suture material (polydiaxonone, dioxanone, glycolide or trimethylene carbonate)
    - Prior mesh procedure performed in the posterior compartment
    - Planned colpocleisis procedure
    - Planned sacrospinous ligament fixation or ileococcygeous suspension procedure
    - Planned concomitant anal or rectal surgery
    - Current or prior rectovaginal fistula
    - Chronic pelvic pain diagnosis
    - Chronic narcotic medication use (daily narcotic use for ≥ 3 weeks before surgery)
    - Active vulvodynia
    - Non-English speaking
    - Inability to provide informed consent
- The study doctor will review your medical and gynecology history. You will be asked about your age, health and medical problems, any medicines that you are taking (including over-

the-counter medicines, vitamins and/or herbal supplements), drug allergies, both OBGYN-related and other recent surgeries.
- We will have you fill out a series of baseline questionnaires and pain scores at your first visit.
- The study doctor will perform a pelvic exam and a pelvic organ prolapse quantification system (POP-Q) to check for pelvic pain and pelvic organ prolapse.

Study Procedure

If you agree to be in the study, you would be randomized to one of two treatments. Being randomized means that you are put in a group by a chance process, like flipping a coin. You won't know what group you are in. We are using this method because it is not clear at the present time if barbed suture is beneficial in the posterior compartment. Your chance of receiving either treatment is equal.

If you agree to participate, you will be randomized in the operating room to receive either:

- Group 1: barbed suture
- Group 2: non-barbed suture

One of these delayed absorbable suture materials will be used to suture your posterior repair incision site while you are still asleep under anesthesia in the operating room. Other than suture material the procedures will be the same and per standard repair technique.

This study will require one additional phone call follow-up with questionnaires at six months after your initial surgery. Otherwise, you will have an office follow-up visit with an examination and questionnaires at six-weeks and twelve-months.

Your involvement in this study will be completed after the twelve-month follow-up visit.

Post-operative Phone Calls
- During the follow-up visit you will be asked for any questions or concerns.
- You will be asked to rate your pain on a scale.
- You will be asked to complete a series of questionnaires.

Office Follow–up Visits
- During the follow-up visit you will be asked for any questions or concerns.
- Pelvic exam and POP-Q test will be done.
- You will be asked to rate your pain on a scale.
- You will be asked to complete a series of questionnaires.

POTENTIAL RISKS

While participating in the study, you are at risk for the following side effects. Most of them are listed below but they will vary from person to person. Many side effects will go away after the treatment is stopped but, in some cases, the side effects may be serious and/or lasting.

You should talk to your study doctor about any side effects that you have while participating in the study.

In addition to the risks or discomforts listed here, there may be other risks that are currently not known. Also, the risks or discomforts described may occur more often or be more severe than has been seen before.

POTENTIAL RISKS OF BARBED SUTURE

The known side effects of the barbed suture are quite rare. The risks listed below are not unique to the study suture material, but rather risks of all delayed absorbable suture materials. These risks include:

- Abnormal wound healing—Although normal healing is expected, surgical dehiscence of wound or wound breakdown is a possibility.
- Sutures remaining in place for longer than expected period (>6weeks), which may be associated with localized irritation, localized erythema or induration.
- Suture extrusion and delayed absorption in tissue with poor blood supply, and broken needles may result in extended or additional surgeries or residual foreign bodies
- Scarring—although normal healing after use of barbed suture is expected, abnormal scars may occur. Scars may be a different texture than the surrounding tissue.
- Pain—pain occurs with almost any procedures; however, it is very unlikely that chronic pain will develop after use of a barbed suture material.
- Infection—bacterial, fungal and viral infections can occur with any surgical procedure. Should any type of infection occur, additional treatments including antibiotics may be necessary.
- Inadvertent needle sticks may expose patient to blood borne pathogens.
- Allergic-Type Reactions—Allergic reactions may range from minor itching or rash to major reactions which can result in death.
- Unknown risks—there is a possibility that additional risk of barbed suture may be discovered.

If you have problems that might be related to the study suture material your study doctor may "break the code" to find out which group, you are in. You would then no longer be in the study.

As with all studies that collect personal health information, there is a risk of possible loss of confidentiality with registries. We will take every precaution to make sure your personal health information is kept confidential. This will include keeping any paper data in locked secure cabinets

in the hospital and storing any electronic data on secure servers. We will also destroy any identifying information as soon as all of the data is collected. We will not report our data with any information that could be linked to your identity.

BENEFITS

This study suture material may or may not improve postoperative pain. The information gained from your case may benefit others undergoing this surgery and change future surgical practice.

ALTERNATIVE PROCEDURE/TREATMENT

If you choose not to be in this study, your surgeon will use suture of his or her choosing at the time of surgery. You will receive the same planned surgical procedure and the same treatment after surgery. You will also have the same postoperative follow-up in clinic. You should talk with your study doctor about all your options and their risks and benefits.

ADDITIONAL COST

The study barbed suture material is more expensive per suture than the non-barbed suture material typically used for a posterior repair; however, the total cost of suture is very much dependent on the number of suture packets used during a surgery, which is surgeon dependent. In our experience suture cost is included in the lump sum hospital/surgical cost so that our subjects do not pay any more than the previously determined price for surgery according to their insurance coverage. If you are paying for your surgery out of pocket however, you may be responsible for this additional cost. Your insurance company may not pay for research treatments. You may wish to discuss coverage with your insurance company before agreeing to participate in this research study.

COMPENSATION FOR INJURY

In the event that you are harmed as a result of your participation in this study, we will provide or arrange for treatment as necessary. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner. You do not waive any legal rights by signing this consent form.

If you become ill or are hurt while you are in the study, get the medical care that you need right away.

In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsor or involved institutions from their legal and professional responsibilities.

YOUR PAYMENT FOR BEING IN THE STUDY

You will not be paid for being in this study.

BEING A STUDY VOLUNTEER AND WITHDRAWING FROM THE STUDY

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, that will not in any way harm your relations with your doctors or with Atrium Health. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Atrium Health.

- You may always say no. You do not have to take part in the study.
- If you start a study, you may stop at any time. You do not need to give a reason.
- If you do not want to be in a study or you stop the study later, you will not be penalized or lose any benefits.
- If you stop, you should tell the study staff and follow the instructions they may give you.

Your part in the research may stop at any time for any reason, such as:

- The sponsor or the study doctor decides to stop the study.
- The sponsor or the study doctor decides to stop your part in the study for your safety.
- You need additional medicine.
- You do not follow the study rules.
- You have a new injury or illness.
- You decide to stop.

You may be asked to stop the study even if you do not want to stop.

NEW INFORMATION ABOUT THE STUDY

We will tell you about new medical findings that may affect your willingness to continue in the study.

CONFIDENTIALITY

The records of this study will be kept private. In any sort of report, we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed and/or photocopied by Atrium Health, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All your study data will be kept in a secure location.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AUTHORIZATION TO USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATION

If you wish to participate in this research study, you

_____

Printed Name of Research Subject

must sign this Authorization. By signing this Authorization, you give all healthcare providers, including Atrium Health, permission to use or disclose (release) your protected health information, both past and present, for the research study described here:

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The protected health information that we may use or disclose (release) for this research may include all information in your medical record, such as results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.

The health information listed above may be used by and/or disclosed (released) to:

- Study investigator and research staff
- Regulatory or other governmental authorities of the United States
- Atrium Health employees
- Other persons or agencies as required by law or allowed by federal regulations, and/or
- Atrium Health Institutional Review Board (Atrium Health IRB).

Atrium Health is required by law to protect your protected health information. By signing this Authorization, you authorize Atrium Health to use and/or disclose (release) your protected health information for this research study. Those persons who receive your protected health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your protected health information with others without your permission, if permitted by laws governing them. Your protected health information may then no longer be protected by the Privacy Rule.

Please note that you do not have to sign this Authorization, but if you do not, you may not receive research-related treatment through this study.
However, Atrium Health may not condition (withhold or refuse) your other Atrium Health providers treating you on whether you sign this Authorization. You may change your mind and withdraw (take back) this Authorization at any time, except to the extent that Atrium Health or the sponsor has already used or disclosed your protected health information based on this Authorization. To withdraw this Authorization, you must write to the Study Doctor at the address listed on the first page of this form.

No publication or public presentation about the research described above will reveal your identity without another Authorization from you. If all protected health information that does or can identify you is removed, the remaining information will no longer be subject to this Authorization or federal rules (such as the Privacy Rule) and may be used or disclosed for other purposes.

When the research for which the use or disclosure is made involves treatment and is conducted by Atrium Health: To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete.

At the conclusion of the research study and at your request, you generally will have access to your protected health information. Access to your protected health information in a medical record is described in the Notice of Privacy Practices provided to you by Atrium Health.

When conducting research, the data and results may be used or disclosed for further treatment outcomes research or to research a secondary result. This Authorization will remain in effect after the end of the current study, and any future related secondary study unless it is revoked by you in writing as described above.

_____

Signature of Research Subject

_____

Printed Name of Research Subject

_____

Date

STUDY STAFF PAYMENT/FINANCIAL DISCLOSURE

The doctors will receive no financial benefit in any form by asking you to participate in this study.

PHOTOGRAPHS/VIDEOGRAPHY

Digital photographs of the internal study treatment area and/or video of the study procedure may be captured in the operating room and/or at follow-up visits. The photographs or videos may be used in presentations or publications.

Do you consent for photographs and/or video to be taken? ☐ Yes ☐ No Initials: _____
Do you consent for video to be taken? ☐ Yes ☐ No Initials: _____

Do you consent for these photographs
to be used in presentations or publications? ☐ Yes ☐ No Initials: _____

Do you consent for this video
to be used in presentations or publications? ☐ Yes ☐ No Initials: _____

GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE STUDY

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a study subject;
- Eligibility to participate in the research;
- The study doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;
- Other questions, concerns, or complaints.

Contact the study doctor or study staff at Atrium Health, listed on the first page of this form, with any questions, concerns or complaints.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT

The researcher performing the study at Atrium Health is Dr. Amanda Merriman. You may ask them any questions you have now. If you have questions later, you may contact her at:

Atrium Health
[redacted]

Telephone: [redacted]

The Institutional Review Board is a group of people who review the research to protect your rights. If you have questions about the conduct of this study or about your rights as a research subject, you may call the chairperson of the Institutional Review Board of Atrium Health for information regarding patients' rights in a research study. You can obtain the name and number of this person by calling [redacted] or by email at: [redacted]

STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____ _____
Signature of Research Subject Date Time

_____
Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____ _____
Signature of Person Explaining Consent Date Time

_____
Printed Name of Person Explaining Consent