

INFORMED-CONSENT – FLEXOR TENDON REPAIR SURGERY

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INFORMED-CONSENT – FLEXOR TENDON REPAIR SURGERY

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you of flexor tendon 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

Flexor tendons connect muscles in the forearm to structures within the hand and fingers. Tendons allow the contractile force of forearm muscles to be used for movement in the wrist, hand, and fingers. Injuries to flexor tendons may severely affect function of the hand due to disruption of the muscle-tendon unit(s).

Injuries to flexor tendons may occur from cuts, crush injuries, sprains, or in rare cases, without apparent injury. Once severed, it is unlikely that a tendon can heal without surgical repair. Partially cut tendons may or may not require repair, depending on the extent of damage. Restoration of hand function after injury to flexor tendons requires surgery, aftercare, and supervised hand rehabilitation in order to obtain the best results.

Hand injuries severe enough to cut flexor tendons may damage other vital structures within the forearm, hand, and fingers such as blood vessels, nerves, bone and soft tissues important to normal hand function. These structures may require repair in addition to the flexor tendon(s). Damage to these structures may be only discovered at the time of surgery.

ALTERNATIVE TREATMENTS

Alternative treatment consists of not undergoing surgery for tendon repair. There is the possibility of loss of function if cut tendons are not repaired. Risks and potential complications are associated with alternative forms of surgical treatment.

RISKS OF FLEXOR TENDON SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with flexor tendon 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 these complications, you should discuss each of them with your plastic surgeon to make sure you understand the risks, potential complications, and consequences of flexor tendon 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. 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- Infections after tendon repair surgery may occur. Additional treatment may be required. There is the possibility of tendon repair failure or scarring from an infection. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary.

Tendon Scarring- Injuries to flexor tendons also affect other structures necessary for proper tendon function. Scarring can occur within the tendon repair itself or in nearby structures to prevent the return of normal tendon function. Additional surgery may not be successful in freeing the tendon from scar tissue which prevents motion. When tendon scarring occurs, other structures such as joints may lose normal motion.

Change in Skin Sensation- A diminished (or loss) of skin sensitivity in the finger, hand or forearm may occur and not totally resolve after flexor tendon repair.

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Failure of Tendon Repair- Sutures are used to hold the tendon repair together until it has healed and has enough strength for function. It is possible to break the sutures or tear apart the tendon repair. Breakage of tendon repairs is a serious problem. If this occurs, additional surgery would be necessary to secondarily repair the tendon. It is important that you follow all post-operative instructions concerning protecting the tendon repair from damage.

Skin Contour Irregularities- Contour irregularities and depressions may occur after tendon repair surgery. Visible and palpable wrinkling of skin 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.

Skin Discoloration / Swelling- Some bruising and swelling normally occurs following surgery. 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.

Scarring- All surgery leaves scars, some more visible than others. 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 the surrounding skin tone. Scar appearance may also vary within the same scar. There is the possibility of visible marks in the skin from sutures. Scars may limit motion and function. In some cases scars may require surgical revision or treatment.

Inability to Restore Function- Hand and forearm injuries often involve more than just a cut tendon. Not all damaged structures can be surgically repaired. Injuries to other soft tissues and bone may prevent adequate tendon function despite a successful tendon repair. Loss of soft tissues in the finger or hand may require other reconstructive surgical operations. Some hand injuries may be so severe that there is no reasonable expectation of return of function. Complications involving other parts of the hand and forearm may occur after hand / injury.

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.

Delayed Healing- Wound disruption or delayed wound healing is possible. Depending on the type of surgery performed, complete healing may be prolonged. 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.**

Damage to Associated Structures- Structures such as nerves, blood vessels, bone and soft tissues may be damaged during surgery. The potential for this to occur varies with the type of surgical technique utilized. Additional surgery may be necessary should this problem occur. Injury to associated structures may be temporary or permanent.

Additional Incisions Necessary- Cut tendons may retract. It may be necessary to extend the original wound where the tendon was cut or make new incisions to retrieve the retracted tendon(s).

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.

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

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.

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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. 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

Unsatisfactory Result- Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. There is the possibility of an unsatisfactory result from the extensor tendon repair surgery. This would include risks such as skin and soft tissue loss, wound disruption, chronic pain, loss of hand function, visible deformities, poor healing, and loss of sensation. **There is the possibility that hand function after tendon repair surgery may not be adequate for return to your regular occupation.** It may be necessary to perform additional surgery to attempt to improve your results.

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.

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.

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.

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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 flexor tendon repair 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

Tendon structures after surgery are vulnerable to breakage until healing has occurred. 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 restoration of tendon function depends on both surgery and subsequent hand rehabilitation. 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 and hand rehabilitation, return for aftercare, and promote your recovery after surgery.

HEALTH INSURANCE

Depending on your particular health insurance plan, flexor tendon repair surgery may be considered a covered benefit. Please review your health insurance subscriber-information pamphlet, call your insurance company, and discuss this further with your plastic surgeon. **Many 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 doctor, the cost of surgical supplies, anesthesia, laboratory tests, and outpatient hospital charges, depending on where the surgery is performed. Additional charges may include hand rehabilitation therapy after surgery. 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 injury or surgery. Secondary surgery or hospital day-surgery charges involved with revisionary surgery would also be your responsibility. Health insurance may not completely cover the costs of surgery and hand rehabilitation. You may require more hand rehabilitation services than your insurance plan covers. **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.

INFORMED-CONSENT – FLEXOR TENDON REPAIR SURGERY
CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1. I hereby authorize Dr. _____ 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 _____