The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title:
A prospective randomized trial comparing Restorelle® Y mesh vs. Vertessa® lite Y mesh for laparoscopic and robotic-assisted laparoscopic sacrocolpopexy
Sponsor: Caldera Medical, Inc.

Principal Investigators:
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After hours phone contact: 216-444-2200, ask for the Gynecologist on call

You are being invited to participate in a research study. A research study is designed to answer specific questions about new ways to prevent, detect, and treat disease. Being in a research study is different from being a patient. The purpose of this document is to provide a written summary of the discussion and exchange of research information you had with the research team. It is also for use as a reference during the study.

Please note:

- **You are being asked to participate in a research study**
- **Ask as many questions as needed so you can make an informed decision.**
- **Carefully consider the risks, benefits, and alternatives of the research**
- **Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw from the study at anytime.**

1. INFORMATION ON THE RESEARCH

Why is the research study being done?
You are being asked to participate in a research study because your doctor has determined you are a good candidate. The study is for minimally invasive abdominal sacrocolpopexy (suspension of the vagina to the ligament on the sacrum using either robotic assistance or conventional laparoscopy) for treatment of your vaginal prolapse and you are planning to have the surgery done. The purpose of this study is to compare outcomes between two types of mesh that we routinely use for this surgery.

Both the Restorelle® Smartmesh (Coloplast, Inc., Minneapolis, MN, USA) and the Vertessa® lite mesh (Caldera Medical, Inc., Agoura Hills, CA, USA) are mesh grafts that are intended for pelvic floor reconstruction. Currently, both types of grafts are used to perform sacrocolpopexy.

How Many People Will Take Part In The Study?
About 100 people will take part in this study at Cleveland Clinic Main Campus and Fairview Hospital.

What is involved if you decide to take part in this research study?
The research involves using either **Restorelle® Y mesh (see figure 2 on page 6)** versus **Vertessa® lite Y mesh (see figure 3 on page 6)** that is necessary to suspend the vagina to the sacrum for repair of your prolapse. This will be done during your surgery while you are under anesthesia. In addition, we will ask you to complete a questionnaire prior to and after your surgery. The questionnaires will take approximately 15-20 minutes to complete. Your participation in this study will end at your 24 month postoperative visit.

Before your surgery, you will be randomized (like the flip of a coin) to one of two groups. Neither the study doctor nor you can choose the treatment. It will be chosen by chance. One group of patients will undergo minimally invasive abdominal sacrocolpopexy **(see figure 1 on page 6)** with the Y mesh and another will undergo the same procedure with the Lite Y mesh. You will not be told to which group you have been randomized. This randomization will not change how your surgery is done.

During your surgery, measurements will be taken of your uterus and cervix, if these are still present. These measurements will be identified by a study number, not your name. The measurements will take less than 2 minutes to obtain, and will be done with a standard measuring tool routinely used during the surgery that will be placed inside the cervix. There are no added risks associated with taking these measurements. Your surgical procedure will not change in any way.
You will return to the office after your surgery for a 6-month, 12-month and 24-month research nurse visit. At the 6, 12 and 24-month visit a pelvic examination will be done by a clinician and you will be asked to complete the same questionnaires you completed prior to your surgery.

How Long Will You Be In The Study?
Your participation in this study will last 24 months, starting from your preoperative visit before your surgery and ending with your 24 month postoperative visit.

2. ALTERNATIVES

What are the alternatives to participation in the research study?
Taking part in this study is voluntary. The alternative to participating in this study is not to participate and to have the surgery with either mesh as chosen by your surgeon. Your decision not to participate or to withdraw from the study will not impact your planned surgery

3. RISKS

What are the risks of participating in the research study?
You are receiving the same surgery you would have received if you were not participating in the study. Your doctor will discuss the risks of the surgery with you. Involvement in the study does not add surgical risks because you are receiving the surgery you would have received if you were not participating in the study. However, the surgery is major surgery which has its risks and your doctor will review the risks with you.

Although Vertessa® lite mesh is approved for use in pelvic floor reconstruction, no data exists at this time on the Vertessa® lite mesh for sacrocolpopexy procedure. Neither the study doctor nor you can choose the treatment. It will be chosen by chance (like the flip of a coin).

You should discuss and understand potential risks, reactions and complications with your doctor before surgery. Your doctor will tell you about the possible risks and complications of a surgical procedure in which an incontinence sling is placed, the known risks of an implanted incontinence sling over time, what can be done to reduce those risks, as well as other alternative treatments.

Some of the questions asked as part of the study, may make you feel uncomfortable. You may refuse to answer any of the questions. There is a potential risk of loss of confidentiality of your data. Every effort will be made to keep your information confidential through the use of codes and storage in a password protected computer accessible only by the research team.

4. BENEFITS

What are possible benefits of participating in the research?

There are no direct benefits to you of being in the study

5. COSTS

Are there any costs to you if you participate in this study?

There are no additional costs to you for participation in this research study. The cost for routine tests and services that would normally be performed even if you don't participate in the study will be billed to you or your insurance provider.

Your 6, 12 and 24-month research nurse visits are not routine visits covered by your insurance and will, therefore, be paid for by the study.

There are no plans to provide financial compensation to you in the event the results from this research lead to the development of new products.

6. COMPENSATION

Are there any payments to you if you participate in this study?

You will receive $200.00 following the completion of your participation. This will be paid in $50 increments following your baseline, 6-month, 12-month and 24-month postoperative visits. A parking voucher will also be provided for all visits.

The IRS requires Cleveland Clinic to report payments to an individual of $600 or greater (in a calendar year) on a Form 1099-MISC. Your name, address and social security number will be collected to track the payments made to you and, if you receive $600 or greater, will be used to process a Form 1099-MISC.

7. RESEARCH RELATED INJURY

What will happen if you are injured as a result of taking part in the research?

If injury occurs as a result of your involvement in this research, medical treatment is available from Cleveland Clinic or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you/your insurance company does not pay the cost of diagnosing and treating your condition, the cost will be covered by Caldera Medical, Inc. if they agree the injury was caused by the research or research activity as described in the Protocol and not the fault of the researchers or study staff. There are no plans for payment for lost wages or

other expenses. To help avoid injury, it is very important to follow all study directions.

If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury".

Further information about research-related injuries is available by contacting the Cleveland Clinic Institutional Review Board at (216) 444-2924.

8. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research (Caldera Medical, Inc.) and their agents. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing**, Cecile Ferrando, M.D., 9500 Euclid Avenue/A81, Cleveland, Ohio 44195.** If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

9. CONFLICT OF INTEREST

Do the researchers or institution have any conflicts of interest relating to this study?

None of the investigators conducting this study serve as paid speakers or consultants for any company that makes products used in this study.

10. QUESTIONS

Who do you call if you have any questions or problems?

If you have any questions, concerns or complaints about the research, or develop a research-related problem, contact Cecile Ferrando, M.D at 216-444-0642 or Marie Paraiso, M.D. at 216-444-3428. After business hours, you may contact the Gynecologist on call by calling the Cleveland Clinic page operator 214-444-2200. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924

11. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

12. SIGNATURES

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date

Figure 1: Sacrocolpopexy

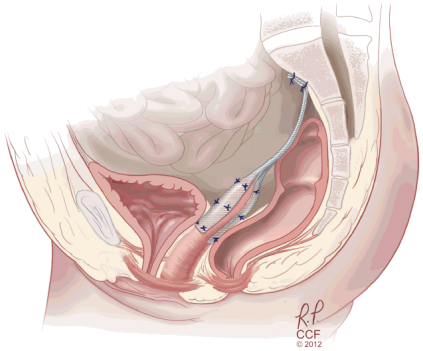

Figure 2: Restorelle Y-Mesh

Figure 3: Vertessa Lite Y-Mesh