Informed Consent

Breast Reconstruction with TRAM Flap

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INSTRUCTIONS

This document is about informed consent. It will tell you about breast reconstruction with transverse rectus abdominus musculocutaneous (TRAM) flap surgery. It will outline the risks and other treatment options.

It is important that you read this whole document carefully. Please initial each page. Doing so means you have read the page. Signing the consent agreement means that you agree to the surgery that you have talked about with your plastic surgeon.

GENERAL INFORMATION

Surgeons have many ways to do a breast reconstruction. Most mastectomy patients can have breast reconstruction right after having the breast removed or later on. It works best for women who have removed breast cancer by mastectomy. There are good reasons to avoid breast reconstruction Some surgeons or oncologists may advise their patients to wait until cancer treatment is done or until the disease staging has finished. Other patients may need more complex breast reconstruction procedures. Surgeons may advise women who smoke or who have other health issues, like obesity or high blood pressure, to avoid surgery. Learning your options for breast reconstruction can help you prepare for a mastectomy and have a more positive outlook. Some thin people may not be suitable for the TRAM flap surgery. People with obesity have a greater risk of surgical issues.

Breast reconstruction does not change the natural history of breast cancer or meddle with other forms of breast cancer treatment like chemotherapy or radiation. However, breast cancer treatment can affect how breast reconstruction is done and its results.

The TRAM flap uses the abdominal muscle flap(s) from the rectus abdominis muscle. This muscle, a piece of lower abdominal skin, and other tissue are placed on the chest to rebuild a breast mound. The muscle flap maintains its own blood supply. That helps nourish the tissue that has been moved to the chest. The lower abdominal cuts are closed after the breast mound is rebuilt. There are many ways the TRAM flap breast reconstruction can be done. Microvascular surgery can be done to attach the flap to the chest. In some cases, your plastic surgeon may insert a breast implant under the muscle flap to help the breast mound stick out.

Muscle flap breast reconstruction can be used if:

- There is not enough chest tissue for breast reconstruction with implants or expanders
- The patient has had radiation on the chest after a mastectomy
- The patient is worried about breast implants, although she may need implants to have the breasts look similar
- A prior breast reconstruction did not work

Contraindications to TRAM flap breast reconstruction include:

- A patient who is not medically or psychologically suitable for breast reconstruction
- A patient who has had abdominal surgery that stops the TRAM flap blood supply

Note: You will need a separate consent form for the use of breast implants in addition to breast reconstruction with TRAM flap. Also, review the Breast Implant Surgery Checklist.

OTHER TREATMENTS

TRAM flap breast reconstruction is not needed medically. Other treatment options are external breast prostheses or padding, breast reconstruction with tissue expansion, or using other body tissue for breast reconstruction. These have their own risks and issues.

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RISKS OF BREAST RECONSTRUCTION WITH TRAM FLAP SURGERY

All surgeries have some risk. It is important that you know these risks. If the surgeon does a TRAM flap surgery without a breast implant, the risks that come with breast implants do not apply. More risks and issues come with the TRAM flap for breast reconstruction than for other breast reconstruction methods. Choosing to have surgery means comparing the risks and benefits. Most patients do not face these issues, but you should talk about them with your plastic surgeon. Make sure you know all possible risks of breast reconstruction with TRAM flap.

SPECIFIC RISKS OF BREAST RECONSTRUCTION WITH TRAM FLAP SURGERY

Slow Healing and Loss of Flap:

The wound may open. It may heal very slowly. Some parts of the chest or TRAM flap tissue may die. You may need to change the bandage often. You may need more surgery to remove the dead tissue. Some areas of the chest or muscle flap skin may heal abnormally or slowly. That can happen when there is less blood flow to tissue before the surgery or if you have had radiation. Your belly button cells could die (called necrosis). Smokers are at more risk of losing skin and having problems with wounds healing. Passive smoke can also cause problems with wound healing.

Microvascular Surgery:

The flap may not be usable if not enough blood is going to it. You may need emergent reoperation to try to save the flap. In some cases, there may be partial or total loss of the flap. That means you may need more surgery. This may affect the way your chest or torso looks. Sometimes blood clotting disorders can affect the blood supply to the TRAM flap. Tell your plastic surgeon if you have had any abnormal clotting. An artery or vein may get blocked where the surgeon attaches the TRAM flap. This may make the flap unusable. If there are no contraindications, you may be on aspirin for at least one month after the surgery. Your blood flow through the vessels is watched carefully after the surgery. If it looks like you have a blockage, you may need urgent surgery to remove it and restart blood flow in the tissue flap. In rare cases, it may not work. That means the flap tissue may die and would need to be removed completely. You can talk with your surgeon about other reconstructive options at that point.

Weakness in the Abdominal Muscle:

Your muscles will feel weak after the abdominal tissue has been relocated. It is more obvious with a TRAM flap than a DIEP flap. Usually, patients can return to most activities in two to four months. Patients may notice weakness in their tummy when they do sit-ups or other such movements.

Abdominal Wall Hernia:

In rare cases the part of the abdomen that has been operated on can become weak. That can cause a hernia. Very rarely, you may need more surgery to fix the bulge. Sometimes the surgeon will insert a mesh or something from a biological source (plant, animal, human) when closing the cut to help support and strengthen the abdomen.

Implant Extrusion:

If you do not have enough tissue to cover the breast implant, it may become visible or push through the skin. This is possible if it is used with the TRAM flap. If the tissue breaks down and you can see the breast implant, it usually needs to be removed. You may not be able to get a new implant at the same time. The wound may need to heal without an implant before your breast reconstruction can be completed.

Firmness:

Your breasts can get too firm after surgery. This is due to scarring inside the chest or around the breast implant. The doctor cannot tell if this will happen. You may need another treatment or surgery to fix it. Getting radiation on the chest after breast reconstruction with a TRAM flap may result in too much firmness or other long-term problems.

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Other Perforator and Tissue Flaps:

Apart from the lower abdomen, the surgeon can use other parts of the body as a donor site to reconstruct the breasts after mastectomy. One area is the buttocks. An elliptic segment of skin and fat can be removed from the upper buttock (superior gluteal) or lower buttock close to the crease (inferior gluteal). Usually, the surgeon tries to remove the tissue and keep the muscles in that region. The skin and fat are removed with their small blood vessels (perforators). These blood vessels are reconnected to the vessels on the chest during the surgery to get the blood flowing in the tissue that has been moved. This process needs microsurgical methods. If the flap tissue is taken from the upper buttock, it is called superior gluteal artery perforator (SGAP) flap. Flap tissue from the lower part of the buttock is called inferior gluteal artery perforator (IGAP) flap. Taking tissue from one buttock may cause asymmetry. You may need more surgeries to balance the look of the buttocks. Sometimes, skin and fat can be taken from the thigh or hip. These tissues can be moved to the chest for breast reconstruction. The surgeon can use the microsurgical methods the same way as described above.

The risks in SGAP, IGAP, and other microvascular surgeries are like the risks of the TRAM flap reconstruction. Ask your surgeon for more details if you want one of these procedures.

Change in Nipple and Skin Sensation:

Breast reconstruction cannot bring back normal feeling to your breast or nipple. You will not have the same sense of touch in the skin that is moved with the muscle flap. Your skin may feel numb on the abdomen where the skin of the TRAM flap used to be. Changes in sensation may affect sexual response or the ability to breastfeed a baby.

Asymmetry:

Most women's left and right breasts do not look the same. There may be a difference in breast and nipple shape, size, or symmetry after surgery. You may need more surgery to fix the asymmetry after breast reconstruction with TRAM flap.

Breast Implants:

The risks that come with breast implants are talked about in another informed consent form.

Unsatisfactory Results:

You may not like the results of breast reconstruction surgery. You may have asymmetry in terms of where the muscle flap is placed or breast shape and size. You may not like how the flap is placed or where the scar is. You may need more surgery to improve your results. Any type of breast reconstruction can fail due to issues with the mastectomy surgery or chemotherapy/radiation. These breast cancer treatments are not related to the TRAM flap surgery. The unwanted results may NOT improve with more surgeries.

Change in Skin Sensation:

Breast reconstruction cannot bring back normal feeling to your breast or nipple. You will not have the same sense of touch in the skin that is moved with the muscle flap. Your skin may feel numb on the abdomen where the skin of the TRAM flap used to be.

Fat Necrosis:

The fat in the flap may die. This may make part of the flap firm. You may need more surgery to remove the fat that has died. The shape of the flap may be uneven because of the fat that has died.

Loss of Abdominal Wall Muscle Function:

Your rectus abdominis muscle might not work right after surgery. That can happen if part or all of it had to be moved with the TRAM flap. This can make your abs feel weak when you move, like when you sit up. The surgeon may not know how much rectus abdominis muscle needs to be used until the surgery happens.

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Acellular Dermal Matrix Usage:

Your surgeon may use acellular dermal matrix (ADM) products to strengthen your insides. This is where your abdomen is closed during the TRAM flap surgery. These products are made from a biological source (animal, plant, human) but have no living cells. Your own cells will grow into the ADM, and the tissue will be like your own. You may not get a complete covering of the product. It may need to be removed in another surgery. You may get a seroma or fluid buildup around the material, or an infection. You can have a hernia or bulge even after the surgeon has used an ADM product.

Surgical Mesh Usage:

Your surgeon may use a synthetic mesh to strengthen your insides. This is where your abdomen is closed during a TRAM flap surgery. Issues with the mesh are infection, pain, and being able to feel it. You may need more surgery to fix it. You can have a hernia or bulge even after getting the mesh.

Breast Implants:

The risks that come with getting breast implants are talked about in another informed consent form.

Implant Extrusion:

If you do not have enough tissue to cover the breast implant, it may become visible or push through the skin. This may only happen if you get a breast implant along with the TRAM flap. If the tissue breaks down and you can see the breast implant, it will need to be removed.

Pregnancy and Breastfeeding:

There is no proof that TRAM flap surgery affects fertility or pregnancy. If a woman has a mastectomy, she will not be able to breastfeed on the side where the breast was removed. After TRAM flap surgery, pregnancy may affect the way your belly looks. Your belly may look loose or bulge. You may need surgery to fix it.

Firmness:

Your breasts can get too firm after surgery. That is due to scarring inside the chest or around the breast implant. The doctor cannot tell if this will happen. You may need more treatment or surgery to fix it. Getting radiation on the chest after breast reconstruction with a TRAM flap may cause too much firmness or other long-term problems.

Asymmetry:

Most women's left and right breasts do not look the same. There may be differences in breast and nipple shape, size, or symmetry after surgery. You may need more surgery to fix the asymmetry after breast reconstruction with TRAM flap.

Unsatisfactory Result:

You may not like the results of the breast reconstruction surgery. You may have asymmetry where the muscle flap is placed or in breast shape and size. You may not like how the flap is placed or where the scar is. You may need more surgery to improve your results. Any type of breast reconstruction can fail due to issues with the mastectomy surgery or chemotherapy/radiation. These breast cancer treatments are not related to the TRAM flap surgery. The unwanted results may NOT improve with more surgeries.

Breast Disease:

Medical researchers have not found more risk of breast disease or breast cancer or its return in women who have reconstructive breast surgery. A person who has had breast cancer or has family members with breast cancer may be at more risk of getting breast cancer than a woman with no family history of this disease. The American Cancer Society guidelines say all women should do regular breast self-exams and a mammography. Seek medical care if you find a lump. If a lump is found before or during breast surgery, you may need more tests and treatment. These have their own costs.

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DISCLAIMER

Informed consent documents give you information about a surgery you are considering. These documents explain the risks of that surgery. They also discuss other treatment options, including not having surgery. However, informed consent documents can't cover everything. Your plastic surgeon may give you more or different information. This may be based on the facts of your case.

Informed consent documents are not meant to define or serve as the standard of medical care. Standards of medical care are determined based on the facts involved in an individual case. They may change with advances in science and technology. They can also change with the way doctors practice medicine.

It is important that you read the above information carefully and get all your questions answered before signing the consent agreement on the next page.

_____ **Patient Initials**

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CONSENT FOR PROCEDURE OR TREATMENT

1. I permit Dr. Thomas Jeneby MD and the doctor's assistants to do the procedure **Breast Reconstruction with TRAM Flap.**
2. I got the information sheet on: Breast Reconstruction with TRAM Flap.
3. I understand that, during the surgery, an unexpected situation may require a different medical procedure than the surgery listed above. I permit the doctor listed above, the assistants and/or designees to do any treatment that my doctor thinks it is needed or helpful. My permission includes all treatments that my doctor does not plan to do at the start of the surgery.
4. I understand what my surgeon can and cannot do. I understand that no warranties or guarantees have been hinted at or stated outright about the outcome of the surgery. I have explained my goals. I understand which outcomes are realistic and which are not realistic. All my questions have been answered. I understand the surgery's built-in risks. I am aware of other risks and possible issues, benefits, and options. I understand and choose to have the surgery.
5. I agree to the anesthetics that are needed or helpful. I understand that all types of anesthesia have risks and may result in complications, injury, and sometimes death.
6. I am aware of the serious risks to my health when blood products are used. I agree to my doctor using them if my doctor, assistants, and/or designees think they are needed or helpful.
7. I agree to the disposal of any tissue, medical devices, or body parts taken out during or after the planned surgery or any other operation that is needed or helpful.
8. I agree to have the right parts of my body photographed or televised before, during, and after the surgery for medical, scientific, or educational reasons, if the pictures do not reveal my identity.
9. For medical education, I agree that onlookers can be in the operating room.
10. I permit my Social Security Number to be given to the right agencies for legal reasons and medical device registration, when necessary.
11. I agree to the charges for this surgery. I understand that the doctor's charges are separate from the charges for the hospital and the anesthesia. I understand that there may be more charges if more procedures or treatments are needed or helpful. I agree to those charges, if any.
12. I understand that not having the surgery is an option and that I can opt-out of having the surgery.
13. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
    a. THE ABOVE SURGERY TO BE PERFORMED
    b. THERE MAY BE OTHER SURGERIES OR TREATMENT OPTIONS
    c. THERE ARE RISKS TO THE SURGERY

I CONSENT TO THE SURGERY AND THE ITEMS LISTED ABOVE (1-13).
I UNDERSTAND THE EXPLANATION AND HAVE NO MORE QUESTIONS.

_____
Patient or Person Authorized to Sign for Patient Date/Time

_____
Witness Date/Time

_____ Patient Initials
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