

Informed-Consent for Breast Reconstruction with Tram Abdominal Muscle Flap

1. I hereby authorize Dr. John P. Stratis and such assistants as may be selected to perform the following procedure or treatment:

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2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgement necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.

3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involves risk and the possibility of complications, injury, and sometimes death.

4. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.

5. I consent to the photographing or televising of the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.

6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.

7. I consent to the disposal of any tissue, medical devices or body parts which may be removed.

8. I authorize the release of my social security number to appropriate agencies for legal reporting and medical-device registration, if applicable.

9. THE FOLLOWING HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND

- a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
- b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
- c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you of breast reconstruction with TRAM abdominal muscle flap surgery, its risks, and alternative treatment(s).

It is important that you read this information carefully and completely.

GENERAL INFORMATION

There are a variety of surgical techniques for breast reconstruction. Most mastectomy patients are medically appropriate for breast reconstruction, either immediately following breast removal or at a later time. The best candidates, however, are women whose cancer, as far as can be determined, seems to be eliminated by mastectomy. There are legitimate reasons to delay breast reconstruction. Some women may be advised by their surgeon or oncologist to wait until other forms of necessary cancer treatment are completed. Other patients may require more complex breast reconstruction procedures. Women who smoke or who have other health conditions such as obesity or high blood pressure may be advised to postpone surgery. In any case, being informed of your options concerning breast reconstruction can help you prepare for a mastectomy with a more positive outlook on the future.

Breast reconstruction has no known effect on altering the natural history of breast cancer or interfering with other forms of breast cancer treatment such as chemotherapy or radiation.

The TRAM flap technique of breast reconstruction involves the use of abdominal muscle flap(s) made from the rectus abdominus muscle. This muscle and a portion of lower abdominal skin and other tissue is repositioned to the chest wall region in order to reconstruct a breast mound. the muscle flap maintains its own blood supply, and helps nourish the tissue that is transferred to the chest wall region. Following the reconstruction of the breast mound, the lower abdominal incisions are closed. There are several variations on the surgical technique of the TRAM abdominal muscle flap breast reconstruction, including microvascular surgery, to attach the flap to the chest region. In some cases, your plastic surgeon may recommend that a breast implant be inserted underneath the muscle flap to give the breast mound additional projection.

Muscle flap techniques of breast reconstruction are useful in the following situations:

- * Inadequate chest wall tissue for breast reconstruction with implants or expanders
- * Past history of radiation to chest wall after mastectomy
- * Patient with concerns about silicone implant/expander
- * Failure of earlier breast reconstruction

Contraindications to TRAM abdominal muscle flap breast reconstruction procedure exist:

- * A patient who is medically or psychologically unsuitable for breast reconstruction
- * A past history of abdominal surgery which has impaired TRAM blood supply

A separate consent form for the use of breast implants in conjunction with breast reconstruction with TRAM abdominal muscle flap is necessary.

ALTERNATIVE TREATMENT

Tram abdominal muscle flap breast reconstruction is an elective surgical operation. Alternative treatment would consist of the use of external breast prostheses or padding, tissue expansion breast reconstruction, saline breast implants or the transfer of other body tissues for breast reconstruction.

Potential risks and complications are associated with alternative techniques of breast reconstruction that involve surgery.

RISKS OF BREAST RECONSTRUCTION WITH TRAM ABDOMINAL MUSCLE FLAP

Every surgical procedure involves a certain amount of risk, and it is important that you understand the risks involved with breast reconstruction with TRAM abdominal muscle flap and the possible use of a saline-filled breast implant in addition to the muscle flap. In the event that a TRAM abdominal muscle flap is used without a breast implant, risks associated with breast implants are not applicable. There is a higher incidence of risk and complications from the use of the TRAM abdominal muscle flap for breast reconstruction than there is with other breast reconstruction techniques. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of women do not experience the following complications, you should discuss each of them with your plastic surgeon to make sure you understand the risks, potential complications, and consequences of breast reconstruction with TRAM abdominal muscle flap.

Bleeding- It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood (hematoma). Do not take any aspirin or anti-inflammatory medications for ten days before surgery, as this may increase the risk of bleeding. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding.

Infection- An infection is quite unusual after this type of surgery. Should an infection occur, treatment including antibiotics or additional surgery may be necessary. Infections with the presence of a breast implant (if used) are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the breast implant may have to be removed. After the infection is treated, a new breast implant can usually be reinserted.

Change in skin sensation- Breast reconstruction cannot resolve normal sensation to your breast or nipple. Skin which is transferred as part of the muscle flap with lack sensation. numbness may occur in the abnormal skin.

Skin scarring- Although good wound healing after a surgical procedure is expected, abnormal scars may occur both within the skin and deeper tissues. Scars may be unattractive and of different color than

surrounding skin tone. There is the possibility of visible marks from sutures used for wound closure. Additional treatments may be needed to treat abnormal scarring after surgery.

Delayed healing and loss of flap- Wound disruption or delayed wound healing is possible. It is possible to have areas of the chest wall or TRAM muscle flap die. This may require frequent dressing changes or further surgery to remove the non-living tissue. Some areas of the chest or muscle flap skin may heal abnormally or slowly when there is reduced blood supply to tissue from prior surgery or radiation therapy treatments.

Smokers have a greater risk of skin or flap loss and wound healing complications.

Fat necrosis- Fatty tissue found in the flap may die. This may produce areas of firmness within the flap. Additional surgery to remove areas of fat necrosis may be necessary. There is the possibility of contour irregularities in the flap from fat necrosis.

Seroma- Pockets of tissue fluid sometimes develop either in the abdomen or in the chest wall after a TRAM abdominal muscle flap breast reconstruction. Additional procedures to drain this fluid accumulation may be necessary.

Breast implants- Risks associated with the potential use of breast implants are covered in separate informed-consent form.

Implant extrusion- Lack of adequate tissue coverage may result in exposure and extrusion of a breast implant, if used, in addition to the TRAM flap. If tissue breakdown occurs and the breast implant becomes exposed, removal is necessary.

Firmness- Excessive firmness of the breast can occur after surgery due to internal scarring or scarring around a breast implant, if one is used. The occurrence of this is not predictable and additional treatment including surgery may be necessary. Radiation therapy to the chest region after breast reconstruction with a TRAM flap may produce unacceptable firmness or other long-term complications.

Pregnancy and breast feeding- There is no evidence that muscle flap surgery has any effect on fertility or pregnancy. However, little information exists concerning the effect of abdominal muscle transfer on labor and delivery. If a woman has undergone a mastectomy, it is unlikely that she would be able to breast feed a baby on the affected side.

Microvascular surgery- Flap loss may result if a blockage occurs at the point of arterial or venous attachment to the TRAM abdominal muscle flap.

Asymmetry- Some breast asymmetry occurs in most women. Differences in breast and nipple shape, size, or symmetry may also occur after surgery. Additional surgery may be necessary to correct asymmetry after a breast reconstruction with TRAM abdominal muscle flap.

Allergic reactions- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may result from drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

Surgical anesthesia- Both local and general anesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

Pulmonary complications- Pulmonary complications may occur secondarily to both blood clots (pulmonary emboli) or partial collapse of the lungs after general anesthesia. Should either of these complications occur, you may require hospitalization and additional treatment. Pulmonary emboli can be life-threatening or fatal in some circumstances.

Breast disease- Current medical information does not demonstrate an increased risk of breast disease, breast cancer, or recurrence of breast cancer in women who have reconstructive breast surgery. Breast disease and breast cancer can occur independently of breast surgery. It is recommended that all women perform regular self-examination of their breasts, have mammograms according to American Cancer Society guidelines, and to seek professional care should a breast lump be detected.

Weakness of abdominal muscle function- Following transfer of abdominal muscle and tissue there is anticipated loss of normal function. Patients may notice feeling of abdominal weakness while doing sit up exercises or similar movements.

Abdominal wall hernia- On rare occasions, the area of the abdominal wall where the muscle has been taken will become weak and produce a hernia. Very rarely, re-operation for repair of this hernia may be necessary. In some cases, a plastic mesh, will be inserted at the time of the breast reconstruction procedure incision closure to help support and reinforce the abdominal wall.

Unsatisfactory result- You may be disappointed with the results of breast reconstruction surgery. Asymmetry may occur after surgery in terms of muscle flap placement or breast shape and size. You may be dissatisfied with the flap placement or location of the surgical scar. It may be necessary to perform additional surgery to improve your results. Breast reconstruction by any technique may fail due to complications attributable to the mastectomy surgery or from chemotherapy/radiation therapy treatments which are independent of the TRAM flap procedure.

ADDITIONAL SURGERY NECESSARY

There are many variable conditions that may influence the long term result of breast reconstruction with TRAM abdominal muscle flap surgery. Secondary surgery may be necessary to perform additional tightening or repositioning of the breasts. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with breast reconstruction with TRAM abdominal muscle flap surgery. Other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied on the results that may be obtained.

HEALTH INSURANCE

Most insurance carriers consider breast reconstruction surgery a covered benefit. However, there may be additional requirements. Please review your health insurance subscriber-information pamphlet, call your insurance company, and discuss this further with your plastic surgeon. Some insurance plans exclude coverage for secondary or revisionary surgery.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, laboratory tests, anesthesia, and hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not

covered. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with revisionary surgery would also be your responsibility.

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatments of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

It is important that you read the above information carefully and have all of your questions answered before signing.