utmb Health

The University of Texas Medical Branch at Galveston
Minimal Risk Consent Form

Protocol Title: Comparing retroperitoneal tunneling versus dissection technique during robotic-assisted sacrocolpopexy for pelvic organ prolapse

IRB Number: 23-0124

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Why am I being asked to take part in this research study?
You are being asked to take part in this study because you are undergoing robotic assisted sacrocolpopexy for your pelvic organ prolapse.

Study Summary:
The reason we are doing this research is to find out if the tunneling technique reduces the operating time when compared to the dissection technique. Both techniques are not "investigational" procedures, and considered the standard of care of robotic-assisted sacrocolpopexy (RASCP). There is no direct benefit to participating in this study.

The following things you should know about this research study:

- The purpose of the study is to compare operative time, as well as patient reported outcomes, surgical complications, and surgical outcomes between the tunneling versus dissection technique during RASCP. If you chose to participate, you will be asked to complete routine clinic visits (preoperative, 2 weeks, 6 weeks, and 12 weeks postoperative). Each visit takes approximately 30-45 minutes. In total, you will be asked to come 4 times to the clinic in 4 months. At the end of four months, the research will be finished.
- Risks or discomforts from this research are minimal. We do not expect any direct risks or discomforts from participating in the study.
- You will not directly benefit from participating in this study, but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.
- Taking part in this research study is voluntary. You do not have to participate and you can stop at any time.

Please take your time to read this entire form and ask questions before deciding if you want to take part in this research project.

DETAILED RESEARCH CONSENT

What is the purpose of this research study?
The purpose of the study is to compare operative time, as well as patient reported outcomes, surgical complications, and surgical outcomes between the tunneling versus dissection technique during RASCP

How many people will take part in this study?
About 40 people will take part in this study at UTMB.

What procedures are involved as part of this research study?
If you agree to take part, you will be asked to sign this consent form. Because we do not know if the tunneling technique reduces the operating time when compared to the dissection technique, we need to compare the two. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin.

Participants in one group will have tunneling technique while participants in the other group will have dissection technique during RASCP. It is important that neither you nor research coordinator know which of the two techniques you are given. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.

The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what surgical technique is doing , we will find out which intervention you are getting and make changes. If there is anything you are concerned about or that is bothering you about the research please speak with the investigator or study personnel. Of note, both tunneling and dissection techniques are considered standard of care during RASCP.

What are the possible risks for choosing to participate in this research study?
Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Risks of surgical complications related to the tunneling technique during RASCP are similar to those risks of RASCP with dissection technique. By participating in this research, you are not at greater risk than you would otherwise be with the routine RASCP. The following includes potential risks: recurrent pelvic organ prolapse, adjacent organs (bladder, urethra, ureter, bowel) injuries, dyspareunia, mesh exposure, lower urinary tract symptoms (nocturia, dysuria, de novo stress incontinence, de novo urgency incontinence, voiding dysfunction), port site hernia, port site nerve entrapment or pain, bleeding with blood transfusion, infection (abscess, discitis, osteomyelitis), vaginal cuff dehiscence, vaginostomy.

What are the potential benefits for participating in this research study?
You will not directly benefit from participating in this study, but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

Will I be reimbursed for participating in this research study?
There will be no reimbursement for participation in this study.

Is there an alternative treatment/procedure?
The alternative is not to participate in the study. If you do not wish to participate in this study, you will be provided with one of these surgical procedures based on your provider's preference.

If I agree to take part in this research study, can I be removed from the study without my consent?
Yes. The researchers may decide to take you off this study if :

- The study is cancelled
- Your surgery is cancelled.
- You are unable to keep appointments
- You cannot follow research instructions
- Participating in the study is no longer safe for you.

How will my information be protected?
All results obtained in this study will be kept confidential and only available to the research study team. Your individual information will not be reported, only the results of all participants as a group.

How will my privacy be protected?
We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The research team will know your identity and that you are in the research study. Other people at UTMB, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety. If you think this study might affect your clinical care, please inform your doctor.

People outside of UTMB may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form; however, people outside UTMB who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect

information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

A description of this clinical trial will be available on 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.

Who can I contact with questions about this research study?
If you have any questions, concerns or complaints before, during or after the research study, or if you need to report a research related injury or bad side effect, you should immediately contact Dr. Kilic at his phone number 409-747-4980 or, if after normal office hours, please send the message through EPIC MyChart.

This study has been approved by the UTMB Institutional Review Board (IRB). If you have any complaints, concerns, input or questions regarding your rights as a subject participating in this research study or you would like more information about the protection of human subjects in research, you may contact the IRB Office, via email irb@utmb.edu.

Do I have to participate?
Your participation in this study is completely voluntary. You may refuse to participate or stop your participation in this research study at any time without penalty or loss of benefits to which you are otherwise entitled.

CONSENT TO PARTICIPATE:
The purpose of this research study, procedures to be followed, risks and benefits have been explained to you. You have been given the opportunity to ask questions, and your questions have been answered to your satisfaction. You have been told who to contact if you have additional questions. By signing this form, you are confirming that you have read this consent form and voluntarily agree to participate as a subject in this study.

Signature of Subject	Date

Using language that is understandable and appropriate, I have discussed this project and the items listed above with the subject.

Signature of Person Obtaining Consent	Date and Time of Consent Obtained

Printed Name of Person Obtaining Consent