Treatment Options for Stress Urinary Incontinence

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Treatment options for stress urinary incontinence (SUI) in women are designed to prevent the involuntary loss of urine from the urethra during increases in intraabdominal pressure that occur during physical activity, coughing, or sneezing. Effective nonsurgical therapies include behavioral therapy (eg, bladder training, fluid and dietary modification) and drug therapy. Surgical therapy for this condition has existed for well over 100 years. Currently, approximately 200 different surgical procedures have been described. Because of the physiologic risks inherent in surgical procedures, the cost of hospitalization, and the loss of productivity during convalescence, surgeons continue to modify their techniques to improve efficacy, safety, and cost-effectiveness, and to minimize invasiveness. No single procedure or intervention is optimal for all patients. Having a variety of treatment options offers the possibility of tailoring therapy to the desires and needs of the individual patient. The key to an optimal therapeutic outcome is an accurate diagnosis combined with the selection of an appropriate intervention that is acceptable to the patient after balancing multiple factors.
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There is a wide spectrum of treatment options available for patients with symptomatic stress urinary incontinence (SUI). Strong opinions exist as to the "best" nonsurgical and surgical therapies for this condition. However, the perfect therapy for SUI has not yet been identified (Table 1). This article reviews the pathophysiology and evaluation of SUI and examines the current treatment options for patients with uncomplicated SUI.

Table 1
Characteristics of the "Perfect" Therapy for Stress Urinary Incontinence

- 100% Effective
- Durable/permanent
- Simple, quick, and easy to perform or implement
- Minimally invasive and completely reversible
- Applicable and effective for all types of stress urinary incontinence
- Low morbidity and/or complications
- Inexpensive for the patient, health care facility, and health care system

Mechanisms of Continence and Incontinence

During bladder filling and urine storage, the bladder accommodates increasing volumes of urine from the upper urinary tract, with no significant increase in bladder (intravesical) pressure.[1] During the filling phase, bladder or detrusor smooth muscle activity is normally suppressed by centrally mediated neural reflexes. In order to maintain continence, the bladder outlet and urethra must be closed at rest and remain so during periods of increased abdominal pressure. Normal bladder emptying occurs with a decrease in urethral resistance followed almost immediately by a volitional bladder contraction. Relaxation of the pelvic floor musculature and urinary sphincters and funneling of the bladder outlet permit urine to flow into the urethra. The rise in intravesical pressure should be of adequate magnitude and duration to empty the bladder almost completely.[1]

With rare exceptions, urinary incontinence occurs when the pressure within the bladder exceeds the total urethral resistance and urine flows involuntarily beyond the urinary sphincter. Alterations in the anatomy and/or function of either the bladder or urethra during the filling/storage or emptying phases of urination may result in urinary incontinence. Simply stated, urinary incontinence occurs as a result of abnormalities of the urethra (ie, the bladder outlet and urinary sphincter) or the bladder or a combination of abnormalities of both of these structures.[2] Abnormalities may result in either overfunction or underfunction of the bladder and/or urethra, resulting in the development of urinary incontinence (Table 2). Although this simple classification scheme excludes rare causes of urinary incontinence, such as congenital ectopic ureters and urinary fistulas, it is, nonetheless, an extremely useful tool.

Urinary incontinence that occurs as the result of a poorly functioning urethra is designated as SUI. As its name implies, this condition occurs when a compromised urethral sphincter is no longer able to resist the flow of urine from the bladder during periods of increased intraabdominal pressure. The following factors contribute to the maintenance of urethral continence: passive urethral closure and coaptation (mucosal "seal," smooth and striated muscle, submucosal connective tissue, neurologic integrity), a critical urethral length, maintenance of the normal anatomic position of the bladder neck and proximal urethra, and adaptive changes to the urethra that occur at periods of increased intraabdominal pressure.[3]

Although the etiology of poor urethral function in the stress-incontinent woman is not completely understood, identifiable risk factors for the condition include pregnancy, childbirth, menopause, cognitive impairment, obesity, and advanced age.[4,5] For example, women who have had vaginal deliveries are at much greater risk for developing SUI than age-matched nulliparous controls or women having delivered by Cesarean section.[6] Furthermore, some studies have shown that the peak prevalence of SUI occurs during or after menopause, implying that hormonal factors, including estrogen levels, are important in maintaining continence. It is well established that the urethra and bladder neck in women have an abundance of both estrogen and α-adrenergic receptors. The degree to which these receptors contribute to the maintenance of urinary continence is unknown, and the question of whether SUI can be success-

Table 2
Functional Classification of Urinary Incontinence

Abnormality	Type of Clinical Incontinence
Bladder overactivity	Urge
Bladder underactivity	Overflow
Urethra overactivity	Overflow
Urethra underactivity	Stress

fully treated with estrogen repletion alone has not been definitively settled.[7]

Choice of Intervention in SUI

Many factors should be considered when determining the optimal therapy for a patient with SUI. These include the etiology and type of SUI; bladder capacity; renal function; sexual function; severity of the leakage and degree of bother to the patient; the presence of associated conditions, such as vaginal prolapse, or concurrent abdominal or pelvic pathology requiring surgical correction; prior abdominal and/or pelvic surgery; and, finally, the patient's suitability for, and willingness to accept, the costs, risks, morbidity, and success (and failure) rates associated with each intervention. The decision to treat symptomatic SUI with surgery should be made when the patient's degree of inconvenience and/or compromised lifestyle are great enough to warrant an elective operation and nonsurgical therapy is either not desired or has been previously ineffective.

There is no optimal therapy for all patients with SUI. However, the selection of an appropriate intervention for a properly motivated patient will most often result in an adequate improvement in symptoms. Oftentimes, the choice of intervention is made by the patient (not the caregiver) after appropriate diagnostic evaluation and counseling. Several therapeutic approaches may be appropriate for each patient with SUI. Interventions for one type of urinary incontinence, especially SUI, may not be applicable to other types of urinary incontinence (Table 3).[8]

Table 3
Potential Treatment Options for Urinary Incontinence

Therapeutic Approach	Solutions for Outlet-Related Disorders (SUI)	Solutions for Bladder-Related Disorders (UUI)
Absorbent products	√	√
Artificial sphincter	√	
Behavioral therapy*	√	√
Bladder overdistention		√
Bladder outlet reconstruction	√	
Closure of bladder outlet	√	
Continuous catheterization	√	√
Electrical stimulation	√	√
External collecting device	√	√
Interruption of innervation, central		√
Interruption of innervation, peripheral		√
Occlusive devices	√	
Pharmacologic therapy		
α-Adrenergic agonists	√	
α-Adrenergic antagonists		√
Anticholinergics		√
ß-Adrenergic agonists	√	√
ß-Adrenergic antagonists	√	
Calcium antagonists		√
Capsaicin, resiniferatoxin		√
Dimethyl sulfoxide		√†
Estrogen	√	√
SNRIs	√	√
Urinary diversion	√	√

*Behavioral therapy consists of education, fluid restriction, bladder training, timed voiding, and pelvic floor muscle training, with or without biofeedback.
†Interstitial cystitis only.
SUI, stress urinary incontinence; UUI, urge urinary incontinence; SNRIs, serotonin-norepinephrine reuptake inhibitors.
Adapted from Wein AJ, Rovner ES. *Urol Clin North Am.* 2000;29:537-550.[8]

For most patients with SUI, however, it is reasonable to discuss first the most reversible, simplest, least invasive, and least expensive intervention (usually behavioral modification). More invasive or expensive interventions, such as surgery, are pursued if the patient decides that the current (presumably nonsurgical) therapy is either ineffective or otherwise undesirable.

The consensus appears to be that the most effective and durable long-term therapies are surgical. The trade-off between nonsurgical and surgical therapies involves factors such as cost, convenience, morbidity, and short- and long-term efficacy. Although cure of SUI is ideal, many patients may only desire an improvement in symptoms and not necessarily complete dryness. This fact is important to recognize when treating a condition such as SUI, for which therapy is purely elective and for which some

Table 4
Pretreatment Evaluation Procedures and Purposes

History taking
- Note onset of problem, impact on QOL, and degree of bother
- Identify symptoms
- Track development of symptoms
- Rule out chronic illnesses that affect fluid balance (eg, CHF, DM, renal insufficiency)
- Rule out medications with urinary adverse effects (eg, diuretics, antidepressants, antipsychotics, anticholinergics, sympathomimetics, OTC agents)
- Determine parity
- Assess prior pelvic surgeries

Physical examination
- Assess vaginal prolapse
- Assess vaginal turgor
- Evaluation for occult neurologic condition
- Objective demonstration of SUI on cough stress test

Urinalysis
- Evaluate for hematuria, pyuria, etc

PVR*
- Rule out overflow incontinence

Cystoscopy*
- Visualize urethral and bladder lumen for signs of anatomic abnormalities, irritation, etc

Urodynamic studies*
- Confirm SUI
- Assess urethral function (VLPP)
- Assess for occult urge urinary incontinence
- Evaluate compliance

*Optional (physician's choice).
QOL, quality of life; CHF, congestive heart failure; DM, diabetes mellitus; OTC, over-the-counter; PVR, post-void residual urine volume; SUI, stress urinary incontinence; VLPP, Valsalva leak point pressure.

types of interventions could potentially worsen the existing symptoms and/or create new problems.

Diagnostic Evaluation

Each patient suspected of having SUI should undergo a thorough history taking, physical examination, and other studies as indicated (Table 4). Voiding diaries and pad tests are important adjunctive assessments. The extent of further diagnostic evaluation, especially urodynamics, can be tailored to the goals and desires of the patient. Urodynamic studies are likely not required if nonsurgical, completely reversible, inexpensive therapy is planned. However, before proceeding with invasive surgical therapy, it is prudent to objectively demonstrate SUI by means of urodynamics that unequivocally reproduce the patient's symptoms.

Recently, the proceedings of the 2nd International Consultation on Incontinence (ICI) were published. Among the many outstanding chapters was a review by a consensus panel of experts of the performance, indications, and utility of urodynamic investigations in a variety of clinical settings.[9] The panel recommended urodynamics for the investigation of incontinence symptoms in women in the following cases only: 1) voiding difficulty or neuropathy is suspected, 2) the patient has failed nonsurgical or surgical therapy, or 3) invasive or surgical treatments are being considered.

For patients in whom urodynamic studies are indicated, the panel recommended that initial noninvasive investigations include uroflow, post-void residual urine volume determination, and filling cystometry with or without provocation. According to the panel, videourodynamic studies are indicated when the patient history and simpler urodynamic tests do not lead to a definitive diagnosis or after failure of initial therapy. The expert panel concluded that, for patients with urinary incontinence, urodynamic studies are *required* in 3 circumstances: 1) when a detailed knowledge of lower urinary tract function is necessary to decide the course of treatment, 2) when investigating the reasons for failure of prior treatment, and 3) in order to predict the outcome of a proposed treatment.[9]

Treatment Decisions

Although the evidence base for determining practice decisions for patients with SUI is growing, there are relatively few prospective studies with adequate sample sizes to assess and compare the effectiveness of SUI interventions. The Agency for Health Care Policy and Research (AHCPR; newly renamed the Agency for Healthcare Research and Quality) and the 1st and 2nd ICIs have published a comprehensive literature

review and consensus opinion of treatment guidelines for the therapeutic interventions for SUI.[10-12] Nevertheless, as previously noted, it is generally accepted that there is no "perfect" therapy for all patients with this condition.

Nonsurgical Interventions

For most patients, the initial management of uncomplicated SUI involves a variety of noninvasive interventions, including behavioral modification, pelvic floor exercises (PFEs) with or without biofeedback, and other accessory teaching aids.[13]

Behavioral Therapy

A behavioral modification program for SUI consists of the following: 1) patient education regarding the function of the lower urinary tract, 2) fluid and dietary management, 3) timed voiding, prompted voiding, or bladder training, and 4) a voiding log or diary, usually combined with 5) PFEs or Kegel exercises. For most patients, the aim of behavioral therapy is to help regain bladder control by increasing the effective capacity of the bladder, thereby reducing the symptoms of urinary incontinence.

The use of a frequency/volume chart or voiding log plays a central role in bladder training. A review of urine output in relation to the patient's fluid-intake record is a valuable educational tool that can be used to modify (and/or reduce) fluid intake in patients who are resistant to fluid management efforts. Through review of the voiding log, patients may realize that they are consuming an excessive volume of fluid each day and thus modify their behavior accordingly. The contribution of dietary items that may precipitate symptoms of urinary incontinence, such as coffee, tea, and alcohol, usually becomes obvious after reviewing the voiding log. The elimination or moderation of these items may improve symptoms considerably.

An additional benefit of the voiding log is documentation of the voiding interval. The patient is asked to gradually increase the intervals between voids and record the volumes voided. It may initially be useful to ask some patients to void hourly, at an appointed time. Once this is managed without leakage, the time between voids is increased by 15-minute intervals, until the elapsed time between voids is more acceptable, perhaps between 2 and 4 hours. Thus, the voiding log acts as a reminder of when to void (timed voiding), while also providing a schedule by which the patient can reliably increase the voiding interval.

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Outcomes with behavioral therapy are quite good. Fantl and colleagues[14] recorded a 57% reduction in incontinence episodes and a 54% reduction in the quantity of urine loss in older women performing bladder training. The reduction in episodes of incontinence was similar in patients with urge incontinence and stress incontinence.

Behavioral therapy can be utilized by any health care professional. It is a simple, inexpensive (as long as not overburdened with "bells and whistles"), effective intervention, with no significant adverse effects (important in the geriatric population). Behavioral therapy does, however, require patient and caregiver motivation and a time commitment. It can and should be easily combined with other nonsurgical regimens.

Pelvic Floor Muscle Training

Pelvic floor muscle training (PFMT) can be one of the most important components of behavioral therapy. PFMT exercises help the patient strengthen the muscles of the pelvic floor. Since Arnold Kegel, MD, first described these exercises almost 50 years ago,[15] numerous studies have evaluated the efficacy and durability of PFMT, with conflicting results.

The levator ani muscle group and the surrounding fascia comprise the pelvic floor and provide the supportive mechanism for the pelvic organs. This group of muscles is found at the base of the pelvic floor and is composed of approximately 70% slow-twitch and 30% fast-twitch muscle fibers. Slow-twitch muscle fibers produce less force on contraction and assist in improving muscle endurance by generating a slower, more sustained, but less intense contraction. Fast-twitch muscle fibers, which aid in quick and forceful contractions, can be used during sudden increases of intraabdominal pressure by contributing to urethral closure. PFMT exercises consist of repeated, high-intensity, pelvic muscle contractions of both types of muscle fibers.

The effects of PFMT on lower urinary tract muscle function are not completely understood; however, it is believed that there is a relationship between changes in various measures of pelvic floor strength, such as anal sphincter strength or increased urethral closure pressure, and resistance, all of which help prevent urine leakage. In teaching PFMT exercises, most of the research has incorporated some form of biofeedback therapy to demonstrate muscle identification. The addition of pelvic floor electrical stimulation has also been used. Biofeedback, when used as part of a

pelvic muscle rehabilitation program for urinary incontinence, translates pelvic muscle activity to the patient in a readily understandable signal. This technique may be particularly helpful for women who have trouble identifying and isolating the correct muscle. Surface, vaginal, and anal electrodes can be used to measure muscle contraction.[16]

Extensive research has detailed the efficacy of pelvic muscle training, both with and without biofeedback therapy.[17-21] Several trials have demonstrated significant improvement and satisfactory cure rates in patients adhering to a strict program of behavior modification and PFMT.[22-24] Patient compliance and motivation, however, are essential to a successful program. Underscoring this point, a relatively recent multicenter trial compared bladder training, biofeedback-assisted PFE, or a combination of both techniques for the treatment of urinary incontinence (stress, urge, or mixed) in 204 women.[24] At the end of this 3-month trial, the combination therapy group reported significantly fewer incontinence episodes, better quality of life, and greater treatment satisfaction, regardless of the urodynamic classification of incontinence (ie, stress vs urge vs mixed). However, 3 months following the trial's completion, there were no differences among the 3 groups in any outcomes measured. This finding implies that, although behavioral interventions including PFEs are effective in the treatment of urinary incontinence, patient compliance and periodic reinforcement is essential for success.

Most PFMT studies report a reduction in incontinence episodes of more than 50%. In a review of 24 randomized, controlled trials, 11 of which were of sufficient quality to be further analyzed, Berghmans and colleagues[25] concluded that there is "strong evidence" to suggest that PFMT is effective in reducing the symptoms of SUI. It was unclear in their analysis, however, if high-intensity PFEs are superior to low-intensity PFEs or whether biofeedback and electrical stimulation can add any benefit over PFEs alone. In contrast, Weatherall[26] concluded from a quantitative review of the literature that biofeedback in combination with PFEs results in a greater chance of cure in patients with genuine SUI than the use of PFEs alone.

A recent study by Diokno and colleagues[27] was the first to demonstrate that a structured behavioral modification and PFMT program may actually prevent the subsequent development of urinary incontinence in older (age >55 y) women. This study has important clinical and public health implications. Further work to substantiate these findings is anticipated.

A successful program of behavior modification and PFEs requires a substantial commitment of time and patience from both physician and patient.

A successful program of behavior modification and PFEs requires a substantial commitment of time and patience from both physician and patient. Historically, understanding the proper PFE technique, recruiting the proper muscle groups, and adhering to a regular program is difficult for many patients. In clinical practice, failure rates for this type of therapy tend to be high, and PFMT has consequently gained a somewhat undeserved reputation for both futility and poor efficacy.

Electrical Stimulation

Pelvic floor electrical stimulation is the external application of electrical current to the pelvic floor. The mechanism of action explaining why this technique may be efficacious for the treatment of both stress and mixed urinary incontinence is not clear; however, some researchers have postulated that low-level electrical currents might stimulate reinnervation of the pelvic floor or modulate a change in muscle fibers from a ratio of slow- to fast-twitch muscle fibers. Pelvic floor electrical stimulation combined with biofeedback may prove useful in that the electrical stimulation provides a passive contraction with increased awareness, via biofeedback, of pelvic muscle contractions. This combination therapy, however, has not been conclusively shown to be more efficacious than either modality alone.

Some investigators have reported spectacular success rates with pelvic floor electrical stimulation for patients with SUI, whereas others have not. The reasons for this disparity are unclear but may be related to the various methods by which the therapy is performed. There is no universally agreed upon method of pelvic floor electrical stimulation application (anal probe, vaginal probe), duration of therapy (weeks, months, permanent), amplitude or frequency of impulse required to optimally treat SUI, or timing of therapy (number of sessions per day, number of days per week).

Goode and colleagues[28] compared behavioral training alone with behavioral training plus pelvic floor electrical stimulation in 200 patients with SUI or mixed urinary incontinence. The control population received only a "self-help" booklet. Both behavioral training and behavioral training plus pelvic floor electrical stimulation significantly reduced the frequency of incontinence (mean reductions, 68.6% and 71.9%, respectively, vs 52.5% for the group using the self-help booklet); however, there was no significant

difference between the PFMT groups with or without pelvic floor electrical stimulation. The investigators concluded that biofeedback-assisted PFMT and pelvic floor electrical stimulation are both adequate techniques for helping patients identify their pelvic floor muscles, that either technique can help reduce the incidence of urinary incontinence, and that the addition of pelvic floor electrical stimulation did not improve the efficacy of PFMT.

Vaginal Cones

The vaginal cone is a tampon-like device that is inserted into the vagina and kept in place by active muscle contraction of the pelvic floor. These commercially available and widely used products come in a variety of weights. The patient is instructed to insert progressively heavier cones as she becomes adept at maintaining the lighter ones in the vaginal canal. It is believed that the sensation that the cone is slipping out of the vagina triggers a strong sensory feedback mechanism that results in contraction of the pelvic floor muscles to keep the cone in place.[29] The 2nd ICI concluded that vaginal cones may have some benefit in selected patients but probably do not have any additional benefit for patients already practicing a PFMT program.[29]

Comparing Nonsurgical Therapies

There are few studies that have prospectively evaluated and compared the efficacy of the various nonsurgical therapies. In one such study, Bo and colleagues[30] randomized 107 women with genuine SUI to 4 arms: PFEs, electrical stimulation, vaginal cones, or no therapy. Patients in the PFE arm received weekly training with a physiotherapist and were instructed to perform the exercises 3 times daily with 8 to 12 repetitions per session. Electrical stimulation was performed for 30 minutes per day with a transvaginal unit, and vaginal cones were inserted for 20 minutes per day.

Pelvic floor muscle strength increased significantly in the PFE group compared with the other 3 groups (P = .03). Reduction in leakage, as measured by a pad test, was also greatest in the PFE group. More than half (14/25) of the patients in the PFE group no longer considered themselves as having an "SUI problem" at the end of the study, which was considerably greater than the results seen in the other 3 groups; only 3 of 25 patients in the electrical stimulation group, 2 of 27 patients using vaginal cones, and 1 of 30 patients in the no-treatment arm no longer considered their SUI to be problematic at the end of the study. The investigators concluded that PFE is superior to both electrical stimulation and vaginal cones in the treatment of genuine SUI in women.[30]

With respect to nonsurgical, nonpharmacologic treatment of SUI, the 2nd ICI made the following conclusions[12]:

- Biofeedback-assisted PFMT is no better than PFMT alone.
- There is insufficient evidence to judge whether electrical stimulation is better than no treatment; some electrical stimulation protocols may be more effective than others and/or some populations may receive more benefit than others.
- Vaginal cones are probably better than control treatments but are of no benefit when added to PFMT.

Continence Devices

Several devices have been used to treat SUI in women. Few such devices are currently available for commercial use in the United States due to voluntary withdrawal from the market by the manufacturers. Some studies (usually sponsored by the device manufacturers) have shown a high degree of success and patient satisfaction; however, caution must be used when analyzing the results. The final reported success rate may not be an accurate reflection of clinical efficacy and utility. Many of these studies are conducted in highly selected and motivated patient populations and have substantial drop-out rates. Subjects must be willing and able to manipulate their genitals to utilize these devices—a situation that many patients may find unacceptable. Furthermore, a number of these devices are single-use or disposable products. Thus, the cost of continence can be substantial, as a new device is applied after each void. Sexual activity may be affected because the device may need to be removed before, or may become dislodged during, coitus; in either case, coital incontinence may result.

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Comfort issues related to the size and/or suppleness of the device, as well as the individual suitability for some types of anatomic variability (eg, prolapse or postmenopausal genital atrophy), are at times problematic. In addition, the ability of some of these devices to prevent incontinence during periods of considerable stress, such as sporting activities, is questionable. For instance, during active sports, the strenuous activity and/or the accompanying perspiration may cause the device to become dislodged and, therefore, ineffective. Moreover, none of these devices treat the under-

lying problem. The patient remains dependent on the device indefinitely; once it is removed or dislodged, the incontinence returns.

Occlusive Devices

Extraurethral. At least 3 types of externally applied (at the external urethral meatus) "blocking" devices have been manufactured at one time or another. Each device must be removed before voiding.

- Miniguard® (Advanced Surgical Interventions, Dana Point, Calif): a triangular foam device that is held in the perimeatal area with an adhesive hydrogel. This is a disposable, single-use device.
- FemAssist® (Insight Medical Corporation, Boston, Mass): a hat-shaped silicone device that is placed over the urethral meatus. Before placement, an adhesive gel is applied to the edge of the device and the central dome is squeezed to create a vacuum. The device is then placed over the meatus and the dome is released to create a suction-like seal. This is a reusable device that can be worn for a maximum of 4 hours or until voiding and then washed with hot soapy water and reinserted. It can be reused for a week.
- CapSure™ (Bard Urological Division, Covington, Ga): a reusable device to which a lubricant is applied before it is kept in place by suction. It can be reused for up to 2 weeks.

Studies of single-use devices have demonstrated significant improvements in subjective and objective (pad test) outcomes. Adverse effects have usually been transient and include vulvar and lower urinary tract irritation, vaginal irritation, and urinary tract infections (UTIs).[29]

Intraurethral. Intraurethral devices are single-use, disposable, and thin and flexible enough to insert directly into the urethra to obstruct the flow of urine into the proximal urethra. They must be removed in order to urinate. Several types have been commercially available (Reliance® [UroMed Corporation, Needham, Mass], VIVA® [B. Braun Melsungen AG, Melsungen, Germany]), but only FemSoft® (Rochester Medical Corporation, Stewartville, Minn) is currently in the marketplace. These devices have several features: a meatal plate to prevent the device from migrating into the bladder, structures that enhance its retention within the urethra (eg, inflatable balloons), and an easy means of removal to permit voiding (eg, a string). As with extraurethral devices, FemSoft has demonstrated efficacy in objective (pad test, cough) and subjective (diary) tests. Adverse effects include hematuria, UTIs, and discomfort.[29]

Intravaginal Supportive Devices (Pessaries)

Often used for the treatment of symptomatic pelvic prolapse in patients unable or unwilling to undergo surgical correction, vaginal pessaries may also be used to treat SUI, especially in patients with mild to moderate anterior vaginal wall prolapse (urethral and bladder neck "hypermobility"). Although currently not commercially available, the Introl® device (UroMed, Needham, Mass), a vaginal ring pessary with 2 prongs on one side of the ring, was specifically marketed for women with SUI. When the device is properly situated in the vagina, the 2 prongs mechanically support the bladder neck and proximal urethra.

Davila and colleagues[31] studied 70 selected patients with SUI or mixed incontinence fitted with the Introl device, 53 of whom completed the 1-month trial. Statistically significant reductions in incontinence on pad testing and bladder diaries were noted. Quality-of-life scores were high, as was the degree of patient satisfaction. Urodynamic evaluation with the pessary indwelling revealed no outlet obstruction. However, 23 patients reported vaginal soreness or irritation, and 5 patients developed UTIs during the trial.

In a study by Moore and colleagues,[32] the Introl device demonstrated limited clinical utility in an unselected patient population. Three gynecologists attempted to fit the device in the 69 women with genuine SUI who met the entry criteria for the study. Only 26 patients could be adequately fitted and completed the 4-week trial. Four patients could not be fitted with the device, and 39 of the 65 remaining patients withdrew before week 4 of the study. Of the patients successfully fitted with the device, 62% achieved objective success and an additional 23% became socially continent. Only 15 of the 26 patients fitted with the device were still using it at the end of 1 year. The authors noted that the device is highly successful in selected patients but that difficulties are often encountered in patients who have undergone multiple prior surgeries, as well as in those who are estrogen-deficient.

Although other single-use intravaginal support devices have been developed, such as Conveen Continence Guard® (Coloplast Corporation, Marietta, Ga), they have not been

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widely studied and/or are not commercially available.

Pharmacologic Therapy

Pharmacologic therapy has been widely used, with varying success rates, for the treatment of SUI in women.

α-Adrenergic Agonists

The bladder neck and urethra contain an impressive concentration of α_1-adrenergic receptors that, when stimulated, induce muscle contraction and, thus, can increase outlet resistance.[33,34] Numerous α-adrenergic agents, including phenylpropanolamine, have been studied in patients with SUI. The AHCPR *Clinical Practice Guideline*[13] reports 8 randomized, controlled trials of phenylpropanolamine therapy for women with SUI. Cure rates (percent effect on drug minus percent effect on placebo) are listed as 0% to 14%, reduction in incontinence as 19% to 60%, side effects as 5% to 33%, and dropouts as 0% to 4.3%. A recent study suggested an increased risk of hemorrhagic stroke with the use of phenylpropanolamine as an appetite suppressant.[35] The widespread publicity surrounding this finding resulted in phenylpropanolamine being withdrawn from the market and a concomitant loss of enthusiasm for this class of agents in the treatment of SUI. Other drugs in this class, specifically ephedrine and pseudoephedrine (a stereoisomer of ephedrine), are, however, still available. Investigators have reported good to excellent results in patients receiving ephedrine for relatively mild symptoms of sphincter incontinence. However, these findings were obtained mostly from non–placebo-controlled trials.[34]

Although some clinicians have reported spectacular cure and improvement rates with α-adrenergic agonists and agents that produce an α-adrenergic effect in patients with sphincter urinary incontinence, our experience mimics the results that indicate that treatment with such agents often produces satisfactory or some improvement in mild cases but rarely brings about total dryness in cases of severe or even moderate SUI. Potential side effects of all α-adrenergic agonists include elevated blood pressure, anxiety, and insomnia due to stimulation of the central nervous system, as well as headache, tremor, weakness, palpitations, cardiac arrhythmias, and respiratory difficulties. These agents should be used with caution in patients with hypertension, cardiovascular disease, or hyperthyroidism.[1]

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Imipramine

Many clinicians believe that tricyclic antidepressants (particularly imipramine hydrochloride) are useful for facilitating urine storage because they decrease bladder contractility and increase outlet resistance.[36] These agents provide varying degrees of at least 3 major pharmacologic actions: 1) they have central and peripheral anticholinergic effects at some, but not all, sites; 2) they block the active transport system in the presynaptic nerve ending, which is responsible for the reuptake of the released amine neurotransmitters norepinephrine and serotonin; and 3) they act as sedatives, an action that occurs presumably on a central basis, but may be related to antihistaminic properties. These agents have been the subject of numerous pharmacologic investigations to determine the mechanisms of action responsible for their varied effects.[37,38]

Theoretically, increases urethral resistance might be expected if, indeed, an enhanced α-adrenergic effect were produced at this level because of an inhibition of norepinephrine reuptake. Many clinicians have noted improvement in patients who received imipramine primarily for bladder hyperactivity but also had some sphincter incontinence. Gilja and colleagues[39] reported a study of 30 women with SUI who received imipramine, 75 mg daily, for 4 weeks. Twenty-one of the study participants subjectively reported continence. Mean maximal urethral closure pressure for the group increased from 34.06 mm Hg to 48.23 mm Hg. In an open-label study by Lin and colleagues,[33] 40 women with SUI received imipramine, 25 mg, 3 times daily for 3 months. Results demonstrated a 35% cure rate by pad test; an additional 25% of subjects experienced an improvement of 50% or more. Success appeared to correlate with a higher urethral closure pressure.

Duloxetine

Duloxetine has nearly equal effect on the reuptake of serotonin and norepinephrine in vivo and shows no appreciable binding affinity for neurotransmitter receptors.[40] In a cat model, this agent has weak effects on bladder and urethral sphincter activities under normal conditions; under conditions of "bladder irritation," however, it suppresses bladder activity through central serotonin receptor mechanisms and enhances urethral sphincter activity through serotonergic and α_1-adrenergic mechanisms. Clinical trials of duloxetine for both sphincter-related and mixed inconti-

nence have been completed.

In a study by Norton and colleagues,[41] 553 patients with SUI were randomized to receive duloxetine, 20 mg/d, 40 mg/d, or 80 mg/d, or placebo. With the highest dosage of duloxetine, 50% of patients had a reduction in incontinence episode frequency (IEF) of 64% or greater, and 67% of patients had a reduction in IEF of 50% or greater. There was a median decrease in IEF of 41% for the placebo group, compared with 64%, 59%, and 54% median IEF decreases for the 80 mg/d, 40 mg/d, and 20 mg/d duloxetine groups, respectively.

Dmochowski and colleagues[42] also demonstrated a statistically significant reduction in IEF with duloxetine therapy compared with placebo (50% vs 27%, respectively). Side effects associated with duloxetine were generally mild; the most frequently reported complaint was nausea (22.7%), followed by fatigue, dry mouth, and insomnia. Notably, 24% of study participants discontinued active drug therapy, but only 6.4% withdrew from the study because of nausea.

ß-Adrenergic Antagonists

It is theorized that ß-adrenergic antagonists should be useful in patients with SUI because ß-adrenergic receptor blockade may enhance the effect of norepinephrine on α-adrenergic receptors in the urethra. Propranolol, a ß-adrenergic antagonist, has been shown to have a beneficial effect in patients with SUI in a small number of uncontrolled studies. Unfortunately, a benefit of this class of drugs has not been identified in randomized, controlled trials.[43]

ß-Adrenergic Agonists

Although it is paradoxical that a ß-receptor agonist should have beneficial effects for patients with SUI, there has been a suggestion that such agents may have some efficacy through an as yet undefined mechanism of action. Yasuda and colleagues[44] reported the results of a double-blind, placebo-controlled trial of therapy with a $ß_2$-adrenergic agonist, clenbuterol, in 165 women with SUI. The drug was significantly more effective than placebo with respect to subjective evaluation of frequency of incontinence, pads per day, and overall global assessment of treatment. Pad test weight decreased from 11.7 ± 17.9 g to 6.0 ± 12.3 g with clenbuterol and from 18.3 ± 29.0 g to 12.6 ± 24.7 g with placebo, raising the question of the comparability of the 2 groups. Maximal urethral closure pressure was reported as increasing significantly in the drug group, but the actual increase was from 46.0 ± 18.2 cm H_2O to 49.3 ± 19.1 cm H_2O.

Hormonal Therapy

Sex steroids can influence continence control through their receptors in the female urinary tract as well as in areas of the brain that are involved with the initiation and control of urination. Estrogen receptors are consistently expressed in the urethra and detrusor muscle, as well as the pubococcygeal muscle in the pelvic floor.[45,46] Androgen receptors are also consistently expressed in the female bladder and urethra, but their function has not yet been clearly defined.

Although many published studies lack objective evidence of a positive effect of estrogen therapy on SUI in women, such therapy seems potentially capable of facilitating urine storage in some postmenopausal patients by increasing the total number of factors contributing to urethral outlet resistance. The clinical experience of many physicians supports an augmentative or perhaps additive effect with α-adrenergic therapy in this regard. If estrogen has a role in the treatment of lower urinary tract symptoms in postmenopausal women, this role is most likely through one or more of the following mechanisms: 1) raising the sensory threshold of the bladder and/or urethra, 2) increasing the α-adrenoceptor sensitivity in urethral smooth muscle, 3) increasing urethral resistance by increasing urethral smooth muscle α-adrenoceptor sensitivity or by another mechanism, and/or 4) correcting underlying urogenital atrophy.

Estrogen receptors are consistently expressed in the urethra and detrusor muscle, as well as the pubococcygeal muscle in the pelvic floor.

A role for estrogen in lower urinary tract disorders has been postulated based on cytologic and clinical changes observed after menopause and the high incidence of incontinence reported by elderly, postmenopausal women. Estrogen may be administered as estradiol implants, conjugated oral estrogen, estriol monotherapy or in combination with high-dose estradiol, or intravaginal estradiol cream.[45,47,48]

The use of estrogens has been reported to improve patient-reported symptoms as well as objective measures—urethral pressure, transmission of intraabdominal pressure to the urethra, and maximal urethral pressure under stress—in patients with SUI.[48] However, both Hextall[45] and Andersson and colleagues[43] have carefully reviewed the literature on this subject and have concluded that, currently, an evidence-based recommendation for the use of estrogens to treat SUI in women is not supported.

Surgery

Many patients may choose to discontinue an initial trial of conservative therapy or may eventually become dissatisfied or disenchanted with nonsurgical SUI therapies because of cost, discomfort, inconvenience, lack of efficacy, or related complications, such as UTI. For these patients, surgery assumes the primary role in the treatment of SUI. The goal of surgical treatment of urethral incontinence in women is to provide sufficient urethral resistance to prevent urine from leaking from the urethra during increases in intraabdominal pressure, while preserving voluntary, low-pressure, and complete bladder emptying.

There are close to 200 different operations that are used to treat SUI in women and, in general, any number of procedures may be considered appropriate for the "index" patient, who is otherwise healthy, desires surgical correction of SUI, and has not undergone prior anti-incontinence surgery.[49] When determining the optimal surgical therapy for patients with SUI, many factors should be considered, including the type of SUI, bladder capacity, severity of the leakage, the presence of associated conditions such as vaginal prolapse, and concurrent abdominal or pelvic pathology requiring surgical correction. In general, surgical correction of female SUI is directed toward one of the 2 following goals: 1) repositioning the urethra and/or creating a backboard of support or otherwise stabilizing the urethra and bladder neck in a well-supported retropubic (intraabdominal) position that is receptive to changes in intraabdominal pressure, or 2) creating coaptation and/or compression or otherwise augmenting the urethral resistance provided by the intrinsic sphincter unit, with (eg, sling) or without (eg, periurethral injectables) affecting urethral and bladder neck support or a combination of both. As shown in Table 5, the goals of each type of surgery are somewhat different.

Table 5
Goals of Surgical Options for Stress Urinary Incontinence

Surgical Option	Goal
Anterior repair	Reposition the urethra or "plicate" the sphincter
Retropubic approach: MMK, Burch colposuspension	Reposition and/or stabilize urethra or create a "backboard" of support for urethral compression during increased intraabdominal pressure
Vaginal approach: Pereyra, Stamey, Gittes, Raz	Same as retropubic approach with avoidance of a large abdominal incision and associated morbidity
Sling: autologous, cadaveric, synthetic, vaginal wall, etc	Same as retropubic approach with or without direct urethral coaptation or compression
TVT and other polypropylene midurethral slings	Dynamic midurethral support
Artificial urinary sphincter	Intermittent, dynamic urethral coaptation and compression
Bulk injectables	Improve urethral coaptation
Radiofrequency	Reposition or stabilize urethra

MMK, Marshall-Marchetti-Krantz procedure; TVT, tension-free vaginal tape.

Choice of Operation

As with most surgeries, the best SUI operation is the first procedure. Repeat incontinence surgery is significantly more complex and less rewarding than the first procedure because the surgical planes are poorly defined and complications are more likely to occur. The etiology of the initial surgical failure (intrinsic sphincter dysfunction [ISD], recurrent hypermobility, obstruction, instability) should be understood before undertaking a repair. For example, the finding of significant urgency and urge incontinence in a patient undergoing repeat surgery may indicate that the initial surgery was performed improperly or for inappropriate indications or, alternatively, resulted in an obstruction.

The best operation is also the one with which the surgeon is the most familiar. There is no substitute for surgical experience. Whichever approach is taken, the goal of the operation is to augment urethral resistance during periods of increased abdominal pressure. Retropubic suspensions, transvaginal suspensions, and slings are effective anti-incontinence surgeries if performed expeditiously, correctly, and for the proper indication. Nevertheless, in certain circumstances, one particular operation may be a better choice than another. The surgeon must determine if the cause of the patient's incontinence stems from anatomic incontinence (urethral hypermobility), ISD, or a combination of both. This determination may have an impact on the choice of surgery. A patient with SUI due primarily to hypermobility of the bladder

neck and proximal urethra (anatomic incontinence) can expect an 80% to 90% success rate with surgery that restores (or stabilizes) the bladder neck in a normal anatomic position. However, an operation designed to restore normal anatomy alone is probably not the optimal choice for a patient who suffers from significant ISD with or without anatomic hypermobility.[50,51] Patients with ISD often have a history of multiple operations (abdominal and/or vaginal), resulting in periurethral fibrosis and a "pipestem" urethra.[51] These patients require more than the simple anatomic restoration of the bladder neck and proximal urethra. The operative procedure will need to create coaptation of the urethral lumen or at least restore some bulk to the attenuated submucosal urethral tissues.

Surgery has been associated with impressive cure rates (Table 6). However, it is also associated with significant potential complications, such as impaired bladder emptying and bladder overactivity (Table 7).[12,49] Careful patient selection is essential to reduce the risk of complications and to ensure optimal efficacy of the selected procedure.

Table 6
Cure and Improvement Rates for Selected Surgical Procedures

Procedure	Cure Rate, Duration: % (CI)	Improvement Rate, Duration: % (CI)
Anterior vaginal repair/plication	1 y: 31-100 >4 y: 37-72	1 y: 65-88* >4 y: 70-76*
Open retropubic procedures		
MMK	1-2 y: 72 (55-85) 2-4 y: 83 (75-89) >4 y: 83 (76-88)	
Burch	1.0 y: 96 1.5 y: 85 1-2 y: 85 (78-91) 2-4 y: 84 (79-88) >4 y: 83 (75-90)	9 mo-16 y: 90
Laparoscopic	1.0 y: 80 1.5 y: 88 3.0 y: 60 5.0 y: 77	
Needle suspension		
Stamey	Initial: 67-91 4 y: 18-85	
Gittes	Initial: 73-87 4 y: 18-70	
Raz	Initial: 75-96 4 y: 14-76	
Pubovaginal sling	<2 y: 82 (73-89) 2-4 y: 82 (73-89) >4 y: 83 (75-88)	2 y: 91 (84-96)* 2-4 y: 85 (77-91)* >4 y: 87 (80-92)
TVT	5 y: 81	5 y: 14.5
Injectables	Short term: 48	Short term: 76*

*Cured or improved.
CI, confidence interval; MMK, Marshall-Marchetti-Krantz; TVT, tension-free vaginal tape.
Data from Abrams P et al. *Incontinence.* 2002[12]; Leach GE et al. *J Urol.* 1997;158:875-880.[49]

Anterior Repair (Kelly Plication)
Originally described in 1914 by Howard A. Kelly, MD, and colleagues at Johns Hopkins Hospital, this operation is still being performed by many surgeons today, despite poor long-term efficacy and durability. Classically, the operation is performed with a midline incision in the anterior vaginal wall. The endopelvic fascia is plicated at the level of the bladder neck, thus serving as a buttress to support the urethra. The procedure is often performed along with an anterior colporrhaphy in patients with a mild to moderate cystocele. It is easy to perform, avoids a retropubic dissection, and is associated with a low rate of complications. However, long-term success is poor relative to other procedures for SUI, and the latest ICI proceedings do not recommended Kelly plication for the cure of SUI.[12,49]

Transabdominal (Retropubic) Suspension
The transabdominal approach to vesicourethropexy has been utilized for many years. The advantages to this approach include the following: the familiarity of retropubic anatomy to most urologists, excellent operative exposure and access to the key anatomic elements for the surgery, long-term data supporting its durability, and the opportunity to repair coexisting abdominal pathology through the same or slightly extended incision. Disadvantages include a large incision, prolonged hospital stay and recovery period, and the inability to access and repair coexistent vaginal

Table 7
Complications of Selected Surgical Procedures

Surgical Procedure	Complication	Rate, %
Anterior vaginal repair/plication	De novo IVC	≤6
	Long-term LUTS	≈0
Open retropubic procedures		
MMK	Overall	22.0
	Osteitis	2.5
Burch colposuspension	Voiding dysfunction	2-27 (mean, 10.3)
	De novo IVC	8-27 (mean, 17)
	Prolapse (at 5 y)	3-27 (mean, 13.6)
	Mortality	0
Needle suspension	Sexual dysfunction	3-16
	Transfusion	1-7
	Bladder injury	1-12
	Pain	2-12
	De novo IVC	5-10
	Nerve injury	?
	Retention (primary)	?
Pubovaginal sling procedures		
Autologous grafts	Voiding dysfunction	2-20
	Long-term CIC	1.5-7.8
	De novo IVC	3-23
Allogenic cadaver grafts	Long-term material failure	>20
Synthetic materials	Vaginal erosion	0-16
	Urethral erosion	0-5
	De novo IVC	4-66
	Removal/revision	1.8-35
TVT	Retention	2.3
	Minor voiding difficulty	7.5
	Bladder perforation	3.8
	UTI	4.1
	Major vessel injury	0.1
	Obturator nerve injury	0.1
	Wound infection	0.8
	Poor healing of vaginal incision	0.7
Injectables	Retention	1-15
	Infection	0.5-4
	OAB symptoms	10-50

IVC, involuntary bladder contraction; LUTS, lower urinary tract symptoms; MMK, Marshall-Marchetti-Krantz procedure; TVT, tension-free vaginal tape; UTI, upper urinary tract infections; CIC, clean intermittent catheterization; OAB, overactive bladder.
Data from Abrams P et al. *Incontinence.* 2002[12]; Leach GE et al. *J Urol.* 1997;158:875-880.[49]

pathology through the same incision.

The 3 most common types of open retropubic suspension procedures are the Marshall-Marchetti-Krantz (MMK) procedure, Burch colposuspension, and the paravaginal (Richardson) repair. When used as primary or secondary surgical procedures, these operations have excellent long-term success rates, that is, in excess of 80% at 4 years postsurgery.[49]

MMK urethropexy. Although not a widely recognized fact, this well-known retropubic procedure for treating SUI in women was first reported as a treatment for urinary incontinence in a man following a transurethral resection of the prostate. With the MMK procedure, which was first described in 1949, the space of Retzius is entered and the anterior bladder and urethra are mobilized.[52] The periurethral fascia anterolateral to the urethra is sutured to the posterior periosteum of the symphysis pubis from the midurethra to the bladder neck with a series of 2 or 3 sutures. The original description of this procedure also included fixation of the anterior bladder wall to the posterior rectus sheath. This procedure will not correct a moderate cystocele. Unfortunately, the MMK procedure carries a risk of osteitis pubis (2.5%) and is believed by some investigators to be more likely to cause urethral obstruction and subsequent voiding dysfunction than other SUI procedures.[53,54]

Burch colposuspension. With Burch colposuspension, after the bladder neck and proximal urethra are mobilized in the retropubic space, suspending sutures are placed laterally into the tissue on either side of the bladder neck (paravaginal fascia), not at the level of the urethra. As originally described, these sutures are then placed through the ipsilateral Cooper's ligament (ileopectineal ligament), thereby supporting the vesicourethral junction within the retropubic space.[55] Of note, the sutures are placed more proximal and lateral with respect to the urethra and bladder neck than with the MMK procedure. An additional set of sutures may be placed 1 cm or 2 cm proximally on the paravaginal fascia correcting a small- or moderate-sized lateral cystocele. This operation is generally

believed to be less obstructive than the MMK procedure. Although Burch colposuspension may correct a mild to moderate cystocele, postsurgical de novo enterocele formation may occur.

Cure rates with Burch colposuspension vary over time but are generally considered to be greater than 80% at 4 years.[49] This procedure was recommended for the surgical cure of SUI by the ICI. Complications include voiding difficulty (10.3%), de novo detrusor overactivity (17%), and genitourinary prolapse (enterocele, cystocele, or rectocele; 13.6%).[12]

Paravaginal repair. If a detachment of the endopelvic fascia from the tendinous arc of the obturator on the pelvic sidewall exists, the paravaginal repair reapproximates the paravaginal fascia laterally to the pelvic sidewall at the level of the tendinous arc (identifiable as a white band along the pelvic sidewall) with several parallel sets of sutures.

Laparoscopic Procedures

Laparoscopic bladder neck suspension has the potential added benefits of less intraoperative blood loss, less perioperative pain, and a shorter duration of catheterization and hospitalization. Both retroperitoneal and intraperitoneal approaches have been described. Long-term data supporting superiority or even equivalence to nonlaparoscopic approaches are, at present, lacking. Some reports suggest worse objective outcomes and a higher rate of complications, as well as a longer operating time, for these laparoscopic procedures compared with open surgery.[56] In addition, it has been suggested that success with laparoscopic procedures may be related to the individual surgeon's experience with these types of surgeries.[12]

Transvaginal Needle Suspension Procedures

Transvaginal "needle suspension" techniques evolved as a minimally invasive alternative to the retropubic procedures for SUI due to urethral hypermobility. The original transvaginal needle suspension was first described by Armand Pereyra, MD, in 1959.[57] Since then, however, many modifications of this procedure have been reported. The common feature of each of these modifications is that the anterior abdominal wall fascia is not incised and the suspending sutures are passed through the retropubic space from the vagina to the anterior abdominal wall with a specialized long ligature (suture) passer.

Originally described almost 100 years ago, slings of various types have had a resurgence in popularity over the past several years.

Advantages to the transvaginal approach include the avoidance of a large, transfascial abdominal incision (and its attendant morbidity, particularly in the obese patient); shorter operative times; less postoperative discomfort; shorter hospital stay; and the ability to repair coexisting vaginal pathology (ie, prolapse) through the same or slightly extended incision. Disadvantages include a potentially lower long-term "cure" rate[49]; poor intraoperative visualization; risk of injury to the bladder and urethra during blind passage of the needles through the retropubic space; risk of significant bleeding in the retropubic space with poor operative access from the vaginal incisions; and, lastly, infection or erosion of a foreign body if suture buttresses are utilized (ie, Stamey operation).

Each transvaginal urethropexy procedure differs with regard to the method of anchoring, as well as the tissues incorporated on the vaginal side of the procedure (Gittes), whether or not the endopelvic fascia is detached from the tendinous arc of the obturator (Raz), and the use of buttresses or bolsters to hold the suture in the vaginal tissues (Stamey). The ICI proceedings concluded that needle suspensions of any kind do not maintain satisfactory success rates with time and currently have few, if any, indications.[12]

Sling Procedures

Originally described almost 100 years ago, slings of various types have had a resurgence in popularity over the past several years.[58-62] This rise in popularity may be attributed to several factors, including a change in surgical philosophy regarding the pathophysiology of urethral incontinence in women (ie, many surgeons now believe that all patients with urethral incontinence have some degree of ISD, regardless of the presence or absence of urethral hypermobility) and a perceived, if not actual, decrease in morbidity associated with the sling surgical procedure as it is currently performed. As opposed to the transabdominal or transvaginal approach to urethropexy, the goal of sling surgery may be not only to provide a "backboard" of support for the vesicourethral junction but also, in some cases, to create some degree of urethral coaptation or compression. Nonetheless, it is important that any type of sling be tied with minimal or no tension to prevent bladder outlet obstruction and/or urinary retention. The synthetic slings that consist primarily of polypropylene mesh, such as TVT® (Ethicon, Inc, a Johnson & Johnson Company, New Brunswick, NJ), are placed at the level of the midurethra

Table 8
Materials Used to Create Suburethral Slings for SUI

Natural
• Rectus fascia
- Full-length
- Patch
• Fascia lata
- Autologous
- Allogenic
• Dermis
- Porcine
- Human
• Dura
• Other
Synthetic
• Gore-Tex
• Nylon
• Perlon
• Prolene
• Mercilene
• Silastic
• Polyglactin mesh

SUI, stress urinary incontinence.

and may provide their anti-incontinence effect by reducing urethral mobility or producing a dynamic kink in the urethra during increases in intraabdominal pressure.

Historically, autologous rectus fascia and fascia lata are among the most commonly used sling materials; however, the vaginal wall tissue, human cadaveric tissues (dermis and fascia), xenograft tissues, and synthetic materials are now commonly used (Table 8). Long-term efficacy data on sling materials other than autologous fascia and synthetic materials are lacking.

Long-term studies using slings made of autologous or synthetic materials have indicated cure rates in excess of 80% and rates of improvement of greater than 90%.[12,49] Some data have associated autologous material with a higher cure rate and lower complication rate than cadaveric or synthetic materials. Some synthetic materials (eg, Gore-Tex® and Silastic®) have been associated with a small risk of vaginal or urethral erosion.

Midurethral polypropylene slings. Introduced during the mid 1990s, tension-free vaginal tape (TVT) is a minimally invasive surgical therapy for women with SUI. To date, this is the only surgical treatment of SUI developed prospectively based on a proposed pathophysiologic mechanism for SUI and its treatment.[63] This procedure and its variants may be performed under local anesthesia or minimal regional anesthesia and are commonly performed as outpatient surgical procedures. In general, pain and postoperative convalescence are far less severe with TVT procedures than with alternative surgical techniques. Through 2 small incisions in the skin of the lower abdominal wall and a 1- to 2-cm incision in the vaginal wall overlying the midurethra, a long thin strip of polypropylene mesh tape is passed through the retropubic space and underneath the urethra from either a transvaginal or transabdominal approach using a proprietary trocar system. The tape is not secured at the level of the urethra or abdominal wall fascia.

Nilsson and colleagues[64] reported an excellent 5-year subjective and objective cure rate (84.7%) and a low failure rate (4.5%) using TVT, with no increase in the failure rate seen over a 5-year follow-up period. Complication rates are minimal in experienced hands, with a urinary retention rate of approximately 4% (but reported in some series to be up to 12%) and de novo urgency or urge incontinence occurring in about 5% of patients.[65] However, there appears to be a higher risk of complications, including intraoperative bladder perforation, in patients undergoing these procedures who have had prior surgery.[66,67]

There does not appear to be any significant difference between TVT and SPARC™ (American Medical Systems, Minnetonka, Minn) in terms of short-term efficacy and complication rates.[68-70] Most recently, a variation of the midurethral sling has been developed that does not traverse the retropubic space but utilizes a transobturator approach. There are no published long-term efficacy or safety data available with this technique.

Bulking Agents

Periurethral injectable agents have been used for the treatment of SUI in women for decades. A variety of substances have been reported to be safe and effective, including bovine glutaraldehyde cross-linked (GAX) collagen, polytetrafluoroethylene (Teflon®, DuPont, Wilmington, Del), polydimethyl-siloxane elastomer (silicone), carbon-coated zirconium beads, and autologous tissues such as fat and cartilage. Each of these agents has variable biophysical properties that influence factors such as tissue compatibility, tendency for migration, radiographic density, durability, and safety. The ideal periurethral injectable agent has yet to be identified.

Most periurethral agents are injected in a retrograde fashion under direct cystoscopic guidance. Retrograde approaches have also been described through a suprapubic puncture site, especially in men with postprostatectomy urinary incontinence. In women, most agents can be applied without general or regional anesthesia.

The mechanism by which periurethral injectable agents exert their beneficial effects on continence has not been well defined, although an obstructive effect or an improved "seal" effect has been suggested.[71] Furthermore, the mechanism of even-

Table 9
Periurethral Injectables: Results of Selected Studies

Reference	Year	Patients, No.*	Mean Age, y	Bulking Agent	Follow-up, Mean, Median, or Minimal	Cure Rate, %	Success Rate (Cure + Improved), %
Herschorn et al[73]	1996	187	63	GAX collagen	22 mo from last injection (cure and improved groups)‡	23	75
Kreder et al[79]	1996	22	n/a	GAX collagen (vs sling)	n/a	40	n/a
Smith et al[80]	1997	94	67.4	GAX collagen	14 mo‡	38.30	67
Haab et al[81]	1997	22	63.7	GAX collagen (vs autologous fat)	7 mo†	24	86
Khullar et al[82]	1997	21	76	GAX collagen	24 mo§	48	57
Cross et al[83]	1998	139	72 (median)	GAX collagen	18 mo from last injection†	n/a	74
Corcos et al[84]	1999	40	62.3	GAX collagen	48 mo	30	70
Groutz et al[77]	2000	63	67.7	GAX collagen	6.4 mo from last injection‡	13	40 (cure + good + fair)
Winters et al[85]	2000	58	73.2	GAX collagen	2 mo	48.30	79.30
Lightner et al[86]	2001	68	n/a	GAX collagen (vs Durasphere)	12 mo from last injection	n/a	69.10
Bent et al[72]	2001	58	n/a	GAX collagen	12 mo§	33	66
Lightner et al[86]	2001	61	n/a	Durasphere (vs GAX collagen)	12 mo from last injection§	n/a	80.30
Haab et al[81]	1997	45	63.3	Autologous fat (vs GAX collagen)	7 mo†	14	43
Lee et al[78]	2001	27	57	Autologous fat	3 mo§	n/a	22.20
Herschorn et al[87]	2000	46	73.8	Polytetra-fluoroethylene (Teflon)	17.9 mo (cured group), 15.9 mo (improved group) from last injection‡	30.40	71.70
Peeker et al[88]	2002	15	n/a	Silicone	24 mo§	68.80	87.50
Tamanini et al[89]	2003	21	47.4	Silicone	12 mo§	57.10	76.10

*Patient group with longest reported follow-up in each series.
†Mean follow-up.
‡Median follow-up
§Minimal follow-up.
GAX, glutaraldehyde cross-linked; n/a, not available.

tual failure for most of these agents is not well understood, although it is thought that biologic reabsorption (eg, GAX collagen), particle migration, and ongoing degeneration of the sphincteric apparatus may be contributing factors. It was initially thought that injectable agents would be most effective in patients with ISD alone; however, subsequent reports have suggested clinical efficacy in patients with urethral hypermobility as well.[72-75]

There is a dearth of well-executed, published, peer-reviewed, randomized, placebo-controlled trials and comparator trials involving periurethral injectables.[76] When strict objective and subjective definitions of cure and cure/

improved are utilized, the success of periurethral injectable therapy appears inferior to that historically reported for other types of anti-incontinence surgery, particularly in long-term follow-up.[77,78] Table 9 summarizes the results of selected studies using periurethral injectables.[72,73,77-89]

In general, the morbidity associated with periurethral injectable agents is low. UTI, short-term voiding dysfunction, including urinary retention, and hematuria are common adverse events with all of the periurethral injectable agents.[90,91] Minor complications have been reported in up to 20% of patients receiving GAX collagen; however, the vast majority of these effects are self limited.[91] ■

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Main Points

- The 2nd International Consultation on Incontinence recommended urodynamic studies for the investigation of symptoms of incontinence in women in the following cases: 1) voiding difficulty or neuropathy is suspected, 2) the patient has failed nonsurgical or surgical therapy, or 3) invasive or surgical treatments are being considered. Urodynamics are *required* in 3 circumstances: 1) when a detailed knowledge of lower urinary tract function is necessary to decide the course of treatment, 2) when investigating the reasons for failure of prior treatment, and 3) in order to predict the outcome of a proposed treatment.
- In most patients with uncomplicated stress urinary incontinence (SUI), the initial management involves a variety of noninvasive measures, including behavioral modification, pelvic floor exercises with or without biofeedback, and other accessory teaching aids.
- Various pharmacologic therapies have been used, with widely varying success rates, for the treatment of SUI in women. These include α-adrenergic agonists, imipramine, duloxetine, and estrogen.
- In general, surgical correction of female SUI is directed toward one of the following 2 goals: 1) repositioning the urethra and/or creating a backboard of support or otherwise stabilizing the urethra and bladder neck in a well-supported retropubic (intraabdominal) position that is receptive to changes in intraabdominal pressure, or 2) creating coaptation and/or compression or otherwise augmenting the urethral resistance provided by the intrinsic sphincter unit, with (eg, sling) or without (eg, periurethral injectables) affecting urethral and bladder neck support or a combination of both.
- The 3 most common types of open retropubic suspension procedures are the Marshall-Marchetti-Krantz procedure, Burch colposuspension, and the paravaginal (Richardson) repair.
- Tension-free vaginal tape is associated with an excellent 5-year subjective and objective cure rate (84.7%).

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