

Dr. James B. Lowe – Plastic Surgery
HIDRADENITIS RECONSTRUCTION
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 chronic infection of the skin and hidradenitis suppurativa 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

The disease hidradenitis suppurativa is one of the most difficult and chronic conditions facing patients and physicians. It is a condition that can affect patients in a number of different areas such as the axilla, breast, face, groin, and thigh. It can range from isolated and mild areas of involvement to diffuse and extensive disease. Often patients have been managed unsuccessfully with antibiotics and wound care. Patients are often angry and frustrated with the disease and their doctors.

Hidradenitis suppurativa is a disease of the oil glands. These glands become chronically inflamed and infected resulting in pain and drainage. The successful treatment of the disease must combine medical and surgical management. Medical management includes medications to control the chronic infection and the oil glands themselves. Often surgeons will want a dermatologist or primary care physicians to assist in controlling the oil glands before surgery is considered. Surgical treatment for this disease is required when medical management fails or not successful alone. Surgery is used to treat isolated areas but is rarely successful at removing all areas of disease.

The surgical treatment of hidradenitis depends on the extent of the disease and the condition of the patient. Our approach to the management of this disease is to perform targeted surgical treatments in a staged manner. The worse areas of disease are excised first without the need for extensive reconstruction or skin grafting when possible. Areas of disease are cleaned and removed and the wounds are then allowed to heal. After the worse areas heal the other areas are then addressed.

It is important to note that patient's with hidradenitis have chronic infections. These infections are complex and do not respond to antibiotics alone. Therefore, the wounds are often prone to opening and drainage after intervention. Patients must be prepared to manage wounds carefully with local wound care and packing. Often times the post-operative wounds can be partially opened and managed with antibiotics until they fully heal. Out-patient cleanliness and meticulous wound care is the most important part these staged procedures. Procedures are usually staged at 2-4 month intervals to allow for complete wound healing and recovery.

The surgical management of hidradenitis may require simple excisions, skin grafts, flaps, or adjacent tissue transfer. Skin grafts require the harvest of skin from a distant area such as the thigh or groin. A flap 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 the disease that need closure. Plastic surgeons use a variety of techniques to close complex

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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. Your plastic surgeon will describe the type of surgery that is best for you in further detail.

ALTERNATIVE TREATMENT

All patients undergoing hidradenitis reconstruction 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 its own risk and benefits and questions regarding alternative forms of treatment should be discussed with Dr. Lowe.

RISKS OF HIDRADENITIS RECONSTRUCTION

Hidradenitis reconstructive surgery involves the removal of sick or inflamed tissue and the closure or partial closure of the wound. Most wounds require extensive washout and drain placement to allow the egress of fluid and infected material. The closure of the wound 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.

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 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 – Hidradenitis 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 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 not unusual after Hidradenitis reconstructive surgery. Should a post-surgical infection occur, additional treatment including antibiotics may be necessary. Infection can cause surgical wound to open and result in scarring. Post-surgical infection is not uncommon in patients with

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Hidradenitis or chronic inflammation in the area of the disease because infection is already present in most cases.

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.

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 – Scarring is usually significant of surgical treatment of Hidradenitis. 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 Hidradenitis 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 Hidradenitis 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 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 procedure requiring a great deal of skin or soft tissue undermining or movement will result in numbness and pain.

Unsatisfactory result – Hidradenitis 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 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.

Numbness – There is the potential for permanent numbness following 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 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

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completely symmetric. If a flap is moved from one are to another this will come at some cost in symmetry.

Swelling – In Hidradenitis reconstruction it is not unusual for the area of disease to swell for some period of time. Surgical sites often swell a significant amount in the period after surgery. Some areas treated such as the groin, axilla, and the extremities may be more prone to swelling. The area where a tissue is as harvested may swell as well. Swelling or edema may be chronic or permanent in some situations.

Chronic pain – Chronic pain may occur very infrequently after Hidradenitis 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 Hidradenitis reconstructive 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.

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 Hidradenitis surgery. Some areas of the body may not heal normally and may take a long time to heal. Skin compromise requires frequent dressing changes or further surgery to remove the non-healed tissue.

Long term effects – Often patient have long term problems after Hidradenitis surgery. These problems may include pain 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.

Need for revision – Most Hidradenitis reconstructive operations 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 multiple washouts, scar revision, liposuction, tissue thinning, Dermabrasion, or steroid injections. Some wounds will require open management or VAC wound treatments for extended periods before revision surgery is planned. Some disease is so severe that further surgical procedures may not be warranted.

Staged procedures – Most Hidradenitis reconstructive surgery requires multiple staged procedures. This requires the patient to be compliant with the wound care and follow-up instructions over an extended period of time. When the disease is severe the first stages simply address the removal of infection or diseased areas. In subsequent surgical procedures patients wounds are more aggressively managed. Medical management is vital to the long term success of the surgical procedures.

Functional alterations – Changes may occur after 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. Reconstructions 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 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.

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Flap or Skin Graft Failure – Not all reconstructive flaps or adjacent tissue transfers are successful. Flaps or skin grafts can fail for a variety of reasons from poor blood flow, trauma, clot, or infection. If the flap, adjacent tissue transfer, or skin graft fails, other procedures or operations may be required. Certain types of reconstructive procedures have a higher failure rate such as those associated with a great deal of inflammation or infection. Sometimes a reconstruction 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 roll in the loss of a flap. Certain 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 patients care, the family, and patient are diligent in watching the area of concern.

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.

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. A Hidradenitis surgery may not improve complaints of musculoskeletal pain. 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 Hidradenitis surgery.

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

Additional Advisories Regarding Hidradenitis Surgery

Interference with Sentinel Lymph Node Mapping Procedures- Hidradenitis surgery in the area of the breast 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 surgical region are advised that a breast infection could develop from this activity.

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

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

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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.

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. Activity that increases your pulse or heart rate may cause additional bruising, swelling, and the need for return to surgery and to control bleeding. It is wise to refrain from sexual activity until your physician states it is safe.

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.

ADDITIONAL SURGERY NECESSARY (Re-Operations)

There are many variable conditions that may influence the long-term result of Hidradenitis surgery. Secondary surgery is almost always necessary to address persistent disease or recurrent disease. Should complications occur, additional surgery or other treatments may be necessary. There is the possibility Hidradenitis surgery may require revision due to scar or asymmetry. Even though serious risks and complications occur infrequently, the risks cited are particularly associated with Hidradenitis 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

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achieve optimal results with a single surgical procedure. **Expect multiple operations to treat your disease in most cases.**

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

Depending on your particular health insurance plan, Hidradenitis surgery may be considered a covered benefit. Most insurance companies do not like staged procedures and will only approve one stage at a time. There may be additional requirements in terms of revision or persistent disease related to Hidradenitis surgery. Insurance companies often require plastic surgeons to obtain permission to perform an elective 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 reconstruction without insurance permission you may be responsible for unpaid fees to the pathologist or Dr. Lowe. 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 which is based on all the facts in your particular case and the current state of medical knowledge.

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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 HIDRADENITIS 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 STAGED HIDRADENITIS
RECONSTRUCTIVE 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 Hidradenitis Reconstruction 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