Dr. James B. Lowe – Plastic Surgery SKIN AND SOFT TISSUE INJURY 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 skin and 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

Skin and soft tissue surgery is frequently performed by plastic surgeons. Skin lacerations or open wounds result from trauma or unexpected injury. These injuries may result in injury to deeper structures such as nerves or blood vessels. These injuries are usually contaminated with a high risk of local debris or infection. Your plastic surgeon will give you an opinion about how to treat your skin injury. This may involve cleaning and closing the wound or leavening the skin open to heal on its own or to close at a later date. It is important to note that no physician can ever be absolutely sure of the best way to treat every skin injury. Therefore, each patient must participate in their own wound care and follow-up. Each patient or their family is expected to keep the physician informed of areas of concern or change.

Skin trauma procedures usually involve operations that attempt to remove dead or damaged tissue and then close and/or reconstruct the area of concern. If a wound is highly contaminated or shows signs of infection it might need to be sampled or removed prior to definitive closure. Based on the skin sample a plan may be devised for observation or local treatment. Wounds that are closed may become red and infected following surgery and require opening and drainage. Plastic surgeons often treat skin trauma that involve large or sensitive areas. In these cases, surgery may need to be staged and performed in an operating room at a hospital or surgical facility. In cases of severe local trauma or injury multiple surgeries are often required to maximize results.

There are a number of surgeons qualified to close open or traumatic wounds. Many times larger or more complex injuries can best be treated by a board certified Plastic Surgeon. However, it is always a good idea to seek second opinions and ideas when addressing complex issues. Successful treatment of acute skin injury requires a commitment from the patient and all those involved in the patient's care. It is also important to wear appropriate skin cover and skin screens after surgery particularly in the summer months. In summary, skin trauma and complex wounds are a team effort that often involves the combined skills of the patient, patient's family, primary care physician, and plastic surgeon.

ALTERNATIVE TREATMENT

All patients with skin and soft tissue trauma should undergo evaluation. There are a number of alternative forms of management that consist of undergoing topical treatments, wound care, delayed closure, observation, or surgery. Patients and their families may elect to simply observe the area of concern. Each option has it own potential risks and benefits. Questions regarding alternative forms of treatment should be discussed with Dr. Lowe.

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RISKS OF SKIN AND SOFT TISSUE SURGERY

Skin and soft tissue surgery involves removal and/or closure of the area of concern. The removal of dead tissue and preparing the wound 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 a comparison of the risks and benefits. 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 skin surgery.

<u>Bleeding</u> – 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 skin 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. 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.

<u>Blood clots / deep vein thrombosis</u> – Skin surgery usually does not require a long 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 or surgery preformed under general anesthesia. 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.

<u>Fluid collections</u> – Fluid collections can form in the period following skin procedures. 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.

<u>Infection</u> – Infection is quite unusual after most skin lesion surgery unless there are open areas, infection, or drainage from the wound prior to surgery. Should an infection occur, additional treatment including antibiotics may be necessary. Infection can cause surgical wound to open and result in extended wound care and scarring. Remember infection with wound break-down is not uncommon in patients with open wounds or inflammation in the area of the skin lesion.

<u>Contour irregularities</u> 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.

<u>Sutures</u>- 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.

<u>Skin discoloration / Swelling-</u> 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.

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<u>Scarring</u> – 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.

<u>Scar length</u> – The length of your scars with skin lesion 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.

<u>Skin compromise</u> – Certain skin and 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 should not smoke for 2 months prior to surgery and at least one month after surgery. Avoid the sun for 6 months after surgery.

<u>Damage to deeper structures</u> – Deeper structures such as nerves, blood vessels, and muscles may be damaged during the course of surgery or as a result of the trauma. The potential for this to occur varies with the type and extent of the injury. 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 permanent numbness and pain.

<u>Unsatisfactory result</u> – Some skin lesions may not be malignant or have a low probability of being malignant. In these cases the patient must weigh the risk of surgery with the benefits of lesion removal. In the case of skin cancer it is usually best to treat the cancer first. Treating the cancer can often result in a defect greater than what was anticipated. Regardless of the type of lesion, 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 skin surgery. The surgery may result in unacceptable visible or tactile deformities, loss of function, or structural malposition. 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.

<u>Numbness</u> – There is the potential for permanent numbness following skin trauma and reconstructive 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 skin cancer surgery.

<u>Asymmetry</u> – The human body is normally asymmetrical. There can be a variation from one side to the other in the results obtained from skin surgery. If a surgical scar is required it is unlikely to ever be completely symmetric.

<u>Chronic pain</u> – Chronic pain may occur very infrequently after skin trauma procedures. In cases of extensive skin and soft tissue injury particularly when in proximity to major local nerves the likelihood of chronic pain increases.

<u>Skin irregularity</u> – Skin irregularities, bumps, and areas of stiffness usually occur after skin procedures. Most of these areas resolve with time but some irregularities may be permanent or require revision. External message techniques may be helpful in some situations.

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<u>Allergic reactions</u> – 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.

<u>Delayed healing</u> – 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. The dirtier the wound is the higher the likelihood of infection and delayed wound healing.

<u>Long term effects</u> – It is important to remember to avoid sun exposure for 6 months after skin 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 lesions or cancers.

<u>Need for revision</u> – Certain skin 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. Dr. Lowe may need to refer you to some one else if he does not have access to the appropriate treatment device.

<u>Staged procedures</u> – When the skin defect following trauma are significant, a staged reconstruction may be necessary. This may involve moving tissue from one are 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.

<u>Functional alterations</u> – Changes may occur after skin and soft tissue surgery that may limit a patient's function. Patients may recover at different rates following skin surgery, but the more surgery you have done the more difficult the recovery.

<u>Surgical anesthesia</u> – 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 or Dr. Lowe are in any way concerned, a preoperative evaluation from your primary care physician or cardiologist is recommended prior to surgery.

<u>Failure to Cure</u> – Complex wounds may be difficult to correct even with multiple procedures. It is unlikely in those cases that the results will be ever as good as prior to the injury. In such cases, the plastic surgeon may utilize the expertise of other specialist to optimize the result and recovery. The result usually relates to the type of skin injury, its location and extent, and the treatment choice. Certain types of skin trauma require other interventions such as a prosthesis or make-up for coverage. It is important that physicians involved in the patients care, the family, and patient are diligent in watching the area of concern.

ADDITIONAL ADVISORIES

<u>Female Patient Information</u>. 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.

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

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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.

Mental Health Disorders and Surgery- It is important that all patients seeking to undergo 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 surgery, effects on mental health cannot be accurately predicted.

<u>Medications-</u> 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 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.

ADDITIONAL SURGERY NECESSARY

There are many variable conditions in addition to risks and potential surgical complications that may influence the long term result from skin and soft tissue surgery. Even though risks and complications occur infrequently, the risks cited are particularly associated with skin 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. Often it is necessary to perform additional surgery to improve or optimize your results.

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. 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.

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HEALTH INSURANCE

Most health insurance companies cover skin and soft tissue operations. Insurance companies often require plastic surgeons to obtain permission to remove skin lesions in advance. Insurance companies may not allow the remove of certain types of lesions and photographs may be required for documentation. If you request Dr. Lowe to proceed with a skin lesion removal without permission you may be responsible for unpaid fees to the pathologist or Dr. Lowe. Most health insurance companies exclude coverage for cosmetic surgical operations and any complications that might occur from cosmetic surgery. Please carefully review your health insurance subscriber information pamphlet. **Most 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 your 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 which 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.

CONSENT FOR SURGERY/PROCEDURE or TREATMENT

1.	I hereby authorize DrLowe and such assistants as may be selected to perform the following procedure or treatment. SKIN AND SOFT TISSUE SURGERY
	I have received the following information sheet: INFORMED CONSENT FOR SKIN AND SOFT TISSUE SURGERY
2.	I recognize that during the course of the operations and medical treatment or anesthesia, unforeseer 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 Skin and Soft Tissue Surgery information sheet. E. I am satisfied with the explanation.
IC	CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9).
Pa	tient or Person Authorized To Sign for Patient.
— Da	te Witness

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