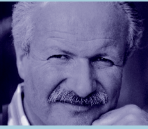

NAFC

National Association For Continence

Surgical Treatment for Female Stress Urinary Incontinence

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Promoting Quality
Continence Care through

Consumer Education

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How to Find a Healthcare Provider

- Call NAFC at 1-800-BLADDER for the name of a urologist or urogynecologist, or visit the NAFC Web site, www.nafc.org, to "Find An Expert" by using your zip code. You can also search other professional databases for additional specialists by clicking on "Other Search Engines" on the NAFC homepage.
- If you cannot find a nearby healthcare professional using the NAFC website, look in your local yellow pages directory or call your local hospital and ask if the hospital has a continence clinic. Your medical insurance company will also have a list of specialty providers.
- Confide in a friend. Often friends will tell you where they had their treatment and if they were satisfied.

About NAFC

NAFC is the world's largest and most prolific consumer advocacy organization dedicated to public education and awareness about bladder and bowel control problems, voiding dysfunction including retention, nocturia and bedwetting, and related pelvic floor disorders such as prolapse.

This material is based on professional advice, published experience and research, and expert opinion. It does not represent individual therapeutic recommendations or prescription. For specific medical advice, consult your personal physician or other knowledgeable healthcare provider. For further information, visit www.nafc.org or call us at 1-800-BLADDER (1-800-252-3337).

Female Stress Incontinence

Surgical Treatment: Is it For You?

Urinary incontinence, or loss of bladder control, is a symptom with many different causes. Therefore, there is no one “best” treatment. Rather, the best possible treatment requires an accurate diagnosis and selection of therapy that is customized to the individual patient. The focus of this brochure is surgical therapy for women with stress urinary incontinence. It is first necessary to review the anatomy of the lower urinary system, define the types of incontinence, and explain the causes of stress incontinence to put this discussion in context.

Anatomy

The lower urinary tract is composed of the urinary bladder (the organ which stores urine) and the urethra (the channel through which the urine exits the body) with the muscular sphincter. The two major types of urinary incontinence are stress incontinence (SUI) and urge incontinence. With SUI, physical stress (exercise, coughing, sneezing, etc.) puts pressure on the top of the bladder. The urethra is unable to stay closed and urine leaks out. In this situation, the abnormality or weakness is in the urethra or pelvic floor (the network of muscles that support the urethra and pelvic organs) (Figure I). Urge incontinence, or overactive bladder, is caused by abnormal, undesired bladder contractions (the bladder muscle

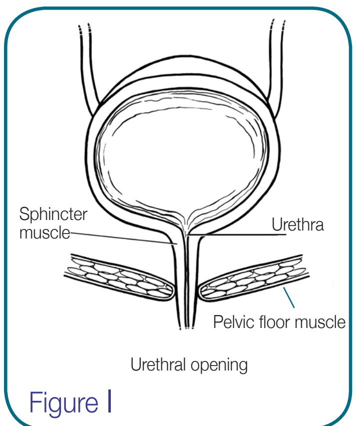

Figure I

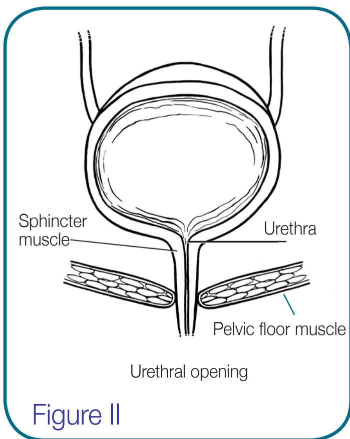

Figure II

does not normally contract until a person is at the toilet and is ready to urinate). This abnormal contraction pushes urine out through the urethra and causes leakage (Figure II). In this situation, the abnormality is in the bladder because it is contracting inappropriately. When these two conditions occur together (which they commonly do), it is referred to as mixed urinary incontinence. SUI can be treated with behavioral and non-surgical therapy as well as with surgery. While non-surgical options are available for women with SUI, the purpose of this brochure is to explain the surgical treatment of SUI. Women who have mixed incontinence should not only explore treatment options for SUI but also for urge incontinence, as they differ.

Causes of Stress Urinary Incontinence

The urethral abnormality that accompanies stress incontinence may be due to either of two causes. First, the urethra may be poorly supported, referred to as urethral hypermobility. The urethra should have strong support from the pelvic floor, composed of ligaments, tendons, and muscles, so that it remains closed during exercise, coughing, and straining. These structures can be injured or weakened by childbirth, pelvic surgery, obesity, frequent prolonged straining, and strenuous exercise such as weight lifting, jogging, jumping, long distance running, and high impact aerobics. The urethra

then drops and opens when exposed to physical stress or straining. Loss of urethral support is frequently associated with loss of support for the other pelvic organs (prolapse), particularly the bladder. The two conditions are nevertheless independent; stress incontinence can occur without pelvic prolapse and vice-versa. In the same way, treatments to correct one of the conditions may not necessarily correct the other.

The second cause of SUI is poor urethral function, or intrinsic sphincter deficiency (ISD). SUI can occur even when the urethra is in a perfectly normal and well-supported position. At one time it was thought that this was a rare problem that occurred after nerve injuries, radiation to the pelvis, or extensive pelvic surgery. We now know that this is a common condition and may be due to aging, hormonal changes, nerve injury during childbirth, pelvic surgery, and other factors. In this situation, the walls of the urethra simply are not able to create an effective seal. It is like a faucet that needs to have a washer replaced to correct a slow drip. While there is no specific test for ISD, it is now generally believed that many women with SUI have at least some degree of ISD.

Evaluation of Incontinence

When incontinence is severe enough to cause embarrassment or limits your activities, it is time to talk to your doctor. To determine which treatment is best for you, the doctor should take a detailed history of your general health and your bladder symptoms. It is helpful for you to be prepared for this visit by keeping a bladder record for a few days detailing the time of each urination and keeping track of the amount and circumstances of any urine leakage (see note below). It is very helpful if you can measure the

volume of each urination for one full 24-hour period. This type of record can tell the doctor a great deal about your bladder function without invasive testing

The doctor will want to know about all of your medical history, particularly details of childbirth and any pelvic surgery. As part of an evaluation

Note: Forms for recording urinartion over several consecutive days are available free to NAFC members. Call 1-800-BLADDER or visit our website at www. nafc.org.

for incontinence, it is important to consider other problems that may be related or that could be addressed at the same time. The doctor will ask you about bladder infections, difficulty urinating, gynecologic problems, problems with your bowels including fecal incontinence, and neurologic problems such as back injury, stroke, or other neurologic diseases. If you have had prior treatment for incontinence—medical, surgical or other therapies—the details of this will be important in making a decision about future treatment. The doctor will then perform a physical examination and test your urine for infection or other problems. The doctor may catheterize you (pass a small tube through the urethra to drain the bladder) to determine if you are emptying the bladder completely. The doctor may examine you while coughing and straining to see if stress incontinence can be demonstrated. This simple type of office evaluation is adequate for many patients, and treatment can often be started at this point. For other patients, X-rays or MRI of the bladder, bladder function tests (urodynamic studies), which measure the bladder and urethral sphincter pressures, and cystoscopy, may be

required. Cystoscopy is a painless examination looking inside of the bladder and urethra using a small telescope, usually performed in the doctor's office.

Surgery for SUI

Surgical treatment of stress urinary incontinence has been the mainstay of therapy, particularly in the United States, for many years. While surgery is still generally acknowledged to be the most effective treatment for stress incontinence, the myriad of operations that have been described attests to the fact that there is no one "best" operation for all patients. Even experienced surgeons disagree as to the preferred treatment; the only way to answer this question would be through large randomized trials comparing the different operations. The National Institutes of Health have recently funded a cooperative group to perform such studies; while this will take many years to produce clear, long-term results, it will greatly improve the understanding of surgical outcomes and an ability for providers to counsel patients appropriately. In the meantime, we must depend on published research to date, accumulated experience and the doctor's judgment.

There has been a dramatic change in the number and types of operations for SUI performed in the past 15 years. The vast majority of SUI procedures are now one of several different pubovaginal (i.e., in the region of the pubis and the vagina) slings. The basic concept of the sling is that a piece of strong material is placed beneath the urethra as a supporting "hammock." The sling thus corrects the poor anatomic support of the urethra and may additionally provide a degree of compression to the urethra. There are many

different sling procedures and the distinguishing features among them have important implications. Slings can be classified by the material used to create the sling, the position of the sling along the urethra, and the route used to place the sling. Slings that rely on tissue-to-tissue suturing do not involve synthetic mesh. The most important development has been the use of synthetic slings placed at the middle portion of the urethra, termed “mid-urethral slings.” These operations have primarily been used for SUI patients who have loss of urethral support, or urethral hypermobility. Most mid-urethral slings are placed loosely and appear less likely to cause problems with urination than earlier generations of materials. Although synthetic materials had been used in the past, the complication rate, primarily urinary tract infection, mesh exposure, and mesh erosion (also tissue ulceration, breakdown, or irritation) was unacceptably high.

Today, there are three main types or approaches of mid-urethral slings: retropubic, transobturator, and the newer mini-sling. All three are effective, but because the standard retropubic and transobturator slings enjoy 10 - 15 years of use and an impressive number of reports of their effectiveness, they are today considered the “gold standard” for surgical treatment of SUI in women by many leading clinicians. Newer materials and a needle approach through the skin with minimal cutting, along with “tension-free” placement in the mid-urethra, have led to these operations becoming the most popular procedures in the United States and Europe. The mini-sling, utilizing the transobturator approach and a single incision, is generally placed with tension in the mid-urethra and is the newest among the three types. There are

now a number of competitive products offering slightly different sling material and/or methods of placement. While a popular and effective procedure, the route used to deliver the tension-free transvaginal tape does not allow surgeons a full view of the pelvic organs. One increasingly popular technique is the transobturator approach that uses a different incision site considered to lower the risk of urethral and bladder injury. There are still other techniques that deliver synthetic slings, which are either meant to lower injury risk and/or achieve greater compression of the urethra. The tradeoff is greater risk of post-operative groin or pelvic pain with the transobturator approach. While mini-slings are considered as safe as the mid-urethral sling procedures performed today, the data are less mature and thus conclusiveness regarding equivalent effectiveness has not been established.

Suspension procedures can be performed through the vagina or through the abdomen. Although abdominal suspensions are less

There are several tension-free mesh tape kits on the market. GYNECARE TVT™ and GYNECARE TVT™ Obturator System are the branded names of Ethicon Women's Health & Urology but several other companies manufacture equivalent kits. These other companies are C.R Bard, AMS, Boston Scientific, Cook, Coloplast, Neomedic, and Caldera. Although some people refer to these procedures generically as "TVT", they are more correctly classified as either "retropubic" or "transobturator" to signify the surgical approach to mesh placement.

popular than slings, the Burch procedure is still considered to be a good choice for patients with stress incontinence especially if it accompanies

another abdominal procedure. In the Burch procedure, an abdominal incision is made, the area where the urethra and bladder connect is surgically exposed and several (usually four) sutures of either permanent or absorbable material are placed next to the urethra at the bladder neck and mid-urethra and tied to a strong ligament nearby on the pelvic bone. This procedure has been used for 50 years with good success and was considered the "gold standard" until the mid-urethral slings using mesh were introduced two decades ago.

Other procedures of historical interest are the anterior repair, which is performed for a bulging, dropping bladder (prolapse) but is not useful for urinary leakage. If performed in a patient with leakage of urine, it will fail within five years in 65% of women, so it has been abandoned. A needle suspension without mesh was also performed in past years and also abandoned due to unreasonably high (55%) five year failure rates. There were non-synthetic materials used such as cadaveric (human donor tissue) or animal donor tissue. Most of these trials as well have been abandoned as these materials are often reabsorbed by the body over time and the failure rates are higher than with the mid-urethral slings, using mesh. The use of screws and bone anchors has also been abandoned as excessively costly, possibly risky, and with no proven advantage.

Classic bladder neck slings may be appropriate for women with repeat surgery for incontinence. Autologous tissue (tissue harvested from the patient herself, most often through a low abdominal incision or from the thigh) is often used, but this adds to the complexity and risk of the surgery. It requires both abdominal

and vaginal incisions and is technically more difficult for the surgeon than other incontinence procedures. It also requires a longer recovery period for the patient and results in more problems voiding, or passing urine, than other operations for incontinence. It is, however, successful in properly chosen patients. Additional non-synthetic material includes "biologic", meaning donated from a bovine or porcine specimen. This option may be beneficial for women with previous surgeries or radiation in the pelvic area.

The Operation and Post-Operative Recovery

In the vast majority of cases, surgical procedures for stress urinary incontinence can be performed under either regional (spinal or epidural) or general anesthesia. Many surgeons perform the mid-urethral slings with the patient under sedation with local anesthesia. When only an incontinence procedure is performed, hospitalization is typically minimal—outpatient surgery or an overnight stay. If additional procedures are performed to correct pelvic organ prolapse, then hospitalization may be required. It is unusual for a patient to be in the hospital for more than two nights after a routine operation.

The mid-urethral slings are simple, well-tolerated procedures. The nylon-like mesh is just over a half inch in width and is inserted with needles under the mid-urethra. After anesthesia, an opening is made under the mid-urethra large enough to admit one finger. In the lower pelvic area two small openings are made just to pass a needle. The sling is then threaded through this track. Because the material is a bit wider than the needles, it is adjusted loosely in the proper

position and held in place with friction. No stitches are needed to keep it in place. The vaginal opening is closed with a few stitches, and the needle exits are often closed with skin glue.

At the time of discharge, the patient should be able to walk without assistance, go up and down short flights of stairs, eat a regular diet, and manage the bladder. A catheter is rarely required after mid-urethral sling procedures, and most patients simply urinate normally, although the stream may be a bit slower. Transient urinary retention (the inability to empty the bladder) may be expected for several days or up to two weeks as with other bladder neck suspension procedures. The patient may have an indwelling urethral catheter for several days, may start intermittent catheterization (passing a small straw like tube into the bladder several times a day to empty), or a suprapubic tube (a small catheter exiting the bladder through the lower abdomen) may be placed during the operation. The expectations and method of postoperative bladder drainage should be discussed and determined prior to surgery. Patients should have no dietary restrictions and can resume light activities immediately. It is typically recommended that patients avoid heavy lifting and strenuous exercise for two months and sexual intercourse for about one month. Some patients who have non-strenuous employment may be able to go back to work between one and two weeks, but it is generally advised not to plan on an early return to work or to schedule any important activities in the first two weeks. Patients may have significant fatigue or discomfort that might interfere with such plans.

In most cases, a patient who has only a simple incontinence operation will feel “back to nor-

mal" at two to three weeks, whereas a patient who has a major prolapse repair along with incontinence surgery may take four weeks or more to regain full strength and stamina. An individual's response to the stress of surgery is of course highly variable, and a person may use their response to other surgical procedures as a guideline.

Is Surgery for You?

The decision to have surgery to treat stress incontinence is often a difficult one. When there are other symptomatic problems such as a prolapse or a significant gynecological disorder, then the choice of surgery becomes easier since these can be corrected at the same time. When a patient has only stress incontinence, the analogy to an athlete with an injured knee may be helpful. The athlete has an injury primarily involving the ligaments and tendons supporting the knee. This athlete may be able to compensate for the weakened ligaments by strengthening the surrounding muscles to stabilize the knee joint. This is similar to pelvic floor muscle exercises, or Kegel exercises, to help correct SUI. When a person has a severe injury or wants to resume vigorous athletic activity, she is more likely to require surgical correction.

Patients with less active lifestyles and less severe problems are more likely to be satisfied with nonsurgical methods such as pelvic muscle exercises and physical therapy/biofeedback. Other less invasive options that can be considered are vaginal support devices (pessaries) and urethral injection therapy. Such options are particularly attractive for the patient with low level, predictable incontinence who may only want to control leakage when exercising or dancing, or for whom surgery is not a viable option or choice.

With urethral injections a material in injected into the urethra with a needle that is usually passed through a cystoscope. The procedure was developed to be done under local or light general anesthesia and there is essentially no recovery time. While not as effective as surgery, some patients, particularly the elderly and those who have failed surgery in the past, prefer this simple approach. Other non-surgical treatment, such as one using thermal energy, has also recently been introduced and is available in the US. Estrogen therapy, vaginal or systemic, may enhance surgical results by improving the integrity and strength of the vaginal tissues that are weakened by aging and menopausal hormone changes.

The patient who has only SUI without significant urgency is more likely to be completely satisfied with the results of surgery, but mixed urinary incontinence is not a reason not to undergo surgery. Many patients with mixed urinary incontinence will not have responded at all to medication for overactive bladder but may become completely dry after successful surgery for the stress leakage. On the other hand, some patients may experience new-found urgency after surgery for SUI. The problem is that it is hard to predict which of these patients will have urgency following surgery. All patients should understand that this is possible, frame expectations accordingly, and accept this as a possibility before agreeing to surgery. The urgency and/or urge incontinence can still be separately treated if it is an issue after correction of SUI.

In summary, any patient in reasonable health for whom SUI is a significant social problem should seriously consider surgical treatment. The patient should also evaluate the non-

surgical alternatives, and it is appropriate to spend a three-month period of time in a serious effort to strengthen the pelvic floor muscles prior to surgery. There are a great number of different operative procedures for the treatment of stress urinary incontinence, and the patient should carefully discuss the alternatives with her physician. Most importantly, the patient should feel comfortable asking her physician why a particular procedure is recommended and how much experience her doctor has in performing it. If treatment is not an option, women may also consider management options, such as absorbent products and urethral inserts.

Surgical mesh is used to repair weakened or damaged tissue. In urogynecologic procedures, it is permanently implanted to reinforce the vaginal wall or to support the urethra. It is porous but may be synthetic or biologic. There is sufficient research and experience of over 15 years in the USA and close to 20 years in Europe with sub-urethral polypropylene slings. Recently, the FDA issued safety communications regarding the potential for serious complications associated with vaginal mesh, of all constructions, in pelvic surgery for prolapse. Before reaching a decision, patients are urged to educate themselves and ask their surgeons about all treatment options, the doctor's experience with such repairs, and the doctor's ability to address any and all complications that may occur during and after surgery. More information can be found at www.nafc.org including a position statement issued publicly by NAFC in 2011.

National Association For Continence is a national, private, non-profit 501(c)(3) organization dedicated to a threefold mission: 1) To educate the public about the causes, diagnosis categories, treatment options, and management alternatives for incontinence, nocturnal enuresis, voiding dysfunction and related pelvic floor disorders, 2) To network with other organizations and agencies to elevate the visibility and priority given to these health concerns, and 3) To advocate on behalf of consumers who suffer from such symptoms as a result of disease or other illness, obstetrical, surgical or other trauma, or deterioration due to the aging process itself.

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