

CONSENT FOR SOFT TISSUE EXCISIONS

Dr. James B. Lowe – Plastic Surgery SOFT TISSUE SURGERY 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 soft tissue 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

Soft tissue surgery may involve the removal of a soft tissue mass or reconstruction of any area of the body under the skin. Soft tissue masses or tumors exist under the skin in the soft tissue of the human body. These lesions usually represent benign processes, but can in rare cases may be malignant or cancers. Plastic surgeons are often asked to perform soft tissue surgery to remove or biopsy masses under the skin and have a great deal of experience with these procedures. Soft tissue surgery may be performed in any number of locations on the human body from head to toe. The risk of soft tissue surgery often relates to the size and location of a mass or lesion. In some cases Dr. Lowe will want to obtain a special study such as a MRI or CAT scan to evaluate the lesion and its involvement.

Your plastic surgeon may give an opinion about the particular nature of a soft tissue mass, but a definitive diagnosis often requires removal. A needle biopsy of a soft tissue mass rarely tells the patient exactly what the lesion is. Once the lesion or soft tissue mass is removed the surgeon will tell you if any further procedures are indicated. It is important to note that no physician can ever be absolutely sure of any soft tissue mass and even skin biopsy can be in-accurate at times. Therefore, each patient must participate in their own health by informing their physician of areas of concern or change. Plastic surgeons role in this area is primarily as a technician for removal of lesions.

Soft tissue procedures usually involve operations that attempt to remove and/or reconstruct the area of concern. If a soft tissue lesion has been present for some time and has not changed, surgery may not be indicated. Often the soft tissue surgery or the removal of a soft tissue mass is up to the patient. Masses should be removed if they are rapidly growing, deforming, painful, or restricts activity. Most insurance companies require plastic surgeons to obtain permission to perform soft tissue surgery or remove soft tissue masses from patients. This means that your plastic surgeon may need to submit a photograph and wait for approval for surgery. Small masses in non-sensitive areas can often be removed in the surgeon's office, large masses in sensitive areas may need to be performed in an hospital operating room.

Patients who develop soft tissue masses often develop them in other places or in the same area. The indications for removal of each lesion should be considered individually. Often times several soft tissue masses can be removed at the same time. In summary, many soft tissue masses are benign, and, therefore patients must fully consider the risks and benefits of surgery in advance. Your plastic surgeon will review the risk and benefits of your surgery in some detail in the office and this information and consent should assist you in making an informed decision regarding treatment.

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ALTERNATIVE TREATMENT

All patients with soft tissue masses or lesions should undergo professional evaluation. However, there are alternative forms of soft tissue mass management that consist of observation, injection treatments, radiation, or non-surgical management. Each option has its own risk and benefits and questions regarding alternative forms of treatment should be discussed with Dr. Lowe.

RISKS OF SOFT TISSUE SURGERY

Soft tissue surgery involves removal and/or closure of the area of concern. The removal of the lesion is usually more straight-forward than the closure or reconstruction. 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.

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 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 removed particularly when procedures are combined there may be a need for blood transfusion. Once your surgery has been scheduled 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 – Soft tissue surgery usually requires a short period of time. 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. When discussing the length of the operation with Dr. Lowe remember that more is not always better. 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 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 is quite unusual after soft tissue surgery. 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.

Contour irregularities- Contour and shape irregularities may occur after surgery. Residual skin irregularities at the ends of the incisions or “dog ears” are always a possibility when there is 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 removal.

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Skin discoloration / Swelling- Some bruising and swelling normally occurs following surgery. 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.

Scarring – Although good wound healing after a surgery is expected, abnormal scars may 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.

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

Skin compromise – Certain soft tissue 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.

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

Unsatisfactory result – Removing any soft tissue mass can often result in a defect greater than what was 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 soft tissue 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.

Numbness – There is the potential for permanent numbness following soft tissue surgery. The occurrence of this is not predictable. It is rare to have numbness past 6 months, but numbness may not totally resolve in some 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.

Chronic pain – Chronic pain may occur very infrequently after soft tissue procedures.

Skin irregularity – Skin irregularities, bumps, and areas of stiffness usually occur after soft tissue 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.

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Delayed healing – Wound disruption or delayed wound healing is possible. Some areas of the body may not heal normally and may take a long time to heal. Skin compromise may require frequent dressing changes or further surgery to remove the non-healed tissue.

Long term effects – It is important to remember to avoid sun exposure for 6 months after soft tissue surgery procedures. Sun tanning can result in tissue loss and scarring even when a bathing suit covers the area. Scars tend to fade with time but will be significantly harmed by sun exposure. Sun exposure will also increase your risk of future skin cancers.

Need for revision – Certain soft tissue operations are more likely to require revision surgery. 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, Dermabrasion, steroid injections, and laser treatments.

Staged procedures – When the soft tissue 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 soft tissue surgery that may limit a patient's function. Patients may recovery at different rates following surgery, but the more surgery you have done the more difficult the recovery.

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.

Cardiac and Pulmonary Complications- Surgery performed in a hospital or under general anesthesia, 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. Air travel, 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 or strokes 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.

Recurrent of Soft Tissue Lesion or Failure to Cure – Soft tissue lesions may recur and this relates to the type of mass, its location, and the treatment choice. If the surgeon removes a soft tissue mass, the sample may later show an incomplete removal. A re-excision may be attempted or a different surgical approach taken. Sometimes the pathologist can misinterpret a margin or the type of soft tissue mass. Certain techniques increase the chances of complete removal of some soft tissue masses. Certain types of soft tissue masses that are removed may require other treatments such as radiation, node biopsy, or radical excisions. It is important that physicians involved in the patients care, the family, and patient are diligent in watching the area of concern.

HEALTH INSURANCE

Most health insurance companies cover soft tissue operations. Insurance companies often require plastic surgeons to obtain permission to remove skin lesions in advance. Insurance companies may not allow the

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remove of certain types of lesions and photographs may be required for documentation. If you request Dr. Lowe to proceed with a soft tissue surgery without 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 soft tissue surgery. Even though risks and complications occur infrequently, the risks cited are particularly associated with soft tissue procedures. 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.

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.

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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:

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- 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 Soft Tissue Surgery 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