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Informed Consent – Congenital Reconstruction Cleft Lip – Cleft Palate

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you about cleft lip and cleft palate surgery, its risks, as well as 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. Brown and agreed upon by you.

GENERAL INFORMATION

Cleft lip and cleft palate are facial and oral malformations that occur very early in the development of a fetus. The incomplete formation of the upper lip (cleft lip) or roof of the mouth (cleft palate) can occur individually, or both defects may occur together. The conditions can vary in severity and may involve one or both sides of the face. Reconstructive surgery for cleft lip and cleft palate is used to correct this abnormal development both to restore function and to restore a more normal appearance. Cleft lip repairs are initially performed when a child is at least 10 weeks of age and 10 pounds in weight and has a hemoglobin (or blood count) of at least 10. Cleft palate repairs are generally performed when a child is somewhat older, from 9 to 18 months of age. Secondary procedures may be needed for functional reasons or to refine appearance. Cleft lip surgery typically involves repair of the nasal deformity as well.

ALTERNATIVE TREATMENTS

Alternative forms of treatment consist of not undergoing the surgery. Risks and potential complications such as the possibility of visible and palpable malformations, and developmental and functional problems related to breathing, eating, hearing, and speech are associated with the non-treatment of cleft lip – cleft palate.

INHERENT RISKS OF 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. Brown to make sure you understand all possible consequences of congenital reconstruction cleft lip and/or cleft palate surgery.

SPECIFIC RISKS OF CLEFT LIP – CLEFT PALATE SURGERY

Cleft Lip:

In general, complications of cleft lip surgery are not common. More common are differences in healing which may result in abnormal scars and other deformities that require additional surgery in the future. Almost all patients with cleft lip repairs may benefit from additional surgery on the lip and/or nose at some point later in life.

Dehiscence (Separation):

Separation of the wound may occur, either due to infection or to the motion of the lip that occurs normally in crying, sucking, feeding, etc. This may require emergent re-repair for complete separation or revision surgery at a later time if it is less severe.

Asymmetry of the Nose or Lip:

Asymmetry of the nose and lip can occur with scarring or growth changes due to the inherent nature of the cleft lip and nose deformity. Typically, future surgery after a child is fully grown is required to correct the asymmetry.

Scars:

Scars are a normal healing process of any surgery. Some scars can become widened or discolored after surgery requiring revision. Some scars can even cause distortion of the lip and nose leading to functional problems such as difficulty breathing through one or both nostrils.

Cleft Palate:**Breathing Problems:**

Breathing problems may occur particularly in the hours immediately after palate repair. A small number of patients may require observation in the intensive care unit after palate surgery to monitor their breathing. Additional oxygen or other breathing treatments may be required after surgery. In rare instances a child after surgery for repair of the cleft palate may need breathing support on a ventilator until swelling of the airway has resolved.

Fistula:

A fistula is a hole between the mouth and the nose or lip. This is most common midway along the palate where the repair is tightest. Fistulae may also become symptomatic when the upper jaw is expanded as a part of orthodontic treatment. If there is a speech problem (nasal air loss) or fluid regurgitation into the nose, additional surgery may be needed for fistula closure.

Speech Problems:

Even with successful cleft palate repair, speech development may not be ideal leading to future difficulties with speaking or swallowing. Speech problems occur in up to 20% of patients after palate repair. Speech therapy is the first line of treatment, but additional surgery may be required if speech therapy is inadequate.

Maxillary Growth:

Growth of the maxilla (the upper jaw) can be altered by cleft palate surgery. 10-40% of patients with a cleft palate not related to a genetic syndrome may require orthognathic surgery (LeFort I maxillary advancement or upper jaw surgery) in their teens. Virtually all patients with clefts require orthodontic treatment as they grow.

Damage to Deeper Structures:

Occasionally injury to surrounding structures can occur during the surgical repair of the cleft such as nerves, blood vessels, muscle, teeth, or tear ducts. The potential for injury to these structures depends on the type of surgery and location of the surgical repair. Injury can be temporary or permanent and may require another surgery to address the injury.

GENERAL RISKS OF SURGERY**Healing Issues:**

Certain medical conditions, dietary supplements and medications may delay and interfere with healing. Patients with diabetes or those taking medications such as steroids on an extended basis may have prolonged healing issues. Smoking will cause a delay in the healing process, often resulting in the need for additional surgery. There are general risks associated with healing such as swelling, bleeding, possibility of additional surgery, prolonged recovery, color changes, shape changes, infection, not meeting patient goals and expectations, and added expense to the patient. There may also be a longer recovery due to the length of surgery and anesthesia. There are nerve endings that may become involved

with healing scars. While there may not be a major nerve injury, the small nerve endings during the healing period may become too active producing a painful or oversensitive area due to the small sensory nerve involved with scar tissue. Often, massage and early non-surgical intervention resolves this. It is important to discuss post-surgical pain with Dr. Brown.

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 or you may require a blood transfusion, though such occurrences are rare. The collection of blood that can occur under your skin following surgery is referred to as a hematoma. Increased activity too soon after surgery can lead to increased chance of bleeding and additional surgery. It is important to follow postoperative instructions and limit exercise and strenuous activity for the instructed time. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding. Hematoma can occur at any time, usually in the first three weeks following injury to the operative area. You could require a blood transfusion. If blood transfusions are necessary to treat blood loss, there is the risk of blood-related infections such as hepatitis and HIV (AIDS). Dr. Brown may provide medications after your surgery to prevent blood clots. Medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

Infection:

Infection, although uncommon, can occur after surgery. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary. It is important to tell Dr. Brown of any other infections, such as a history of MRSA infections, an open wound, recent upper respiratory infection/ pneumonia, ingrown toenail, insect bite, tooth abscess, or urinary tract infection. Infections in other parts of the body, may lead to an infection in the operated area. Post-operative infections often result in more extensive scarring and predispose to revision 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 be unattractive and of a 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.

Ileus:

The return of bowel function following surgery is important. An ileus are disruptions in bowel function caused by the failure of peristalsis or hypomobility of your bowels/ gut resulting in a lack of defecation and possibly repeated vomiting. Anesthetics and medications like pain medications given to you at the time of surgery can contribute to the development of an ileus in the post-operative period. An ileus can result in abdominal distention, vomiting, inability to absorb oral medications and possibly hospitalization. Repeated vomiting could result in an aspiration pneumonia and respiratory failure. It can be essential to have regular bowel function after your surgery.

Firmness:

Excessive firmness can occur after surgery due to internal scarring. The occurrence of this is not predictable. Additional treatment including surgery may be necessary.

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.

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.

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. There is the possibility of contour irregularities in the skin that may result from fat necrosis.

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.

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 surgery. If you are a chronic pain patient followed by a Pain Therapy Practitioner you may be asked to see this practitioner pre operatively to assist you in the management of your pain disorder in the post-operative period. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.

There are nerve endings that may become involved with healing scars from surgery. While there may not be a major nerve injury, the small nerve endings during the healing period may become too active producing a painful or oversensitive area due to the small sensory nerve involved with scar tissue. Often, massage and early non-surgical intervention resolves this. It is important to discuss post-surgical pain with Dr. Brown.

Cardiac and Pulmonary Complications:

Pulmonary complications may occur secondarily to blood clots (pulmonary emboli), fat deposits (fat emboli), pneumonia, 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 Dr. Brown any past history of swelling in your legs or blood clots 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.

Venous Thrombosis (Clot) and Sequelae:

Thrombosed veins, which resemble cords, occasionally develop in the area or around IV sites, and usually resolve without medical or surgical treatment. A personal history of bleeding and clotting problems may also increase your risk of thrombosed veins.

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 in response to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment. It is important to notify Dr. Brown of any previous allergic reactions.

Drug Reactions:

Unexpected drug allergies, lack of proper response to medication, or illness caused by the prescribed drug are possibilities. It is important for you to inform Dr. Brown of any problems you have had with any medication or allergies to medication, prescribed or over the counter, as well as medications you now regularly take. Provide Dr. Brown with a list of medications and supplements you are currently taking.

Persistent Swelling (Lymphedema):

Persistent swelling can occur following surgery.

Unsatisfactory Result:

Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. The body is not symmetric and almost everyone has some degree of unevenness which may not be recognized in advance. One side of the face may be slightly larger, one side of the face droopier. The breast and trunk area exhibits the same possibilities. Many of such issues cannot be fully corrected with surgery. The more realistic your expectations as to results, the better your results will appear to you. Some patients never achieve their desired goals or results, at no fault of Dr. Brown or surgery. You may be disappointed with the results of surgery. Asymmetry, unanticipated shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. Size may be incorrect. Unsatisfactory surgical scar location or appearance may occur. It may be necessary to perform additional surgery to improve your results. Unsatisfactory results may NOT improve with each additional treatment.

ADDITIONAL ADVISORIES

Medications and Herbal Dietary Supplements:

There are potential adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with forming blood clots, and therefore may contribute to more bleeding issues. If you have a medical condition (such as heart arrhythmia, heart stent, blood vessels with blockages, or blood clots) and are taking medications to thin your blood and prevent clotting such as Plavix, Warfarin, Coumadin, Xarelto, Effient or Pradaxa, discuss management of these medications around the time of surgery with Dr. Brown. Dr. Brown may sometimes coordinate a plan for these medications with the doctor that prescribed them for your medical condition. If you have been prescribed drugs for a medical condition, do not stop them without discussing it first with Dr. Brown. Stopping these medications abruptly may result in a heart attack, stroke, or death. Be sure to check with Dr. Brown 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 Dr. Brown 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.

Sun Exposure:

The effects of the sun are damaging to the skin. Exposing the treated areas to sun may result in increased scarring, color changes, and poor healing. The damaging effect of sun exposure occurs even with the use sun block or clothing coverage.

Travel Plans:

Any surgery holds the risk of complications that may delay healing and your return to normal life. Please let Dr. Brown know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired time frame. Allow at least 14 days to travel via airplane. Medications may be required should you have a long flight/ trip to prevent DVT/ PE in the immediate post-operative period.

Long-Term Results:

Subsequent alterations in the appearance of your body may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause or other circumstances not related to your surgery.

Jewelry:

Jewelry should not be brought with you at the time of your surgical procedure. Items such as earrings, necklaces, etc. should be removed and placed in a safe place. Do not bring your jewelry with you for your surgery.

ADDITIONAL SURGERY NECESSARY (Re-Operations):

There are many variable conditions that may influence the long-term result of surgery. It is unknown how your tissue may respond or how wound healing will occur after surgery. Secondary surgery may be necessary to perform additional tightening or repositioning of body structures. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are associated with this surgery. Other complications and risks can occur but are less common. 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. You and Dr. Brown will discuss the options available should additional surgery be advised. There may be additional costs and expenses for such additional procedures, including surgical fees, facility and anesthesia fees, pathology and lab testing.

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 Dr. Brown. 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 important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

ATTESTATIONS

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

Patients who are exposed to or are themselves currently smoking or use tobacco or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin loss and 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 these type of complications. Please indicate your current status regarding these items below:

___ **Patient/parent is** a non-smoker and do not use nicotine products. I understand the potential risk of second-hand smoke exposure causing surgical complications.

___ **Patient/parent is** a smoker or uses tobacco / nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

___ **Patient/parent** have smoked and stopped approximately _____ ago. I understand the patient may still have the effects and therefore risks from smoking in their system, if not enough time has lapsed.

___ **Patient/parent** has been advised to stop smoking immediately and have been informed of the risks, benefits, expectations and alternatives to surgery if smoking continues.

It is important to refrain from smoking at least 6 weeks before surgery **Patient/parent** acknowledge that they will inform physician if smoking continues within this time frame, and understand that for safety, the surgery may be cancelled and any surgery, scheduling fee, and other prepaid amounts may be forfeited.

Sleep Apnea / CPAP:

Individuals who have breathing disorders such as "Obstructive Sleep Apnea" and who may rely upon CPAP devices (continuous positive airway pressure) or utilize nighttime oxygen are advised that they are at a substantive risk for respiratory arrest and death when they take narcotic pain medications following surgery. This is an important consideration when evaluating the safety of surgical procedures in terms of very serious complications, including death, that relate to pre-existing medical conditions. Surgery may be considered only with monitoring afterwards in a hospital setting in order to reduce risk of potential respiratory complications and to safely manage pain following surgery.

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. Brown 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. Michael Brown and such assistants as may be selected to perform **Congenital Reconstruction of Cleft Lip and/or Cleft Palate**.

I have received the following information sheet: **Congenital Reconstruction of Cleft Lip and/or Cleft Palate**.

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 Dr. Brown 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 understand what Dr. Brown can and cannot do, and understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
5. I consent to be photographed, internet broadcasted or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific, educational or marketing purposes. I hereby grant permission to Michael J Brown, MD, PLLC the rights of my edited and non edited surgical image, in video or still, and of the likeness without consideration and waive any right to inspect or approve the images or receive compensation or rights to royalties. There is no time limit on the validity of this release nor is there any geographic limitation on where these materials may be distributed.
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 am aware that there are potential significant risks to my health with the utilization of blood products, and I consent to their utilization should they be deemed necessary by Dr. Brown and/or his appointees.
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 Dr. Brown's 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. I opt out of having this procedure _____.
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/Time _____ Witness _____