

Dr. James B. Lowe – Plastic Surgery
FREE FLAP RECONSTRUCTION WITH POSSIBLE SKIN GRAFT & ADJACENT
TISSUE TRANSFER INFORMATION SHEET AND INFORMED CONSENT

Instructions

This is an informed consent document that has been prepared to assist your plastic surgeon to inform you concerning free flap surgery, its risks, and alternative treatment.

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.

INTRODUCTION

Flap reconstruction or adjacent tissue transfer is the movement of tissue from one place to another on the body. Flaps can be moved from any area of the body from head to toe. Often patients have defects that are created or holes left by other surgeons that need closure. Plastic surgeons use a variety of techniques to close complex wound that involve the movement of tissue from one place to the other. Plastic surgeons usually attempt to manage a defect with the simplest approach first that is associated with the least amount of risk or deformity. Often time patients with large defects will require multiple procedures to maximize the results. The risk of flap surgery relates to the size and location of a defect and the reconstructive procedure planned. In some cases Dr. Lowe will want to obtain a special study such as a MRI, CAT scan, or arteriogram to evaluate a defect and its involvement.

Flap reconstruction can be performed in a variety of ways. Flaps can be moved from an area that is close or far from a defect. When a flap is moved a long distance from a defect the risk of the procedure increase a great deal. Flaps that are detached and attached back to the body are called “free flaps.” Free flaps need to be re-attached to the body using microscopes and often require a greater time in the operating room and hospital. Free flaps require a great deal of preparation and surgical time to perform. These flaps require a great deal of recovery and care after surgery as well. Flaps are harvested from a variety of places in the body and are transferred to the area of a complex soft tissue defect. Your plastic surgeon will describe the type of free flap that you are undergoing in further detail.

ALTERNATIVE TREATMENT

All patients undergoing free flap reconstruction with skin grafts or adjacent tissue transfers should discuss with the surgeon the alternative treatments. Many times there are a number of options available. There is the option to not undergo the reconstruction or get a second opinion about the reconstructive option best for you. Each reconstructive option has it own risk and benefits and questions regarding alternative forms of treatment should be discussed with Dr. Lowe.

RISKS OF FREE FLAP RECONSTRUCTION WITH SKIN GRAFT AND ADJACENT TISSUE TRANSFER

Free Flap reconstructive surgery involves the movement of tissue from one are to another. This movement of tissue may result in loss of function or disability. With any type of activity there is inherent risk. An individual’s choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of patients 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 surgery.

Free Flap Reconstruction with Skin Graft & Adjacent Tissue Transfer

Bleeding – It is possible, though unusual, that you may have problems with bleeding during or after surgery. Should postoperative bleeding occur, it may require emergency treatment to stop the bleeding or a trip back to the operating room. Certain flap operations are more prone to bleeding (i.e. face or scalp). Often these areas will bleed for several hours and then stop. When a large amount of tissue is moved particularly when procedures are combined there may be a need for blood transfusion. Do not take any aspirin or anti-inflammatory medications for ten days before surgery, as this contributes to a greater risk of bleeding. Hypertension (high blood pressure) that is not under good medical control may cause bleeding during or after surgery. Accumulations of blood under the skin may delay healing and cause scarring.

Blood clots / deep vein thrombosis – Free flap reconstruction surgery may require a significant period of time to perform. Although any operations can be associated with a blood clot in the legs, it is more likely following more lengthy operations. It is important to note that birth control pills and other medications can increase your risk of this problem. After surgery patients must make every effort to be active and ambulate while in the hospital and at home. Deep vein thrombosis can be a potentially life threatening complication that may require further medical care and expense.

Fluid collections – Fluid collections can form in the period following free flap surgery. These collections are called seromas and may be prevented by the use of compression or drains. If the patient develops a fluid collection it may require multiple tapping, medical treatment, a new drain, or a trip back to the operating room.

Infection – Infection may occur after free flap reconstructive surgery and the risk depend on the area of surgery and the overall health of the wound and patient. Should an infection occur, additional treatment including antibiotics may be necessary. Infection can cause surgical wound to open and result in scarring. Infection is not uncommon in patients with open wounds or inflammation in the area of the skin lesion.

Scarring – Although good wound healing after a surgery is expected, abnormal scars occur both within the skin and deeper tissues. Scars may be unattractive and of different color than surrounding skin. There is the possibility of visible marks from sutures. Additional treatments including surgery may be needed to treat scarring. Scarring is dependent of the size and area of the defect. A scar will be required in the area of flap harvest as well as around the area of the soft tissue defect. Further scars may be required to harvest tissue such as nerves, skin, or blood vessels for reconstruction.

Scar length – The length of your scars with Free Flap surgery is related to the size of the defect and procedure performed. Often the surgeon will limit the scar but need to lengthen it in the future if redundancy does not settle out.

Skin compromise – Certain flap procedures require significant undermining and can be associated with separation of the wound. This wound separation will require local wound care and scar revision. Wound separation may be the result of skin death or infection and certain areas are more prone to this problem than others. Smoking will compromise the skin, so patients can not smoke for 2 months prior to surgery and at least one month after surgery. Avoid the sun for 6 months after surgery. Radiation will significantly increase the risk of wound problems including scarring, infection, and wound healing in general.

Damage to deeper structures – Deeper structures such as nerves, blood vessels, and muscles may be damaged during the course of surgery. The potential for this to occur varies with the type of flap procedure. Injury to deeper structures may be temporary or permanent. Undermining or flaps are often associated with post operative pain or numbness which usually resolves within several months. Any

Free Flap Reconstruction with Skin Graft & Adjacent Tissue Transfer

procedure requiring a great deal of skin or soft tissue undermining or movement will result in numbness and pain.

Unsatisfactory result – Free Flap reconstruction can result in a deformity that is greater than anticipated. Dr. Lowe tries to offer patients the best cosmetic result in a timely way while taking into account your medical problems and personal wishes. There is the possibility of an unsatisfactory result from the free flap reconstructive surgery. The surgery may result in unacceptable visible or tactile deformities, loss of function, or structural mal-position. You may be disappointed that the results of surgery do not meet your expectations and additional surgery may be necessary should the result be unsatisfactory. It should be noted that free flaps are usually performed as a surgery of last resort. These surgeries are lengthy and at times unpredictable, and expectations should be limited in terms of cosmetic outcomes, scars, or disabilities.

Numbness – Permanent numbness following free flap reconstructive surgery is expected in the donor area and soft tissue defect. The occurrence of this is not predictable. It is rare for numbness to improve after 12 months, but numbness may not totally resolve in many cases. As nerves recover they may become hypersensitive or even painful. Sometimes a nerve will need to be removed or cut during the surgery.

Asymmetry – The human body is normally asymmetrical. There can be a variation from one side to the other in the results obtained body contouring. If a surgical scar is required it is unlikely to ever be completely symmetric. If a flap is moved from one area to another this will come at some cost in symmetry.

Swelling – It is not unusual for the free flap or area of surgery to swell for some period of time. Flaps often swell a significant amount in the period after surgery. Some flaps particularly on the extremities may be more prone to swelling. The area where a flap was harvested may swell as well. Swelling or edema may be chronic or permanent in some situations. Swelling can cause a free flap to fail in some cases.

Chronic pain – Chronic pain may occur infrequently after free flap with skin graft and adjacent tissue transfer procedures. Chronic pain can usually be managed by a pain specialist or medications.

Skin irregularity – Skin irregularities, bumps, and areas of stiffness usually occur after free flap reconstructive procedures. Most of these areas resolve with time but some irregularities may be permanent or require revision. External massage techniques may be helpful in some situations.

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

Delayed healing – Wound disruption or delayed wound healing is expected following free flap reconstruction in the donor site or soft tissue defect. Some areas of the body may not heal normally and may take a long time to heal particularly in the areas of infection or radiation. Skin compromise may require frequent dressing changes or further surgery to remove the non-healed tissue.

Long term effects – Often patient have long term problems after free flap surgery. These problems may include pain, swelling, or loss of function. Some problems relate to scarring and inflammation. It is important to remember to avoid sun exposure for 6 months after flap reconstructive surgery procedures. Scars tend to fade with time but will be significantly harmed by sun exposure.

Free Flap Reconstruction with Skin Graft & Adjacent Tissue Transfer

Need for revision – Certain free flap operations are more likely to require revision surgery or fail. In sensitive areas Dr. Lowe will often tell you to expect a number of reconstructive stages to optimize the results. This may involve scar revision, liposuction, tissue thinning, Dermabrasion, steroid injections, or new flap procedures.

Staged procedures – When the free flap reconstructive surgery is large, a staged reconstruction may be necessary. This may involve moving tissue from one area to the next and creating a new defect in the process. Often local tissue will be moved with an attachment that must be divided at a later date. These staged procedures are often necessary to obtain the best results.

Functional alterations – Changes may occur after surgery that may limit a patient's function. Patients may recover at different rates following free flap surgery, but the more surgery you have done the more difficult the recovery. Flaps that involve the harvest or movement of muscle will result in loss of function of the muscle moved. Flaps that involve the movement of soft tissue only usually leave a greater scar without loss of muscle function.

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. If you are over 45 years of age, have a known medical condition, or you are in any way concerned, a pre-operative evaluation from your primary care physician or cardiologist is recommended prior to surgery.

Flap Failure or Flap Death – Not all reconstructive free flaps with skin grafts and adjacent tissue transfers are successful. Flaps can fail for a variety of reasons from poor blood flow, trauma, clot, or inflammation. If the free flap or adjacent tissue transfer fails other procedures or operations may be required. In some cases no other reconstructive options may be available. Certain types of flaps have a higher failure rate such as those to the lower extremity. Sometimes a flap will fail in some areas but not entirely. Radiation or injury to the local area may increase the rate of failure of your reconstruction. Infection or bleeding may play a role in the loss of a flap. Free flaps require a great deal of expertise to perform and have a higher complete failure rate due to the complexity of the operation. Your surgeon will discuss the risk of failure and options if failure occurs prior to your surgery. It is important that physicians involved in the patient's care, the family, and patient are diligent in post-operative instructions and watching the area of concern.

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.

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 and fat 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

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

Medications- There are many 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. 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.

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, smokers 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. Free flaps usually fail in patients who smoke after surgery.

HEALTH INSURANCE

Most health insurance companies cover free flap reconstruction with skin grafts and adjacent tissue transfers. Insurance companies often require plastic surgeons to obtain permission to perform and elective flap reconstruction in advance. Insurance companies may require photographs of the defect for documentation prior to surgery. If you request Dr. Lowe to proceed with a free flap reconstruction without insurance permission you may be responsible for unpaid fees to the pathologist or Dr. Lowe. Please, carefully review your health insurance subscriber-information pamphlet and discuss any questions with Dr. Lowe.

ADDITIONAL SURGERY NECESSARY

There are many variable conditions in addition to risks and potential surgical complications that may influence the long term result from free flap reconstructive surgery. Even though risks and complications occur infrequently, the risks cited are particularly associated with reconstruction. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. 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. Infrequently, it is necessary to perform additional surgery to improve your results.

Free Flap Reconstruction with Skin Graft & Adjacent Tissue Transfer

PATIENT COMPLIANCE

Free flap reconstruction with skin grafts and adjacent tissue transfer surgery are vulnerable to failure if post operative precautions and instructions are not followed. 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 splints should not be removed unless instructed by your plastic surgeon. 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 and rehabilitation, return for aftercare, and promote your recovery after 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 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-payment, deductibles, and charges not covered. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day surgery charges involved with revision surgery not covered by your insurance would also be your responsibility.

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). This 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 the consent below.

CONSENT FOR SURGERY/PROCEDURE or TREATMENT

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

I have received the following information sheet:

**INFORMED CONSENT FOR FREE FLAP RECONSTRUCTION
WITH POSSIBLE SKIN GRAFT AND ADJACENT TISSUE TRANSFER SURGERY**

2. I recognize that during the course of the operations 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 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. **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 including those listed above.
 - D. I have read, understood, and have had the opportunity to ask questions concerning the above, as well as the Informed Consent for Flap Reconstruction and Adjacent Tissue Transfer Information sheet.
 - E. I am satisfied with the explanation.

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9).

Patient or Person Authorized To Sign for Patient.

Date

Witness