TITLE: Prospective, Single-Blinded, Randomized-Controlled Trial Comparing the Performance Profiles of Two Non-Cross-Linked Porcine Dermal Matrices in Abdominal Wall Reconstruction

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Sponsor: None

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You are still eligible to have surgery if you decline to participate in this study.** Your willingness to participate, or not participate, in this study does not change your candidacy for surgery. You will still be eligible and allowed to have surgery, if indicated, if you decline participation.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

The goal of this study is to compare two types of mesh in abdominal wall reconstruction and hernia repair. A mesh is a "net" of material that is used in hernia surgery and abdominal wall reconstruction to strengthen the body's tissues during the repair. Both meshes in this study are derived from pig skin that has had the cells removed from it,

meaning that the living cells that made up the pig skin are removed, and what is left is ascaffold that looks like a net under the microscope. This makes those meshes safe to implant in human beings, and compatible with the human body. Although both types of mesh have been used in abdominal wall reconstruction and hernia repair for several years with good outcomes, it is unclear which has one has better outcomes.

2. How many people will take part in this study?

Approximately 70 people will be included in this study

3. What will happen if I take part in this study?

If you take part in this study, you will be asked to sign informed consent forms, HIPAA permission forms, and 4 questionnaires before surgery. The surveys consist of multiple-choice questions, and the total length of all the surveys combined is 22 pages. If you are a candidate for abdominal wall reconstruction using pig-derived mesh, you will be randomized to one of the two meshes used in this study (Xenmatrix or Strattice) (The process of randomization is like the flip of a coin, meaning you will have a 50-50 chance of being assigned to either mesh). You will not know which mesh you are randomized to. You will then undergo the surgery as planned and be followed-up on a regular basis. The details of the surgery are different for every patient, depending on the size, location and cause of the missing tissue in the abdominal wall. In general, if the missing tissue is because a growth or tumor is being removed, techniques to close the abdominal wall after tumor removal will be used, and may consist of closing the deep, strong layer of your abdominal wall (fascia), with or without mesh. If the missing tissue is because of a hernia, the hernia will first be exposed, and any scar between bowel and abdominal wall will be released. The hernia will then be closed, with or without mesh. The decision whether to use mesh or not depends on the specific clinical situation of each patient, and is often made during surgery. Patients whose abdominal tissues are thinner or weaker are more likely to require mesh.

The choice of mesh will depend on your specific clinical situation. Biologic mesh (mesh obtained from an animal source) may be used. The two biologic meshes being compared in this study are both made from pig skin. They are very similar, but they are made by two different companies using their own proprietary processes. The companies use different processes of removing the cells from those meshes. Both meshes are completely sterilized by the manufacturing company (bacteria are removed completely). Both companies use a beam of electrons to remove bacteria from the meshes. If your specific clinical situation does not meet the criteria for use of either of the two types of biologic mesh, you will not be included in the study and synthetic mesh may be used.

Your exact postoperative follow-up schedule will depend on your specific clinical situation. However, at a minimum, you will be asked to follow-up 1 week, 2 weeks, 3 weeks, 4 weeks, 3 months, 6 months, 9 months and 1 year after surgery.

You will be asked to fill out the same 4 questionnaires 12 months after surgery. The surveys consist of multiple-choice questions, and the total length of all the surveys combined is 22 pages, which will take you about 30 minutes to complete.

The investigators in the study will then look through your medical chart, including the surveys, any history of medical problems that you have, the details of the surgery, and the outcome of your surgery, and will analyze the data of all the patients in the study in order to determine whether one mesh is better than the other. Data will be collected before surgery, and for 1 year after surgery. Your agreement to participate in the study includes an agreement to allow the study investigators to look in your medical chart.

4. How long will I be in the study?

You will be in the study for 12 months.

5. Can I stop being in thestudy?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University. In addition, you will still receive the surgery that you are a candidate for.

6. What risks, side effects or discomforts can I expect from being in the study?

If you are a candidate for abdominal wall reconstruction using pig-derived mesh, you will be randomized to one of the two meshes used in this study (Xenmatrix or Strattice). You will not know which mesh you are randomized to. The study itself does not pose any risk of side effects or discomfort, and the use of either mesh will not cause any additional discomfort. The meshes are both routinely used in abdominal wall reconstruction, and serve to reinforce the abdominal wall repair. Possible side effects/complications of the surgery itself include bleeding, infection, hernia recurrence (risk that the hernia will come back), bulge in the abdomen, incision dehiscence (separation), mesh exposure, mesh infection, need for mesh removal, skin necrosis (skin death leading to a scab or a wound), more surgery. Complications that are specific to the mesh are mesh infection, mesh exposure, need for mesh removal, fluid collection near the mesh, and enterocutaneous fistula (connection between the bowel and the skin, through the mesh).

7. What benefits can I expect from being in the study?

There are no benefits directly related to being in the surgery. You will be offered surgery if you are a good candidate for it regardless of whether you choose to participate in the study or not.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. Your eligibility for surgery will not change as a result of declining participation in this study. If you are otherwise a good candidate for surgery, you may still undergo surgery without study participation.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

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 the website at any time.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. What are the costs of taking part in this study?

There are no costs to you related to taking part in this study

11. Will I be paid for taking part in this study?

By law, payments to subjects are considered taxable income.

You will **not** be paid for taking part in this study

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact ~~**Ryan Jefferson, MD**~~**Dr** ~~at ryan.jefferson@osum.edu, or **Dr**~~**. Jeffrey E. Janis, MD** at Jeffrey.janis@osumc.edu or 614-366-1704

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact contact ~~**Ryan Jefferson, MD** at ryan.jefferson@osum.edu,~~

~~or at 614-293-9030, or~~ Dr. Jeffrey E. Janis, MD at Jeffrey.janis@osumc.edu or 614-**366-1704**

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15. Do any of the investigators have a conflict of interest in this study?

Dr. Janis is a paid consultant for LifeCell. LifeCell is not sponsoring the study. The study is randomized, and his relationship with LifeCell will not affect the study. It will not affect patient selection or data analysis. The study is being done in order to determine whether Strattice and Xenmatrix have different performance profiles.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time

216