

INFORMED CONSENT – OTOPLASTY SURGERY

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you of otoplasty surgery, its risks, as well as alternative treatments.

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 and agreed upon by you.

GENERAL INFORMATION

Otoplasty is a surgical process to reshape the ear. A variety of different techniques and approaches may be used to reshape congenital prominence in the ears or to restore damaged ears. Each individual seeking otoplasty is unique both in terms of the appearance of their ears and expectations for results following otoplasty surgery. It is important that you fully discuss your expectations with your plastic surgeon prior to surgery.

ALTERNATIVE TREATMENTS

Otoplasty is usually an elective surgical operation. Alternative forms of management consist of not undergoing the otoplasty operation.

RISKS OF OTOPLASTY SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with otoplasty surgery 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 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 otoplasty surgery.

Bleeding- It is possible, though unusual, to experience a bleeding episode during or after surgery. Intraoperative blood transfusions may be required. Should post-operative bleeding occur, it may require an emergency treatment to drain the accumulated blood or blood transfusion. Accumulations of blood under the skin may delay healing and cause scarring. Do not take any aspirin or anti-inflammatory medications for ten days before surgery, as this may increase the risk of bleeding. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding. If blood transfusions are needed to treat blood loss, there is a risk of blood related infections such as hepatitis and the 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 surgery. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary.

Change in Skin Sensation- It is common to experience diminished (or loss) of skin sensation in areas that have had surgery. Diminished (or complete loss of skin sensation) may not totally resolve after otoplasty surgery.

Ear Trauma- Physical injury after the otoplasty procedure would disrupt the results of surgery. Care must be given to protect the ear(s) from injury during the healing process. Additional surgery may be necessary to correct damage.

Skin Contour Irregularities- Contour irregularities and depressions may occur after otoplasty. Visible and palpable wrinkling of skin and ear cartilage can occur. Residual skin irregularities at the ends of the incisions or "dog ears" are always a possibility and may require additional surgery. This may improve with time, or it can be surgically corrected.

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 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 used during an otoplasty. In some cases scars may require surgical revision or treatment.

Surgical Anesthesia- Both local and general anesthesia involves risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

Asymmetry- The human face is normally asymmetrical. There can be normal differences between ears in terms of shape and size. There can be a variation from one side to the other in the results obtained from an otoplasty procedure. Additional surgery may be necessary to attempt to revise asymmetry.

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Delayed Healing- Wound disruption or delayed wound healing is possible. Some areas of the ear may heal abnormally or may take a long time to heal. Areas of skin may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue. **Smokers have a greater risk of skin loss and wound healing complications.**

Allergic Reactions- In rare cases, local allergies to tape, suture materials 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.

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. Pain of varying intensity and duration may occur and persist after otoplasty surgery. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue after an otoplasty.

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.

Sutures- Some surgical techniques use deep non-absorbable 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 otoplasty. 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.

Skin Sensitivity- Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after surgery. Usually this resolves during healing, but in rare situations it may be chronic.

Cardiac and Pulmonary Complications- Surgery, especially longer procedures, may be associated with the formation of, or increase in, blood clots in the venous system. Pulmonary complications may occur secondarily to both blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs after general anesthesia. Pulmonary and fat emboli can be life-threatening or fatal in some circumstances. 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 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.

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ADDITIONAL ADVISORIES

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 of otoplasty surgery. This would include risks such as asymmetry, unsatisfactory surgical scar location, unacceptable visible deformities at the ends of the incisions (dog ears), loss of facial movement, poor healing, wound disruption, and loss of sensation. It may be necessary to perform additional surgery to improve your results.

Long-Term Results- Subsequent alterations in ear appearance may occur as the result of aging, sun exposure, pregnancy, menopause, or other circumstances not related to otoplasty surgery. Due to the resilient nature of ear cartilage, revisionary surgery may be necessary in order to improve or maintain the results following otoplasty surgery.

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

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

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

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

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

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

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.

Medications- There are many adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process. Do not drive, do not operate complex equipment, do not make any important decisions, and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

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ADDITIONAL SURGERY NECESSARY

There are many variable conditions that may influence the long-term result of otoplasty. Secondary surgery may be necessary to obtain optimal results. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are particularly associated with otoplasty 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 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

Most health insurance companies exclude coverage for cosmetic surgical operations such as otoplasty surgery or any complications that might occur from 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 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.

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 SURGERY / PROCEDURE or TREATMENT

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

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I have received the following information sheet:

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- 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 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 or representation has been given by anyone as to the results that may be obtained.
- 5. I consent to be photographed or televised before, during, and after 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 consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
- 9. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
- 10. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
- 11. I realize that not having the operation is an option.
- 12. 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 (1-12). I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Date _____ Witness _____