INFORMED-CONSENT - OTOPLASTY SURGERY

INSTRUCTIONS

This is an informed consent document that has been prepared to help inform you of otoplasty surgery, 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.

INTRODUCTION

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 in 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

Alternative forms of management consist of not undergoing the otoplasty operation.

RISKS OF OTOPLASTY SURGERY

Every surgery procedure involves a certain amount of risk and it is important that you understand the risks involved with otoplasty. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefits.

Bleeding – It is possible, though unusual, to experience episode during or after surgery. Should postoperative bleeding occur, it might require emergency treatment to drain accumulated blood (hematoma). Do not take any aspirin or anti-inflammatory medications for ten days before surgery, as this may increase the risk of bleeding. Accumulations of blood under the skin may delay healing and cause scarring.

Infection – Infection is unusual after this type of surgery. Should an infection occur, treatment including antibiotics or additional surgery may be necessary.

Change in skin sensation – Diminished (or loss) of skin sensation in the ear area may not totally resolve after otoplasty surgery.

Ear trauma – Physical injury after the otoplasty procedure would disrupt the results f 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.

Risk of Otoplasty surgery, continued

Skin scarring – In rare cases, excessive or abnormal scars may result. Scars may be unattractive and of a different color than surrounding skin. There is the possibility of visible marks from sutures used during an otoplasty. Additional treatments including surgery may be necessary to treat abnormal scarring.

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 difference between ears in terms of shape and size. There can be variation form one side to the other in the results obtained from the otoplasty procedure.

Delayed healing – Wound disruption or delayed wound healing is possible. Some areas of the ear may heal abnormally or slowly. Frequent dressing changes or further surgery to remove the non-healed tissue may be required.

Allergic reactions – In rare cases, local allergies to tape, suture material, of topical preparations has been reported. Systemic reactions, which are more serious, may result from drugs during surgery and prescription medicines. Allergic reactions may require additional treatment.

Long-term effects – Subsequent alterations in ear appearance may occur, as the result of aging 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 the results following otoplasty surgery.

Pain – Very frequently, chronic pain may occur from nerves trapped in scar tissue after an otoplasty.

Deeper structure – Some surgical techniques use deep non-absorbable sutures. These items may be noticed by the patient following surgery. Suture may spontaneously poke through the skin, be visible, or produce irritation that requires removal.

Unsatisfactory result – You may be disappointed with the results of surgery. Infrequently, it is necessary to perform additional surgery to improve your results.

ADDITONAL SURGERY NECESSARY

Should complications occur, additional surgery or other treatment might be necessary. Even though risks and complications occur infrequently, the risks cited are particularly associated with otoplasty. 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.

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HEALTH INSURANCE

Most health insurance companies exclude coverage for procedures such as otoplasty or any complications that might occur from surgery. Please carefully review your health insurance subscriber-information pamphlet.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, anesthesia, laboratory test, and possible outpatient hospital charges, depending on where the surgery id performed. Depending on whether the cost of surgery is covered by insurance plan, you will be responsible for necessary co-payments, deductibles, and charges covered. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with revisionary surgery would also be your responsibility.

DISCLAIMER

Informed consent documents are used to communicate information about the surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed consent process attempts to define principles of risk disclosure that should generally meet the need of most patients in most circumstances.

However, every patient is unique and informed consent documents should not be considered all inclusive in defining other methods of care and risks encountered when medical care is reasonable and directed at obtaining appropriate results. Your plastic surgeon may provide you with additional or different information, which is based on all the facts in your particular case and the state of medical knowledge.

Informed consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all 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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ADDITIONAL ADVISORIES:

Deep Venous Thrombosis, 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 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 travelling 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 pain or unusual heartbeats, seek medical attention immediately. Should any of these complications occur, you might require hospitalization and additional treatment.

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.

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.

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.

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 that 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.

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 <u>not</u> be removed unless instructed by your plastic surgeon. Successful post-operative function depends o both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation around implants and the need for the return to surgery. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

CONSENT FOR SURGERY/PROCEDURE OR TREATMENT

1. I hereby authorize Danny Oh, M.D. and such assistants as may be selected to perform the following Procedure or treatment:

I have received the following information sheet:

INFORMED CONSENT for OTOPLASTY SURGERY

- 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 know 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 even 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 the pictures do not reveal my identity.
- 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 that may be removed.
- 8. I authorize the release of my identity card 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

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9).

I AM SATISFIED WITH THE EXPLANATION.

Patient for Person Authorized to Sign for Patient/Name

IC No

Date _____ Witness __

Signature / Name