

INFORMED CONSENT - BREAST RECONSTRUCTION WITH TRAM ABDOMINAL MUSCLE FLAP

INSTRUCTIONS

This informed-consent document 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. Please initial each page, indicating that you have read the page, and sign the consent for surgery as proposed by your plastic surgeon and agreed upon by you.

GENERAL INFORMATION

There is 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 TRAM abdominal muscle flap for 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 breast 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 flap 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 TREATMENTS

TRAM abdominal muscle flap breast reconstruction is an elective surgical operation. Alternative treatments would consist of the use of external breast prostheses or padding, tissue expansion technique of breast reconstruction, breast implants, or the transfer of other body tissues for breast reconstruction. Potential risks and complications are associated with alternative surgical forms of treatment.

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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 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 would not be 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) or blood transfusion. Intra-operative blood transfusion may also be required. Do not take any aspirin or anti-inflammatory medications for ten days before or after surgery, as this may increase the risk of bleeding. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding. Hematoma can occur at any time following injury to the breast. If blood transfusions are necessary to treat blood loss, there is the risk of blood-related infections such as hepatitis and HIV (AIDS). Heparin medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

Infection- An infection is unusual after this type of surgery. If an infection occurs, treatment including antibiotics, hospitalization, 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 Nipple and Skin Sensation- Breast reconstruction cannot restore normal sensation to your breast or nipple. Skin that is transferred as part of the muscle flap will lack sensation. Numbness may occur in the abdominal skin. Changes in sensation may affect sexual response or the ability to breast-feed a baby.

Skin Contour Irregularities- Contour and shape irregularities may occur. One breast may be smaller than the other. Nipple position and shape will not be identical one side to the next. Residual skin irregularities at the ends of the incisions or "dog ears" are always a possibility when there is excessive redundant skin. This may improve with time, or it can be surgically corrected.

Sutures- Most surgical techniques use deep sutures. You may notice these sutures after your surgery. Sutures may spontaneously poke through the skin, become visible or produce irritation that requires suture removal.

Skin Discoloration / Swelling- Some bruising and swelling normally occurs following a breast reconstruction. The skin in or near the surgical site can appear either lighter or darker than surrounding skin. Although uncommon, swelling and skin discoloration may persist for long periods of time and, in rare situations, may be permanent. Additionally, these areas may have exaggerated responses to hot or cold temperatures.

Scarring- All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of different color than the surrounding skin tone. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the right and left side of the body). There is the possibility of visible marks in the skin from sutures. In some cases, scars may require surgical revision or treatment.

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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. Individuals who have decreased blood supply to breast tissue from past surgery or radiation therapy may be at increased risk for delayed wound healing and poor surgical outcome. **Smokers have a greater risk of skin loss and wound healing complications.**

Damage to Deeper Structures- There is the potential for injury to deeper structures including nerves, blood vessels, muscles, and lungs (pneumothorax) during any surgical procedure. The potential for this to occur varies according to the type of procedure being performed. Injury to deeper structures may be temporary or permanent.

Fat Necrosis- Fatty tissue found in the flap or skin may die. This may produce areas of firmness within the skin. Additional surgery to remove areas of fat necrosis may be necessary (breast biopsy). There is the possibility of contour irregularities in the skin that may result from fat necrosis.

Seroma- Pockets of tissue fluid sometime 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 a 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.

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

Allergic Reactions- In rare cases, local allergies to tape, suture material and glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur in response to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

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

Weakness of Abdominal Muscle Function- Following transfer of abdominal muscle and tissue there is anticipated loss of normal function. Patients may notice a 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.

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Unsatisfactory Result- Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. You may be disappointed with the results breast reconstruction surgery. Asymmetry in muscle flap placement, unanticipated breast shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. Breast size may be incorrect. Unsatisfactory surgical scar location or visible deformities at the ends of the incisions (dog ears) may occur. Breast reconstruction by any technique may fail due to complications attributable to the mastectomy surgery or from chemotherapy/radiation therapy treatments that are independent of the TRAM flap procedure. It may be necessary to perform additional surgery to improve your results.

Shock- In rare circumstances, your surgical procedure can cause severe trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment would be necessary.

Pain- You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after surgery. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue after breast reconstruction.

Thrombosed Veins- Thrombosed veins, which resemble cords, occasionally develop in the area of the breast and resolve without medical or surgical treatment.

Cardiac and Pulmonary Complications- Surgery, especially longer procedures, may be associated with the formation of, or increase in, blood clots in the venous system. Pulmonary complications may occur secondarily to both blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs after general anesthesia. Pulmonary emboli can be life threatening or fatal in some circumstances. Inactivity and other conditions may increase the incidence of blood clots traveling to the lungs causing a major blood clot that may result in death. It is important to discuss with your physician any past history of blood clots or swollen legs that may contribute to this condition. Cardiac complications are a risk with any surgery and anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heart beats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

ADDITIONAL ADVISORIES

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 had reconstructive breast surgery. Breast disease and breast cancer can occur independently of breast surgery. Individuals with a personal history or family history of breast cancer may be at a higher risk of developing breast cancer than a woman with no family history of this disease. It is recommended that all women perform regular self-examination of their breasts, have mammograms according to American Cancer Society guidelines, and seek professional care should a breast lump be detected.

Interference with Sentinel Lymph Node Mapping Procedures- Breast surgery procedures that involve cutting through breast tissue, similar to a breast biopsy, can potentially interfere with diagnostic procedures to determine lymph node drainage of breast tissue to stage breast cancer.

Breast and Nipple Piercing Procedures- Individuals who currently wear body-piercing jewelry in the breast region are advised that a breast infection could develop from this activity.

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.

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Long-Term Results- Subsequent alterations in breast shape may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause, or other circumstances not related to your surgery. Breast sagging may normally occur.

Female Patient Information- It is important to inform your plastic surgeon if you use birth control pills, estrogen replacement, or if you suspect you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

Intimate Relations After Surgery- Surgery involves coagulating of blood vessels and increased activity of any kind may open these vessels leading to a bleed, or hematoma. Increased activity that increased your pulse or heart rate may cause additional bruising, swelling, and the need for return to surgery and control bleeding. It is wise to refrain from sexual activity until your physician states it is safe.

Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray)-

Patients who are currently smoking, use tobacco products, or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin dying, delayed healing, and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smoking may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complication. Please indicate your current status regarding these items below:

_____ I am a non-smoker and do not use nicotine products. I understand the risk of second-hand smoke exposure causing surgical complications.

_____ I am a smoker or use tobacco / nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

It is important to refrain from smoking at least 6 weeks before surgery and until your physician states it is safe to return, if desired.

Medications- There are potential adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

Mental Health Disorders and Elective Surgery- It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery and often are stressful. Please openly discuss with your surgeon, prior to surgery, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

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ADDITIONAL SURGERY NECESSARY

Many variable conditions 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. In some situations, it may not be possible to achieve optimal results with a single surgical procedure.

PATIENT COMPLIANCE

Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon. Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

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. **Many 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 surgeon, the cost of surgical supplies, anesthesia, laboratory tests, and possible outpatient 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. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with revision surgery will also be your responsibility. **In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.**

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s), including no surgery. 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 that is based on all the facts in your particular case and the current 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 the consent on the next page.

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CONSENT FOR SURGERY / PROCEDURE or TREATMENT

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

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I have received the following information sheet:

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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 judgment 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 involve risk and the possibility of complications, injury, and sometimes death.
4. I acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained.
5. I consent to be photographed or televised before, during, and after 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 consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
9. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
10. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
11. I realize that not having the operation is an option.
12. IT 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

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-12). I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

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Date _____	Witness _____
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