



Plastic Surgery & Dermatology Associates (PSDA)
CLEFT LIP AND/OR PALATE ASSOCIATED NOSE / RHINOPLASTY 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 rhinoplasty 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

Surgery of the nose (rhinoplasty) is an operation frequently performed by plastic surgeons. This surgical procedure can produce changes in the appearance, structure, and function of the nose. Rhinoplasty can reduce or increase the size of the nose, change the shape of the tip, narrow the width of the nostrils, or change the angle between the nose and the upper lip. This operation can help correct birth defects (i.e. cleft lip and/or palate, nasal injuries, and help relieve some breathing problems. Secondary procedures or procedures performed as a result of a birth defect are usually more complicated and unpredictable.

There is not a universal type of rhinoplasty surgery that will meet the needs of every patient. Rhinoplasty surgery is customized for each patient, depending on his or her needs and age. Incisions may be made within the nose or concealed in inconspicuous locations of the nose in the open rhinoplasty procedure. Internal nasal surgery that attempts to improve nasal breathing can be performed at the time of the rhinoplasty.

Rhinoplasty surgery following cleft lip and/or palate surgery has limitations and will often require multiple procedures for the best results. It is not possible for the results to be perfect or completely satisfactory. The best candidates for this type of surgery are individuals who are looking for improvement, not perfection, in the appearance of their nose. In addition to realistic expectations, good health, psychological stability, and maturity are important qualities for a patient considering rhinoplasty surgery. Rhinoplasty can be performed in conjunction with other surgeries which can increase the operative time and risk of surgery. It is important that these procedures are performed at the best time and development of the patient based on their unique situation and experience.

ALTERNATIVE TREATMENT

Alternative forms of management consist of not undergoing the rhinoplasty surgery. Certain internal nasal airway disorders may not require surgery on the exterior of the nose. Risks and potential complications are associated with alternative forms of treatment that involve surgery such as septoplasty to correct nasal airway disorder.

RISKS OF RHINOPLASTY SURGERY FOLLOWING CLEFT LIP / PALATE

With any type of activity there is inherent risk. An individual's or family's choice for a patient 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 rhinoplasty.

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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 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.

Infection – Infection is quite unusual after surgery. Should an infection occur, additional treatment including antibiotics may be necessary.

Scarring – Although good wound healing after a surgical procedure 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.

Damage to deeper structures – Deeper structures such as nerves, tear ducts, blood vessels, and muscles may be damaged during the course of surgery. The potential for this to occur varies with the type of rhinoplasty procedure performed. Injury to deeper structures may be temporary or permanent.

Numbness – There is the potential for permanent numbness within the nasal skin after rhinoplasty. The occurrence of this is not predictable. Diminished (or loss of skin sensation) in the nasal area may not totally resolve after rhinoplasty.

Asymmetry – The human face is normally asymmetrical. There can be a variation from one side to the other in the results obtained from a rhinoplasty procedure.

Chronic pain – Chronic pain may occur very infrequently after rhinoplasty.

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 used during pregnancy and prescription medicines. Allergic reactions may require additional treatment.

Delayed healing – Wound disruption or delayed wound healing is possible. Some areas of the face may not heal normally and 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.

Long term effects – Subsequent alterations in nasal appearance may occur as the result of aging, sun exposure, or other circumstances not related to rhinoplasty surgery. Future surgery or other treatments may be necessary to maintain the results of a rhinoplasty operation.

Nasal septal perforation – There is the possibility that surgery will cause a hole in the nasal septum to develop. The occurrence of this is rare. However, if it occurs, additional surgical treatment may be necessary to repair the hole in the nasal septum. In some cases, it may be impossible to correct this complication.

Nasal airway alterations – Changes may occur after a rhinoplasty or septoplasty operation that may interfere with normal passage of air through the nose.

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.

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Substance Abuse Disorders- Individuals with substance abuse problems that involve the inhalation of vasoconstrictive drugs such as cocaine are at risk for major complications including poor healing and nasal septal perforation.

Skin Contour Irregularities- Contour irregularities may 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.

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.

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 rhinoplasty surgery. This would include risks such as asymmetry, loss of function, structural mal-position, unacceptable visible or tactile deformities, unsatisfactory surgical scar location, poor healing, wound disruption, and loss of sensation. It may be necessary to perform additional surgery to attempt to improve your results.

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.

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.

ADDITIONAL ADVISORIES

Skin Disorders / Skin Cancer- Rhinoplasty is a surgical procedure to reshape of both internal and external structure of the nose. Skin disorders and skin cancer may occur independently of a rhinoplasty.

Long-Term Results- Subsequent alterations in nasal appearance may occur as the result of aging, weight loss or gain, sun exposure, pregnancy, menopause, or other circumstances not related to rhinoplasty surgery. Future surgery or other treatments may be necessary.

Children Patient Information- Patients who are younger may not be fully developed. As a child ages there may be more significant changes in the surgery and more unreliable results. Patients or their families may elect to delay surgery to allow for further development or stability in the area. It is important to talk to your surgeons about the impact of age on the recovery, compliance and long term results. Future surgery or other treatments are to be expected in the future.

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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. Activity that increases your pulse or heart rate may cause additional bruising, swelling, and the need for return to surgery and control 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 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 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.

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 splints 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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Children are not always able or willing to be compliant with post operative instructions. Parents are expected to assist minors in protecting the surgical site and be aware of any complications that need to be brought to the attention of the surgeon.

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical operations or any complications that might occur from cosmetic surgery. If the procedure corrects a breathing problem or marked deformity after a nasal fracture or cleft lip and/or palate, a portion or all may be covered. **Many insurance plans exclude coverage for secondary or revisionary 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 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. 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.

ADDITIONAL SURGERY NECESSARY

There are many variable conditions that may influence the long-term result from rhinoplasty or septal surgery following cleft lip and/or palate reconstruction. Secondary surgery or staged procedures 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 nasal surgery in cleft lip and/or palate patients. 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.

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 SEPTAL/RHINOPLASTY SURGERY

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1. I hereby authorize Dr. _____Lowe_____ and such assistants as may be selected to perform the following procedure or treatment: **NASAL SURGERY**
I have received the following information sheet: **INFORMED CONSENT – SEPTAL/RHINOPLASTY SURGERY ASSOCIATED CLEFT LIP AND/OR PALATE 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 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 _____