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INFORMED CONSENT – NIPPLE RECONSTRUCTION

INSTRUCTIONS

This informed-consent document has been prepared to help inform you about nipple reconstruction surgery, its risks, and alternative treatment(s).

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page, and sign the consent for surgery as proposed by Dr. Eades and agreed upon by you.

GENERAL INFORMATION

Nipple reconstruction involves the restoration of the nipple-areolar complex lost due to injury, breast cancer or other conditions. A variety of different techniques exist for reconstruction of the nipple and its surrounding areolar tissue. These include the use of skin grafts taken from other regions of the body, local flaps of breast skin that are shaped into a nipple, or the sharing of tissue from the opposite nipple-areolar region. Additional techniques such as tattooing may be used to add color to the tissue if needed.

Nipple reconstruction may be performed as a single surgical procedure, or combined with other breast reconstruction procedures.

ALTERNATIVE TREATMENTS

Nipple reconstruction surgery is an elective surgical operation. Alternative treatment would consist of not undergoing the surgical procedure or the use of external nipple-areolar prostheses.

RISKS OF NIPPLE RECONSTRUCTION SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. 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 these complications, you should discuss each of them with Dr. Eades to make sure you completely understand all possible consequences of nipple reconstruction surgery.

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

Infection- Infection is unusual after this type of surgery. If an infection occurs, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary. It is possible that skin graft loss or nipple loss may occur from an infection following nipple reconstruction surgery.

Scarring- All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scars may occur within the skin and deeper tissues. Scars may occur in both the nipple reconstruction site and the donor site for tissues used in the nipple reconstruction. Scars may be unattractive and of different color than the surrounding skin tone. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the

right and left side of the body). There is the possibility of visible marks in the skin from sutures. In some cases, scars may require surgical revision or treatment.

Skin Grafts- Skin grafts are used in some nipple reconstruction techniques. The location of where the graft is taken may have residual scarring, poor healing, or abnormal color. Chronic itching sensations have been reported. Skin graft loss can occur due to infection or other causes. Additional skin grafts may be needed.

Hair Growth- Skin grafts used in nipple reconstruction may contain hair follicles. Unattractive hair growth may occur in the reconstructed nipple. Additional treatment may be required to remove the hair follicles.

Tattoos- If tattooing is required as an additional procedure, it may be impossible to precisely match the color and texture of the opposite nipple-areolar complex.

Change in Nipple Sensation- Nipple reconstruction cannot restore normal sensation to the breast or nipple.

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

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

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

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

Delayed Healing- Wound disruption or delayed wound healing is possible in either the site of nipple-areolar reconstruction or donor location(s) for tissue. Some areas of the nipple reconstruction or tissue donor sites may heal abnormally or slowly. Some areas of skin may die, requiring frequent dressing changes or further surgery to remove the non-living tissue. Individuals who have decreased blood supply to breast tissue from past surgery or radiation therapy may be at increased risk for delayed wound healing and poor surgical outcome. **Smokers have a greater risk of skin loss and wound healing complications.**

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.

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

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

Seroma- Fluid accumulations infrequently occur between the skin and the underlying tissues. Should this problem occur, it might require additional procedures for drainage of the fluid.

Breast Implant Damage- Breast implant damage can occur during a nipple reconstruction surgery. A damaged or broken implant will require surgery for replacement or removal.

Asymmetry- Some breast asymmetry naturally occurs in most women. Differences in breast and nipple shape, size, or symmetry may also occur after surgery. Additional surgery may be necessary to attempt to correct asymmetry.

Damage to Opposite Nipple- Some nipple reconstruction procedures use a tissue-borrowing technique from the opposite nipple region. It is possible that the donor nipple region may be damaged or lose normal sensation.

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

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.

Unsatisfactory Result- Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. You may be disappointed with the results nipple reconstruction surgery. Asymmetry in nipple placement, shape, projection, and appearance may occur after surgery. Unsatisfactory nipple placement may occur. It may not be possible to precisely match the opposite nipple areolar complex. Other risks include unsatisfactory or highly visible surgical scar location, unacceptable visible deformities, bunching and rippling in the skin near the suture lines or at the ends of the incisions (dog ears), poor healing, wound disruption, and loss of sensation. It may not be possible to correct or improve the effects of surgical scars. Nipple reconstruction may fail due to complications attributable to the surgery or from chemotherapy/radiation therapy treatments that are independent of the procedure. Additional surgery may be required to improve results.

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

ADDITIONAL ADVISORIES

Breast Disease- Current medical information does not demonstrate an increased risk of breast disease, breast cancer, or recurrence of breast cancer in women who have had reconstructive breast surgery. Breast disease and breast cancer can occur independently of breast surgery. Individuals with a personal history or family history of breast cancer may be at a higher risk of developing breast cancer than a woman with no family history of this disease. It is recommended that all women perform regular self-examination of their breasts, have mammograms according to American Cancer Society guidelines, and seek professional care should a breast lump be detected.

Long-Term Results- Subsequent alterations in the shape, size, color, and prominence of the reconstructed nipple-areolar complex may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause, or other circumstances not related to your surgery.

Pregnancy and Breast Feeding- If a woman has undergone a mastectomy, it is unlikely that she would be able to breast feed a baby on the affected side. Reconstructed nipples cannot be used for breast feeding.

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

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

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

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

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

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

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

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

Medications- There are potential adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your Dr. Eades 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 Dr. Eades, 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

Should complications occur, additional surgery or other treatments may be necessary. Secondary surgery may be necessary to obtain optimal results. Even though risks and complications occur infrequently, the risks cited are particularly associated with nipple reconstruction surgery. Other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied on the results that may be obtained. In some situations, it may not be possible to achieve optimal results with a single surgical procedure.

PATIENT COMPLIANCE

Follow all of Dr. Eades' 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 Dr. Eades. 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 Dr. Eades states it is safe. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

HEALTH INSURANCE

Most insurance carriers consider nipple reconstruction surgery a covered benefit. There may be additional requirements. Please review your health insurance subscriber-information pamphlet, call your insurance company, and discuss this further with your plastic surgeon. **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 Dr. Eades, 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. Dr. Eades 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 Dr. Eades to perform the following procedure or treatment:

NIPPLE RECONSTRUCTION

I have received the following information sheet:

INFORMED CONSENT - NIPPLE RECONSTRUCTION

2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize Dr. Eades and/or his appointees to perform such other procedures that are in the exercise of his professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to Dr. Eades at the time the procedure is begun.
3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. I acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained.
5. I consent to be photographed before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body for medical documentation in my confidential medical chart. (If Dr. Eades wishes to use your photographs for scientific or educational purposes, he will first ask for your written permission.)
6. I consent to the disposal of any tissue, medical devices or body parts which may be removed.
7. I consent to the utilization of blood products should they be deemed necessary by Dr. Eades and/or his appointees, and I am aware that there are potential significant risks to my health with their utilization.
8. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
9. I understand that Dr. Eades' fees are separate from the anesthesia and hospital charges, and his fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
10. I realize that not having the operation is an option.
11. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
 - a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
 - b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
 - c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-11). I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Date _____ Witness _____