Surgical Consent

Name: DOB: Date:

Consent Details

Your doctor has recommended surgery as an option for you in hopes of relieving certain symptoms and/or problems about which you have complained. This is an introduction to what you can expect from this surgery.

Procedure

Mini Sling, Cystoscopy

Indication

Stress Urinary Incontinence

Patients who have stress urine incontinence (cough or sneeze leakage) are candidates for a **sling procedure**. This procedure involves making a vertical 1 inch incision in the skin of the vagina directly beneath the urethra and then placing the sling (synthetic mesh tape) under and beside the urethra and inserting into the obturator muscle & possibly the obturator fascia. Unlike the TOT and TVT slings this minimally invasive sling does not have an exit would and thus is truly minimally invasive. The whole surgery is performed using one small incision. This operation is known as the Mini Sling which was first introduced into the USA in 2006 and has been used since that time with great success. The cure rates of the mini sling approximates 90% after the first year, 5 year studies and their cure rates are pending. The mesh that is used is FDA approved and is a Type I, macroporous polypropylene mesh. Many studies have confirmed the mesh tapes safety and efficacy when used for treating SUI.

Stress urine incontinence is not a life threatening condition and only the patient and makes the final decision as to surgery. She should make this decision only after being made an informed consumer by knowing the risks, benefits as well as the alternatives to surgery. Options to this therapy include nonsurgical therapies such as: kegel exercises, electrical stimulation, biofeedback, and barrier devices. Other options (surgical) include: periurethral injection of bulking agents such as collagen, traditional slings using biologic

grafts or a piece of the patient's own fascia, abdominal bladder neck suture suspensions such as the Burch or MMK or artificial urethral sphincters (AUS). The latter (AUS) is rarely used in women because of the high rate of erosion of the device, and the need to replace the device after ten years (a second surgery).

Post procedure

You will be in the recovery room for a short time before being sent home. There may be discomfort around the incision sites, within the vagina, and on the lower abdomen depending on the sling procedure you had performed. Most patients have some sense of urgency (the feeling of a need to urinate).

There may be small blood stains on the menstrual pad. If the pad becomes soaked, or you see active blood oozing, please contact us immediately. You may shower the day after surgery, but no swimming, or tub baths. It is normal to have some bloody discharge from the vagina for up to a week. If you have significant bleeding you should call our office. We ask that you refrain from any strenuous activity, heavy lifting, intercourse, or straining (usually for 6-8 weeks) until Dr. Hawkins tells you that you may resume. Every patient has some degree of swelling and bruising, and it is not possible to predict in whom this might be minimal or significant.

We strongly encourage you to take one weeks off from work following a sling, four weeks, with longer time off if your occupation requires strenuous activity or heavy lifting. In the first 48 hrs., it is to your advantage to often rest in a lying down position. Periodic walking is encouraged. Some patients have almost no discomfort while others are somewhat uncomfortable for a few days to weeks. Severe pain is unlikely but possible. You will be provided with a prescription for pain medication to alleviate most of your discomfort. Take the medication as prescribed and as needed.

Expectations of Outcome

The sling procedures are very effective for treating stress incontinence, but require careful consideration for selection of the proper procedure. The majority of patients will have surgical correction of other uterine and wall prolapse performed in conjunction with incontinence procedures. Between 80-90% of women will report cure or improvement in incontinence following surgery. The goal of all treatments for incontinence, non-surgical and surgical, is improved quality of life.

“Normal Voiding: after a sling procedure may be delayed for many weeks due to swelling and operative manipulation. Improvement is usually gradual and not immediate.

There is an entitiy termed "bladder instability" that should be understood. It is actually not a complication of surgery because we expect some degree of its presentation in anywhere form 30-40% of patients following repair of urethral hypermobility. Because the bladder neck support has been restored, you may develop urinary frequency and urgency. When sever, this rarely can be associated with urge-type incontinence. The symptoms are usually mild and resolve with time. In some patients medication could be necessary to relax the bladder. Very rarely are other treatments needed.

Risks

All surgical procedures, regardless of complexity or time, can be associated with unforeseen problems. They may be immediate or even quite delayed in presentation. While we have discussed these and possibly others and your consultation, we would like you to have a list so that you may ask questions if you still have concerns. Aside from anesthesia complications, it is important that every patient be aware of all possible outcomes, which may include but are not limited to:

Damage to adjacent organs: There is a risk during the sling procedure of recognized and unrecognized damage to bowel, bladder, urethra, nerves, vessels, and the kidney tubes (ureters). Often the injury is minor and can be treated with relative ease. In other instances, when the injury is extensive or the repair is complicated, more extensive surgery may be necessary and occasionally other surgical specialists are called to assist.

Mesh complication: The sling has potential complications when a permanent synthetic material (mesh tape) is used. Though there are many types of complications, mesh complications can be divided into four different types: 1) erosion - into the urethra, bladder, or bowel (<1%) 2) extrusion - of the mesh into the skin of the vagina (1%) 3) infection- the synthetic mesh gets a bacterial load and this makes the mesh a focal point for pus collection (<1%). 4) pain - the mesh heals in a way that causes pain in the vagina or pelvis (<1%).

Urinary retention: Retention is the inability to urinate and occurs in fewer than 5% of cases. Usually a patient is able to urinate normally within two to three weeks following the procedure. However if retention is prolonged, a catheter may be necessary. In rare cases of prolonged retention, a corrective procedure may be required.

Wound infection: The incision site can become infected. While infections typically resolved with antibiotics and local wound care, occasionally part or of all of the incision may open and require revision. Keeping it dry and avoiding baths and swimming helps reduce the risk of infection.

Scar Tissue Formation: Scar tissue can form around the mesh that can lead to chronic pain.

Treatment failure: Failure of the procedure to prevent stress urinary leakage development of Urinary urgency, frequency and/or urge leakage (1-3%)

Bleeding/hematoma: When a small blood vessel continues to ooze or bleed after the procedure is over, the area of collecting blood is referred to as a hematoma. The body normally reabsorbs this collection over a short period of time, and surgical drainage is rarely necessary.

Painful intercourse and vaginal shortening: After a sling procedure excessive scar tissue can form. While usually not a probable, some women may complain of pain or difficulty with intercourse. Most of the time it is temporary.

Chronic pain: As with any procedure, a patient can develop chronic pain in the area that has undergone surgery. Typically, the pain disappears overtime, although some feeling of numbness may persist. If persists, further evaluation may be necessary.

Lower Extremity Weakness/ Numbness: This, too, is a rare event that may arise due to your positioning on the operating table. It is possible with the procedures in which you are in the lithotomy (legs up in the air) for a long time. The problem is usually self-limited, with a return to baseline expected.

Urinary Tract Infection or sepsis: Although we may give you antibiotics prior to and after the operation, it is possible for you to get an infection. The most common type is a simple bladder infection that presents with symptoms of burning urination, urinary frequency, and a strong urge to urinate. This usually resolves with a few days of antibiotics. If the infection enters into your bloodstream, you may feel very ill. This type of infection can present with both urinary symptoms and any combination of the following: fevers, shaking chills, weakness, or dizziness, nausea and vomiting. You may require a short hospitalization for intravenous antibiotics, fluids, and observation. This problem is more common in diabetics, patients with long term steroids, or in patients with disorders of the immune system.

Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE): In any operation, especially long operations, you may develop a clot in the vein of your leg (DVT). Typically this presents 2 to 7 days (or longer) after the procedure as pain, swelling, and tenderness to touch in the lower leg (calf). Your ankle and foot may become swollen. If you notice these signs, you should go directly to the emergency room and also call our office. Although less likely, this blood clot can move through the veins and block part of the lung (PE). This would present as shortness of breath and possibly chest pain.

You are consenting to the surgery mentioned above in light of these risks. All questions were answered to your satisfaction. You are also consenting to the use of videotaping or pictures for educational purposes only.

____________________________________ ____________________________________

Signature of person giving consent (patient)/Date Signature of person obtaining consent/ Date

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