Stress Urinary Incontinence: Surgery (Female)

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1. Introduction

Stress Urinary Incontinence (SUI) is the involuntary loss of urine associated with increases in abdominal pressure (Valsalva maneuver). SUI may occur during/after lifting, physical exertion, sneezing, coughing, laughing, sexual activity, or other activities that increase intra-abdominal pressure. It is a distinct clinical entity from urgency urinary incontinence (UUI), which is loss of urine associated with urinary urgency and/or frequency.

1.1. Keywords

Stress urinary incontinence; female; surgical treatment; mesh

2. Risk Factors and Pathophysiology

Risk factors for SUI include higher parity, increasing age, Caucasian race, smoking, lung disease and obesity.[2,3,4] Continence in women is a result of a functioning urethral sphincter and urethra that act as a closure mechanism as the bladder fills. The pelvic floor supports the bladder and urethra in their anatomic position allowing normal abdominal pressure transmission to the proximal urethra.[5] The neurological innervation to these pelvic structures is also critical in maintaining continence. Additional investigation into the mechanisms of SUI have shown that urethral failure contributes to SUI and age-related striated muscle loss contributes to poor urethral closure. Further studies are ongoing to better understand changes in urethral function and their contribution to incontinence.[6]

There are two major mechanisms for SUI in women: urethral hypermobility and intrinsic sphincter deficiency (ISD). In women these conditions coexist. Urethral hypermobility occurs when the urethra has lost its anatomic support. **In the setting of urethral hypermobility, coaptive forces are not transmitted to the proximal urethra during Valsalva and urinary leakage may occur. There are various etiologies for ISD but this condition is essentially failure of the urethra to coapt independently of its supporting tissue structures. ISD is typically diagnosed when Valsalva Leak Point Pressure (VLPP) is less than 60 cm of H_2O.** The distinction between ISD and urethral hypermobility is an important one as it affects the type of surgical repair that should be considered.[7] The impact of these conditions on the success of surgical treatment for SUI remains controversial.[8]

3. Epidemiology

Estimates on the prevalence of SUI in women vary widely. The Boston Area Community Health (BACH) Survey reported weekly urinary incontinence in 10.4% of women aged 30-79 years; of those women 26.4% had stress type incontinence and 56.7% reported mixed incontinence (i.e. SUI and UUI).[4,f]

4. Diagnosis and Evaluation

The standard evaluation of all patients considering surgery for SUI should include a medical history and physical exam to demonstrate SUL, urinalysis, post-void residual. (see Surgical Treatment of Female Stress Urinary Incontinence (SUI): AUA/SUFU Guideline (2017)) The recently updated EAU guidelines also summarize many of the key points regarding diagnosis and evaluation and considerations for therapy.[9] The differential diagnoses of SUI in women includes UUI,[1] overflow incontinence (due to severe urinary retention), and total incontinence (e.g. urinary fistula or other abnormal connection of urinary tract to vagina). UUI and SUI frequently coexist and are termed mixed incontinence, which is defined as "involuntary loss of urine associated with urgency and also with effort or physical exertion or on sneezing or coughing".[1] It is important to determine which of these symptoms poses a greater bother in order to prioritize treatment goals. "**Women with UUI and no evidence for SUI should not be offered a surgical procedure for SUI**".[10]

Recommended elements of the history include characterization of triggers for incontinence, frequency of incontinence, subjective bother, quantity of leakage, and treatment goals/expectations.[10] These relevant portions of the incontinence history are commonly measured by a variety of symptom scores[11,12,13,14,15,16,17,18,19,20] with no one questionnaire being universally utilized[21] (**Table 1**).

Table 1: Symptom scores and Quality of life Questionnaires for Stress Urinary Incontinence in Women

Full name	Abbreviation	Target Population/Condition	Urinary Symptom Evaluated	QoL Assessed	Items
Urogenital Distress Inventory[11,12]	UDI-6	Women with UI	Stress and urgency incontinence	No	6 (full version 30)
Incontinence Impact Questionnaire[12]	IIQ-7	Women with UI	No	Yes	7 (full version 30)
Kings Health Questionnaire[14]	KHQ	UI	Both urgency and stress incontinence	Yes	21
Incontinence Quality of Life Instrument[13]	I-QOL	UI	Both urgency and stress incontinence	Yes	22
Patient Global Impression of Severity and Improvement Questionnaire[15]	PGI-I, PGI-S	UI	Improvement in incontinence after treatment, severity of UI		2
Bristol Female Lower Urinary Tract Symptoms[22]	B-FLUTS	Women with UI	Bothersomeness of incontinence, sexual function	Yes	20
Stamey Grade[16]		Stress incontinence	Incontinence	No	1
Incontinence Severity Index[17]	ISI	Incontinence	Frequency and amount of urine lost	No	2
International Consultation on Incontinence Questionnaire Short Form[18]	ICIQ-SF	Stress and urgency incontinence	Stress and urgency incontinence	Yes	4
Pelvic Floor Distress Inventory short form[19]	PFDI-20	Women with urinary incontinence, fecal incontinence and prolapse	Incontinence	No	20
Michigan Incontinence Symptom Index[23]	M-ISI	Men and women with urinary incontinence	Both urgency and stress incontinence	Yes	10
Lower Urinary Tract Symptom tool[20]	LUTS tool	men and women with urinary symptoms	LUTS, multiple kinds of incontinence and related bother	No, only bother	16 items and item 16 divided into 7 parts

Essential components of the physical include a focused abdominal and pelvic exam with evaluation of pelvic organ prolapse and urethral hypermobility, **assessment for vaginal atrophy, objective demonstration of SUI**, **and a focused neurologic examination**. **A supine or standing stress test should be performed to assess leakage**; **the simplest form of stress test is to ask the patient to cough and observe for urinary leakage**. **A woman with negative office stress test requires some objective confirmation of SUI prior to surgery**. **A urinalysis should be performed to screen for hematuria and urinary tract infection (UTI) and a post void residual (PVR) should be performed to rule out urinary retention**.[10]

Additional diagnostic testing may need to be performed in select circumstances.[10] Additional testing options include voiding diaries, pad weights, urodynamic testing, and "pyridium pad testing". Specific indications for adjunctive testing include symptoms of mixed urinary incontinence, failure of prior anti-incontinence procedures, neurogenic bladder, high post-void residual urine volume, and significant pelvic organ prolapse.

The voiding diary can both diagnose and guide therapy in incontinence.[24] A one to three-day diary is sufficient[25] and is much more reliable than patient recall. While it combines both objective and subjective assessments of voiding habits, diaries are universally held to be a useful tool for patients with incontinence.[24,25]

Pad testing is performed with the patient collecting all wet pads from a 24-hour period and sealing them in an airtight bag, so they can be weighed. A dry identical pad's weight is subtracted to yield the total incontinence volume. A pad weight serves to objectively quantify the amount of incontinence. Less accurate means (e.g. counts of number of pads and thickness) is highly dependent on patient preference and as such is less reliable[25].

Urodynamics can be used in the event that a definitive diagnosis cannot be made on initial evaluation, to exclude detrusor overactivity, neurogenic bladder, voiding dysfunction, or obstruction and measure leak point pressures. The routine use of urodynamics in index cases with straightforward uncomplicated SUI is not supported.[26]

Cystoscopy is not routinely necessary in the diagnosis of the index patient with stress incontinence, but is important if the woman has unexplained hematuria, pyuria, has had prior surgery, or has overactive bladder symptoms possibly related to foreign body (e.g. prior procedures, urinary stones, etc.).[10]

Pyridium pad testing may be useful for the rare case in which the patient is not certain whether pelvic wetness is from a urinary, vaginal, or sweat source. Phenazopyridine hydrochloride is an azo dye oral analgesic excreted in the urine that turns the urine a dark yellow or red color. It can be given in a single dose while the patient wears a pad for the day to collect any wetness. Vaginal secretions and sweat are not routes of excretion of the dye hence a positive orange stain on the pad is indicative of urinary incontinence. [27]

5. Non-surgical Treatment

Women should be counseled on surgical and non-surgical options for SUI; **discussion should involve benefits and risks of all treatment options including: observation; pelvic floor muscle training; other non-surgical options (intravaginal or intraurethral devices) and surgical intervention**.[10] **Excellent patient information is available in A Patient's Guide to Stress Urinary Incontinence (SUI)**.

5.1 Behavioral Modification

Behavioral modification may consist of timed voiding,[28] voiding before physical activity, pelvic floor muscle training[29,30] with or without biofeedback or electrical stimulation and weight loss[31] including bariatric surgery.[32] These interventions can significantly reduce incontinence and bother. Newer conservative therapies include pulsed magnetic stimulation which is not FDA approved but have shown some early promising results.[33]

5.2 Devices

Three devices are available that may be utilized in the treatment of SUI in women: urethral inserts[34] short silicone single use tubes that are placed in the urethra to create obstruction to leakage), continence pessary rings or dishes that are placed vaginally with a knob or prongs that face the urethra to promote continence by obstructing the urethra,[35,36] and disposable vaginal insert devices that are available over the counter. These are used to provide tension free anterior vaginal wall support preventing leakage via urethral hypermobility (Impressa™ Kimberly-Clark, worldwide). The device is similar to a tampon with an applicator and string attached for removal but is a nylon fabric covering that is stretched between the flexible support poles. [37] A systematic review and meta-analysis of incontinence pessaries found that both subjective and objective measures improved with minimal adverse events, further supporting their use in the conservative management of SUI.[38]

Not currently FDA approved (available in the European Union), but undergoing clinical testing, is a removable intravesical air filled balloon that acts as a pressure-attenuating system in the bladder absorbing increases in pressure and preventing stress incontinence (Vesair™, Solace Therapeutics, Framingham, MA). Early clinical trials have shown some promise compared to placebo.[39]

5.3 Medications

Currently, no medications are approved by FDA for the treatment of SUI. Estrogen had been used widely in the past to treat SUI in women, due to its theoretical ability to improve urethral closure through increased urethral vascularity/thickness and sensitized alpha-adrenergic receptors in the bladder neck.[40] However, a Cochrane review of 31 published studies failed to show objective improvement in SUI; in fact there was some evidence for worsening incontinence with oral estrogenic agents.[41,42]. Vaginal administration of estrogen may improve incontinence with decrease of 1-2 voids per 24 hours.

In Europe, duloxetine is an option. A systematic review showed improvement in SUI however, the EAU guidelines recommend careful counseling about the risks of adverse events.[9]

5.4 Thermal Therapies

Office-based transurethral radiofrequency collagen denaturation is a procedure that can be performed under local anesthesia. It is thought to reduce urethral funneling and compliance via denaturation of submucosal collagen. Subnecrotic temperatures are used to promote collagen remodeling rather than tissue death and scar. Renessa™ is an FDA approved device to provide this therapy.[43] A Cochrane review[44] found only one study that was a sham controlled randomized trial with 173 women and no studies comparing this treatment to any standard therapy including pelvic floor physical therapy. Adverse events were very low, but efficacy could not be determined from the study.

The use of vaginal laser therapy has become another treatment modality of interest for SUI. Laser therapies currently in use are either microablative fractional carbon dioxide (CO2) laser therapy, dual-phase erbium-doped yttrium aluminium garnet (Er:YAG) laser therapy, and non-ablative Er:YAG laser therapy. Laser therapies induce neocollagenesis of the anterior vaginal wall, thought to improve the support of the urethra and thereby improve SUI. A study of 59 women with SUI who underwent non-ablative ErYAG laser therapy had objective cure rate of 74% for mild to moderate SUI that persisted at 2 years for premenopausal women with minimal adverse effects.[45] A recent multicenter, sham controlled RCT of 59 women with SUI who received laser therapy compared to 49 who received sham failed to show improvement in SUI.[46] Limited data is currently available and further study of these therapies is needed to determine the role of thermal therapies for SUI.[47]

6. Surgical Therapy for SUI

Surgical therapies for SUI can be grouped into cystoscopic injection of urethral bulking agents, **retropubic suspensions**, **and slings (pubovaginal and mid-urethral synthetic)**. The success rate of SUI treatment is highly dependent on the definition of success;[48] and there is great heterogeneity in definition of "success" in the published literature. Some authors measure patient reported outcomes utilizing validated incontinence questionnaires; others have utilized a simple improvement rate. The most rigorous studies have employed pad weight testing combined with repeat urodynamics/full bladder cough testing. Based on this heterogeneity, outcomes cannot easily be compared across studies.

Deciding on a surgical treatment is a complex decision. **Patients need to be informed of the invasiveness**, **operative risk**, **expectations of outcomes and specifically**, **if utilizing mesh or other implant**, **of the nature of the implanted material, and of the alternatives to a mesh sling**.[10]

Patients who desire a minimally invasive option with little to no recovery and little risk are ideal candidates for injectable agents. However, they should be counseled that success rates with injection therapy tend to be lower. Open surgical approaches are the most invasive option but have generally good success rates in index patients; surgeon experience and patient preference are often the deciding factor when determining which surgical procedure to pursue. Midurethral slings are the most commonly utilized option in contemporary surgical management of SUI. The decision of whether to use autologous tissues or synthetic mesh for the sling is an important consideration given recent concerns about the long-term safety of mesh used in prolapse repair. As a response to patient concerns the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) and the American Urogynecologic Society (AUGS) have issued a joint position statement on **mesh slings** stating that they are safe, the most widely studied surgical procedure for incontinence and that they consider this procedure to be the standard of care.[49] Patients should be appropriately counseled regarding specific risks associated with mesh including risk of mesh extrusion, erosion, and dyspareunia.

"Synthetic sling surgery is contraindicated in SUI patients with a concurrent urethrovaginal fistula, **urethral erosion from mesh**, **intraoperative urethral injury and/or urethral diverticulum**."[10] Other less well-defined risk factors for mesh exposure or erosion include prior urethral fistula repair, prior diverticula surgery, pelvic radiation, presence of significant scarring and poor tissue quality. These should be considered in the decision to use a mesh or non-mesh approach.

The ideal surgical treatment for a woman who has failed a prior sling is not known.[48] The rate of reoperation for incontinence in a nationwide cohort study in England from 2006-2013was 21.3% for retropubic colposuspension, 10.9% for synthetic retropubic slings and 12% for autologous fascia slings.[50] Women who have had a failure due to mesh exposure and subsequent sling removal are often hesitant to undergo repeat mesh sling (there is no current evidence of an increased risk of subsequent erosion). In women who have simply failed a mid-urethral sling the best treatment option is not well defined. In a retrospective series comparing repeat midurethral sling (n=98) and urethral bulking agent (n=67) for recurrent SUI after mesh sling, 11.2% of the slings failed and 38.8% of the bulking

agents failed (p=0.004). Despite the lower success rate, these patients did avoid a repeat surgical procedure.[51] In a case series of 1,316 women undergoing synthetic sling for SUI, 10% had a prior failed mesh sling. Although the odds of failure were twice that in the repeat sling patients (cure of 71% vs. 54% p < 0.001), the repeat sling patients demonstrated the greatest improvement in quality of life and symptom impact.[52]

Some women who fail midurethral sling may have occult ISD; **this possibility should be investigated prior to proceeding with repeat sling.**[7] Urodynamic finding of ISD (VLPP < 60 cm H_2O) and/or a physical exam finding of a fixed urethra suggest ISD. Midurethral slings and retropubic suspensions are designed to correct hypermobility but will not adequately manage ISD; in these cases, urethral bulking agents and/or autologous slings should be considered. [7] In a series of 66 women who failed one or more mesh slings and in whom half had their mesh removed for complications, autologous sling placement cured 70% of their stress incontinence.[53] In a recent study of 57 women who received bulkamid after midurethral sling for recurrent SUI, they reported a cure rate of 72.9% and a satisfaction rate of 73.7% with mean follow-up of 11.7 months:[54]

"In patients with SUI and a fixed, immobile urethra (ISD) who wish to undergo treatment, physicians should offer pubovaginal slings, retropubic midurethral slings or bulking agents"[10]

A relative contraindication for open surgery and midurethral sling is a woman who anticipates a future pregnancy. Such patients are probably better served with conservative therapy or injectable agents since it would seem prudent that a woman finish childbearing and the resulting pelvic floor trauma before undergoing surgical repair.[55] However "**physicians may offer synthetic midurethral slings, in addition to other sling types, to patients planning to bear children"**[10] There does not appear to be any extra risk to the infant from vaginal delivery after urethral sling; however there is a high risk of recurrent incontinence in the woman regardless of the mode of delivery.[56]

7. Bulking Agents

7.1 Rationale

The least invasive surgical approach to SUI is cystoscopic injection of a urethral bulking agent. These agents have the advantage of application in the clinic setting with no need for general anesthetic and minimal morbidity[57] making them ideal for individuals who are poor surgical candidates. They are best suited for women with ISD since they function by increasing the coaptation of the sphincter and act as a central filler volume increasing the length of muscle fibres.[58] Bulking agents can be injected either peri-urethrally or intra-urethrally via cystoscopy. Pre-procedure topical or injectable local anesthesia can be used.

Bulking agents are considered a cystoscopic procedure with manipulation and the "**Best Practice Policy Statement**" from the AUA regarding antibiotics recommends that all patients receive prophylactic treatment with trimethoprim-sulfamethoxazole or a fluoroquinolone. Second line options include an aminoglycoside plus ampicillin, a first or second generation cephalosporin, or amoxicillin/clavulanate. These antibiotics should be given to cover no more than a 24-hour period.[59]

Numerous bulking agents have been employed over the years with many no longer recommended due to particle migration, local abscess reaction, or lack of efficacy[57,60,61,62,63,64,65,66] (**Table 2**). Collagen, which was the standard agent, is no longer commercially marketed although there have not been safety issues associated with this product. There are currently four FDA approved agents in clinical use: silicon microparticles (Macroplastique®); pyrolytic carbon-coated zirconium oxide bead (Durasphere™) calcium hydroxyapatite (Coaptite®), polyacrylamide hydrogel (Bulkamid®).[67]

Table 2: Summary of Injectable Agent Materials

Material	FDA Approval	Bulking Component	Carrier	Pros	Cons	Particle Migration
Autologous fat	n/a	Fat obtained from liposuction	n/a	Non antigenic, easily available	Biodegrades rapidly, no better than saline.	Yes[60]- fatal emboli
Polytef	no	Polytetrafluoroethylene (Teflon) 4-100µm	Glycerine and polysorbate	Easy to inject, non-antigenic	Distant particle migration and granuloma formation.	Yes[61]
Contigen[57]	1993	Glateraldehyde cross-linked bovine collagen	none	Excellent safety profile, easily injectable with small caliber needle	Slowly absorbed hence need for retreatment. Allergic reaction in 4% hence need for skin test. Currently off the market due to supply issues.	no
Durasphere[68]	1999	Carbon coated zirconium oxide beads (200-550µm) old formulation EXP (95-200µm)	glucan	Non-reactive	Periurethral mass formation.[64] Direct embolization into vessels seen.	Yes[62]
Macroplastique[64]	2006	Polydimethylsiloxane microparticles ~140µm	Polyvinylpyrrolidone gel	Inert, non-migratory, no reports of urethral abscess or masses.	Requires special administration device (gun)	no
Coaptite[69]	2005	Calcium hydroxylapatite (equivalent to bone and teeth) (75-125µm)	carboxymethlycellulose gel	Non-antigenic	Thick substance, urethral mass formation	no
Tegress[65]	Approved in 2004, but voluntarily removed from the market	Ethylene vinyl alcohol that precipitates into a sponge-like mass.	DMSO which diffuses out of the injection within 60 seconds	Simple to inject	High rate of urethral erosion leading to its removal from the market.	no
Zuidex[66]	no	Detranomer (hydrophilic dextran polymer)	hyaluronic acid (non-animal)	Easily injectable with small diameter needle	High prevalence of urethral complications	no
Bulkamid[70]	2019	No solid particles, polyacrylamide hydrogel	water	Specially designed cystoscope and injection system	None reported	no
Autologous muscle derived cells[71]	No (investigational only)	Autologous muscle cells expanded in culture	saline	Patient's own cells, possible regeneration of sphincter	Cost and complexity of tissue culture	no

7.2 Outcomes

The major drawback of injectable therapies is significantly diminished success than open surgical approaches (cure rate 19-72% lower).[57,72] A Cochrane review[73] on urethral bulking agents in 2017 included fourteen trials. The data was found to be insufficient to make a recommendation on this practice, however, five high quality randomized controlled trials (RCT) have been recently published suggesting some degree of efficacy.[64,66,69,74,75] A contemporary series following 70 women 3 years after Macroplastique reported stable outcomes with 51.4% composite success rate (Stamey grade and QOL) with 68% overall satisfaction.[76] Patient factors that may improve continence after the procedure are age over 60 and having less severe incontinence with 2.5 or less SUI episodes per day.[77] In some patients re-bulking may be indicated. In a study of 62 patients who underwent re-bulking for persistent SUI or mixed UI, significant improvement was observed with 85.4% of patients reporting improvement with 1 major complication of urethra-vaginal fistula.

7.3 Adverse Events

(See Reference 78)

Common adverse events after injection of a bulking agent include temporary irritative voiding symptoms (17-46%), transient hematuria (8-40%), temporary urinary retention that lasts less than a week (0-12%), transient difficulty voiding, elevated post void residual urine (55-75%), and urinary tract infection (0-23%). Less common adverse events include material extrusion or erosion (0-2%).[57,64,69,72,68,75,79,80] (**Table 3**).

Suspicion amongst medical providers about the true safety of injectable agents is not unfounded. Teflon urethral injections in animal studies confirmed distant migration and granulomatous reaction in the lymph nodes, lung and brain.[61] A randomized controlled trial failed to show a significantly increased risk of complications after urethral injection of an ethylene vinyl alcohol polymer (Tegress™)[81] which was subsequently FDA approved; this agent was later withdrawn from the market due to urethral erosions in up to 37% of patients.[65] Other agents such as a dextranomer/hyaluronic acid polymer (Zuidex™) have unacceptably high rate of urethral complications such as pseudoabsecess[82] and were less effective than the reference standard of collagen in RCT.[66]

Table 3: Summary of FDA Approved Injectable Agent Efficacy

Material	Comparison substance	F/U month	Definition of cure	Cure	Improvement	QoL/satisfaction	Adverse events	Note
Collagen[57]	Collagen (n=20), Sling or retropubic suspension (n=45)	12	2.5g or less on 24 hour pad test	53.1% vs 72.2%	-	Satisfaction: • 67.2% after collagen • 79.6% after surgery • IIQ change no different between groups	• 1/20 retention >48 h • 11/20 straining to void • 0 UTI • 8/20 transient hematuria (significantly higher in surgery group)	Collagen group received mean of 2.9 injections
Durasphere[79]	Durasphere (n=25), collagen (n=21)	32	Stamey grade of 0	40% Durasphere. 14.5% collagen	1 Stamey Grade 40% Durasphere, 47.4% collagen	-	Similar between groups	All patients had ISD
Durasphere[68]	Durasphere (n=115), collagen (n=120)	12	-	Not reported	1 Stamey grade improved 66.1% Durasphere, 65.8% collagen	Not reported	Equivalent except increase in temporary urgency (24.7% vs. 16.9%) and transient retention (11.9% vs. 3.4%) in Durasphere	• 1 hour pad weights decreases by 27.9g in Durasphere, 26.4g in collagen • All patients had ISD
Macroplastique[64]	Macro (n=122), collagen (n=125)	12	Stamey grade of 0 and negative pad test	36.9% macro, 24.8% collagen	Improved 1 Stamey grade 61.5% vs. 48%	Urinary Incontinence QoL (I-QoL) not different	59.0% vs. 54.4% (no difference) 23% UTI, 9% dysuria, 8% retention, 1.6% urethral erosion	All patients had ISD
Macroplastique[72]	Macro (22), autologous pubovaginal sling (n=21)	12 months and 5 years	Repeat urodynamics	At 1 year 9% for macro and 81% for PVS	Subjective cure as defined by patients 77% after macro and 90% after PVS	Satisfaction at 5 years 29% for Macro and 69% for PVS	3/21 UTI after PVS and 2/22 after macro, 1 incisional hernia after sling	
Coaptite[69]	Coaptite (n=131) collagen (n=100)	12	Stamey grade of 0	39% CaHa, 37% collagen	Improved 1 Stamey grade 63.4% CaHa, 57.0% collagen	Not reported	Complications similar except Transient retention 5.7% vs. 12% in collagen) and 2 serious events with 1 vaginal wall erosion and 1 dissection of material under trigone	
Bulkamid®[83]	Bulkamid (n=113) TVT (n=111)	12	Negative cough stress test, pad test, subjective Likert scale	66.4% PAHG 95% TVT		80 or greater on VAS score 60% PAHG 95% TVT	PAHG 19.6% complications TVT 44.6% perioperative/postoperative complications	TVT had higher cure and satisfaction rates however PAHG also had reasonable improvement rates with minimal complications
Bulkamid®[84]	Bulkamid (n=388) None	84	Patient satisfaction 4-point scale	67.1% cured or improved	Q	VAS QoL score improved 4.4 points, Daily pads from 4.8 to 1.2, ICIQ-UI SF by 8.4 points	Prolonged emptying15.3%, UTI 3.5%	Safe and effective as first-line treatment

7.4 Available Products

Coaptite® is a spherical synthetic calcium hydroxylapatite (principal constituent of bones and teeth) suspended in a carboxymethlycellulose gel carrier.[69] In animal experiments fibroblast infiltration occurs as the gel carrier degrades over months; heterotopic ossification does not occur. The substance is more viscous than collagen but may be injected via a 21-gauge needle. A RCT in 296 women with ISD and no urethral hypermobility demonstrated no significant difference in outcome (defined as at least one grade of improvement) according to the Stamey classification at one year (64% of the Coaptite ® patients versus 57% of the collagen patients, p=0.34). The overall cure rate was 39% and 37% for Coaptite® and collagen, respectively (p=0.78).[69]

The material is not believed to be biodegradable. There have been reports of large urethral mucosa prolapses requiring surgical intervention after injection of Coaptite®.[85-86]

Macroplastique® is a solid polydimethylsiloxane polymer suspended in inert gel. A systematic review did not support Macroplastique® due to insufficient evidence;[87] however three RCTs have been published since that time and have shown some benefit.[64-72-75] A large multi-center RCT comparing Macroplastique® to collagen in 247 women with ISD showed improvement (change of at least one Stamey grade) in 62% of Macroplastique® and 48% of collagen patients at 12 months. The overall cure rate was 37% and 25% for Macroplastique® and collagen treated patients, respectively ($p<0.05$) with no significant difference in adverse events.[64] The investigators later followed the responders to Macroplastique® for two years and showed 84% sustained success.[88]

Durasphere™ is pyrolytic carbon-coated zirconium oxide beads suspended in a 2.8% glucan (a polysaccharide used in wound healing) carrier gel.[68] It was found to be equally effective as collagen in 355 women with SUI and VLPP less than 90 cm of H_2O; improvement of one Stamey grade or higher was reported in 66% of both Durasphere™ and collagen (p=0.162) treated women at one year. There were equal number of injections required (1.69 vs. 1.55) and the adverse events were similar for both groups except for slightly increased rates of acute retention lasting less than seven days and urgency in the Durasphere™ group. This trial showed no evidence of antigenicity and pelvic x-rays taken post procedure and at 1 and 2 years follow up showed no migration.[68]

Durasphere™ in its original formulation (particle size 200-550µm) was difficult to inject due to viscosity. Recently, Durasphere-EXP™ (particle size 95-200µm) has been introduced to resolve this issue. High pressure injection is believed to be the cause[89] of particle migration into the urethral mucosa and both regional and distant lymph nodes.[62] To avoid particle migration of any agent the minimum particle size should be >80µm.[61] Periurethral masses have also been reported following Durasphere™ requiring surgical drainage or excision in 2.9% of patients.[63]

Bulkamid® is a sterile gel composed of 2.5% cross-linked Polyacrylamide and 97.5% non-pyrogenic water.[90] It was introduced as a urethral bulking agent in 2006 and received FDA approval in January 2020. It has been found to be biocompatible and non-resorbable. In several recent studies of 100 to 200 patients with follow-up ranging from 1 to 5[91-92] years the investigators note that 60 to 70% of patients report an objective benefit to their symptoms.. Similar to results with other bulking agents they note that patients with mild to moderate incontinence had better outcomes. Adverse events were low and Clavien grade 1. [93]

8. Open Surgical Therapy for SUI in Women

There are three major contemporary types of open surgical repair that may be considered for an index patient:[10] **Burch colposuspension**, **synthetic midurethral slings** (**retropubic**, **transobturator**), **and pubovaginal sling** (**PVS**).

All of these approaches share the risk of bladder and or urethral injury hence **intraoperative cystourethroscopy should be performed in all patients undergoing sling surgery.**[10] Appropriate first line antibiotic prophylaxis options for any vaginal surgery or surgery involving the GU tract and skin include a 1st/2nd generation cephalosporin, an aminoglycoside with Metronidazole, or an aminoglycoside with clindamycin. Second line options include ampicillin/sulbactam or a fluoroquinolone. Antibiotics should be administered for a maximum of 24 hours.[59]

8.1 Surgical procedures that are rarely if ever indicated

Surgical therapies generally no longer performed for SUI include bladder neck needle suspensions and anterior repairs; these procedures have lower efficacy long term and have been supplanted by less invasive and more efficacious options.

Bladder neck needle suspensions are performed by passing a suture on a needle passer from the vagina to the anterior abdominal fascia via an abdominal or vaginal approach. There are three basic techniques: Pereyra, Raz and Stamey. Each of these has been modified to utilize slightly different techniques or different suture material, but all have the goal of correcting urethral hypermobility. [67] A Cochrane review[94] evaluated ten trials (375 women who had needle suspension and 489 who had other procedures). The perioperative risk was similar, but the failure rate was increased one year and beyond (29% vs. 16% in needle suspensions versus other procedures, respectively).

Anterior repair is a purely vaginal approach to SUI that aims to correct urethral hypermobility. The vaginal mucosa overlying the urethra is dissected and sutures are placed in the peri-urethral tissue and pubocervical fascia to support and elevate the bladder neck (Kelly plication). This is typically done in conjunction with a cystocele repair.[67] A Cochrane review evaluated 10 trials including 385 women who had an anterior repair for SUI. Eight of these trials compared anterior repair to open retropubic suspensions. Failure rates were doubled in the anterior repair groups at one year (29% vs. 14%). There were few differences in the urological and overall morbidity.

Laparoscopic retropubic suspension was developed as a minimally invasive approach to female SUI; the surgery is performed as a Burch procedure using laparoscopic instruments. A Cochrane review including trials through 2019 included 26 trials.[95]. Thirteen articles compared laparoscopic to open Burch and found little difference in cure rates between the two methods but fewer complications and shorter hospital stay in laparoscopically treated patients. Nine studies compared the laparoscopic surgery to synthetic mid urethral slings and found similar subjective cure rates but better objective cure rates in patients treated with slings. With the shorter operative time and comparative simplicity of midurethral slings, laparoscopic Burch procedure is still rarely performed. [64]

Marshall-Marchetti-Krantz and **paravaginal repair** are both open abdominal retropubic suspensions similar to the Burch procedure. Permanent sutures are placed in the anterior vaginal wall around the bladder neck and proximal urethra and tied to the fibrocartilage of the symphysis pubis in the Marshall-Marchetti-Krantz (MMK) procedure. The paravaginal repair or the vagina-obturator shelf repairs are variations of the Burch procedure with more lateral placement of the sutures. [67]

Artificial Urinary Sphincters are frequently used in the male population for the treatment of SUI; however these are not currently FDA approved in the US and there are only case series to describe use of these devices in women.[96-97] The AUS is more widely employed for female SUI in European countries. The surgical technique requires bladder neck placement and carries a high risk of erosion and the need for revision surgery. Evidence to make recommendation on use of these devices for SUI in women is insufficient but they may be considered under certain circumstances.[10] The laparoscopic technique of implanting the device at the bladder neck has demonstrated promising long term results and had reduced the complication rate of erosions into the vagina or urethra down to 7% in long term series.[98]

8.2 Retropubic Suspensions

See **(Table 4)**

Table 4: Summary of Autologous PVS and Retropubic Colposuspension (Burch) Efficacy

Slings	Type of incontinence	Follow up months	Definition of cure	Cure	Adverse events	Note
Burch (n=255)vs. AFPVS (n=265)[99]	Predominant SUI, positive stress test and urethral hypermobility	24	No self-reported incontinence, negative 24 hour pad test, no incontinence on voiding diary, negative full bladder stress test	• Overall no incontinence 38% Burch, 47% AFPVS (p=0.01) • Stress incontinence cure: 49% Burch, 66% AFPVS (p<0.001) • Treatment satisfaction 78% Burch, 86% AFPVS (p=0.02)	• EBL: Burch 238ml, AFPVS 229ml • Surgical time same 137 minutes • UTI: AFPVS 48%, Burch 32% • Serious events:Overall serious AE (10%, 13% p=0.20) • Burch- 2 ureteral injuries, 1 ureterovaginal fistula, erosion of suture into bladder=1 • Incidental cystotomy: Burch 10, AFPVS=2 • Recurrent cystitis: AFPVS=6, Burch=5 • Need for surgical revision for obstruction only in AFPVS group (n=19) • Pelvic pain AFPVS=2, wound complications requiring intervention Burch 13, AFPVS 11 • DVT=1 total, bleeding=13 total • Wound complications not requiring surgery 71 and 69	
Synthetic MUS vs. open retropubic suspension[100]	Presented with SUI or urodynamic SUI (none with MUI)	12	Patient self-reported absence of incontinence or negative stress test/ pad weights	• Subjective cure (n=729): synthetic sling=79%, Burch 82% • Objective cure: 79% synthetic and 77% Burch neither different	De novo UUI (9% vs. 13%) and voiding dysfunction (5.5-8.9%) no different between groups. Bladder perforations more common after synthetic slings (6% vs. 1%). Burch group more likely to need prolapse surgery in the future.	Surgical time shorter for synthetic sling (30 min. vs. 47 min)
Synthetic sling vs. Burch[101]	Stress incontinence		variable	Subjective and objective cure similar between groups	8x greater risk of prolapse after burch compared to sling, voiding dysfunction similar between groups, bladder perforation 0.9% vs. 6.3% for TVT	TVT had shorter hospital stay
Burch (n=33), AFPVS (n=28), TVT (n=31)[102]	Urodynamic SUI and Stamey grade 1 or 2 incontinence	12	No reported incontinence and negative 300ml stress test	Cure: Burch 87.8%, AFPVS 92.8%, TVT 87% (significantly higher in AFPVS only)	• Burch: 3 de novo overactivity, 1 hesitancy • AFPVS: 2 retention • TVT: 4 retention	
AFPVS (n=91) vs. MUS (n=110)[103]	Urodynamic proven SUI, no prior incontinence surgery	14	Objective: negative cough stress test and score of 0 on questionnaires	Cure PVS 76%, MUS 81% (p=0.38)	• AFPVS: 1 wound infection, 4 voiding dysfunction • MUS: 3 voiding dysfunction, 1 mesh exposure, 1 unrecognized bladder injury, 2 pain • TOT: 1 mesh exposure, 2 retention • AFPVS: 1 cystotomy, 1 fascial dehiscence, 5 seromas, 3 retention, 1 wound infection	
AFPVS (n=20), TOT (Safyre-t®) (n=21)[104]	Stress incontinence (51% urethral hypermobility, 49% ISD)	12	Patient self-report dryness x 12 months and negative office stress test	20/21 AFPVS, 19/21 TOT Remainder are failures	• TOT: 1 mesh exposure, 2 retention • AFPVS: 1 cystotomy, 1 fascial dehiscence, 5 seromas, 3 retention, 1 wound infection	• Or time 12.8 minutes for TOT and 59.7 minutes AFPVS. • Length of stay 24h for TOT and 48h for AFPVS

AFPVS (n=10), TOT Safyre® (n=10)[105]	SUI on history and urodynamics with no detrusor overactivity.	6	Post op24 hour pad weight of <8 g	• Mean pad weight 8.4 g in AFPVS, 39.4 g in TOT (pad weights unchanged in TOT pre op 40.6g) • King's Health Questionnaire: improved in AFPVS group only	Retention requiring CIC for 7 days in 1 TOT patient	• Or time shorter for TOT 21.1 minutes vs. 69.5 minutes hospital stay shorter in TOT 28.8 hours vs. 44.4 hours for AFPVS • Conclusion: TOT less effective at treating SUI
AFPVS (n=36), TVT (n=25)[106]	Type II SUI with urethral hypermobility and abdominal LPP 60-90cmH2O	39	Negative full bladder office stress test and 1 hour pad weight <2 grams	• Objective cure 88% TVT, 83% AFPVS (p=0.78) based on stress test and 76% and 75% on 1 hour pad test (p=0.83) • IIQ: TVT 44.3 and 48.5 AFPVS (p=0.46)	• Bladder injury: 24% TVT, 8% AFPVS, bleeding >100cc 24% TVT, 30% AFPVS, sling revision 4% TVT, 5% AFPVS • Do novo UUI 4% TVT, 22% AFPVS, change in voiding pattern 20% TVT, 31% AFPVS	• No objective or QoL difference between TVT and AFPVS • Surgery 45 minutes TVT, 80 minute AFPVS
TVT™ (n=28), AFPVS (n=25)[107]	SUI leading symptom	6	Patient reported complete dryness with no pad usage, negative stress test and anti-incontinence surgery response score=0	92.9% cure in TVT and 92% cure in AFPVS	• TVT: 1 stitch sinus, 2 bladder injuries, 3patients required catheterization beyond 1 week, at 6 months no de novo detrusor overactivity, 2 wound pain • AFPVS: 1 bladder injury, 7 patients required catheter beyond 1 week, at 6 months 1 de novo detrusor overactivity, 7 wound pain	OR time: TVT 48 min, AFPVS 68 min (p=0.02)
AFPVS (n=29), TVT (n=31)[108]	Urodynamic proven SUI or MUI	24	Objective: No leakage on 250ml stress test and subjective: completely dry or only a few drops of urine loss	• Objective cure: AFPVS 48.3%, TVT 70.3% (p=0.056) • Subjective cure: AFPVS 64.5%, TVT=83.3% (p=0.1) • IIQ-7 and UDI-6 equivalent improvements in both groups	• AFPVS: 7 bladder injury, 4 elevated PVR > 100cc requiring suture loosening at 1 week, 3 de novo overactivity • TVT: 7 bladder injury, 1 urethral injury, 1 subcutaneous hematoma, 2 de novo overactivity	• OR time: TVT 43.9 min, AFPVS 87.1 min (p=0.001) • Hospital Cost: TVT $3342, AFPVS $3546 (p=0.01)
Long 21 cm AFPVS (n=81), Short 10 cm sling on a string AFPVS (n= 84)[109]	Clinical and urodynamic SUI (DO excluded)	60	No stress incontinence on UDI-6	• Recurrent SUI at 5 years in 57% of long sling and 49% short sling (p=0.59) • UDI-6= similar improvements	De novo UUI 7% long sling, 2% short sling, EBL 273 vs 230ml, bladder injury 3% total, UTI 9.7% overall, voiding difficulty at 12 months 21% overall, 3% urethrolysis rate	• Time: 62.4 min long, 54.0 short. • The rate of SUI was 13% at 3 months but rose to 53% at 5 years.
TVT™ (n=72), Pelvicol™ (n=50) AFPVS (n=79)[110]	Urodynamic proven SUI	120	Patient reported: have not wet myself at all since my operation and dry on	• Success: TVT=73%, AFPVS=75%, Pelvicol=58% • Dry rates: TVT=32%, AFPVS=51%, Pelvicol=16%	• Bladder injury: 2% Pelvicol, 5.5% TVT, 2.5% AFPVS, retention at 6 weeks: Pelvicol 0%, TVT 1.5%, AFPVS 9.9%, urethrolysis in 1 pelvicol and 1 AFPVS • Reoperation 13.1% Pelvicol, 3.2% TVT, 0% AFPV	• Pelvicol arm suspended at interim analysis due to poor results • OR time 50 minutes Pelvicol, 35 TVT, 54 AFPVS

8.2.1 Rationale

Open abdominal retropubic suspensions (urethropexies) such as the Burch procedure are procedures performed via a Pfannenstiel incision whose goal is to correct urethral hypermobility. The retropubic space is exposed and permanent sutures are placed in the anterior vaginal wall around the bladder neck and proximal urethra. These sutures are tied to the ileopectineal ligament.[67]

8.2.2 Outcomes

A Cochrane review published in 2016[101] reviewed 55 trials enrolling 5,412 women total. **It was concluded that open retropubic suspensions are effective in management of SUI with one-year success rates of 85-90% and an approximately 70% five-year dry rate**

Four small trials compared MMK to Burch with limited data available. In the short and medium term there were fewer surgical failures in women treated with Burch versus MMK at one and 5 year follow up. [101]

Six trials compared retropubic suspension to pubovaginal sling, but only two of these utilized autologous fascia.[99,111] Albo et al compared PVS and Burch in a large, well designed trial[99] that evaluated the outcomes of 655 women both objectively and subjectively with multiple outcome measures. This population had a high VLPP with the average for the group over 115 cm of H_2O.[112] **At 24 months post-operative, comparison between the PVS and Burch groups demonstrated greater overall (47% vs. 38%, respectively p<0.001) and stress specific (66% vs. 49%, respectively p<0.001) continence rates for PVS**. The low success rates compared to prior trials may be explained by the extremely rigorous definition of success in this trial (i.e. all required objective and subjective measures of continence had to be met for a patient to be deemed cured. More women in the sling group had voiding dysfunction and UTI and all 20 women who required surgical revision due to urinary obstruction were in the PVS group. Women were 1.7 times as likely to need treatment for urgency incontinence after PVS,[113] however sexual function improved and was not different between groups.[109] **Only 3.5% of the recruited women had ISD with VLPP < 60 cm H_2O so these results cannot be extrapolated to that group**.

Twelve trials in the Cochrane review[114] compared Burch colposuspension to transvaginal tape (TVT™) and three Burch to transobturator tape (TOT™), but most were of very small size and of short follow up except a trial by Ward in 2002.[115] In the short, medium and long term TVT and retropubic suspensions did not have significantly different success rates. Operative time was shorter for the TVT[115] as was hospital stay and cost was 25% less.[115] There was a higher rate of vaginal and bladder perforation in patients treated with TVT versus patients treated with the Burch procedure.

8.2.3 Adverse Events

Burch suspensions require an open abdominal incision and hence carry the typical risks of any abdominal surgery including wound complications (28%) and DVT (0.4%). Other known complications of the procedure include: UTI (32%); de novo urgency incontinence (9-13%); voiding dysfunction (3-8.9%); and intraoperative cystotomy (1-4%). Long term urinary retention requiring surgical revision is very uncommon (~ 0%).[100,101]

The suture material is typically permanent and can erode into the bladder or bladder neck many years after the procedure[116] and due to vaginal angulation, a de-novo enterocele/high rectocele can occur.

Overall, retropubic suspensions are very effective at correcting stress urinary incontinence in women with urethral hypermobility and high leak point pressures. The risk of developing voiding dysfunction is very low after retropubic suspension but there is an eight fold risk of developing new or recurrent pelvic organ prolapse compared to any sling procedure.[117] Given the availability of midurethral slings, **in contemporary practice the Burch procedure is typically performed for correction of urethral hypermobility in conjunction with a concomitant pelvic surgery , (e.g. abdominal sacrocolpopexy, open hysterectomy)**.

8.3 Synthetic Midurethral Slings

See **Table 5**

8.3.1 Rationale

The synthetic mid urethral sling can be performed in the outpatient setting and has an extensive safety profile with over 20 years of data. In a large study from the National Surgical Quality Improvement Database between 2010 to 2018, synthetic slings represented 99% of procedures performed.[118] **There are two well-studied approaches: the retropubic and trans-obturator**. The retropubic sling may be placed from the vagina to the abdomen (bottom up approach) or from the abdomen to the vagina (top down approach). Similarly, trans-obturator slings may be placed from a skin incision at the superior-medial aspect of the obturator foramen and passed to a vaginal incision with a helical needle (outside-in) or in reverse passed from a vaginal incision through the obturator foramen (inside-out).

The newest variant on synthetic sling placement is the mini sling (single incision), which is placed via a vaginal incision anchored to the obturator membrane. Each consecutive iteration of the mid urethral sling has been devised to minimize complications and increase ease of placement. All mid urethral slings function to provide a hammock[5] of support to the urethra during stress maneuvers and function optimally in the presence of urethral hypermobility. Notably, the TVT-Secur mini sling has been withdrawn from the market for poor efficacy. All data presented in **Table 5** on sling comparisons will exclude any data on this sling. A recent Cochrane review[119] concluded that there was not enough evidence to compare the mini slings with more traditional retropubic or obturator slings.

"Physicians may offer single-incision slings to index patients undergoing midurethral sling surgery with the patient informed as to the immaturity of evidence regarding their efficacy and safety.[10]

All midurethral sling procedures are performed with the patient in lithotomy position. A vaginal incision is made at the level of the mid urethra with dissection periurethrally to create a space for the sling. Typically, manufacturer kits containing needle passers (trocars) and the synthetic sling with a plastic covering sheath are utilized. The trocar is passed according to the sling type. **Cystoscopy should be performed to assess for bladder, urethral, or ureteral injury post-trocar placement.** The sling then attached to the trocar and passed through the incisions. The sling is then adjusted and if present the plastic covering sheath removed. **Trans-obturator and retropubic slings are designed to be placed in a tension-free fashion with the tape loosely adjacent to the urethra**. The exception is the mini slings which are optimally placed in closer approximation to the urethra.

Table 5: Summary of Synthetic MUS Efficacy

Slings	Reference	Type of incontinence	F/U months	Definition of Outcome:	Cure	Adverse events	Note
Retropubic bottom to top (TVT™) retropubic top to bottom (example SPARC™)	5 trials meta-analysis Cochrane (Ford 2015)[100]	SUI based on history or urodynamics and 4 trials included MUI	Median 12 months (1.5-24 months)	• Subjective: self-reported absence of leakage • Objective: variety of definitions	• Subjective (n=492): bottom to top 85%, top to bottom 77% • Objective (n=636): bottom to top 92%, top to bottom 87%	• Bottom to top had fewer bladder perforations (4.7% vs. 8.5% and less vaginal erosion (0.7% vs. 3.5%) • Similar de novo overactivity • Voiding dysfunction less frequent after bottom to top (RR 0.40)	No difference in operative time (2 trials)
Obturator medial to lateral (TOT™) to lateral to medial (TVT-O™)	10 trials meta-analysis Cochrane (Ford 2015)[100]	SUI based on history or urodynamics and 2 trials included MUI	All 12 months	• Subjectively reported cure in 2 trials • Objective: negative stress test and 1 hour pad weight	• Subjective (n=160): no difference rate 81% • Objective: (n=214) no difference rate 89%	No difference between groups. Bladder perforation, de novo overactivity, tape exposure, groin pain, more vaginal perforation in lateral to medial approach (mean 7.4%) and more voiding dysfunction in medial to lateral	No difference in OR time, return to activity, blood loss
Transobturator vs. Retropubic approach	55 trials meta-analysis Cochrane (Ford 2015)[100]	SUI as presenting symptom or SUI on urodynamics, some studies included MUI	1-60 months	• Subjective: self-report or questionnaire • Objective: pad weights, cough stress test	• Subjective: 36 trials (n=5514) showed no difference TOT 62-98%, TVT 71-97%, overall 83% • Objective: 40 trials (n=6145) TOT 86%, Retropubic 87%	• Less major vascular injury or visceral injury with TOT (RR 0.33) • Bladder perforation less with TOT (RR: 0.13) mean 2.5% • Tape erosion: no difference mean=2% • Pain: TOT groin 12% • TVT suprapubic 1.7% • De novo overactivity not different mean 8% • Voiding dysfunction: less with TOT (RR:4%), TVT 7%	OR time shorter with transobturator = 20 min vs. retropubic=27 min
TVT (n=274) vs. TOT (n=278) 404 completed five-year follow up	Kenton 2015[120]	Stress predominant incontinence and positive stress test	60	Objective: Negative stress test, negative 24 hour pad test and no retreatment	• Objective: TVT 51%, TOT 43%	• Denovo urgency incontinence: 0% TVT, 0.3% TOT, • Mesh exposure: TVT 4.4%, TOT 2.7% (p=0.26) at 2 years, 3 new TVT mesh exposures, 4 new TOT at 5 years	
TVT (n=131) vs TVT-O (n=123)	Laurikainen 2014[121]	Primary stress incontinence	60	• Subjective: questionnaires • Objective: negative cough stress test and negative 24 hour pad	• Subjective cure TVT 94.2%, TVT-O 91.7% • Objective cure TVT 84.7%, TVT-O 86.2%		
TVT (n=55) vs TOT (n=55)	Offiah 2021[122]	Stress or MUI	120	• PGI-I • ICIQ FLUTS • Pain	- TVT – 41% with no SUI vs TOT – 21.8% - 14.5% reported urge UI - TVT – 80% and TOT – 77% had improvement on PGI-I	17/121 reported moderate or severe pain[122]	

8 trials (n=399) TVT (n=200) vs TOT (n=199)	Ford 2016 systematic review[123]	Women with ISD on urodynamics	12-36	• Subjective: absence of SUI symptoms • Objective: negative stress test	• Subjective: TVT 82.5%, TOT 77.5 • Objective: TVT 171/200, TOT 150/199	Need for reoperation RR 14.4 in favor of TVT	
TOT-O (n=31) vs Mini (n=33)	Sun 2019[124]	Stress incontinence	120	• Subjective: patient reported cure and no retreatment • Objective: negative cough and pad test	• Subjective: similar • Objective: • TVT-O 80.6%, mini 57.6% (p=0.06)	At 10 year f/up all complications were minor and similar between groups	Objective cure rate decreased more in the mini group from 2 to 10 years
TVT-O (n=108) vs mini sling (n=131)	Franco 2015[125]	Stress incontinence on cough stress test	54	• Subjective: Sandvik Severity Index • Objective: cough stress test	• Subjective: TVT-O 95.4%, Mini 90.7% • Objective cure: TVT-O 88.9%, Mini 84.7%	More post-op pain and need for catheterization in TVT-O	
TOT (n=89) vs mini (n=89)	Dogan 2018	Stress incontinence	24	• Subjective: absence of SUI symptoms • Objective: negative stress test	• Subjective: not different • Objective: TOT 85%, Mini 89%	Mesh exposure <1cm 3.4%, >1 cm 2.2%, same for both groups	
Mini sling vs TVT and TOT (26 RCT 3308 women)	Mostafa 2014 systematic review[126]	Stress incontinence	18	• Subjective cure RR 0.94 • Objective cure the same RR 0.98	• Subjective cure RR 0.94 • Objective cure the same RR 0.98	Less pain in mini sling, no difference in other complications	Mini slings had shorter operative time and return to work
Ajust mini sling (n=107) vs midurethral sling (TVT, TVT-O, TOT) (n=98)	Alexandriris 2019 RCT[127]	Stress incontinence	36	• Subjective: ICIQ-UI-SF questionnaire	• No difference in subjective cure rate	No major adverse events at 3 years	No significant difference in dyspareunia
Solyx SIS mini sling (n=141) vs TOT (n=140)[128]	White 2020 prospective FDA 522 study	Stress incontinence	36	• Objective cough stress test • Subjective PGI-I measure	• No difference in objective and subjective cure rates	Similar rates of mesh exposure, pain, and urinary retention. Low rates for both. SIS was not inferior to TOT.	Secondary study showed improved sexual function after both. Low de novo sexual pain.[129]

Retropubic approaches have an objective cure rate of 71-97% and transobturator slings have cure rate of 62-98%[100,130] with no apparent difference in success between the two slings at one year or in the medium term. Mini slings have less long term follow up, but short term cure rate is between 81-84%, [75,79,131] similar to obturator slings but slightly inferior to retropubic slings.

The retropubic approach is more likely to cause voiding dysfunction and is thought to be more obstructive than the obturator approach. The retropubic approach does appear to have better results in patients with concomitant ISD; in a RCT of 163 women with ISD 1.4% of the TVT group required repeat surgery compared to 20% of the TOT group within three years post-treatment.[132] **(Table 5)** Patient BMI is also significantly associated with poorer outcomes after TVT[133]

8.3.3 Adverse Events

Despite the controversy surrounding the use of mesh slings and fear of complications, adverse events are uncommon and in a landmark population based study of all incontinence procedures performed in Scotland from 1997-2016, women who underwent mesh sling had fewer immediate complications or risk of future prolapse surgery compared to colposuspension. Late complications and need for future incontinence procedures were the same .[134]

Recognized intraoperative bladder injuries occur in 4.5% of retropubic sling procedures. The transobturator and mini-sling approaches have much lower rates of bladder injury (0-0.6% for both obturator and mini slings). Vaginal mucosal injury occurs in 4.5-7.1% of obturator and mini slings. Blood loss for all sling procedures is typically 50 ml for all approaches; however major vessel injury or bowel perforation can occur with the retropubic approach (< 1/1000) and may be life threatening. Urethral injury intra-operatively is rare but mandates the surgeon to abandon mesh placement.[10]

All contemporary mid-urethral slings are composed of macroporous knitted type I polypropylene that is not heat sealed.[135] This differs from the mesh used in vaginal prolapse repair, which has received significant negative publicity due to the high rates of complicated vaginal exposure.[136] Mid-urethral slings have a low rate of vaginal extrusion (7%)[10] that can typically be managed with simple excision of the exposed portion or can be managed expectantly in the absence of symptoms.[137] In RCTs the different slings have similar mesh exposure rates (0.7-4.4% at one year). In a large study of 36,195 women in New York State, risk of erosion was 3.7% after 7 years.[129] The International Urogynecological Association (IUGA) has devised a classification of mesh related complications.[135]

Groin pain is a complication unique to the transobturator (12-26%) and mini (~1.5%) sling approaches and likely relates to passage of the tape near the adductor muscles. In a recent review of patients that underwent midurethral sling removal for pain, overall pain improved or resolved in 78.1% of cases.[138] Voiding dysfunction due to obstruction is more common after retropubic slings (0.3-7%) than the transobturator (0-4%) or mini slings (1.4-1.7%) and can be treated with sling division. *De novo* symptoms of overactive bladder occur in 0-7% of cases and may be related to obstruction should be ruled out.[100,120,139,140,141,132]

8.4 Pubovaginal Slings (PVS)

Rationale: PVS are placed via a combined abdominal and vaginal approach. **A strip of material, most commonly autologous fascia, is passed under the proximal urethra/bladder neck and tunneled up to be tied above the rectus fascia. The pubovaginal sling is designed to treat ISD but is also effective at treating incontinence due to urethral hypermobility**. The material utilized is typically abdominal rectus fascia harvested from the same incision; autologous fascia lata from a separate incision may also be used. [67] Porcine dermis, cadaveric fascia, Teflon™, Gore-Tex®, Marlex®, Silastic®, and Mersilene® have also been used but complication rates tend to be higher using non-autologous tissue. Only autologous fascia will be discussed in this summary.

8.4.1 Outcomes

A Cochrane review of traditional suburethral slings[142] includes 34 trials with 3,244 women.[143] The quality of these studies was modest with small sample sizes in most studies (except the previously mentioned study by Albo et al.) and only short term follow up (6 to 24 months).

Trials comparing Burch procedure to autologous PVS show superior cure rates at the expense of a higher voiding dysfunction and obstruction in PVS treated patient as **discussed above**.

Twelve trials have compared PVS and midurethral slings.[142] Only short- and medium-term results are available, but at both time points there is no difference in patient reported incontinence between these slings. The success of PVS varies widely (48-92%) depending on the definition used for cure **(Table 4)**.[99,100,104,105,106,109,110,107,102,108]

8.4.2 Adverse Events

As with retropubic suspensions there is an abdominal wound with the inherent risk of wound complications (26%). It is also not uncommon to have temporary (2 weeks or less) urinary retention after PVS. UTIs occur frequently after PVS (9.7-48%). The revision rate for PVS due to obstruction or *de novo* voiding dysfunction is 5-7.2%. *De Novo* urgency incontinence can occur (2-22%) as well as voiding pattern changes (31%). Operating times and blood loss are similar to retropubic suspensions and incidental cystotomy is uncommon (0.7-8%).[99,100,104,105,106,109,110,107,102,108]

9. Costs

It is difficult to estimate the cost of pure SUI in the population since many patients have urinary leakage that has not been defined and have a significant usage of pads and routine care that is not specific to incontinence type. In a 2001 study, the annual direct cost of urinary incontinence in the United States in 1995 was estimated as $12.4 billion for women; this represents 76% of the total cost for both genders. The costs for community-dwelling women ($8.6 billion, 69% of costs for women) greatly exceeded that of women who were institutionalized ($3.8 billion). Costs for women over 65 years of age were more than twice the costs for those under 65 years and the greatest contributor to this cost was routine care (70% of costs for women).[144]

10. Clinical Care Pathway

Patients should first be thoroughly evaluated with a history, **physical exam**, **symptom evaluation**, **urinalysis**, **PVR and an objective observation of SUI**. **Pad testing**, **voiding diaries and symptom questionnaires can provide additional information**. **Cystoscopy and urodynamics are needed only in specific clinical circumstances**.

See **Surgical Treatment of Female Stress Urinary Incontinence (SUI): AUA/SUFU Guideline (2017)**

Patients should be educated about SUI and offered behavioral and non-surgical options first.

If a woman has decided to undergo surgery, the injectable agents, midurethral slings, retropubic slings, and autologous pubovaginal slings should all be discussed along with their success rate and complications. In the case of midurethral mesh slings, the FDA warning on the use of mesh should be discussed. Patient handouts are helpful in providing better patient education and providing a copy of the SUFU/AUGS position statement on vaginal mesh can alleviate patient concerns.

See **Stress Urinary Incontinence (SUI)**

Before any surgical procedure on the urinary tract, the urine must be sterile as confirmed with urinalysis. Most injectable agents can be performed in the office with little preparation other than a pre-procedure antibiotic; however, the more invasive open surgical procedures require anesthesia and therefore an age and comorbidity specific preoperative workup.

Post-procedure, a voiding trial should be performed to ensure that the patient is not in retention. Should retention occur, clean intermittent catheterization can be instituted or an indwelling catheter can be placed, and a repeat voiding trial can be performed within a week since the majority of the surgical edema will have subsided. “Physician or their designee should communicate with patients within the early postoperative period to assess if patients are having any significant voiding problems, pain, or other unanticipated events. If patients are experiencing any of these outcomes, they should be seen and examined.” [10]

“Patients should be seen and examined by their physicians or designees within six months post-operatively (ideally 4-8 weeks post-surgery). Patients with unfavorable outcomes may require additional follow-up. The subjective outcome of surgery as perceived by the patient should be assessed and documented. Patients should be asked about residual incontinence, ease of voiding/force of stream, recent urinary tract infection, pain, sexual function and new onset or worsened overactive bladder symptoms. A physical exam, including an examination of all surgical incision sites, should be performed to evaluate healing, tenderness, mesh extrusion (in the case of synthetic slings), and any other potential abnormalities and post-void residual should be obtained.”[10]

11. AUA Guideline Webcast

- **AUA Guidelines 2017: Stress Urinary Incontinence**

12. Podcasts

- **AUAUniversity Podcast Series: Episode No. 175**

Videos

BULKAMID. Urethral bulking system

Urethral Injection

Urethral Bulking Agents

The use of mesh in Female Pelvic Surgery: An educational video

Pubovaginal Sling with Tensor Fascia Lata

Transvaginal Approach to Urethral Reconstruction After Midurethral Sling Complication

Robotic Assisted Laparoscopic Excision of Retropubic Mesh

Transvaginal Removal of Intraurethral Mesh

Abdominovaginal Technique for Complete Removal of Retropubic Mesh Slings

Surgical Technique for Placement of a Retropubic Midurethral Sling for Female Stress Urinary Incontinence

Female SUI-Midurethal Sling

Female SUI-Autologous Fascial Sling

Female SUI- Placement of a Retropubic Midurethral Sling

Autologous Fascial Pubovaginal Sling: Contemporary Indications, Techniques, and Challenges

Retropubic Midurethral Sling: Top-Down Approach

Presentations

SURGERY FOR FEMALE SUI Presentation 1

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