Sling and Bulking Agent Placement Procedures

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Sling procedures have been used for the treatment of stress urinary incontinence since the early 1900s. Traditional sling procedures are best performed with autologous rectus fascia or fascia lata, and the sling material should penetrate the urogenital diaphragm (perineal membrane) into the retropubic space. Tension-free slings using polypropylene have excellent efficacy and safety data and are applicable in an outpatient setting. They are a good first-line surgical choice. Periurethral bulking agents have application for patients with a relatively immobile bladder neck and in cases of medical compromise or a desire for a simple, office-type treatment.
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Key words: Bulking agents • Incontinence • Slings • Tension-free vaginal tape

Sling procedures were introduced by Giordano in 1907 with the use of gracilis muscle transposed beneath the bladder neck. In 1910, Goebell formed a sling under the bladder neck using pyramidalis muscles transposed through the space of Retzius. Frangenheim, in 1914, described using a strip of anterior abdominal fascia with the pyramidalis muscles, and Stoeckel, in 1917, refined this further.

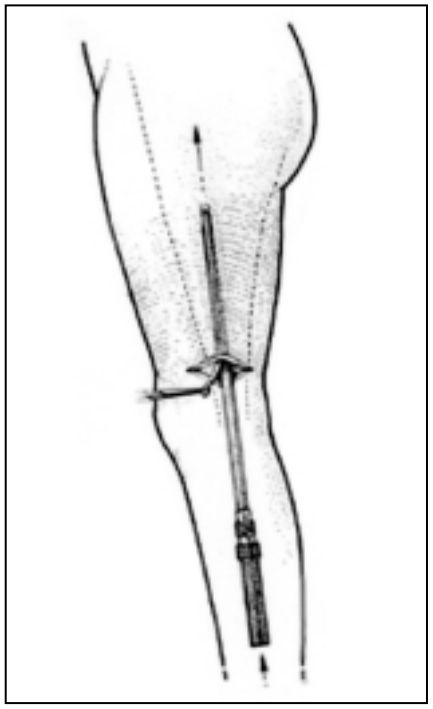


Figure 1. *Masson fascial stripper. Reprinted, with permission, from Ridley JH.* Gynecologic Surgery: Errors, Safeguards, Salvage.*1974:114-154.*[1]

Conventional Sling Procedures

In 1933, Price used a sling of a patient's fascia lata, which he passed beneath the urethra, then retropubically, and attached to the anterior rectus fascia on either side of the midline.[1] This technique and its modifications[2,3] have become the frequently used procedure called either the Goebell-Stoeckel-Frangenheim procedure or the fascia lata sling. In 1942, Aldridge[4] developed strips of rectus fascia from a transverse abdominal incision, passed them retropubically, and secured them beneath the urethra. McGuire and Lytton[5] described a sling procedure using rectus fascia supported by sutures extending through the space of Retzius and attached to the rectus fascia. This procedure and its modifications[6] have also become widely used. These 2 autologous fascia sling procedures comprise the gold standard of sling operations.

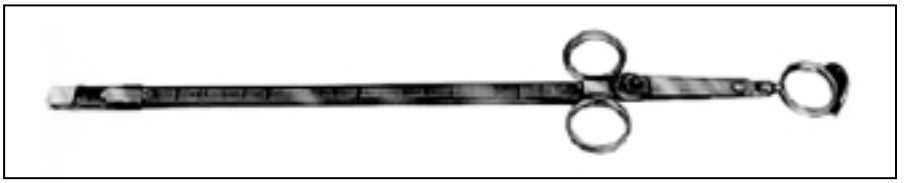


Figure 2. *Crawford fascia stripper.*

Materials

Autologous materials currently used for suburethral slings include fascia lata, rectus fascia, and vaginal wall.[7] Although readily available, vaginal wall has not proved durable enough to gain support among many surgeons. Fascia lata is harvested from the lateral aspect of the thigh.[1,8] Harvest is accomplished with instruments designed to separate a strip of fascia, such as the Masson fascial stripper (Marina Masson Fascialata Stripper, Marina Medical, Hollywood, Fla) or the Crawford fascia stripper (Storz Instrument Company, Rochester, NY). Alternatively, a direct surgical approach allows opening and dissection of the tissues overlying the fascia and direct excision of desired amounts. The Masson fascial stripper is available in 1-cm and 2-cm sizes and can remove a strip up to 3 cm in width and 20 cm long (Figure 1). The Crawford fascia stripper can remove a strip 1 cm wide and 20 cm long (Figure 2).

The patient may be placed on her side, though a leaning position will also work, with one leg flexed and positioned on a pillow over the other leg and the chest only partially turned to the side (Figure 3). Three inch–wide tape is used to secure the patient in position. The leg is prepped and draped, and the iliotibial fan of fascia lata is palpated over the lateral thigh, near the knee. A vertical or transverse incision is made 2 to 3 cm above the knee over the fascia, the subcutaneous tissue is cleared, and the fascia lata is cleaned with a gauze-tipped finger. Two incisions are made in the fascia, 1.5 to 2.0 cm apart, and the fascia lata is transected above the attachment into the lateral condyle of the femur. The distal 4 to 5 cm of fascia is mobilized with sharp dissection, and the free end is threaded into the Masson or Crawford fascial stripper and held firmly with straight Kocher clamps (Figure 4).

The fascia is freed superiorly from the attachments by passing a long

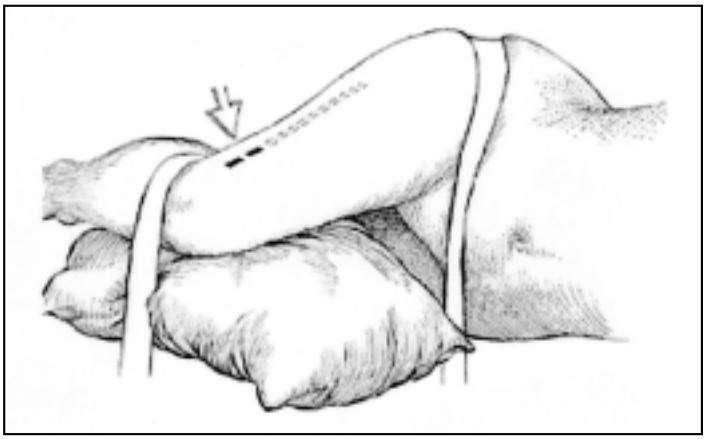


Figure 3. *Patient positioning for fascia lata harvest. Reprinted, with permission, from Wheeless CR Jr.* Atlas of Pelvic Surgery. *1997:125-133.*[8]

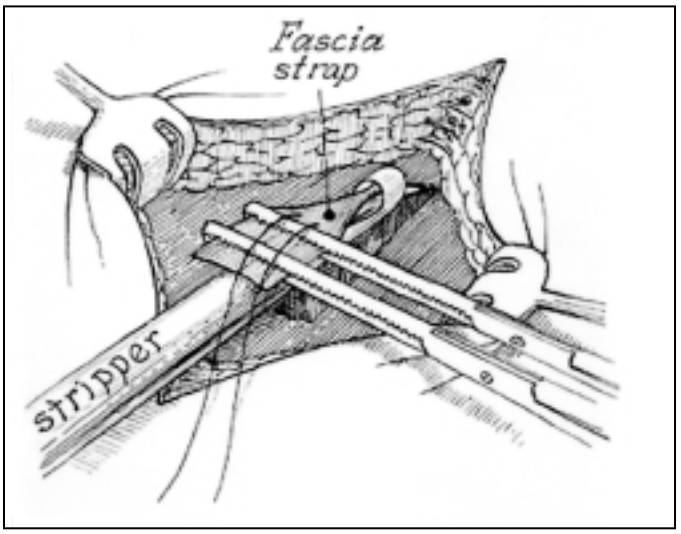


Figure 4. *Placement of fascia lata in the Masson fascial stripper. Reprinted, with permission, from Wheeless CR Jr.* Atlas of Pelvic Surgery. *1997:125-133.*[8]

forceps (handle end) over the superior and inferior surfaces of the fascia. The stripper is then advanced parallel to the fascia lata fibers, toward the greater trochanter of the hip, until it will advance no further. The Masson stripper has an inner and outer component, and the outer sheath is disengaged and advanced briskly or turned over the inner portion, which severs the fascia at the uppermost area of the leg. The strip is up to 20 cm in length but can be lengthened by one of several methods to achieve a full-length sling (Figure 5). The Crawford stripper requires a pulley action to advance a cutter at the end of the instrument to cut the fascial strip. The 1 cm–wide strip obtained with the Crawford stripper requires a second pass to get a second strip if a full-length sling is desired, and the 2 strips are sutured together, overlapping in the center 2 or 3 cm, to make that area thicker as well as wider. It is usually difficult to approximate the defect in the fascia lata, so only the skin is closed, and a pressure dressing is applied overnight to minimize bleeding. The patient is returned to the dorsal lithotomy position.

Rectus fascia is harvested at the time of a suprapubic incision by excising a strip of rectus fascia and closing the residual defect.[9,10] The portion excised through a 4-cm incision may be 2 cm wide and 8 to 10 cm long. A fascial closure suture is placed beyond the harvest site, a strip of rectus fascia is developed medially, and 2 sutures are placed at the corners of the strip (Figure 6). Likewise, at the opposite corner, a fascial closure suture is placed, and the strip of fascia is developed toward the center to meet the other portion of fascia. The graft is kept moist in an antibiotic solution (Figure 7). The fascial incision is closed commencing with the previously placed sutures. The fascia is mobilized off the underlying muscle to avoid tension in the closure. The dissection is best performed sharply to avoid contraction with cautery. The fascia is cleared of fat just above the symphysis pubis on either side, at the sites of anticipated penetration of sling arms passed from the vagina through the retropubic space.

Allogenic grafts from cadaver donors include fascia lata, which may be solvent-dehydrated (Tutoplast®, Mentor Corporation, Santa Barbara, Calif) or freeze-dried and γ-irradiated (Table 1). Since cadaveric fascia lata for suburethral sling procedures was first described in 1996,[11] there have been reports of delayed failures of cadaver materials.[12] However, the majority of authors report on the benefits and ease of use of these materials.[13–15] Although allograft fascia materials have been in use for over 25 years,[16,17] they have to be harvested, processed, preserved, and distributed by tissue banks regulated

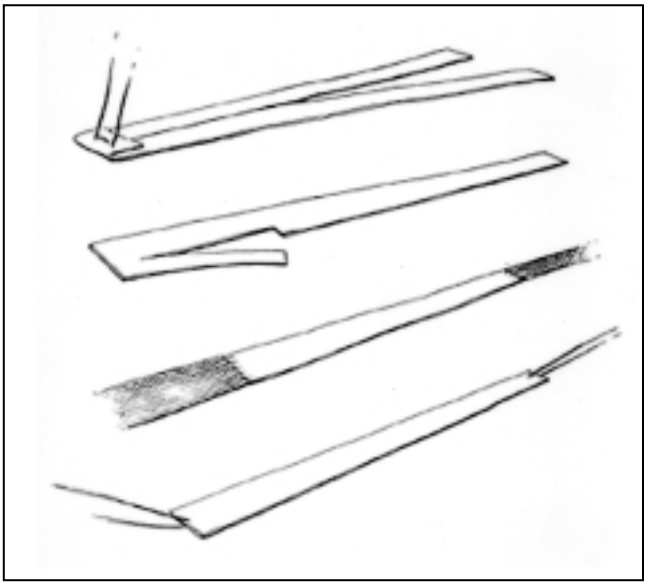


Figure 5. *Lengthening methods for sling materials (from top to bottom): splitting the fascial strip lengthwise, splitting off part of the sling, suturing other material to either end or to both ends, and suture placement at the ends of the sling arms. Reprinted, with permission, from Wall LL. In:* Te Linde's Operative Gynecology. *1997:1125.*[56]

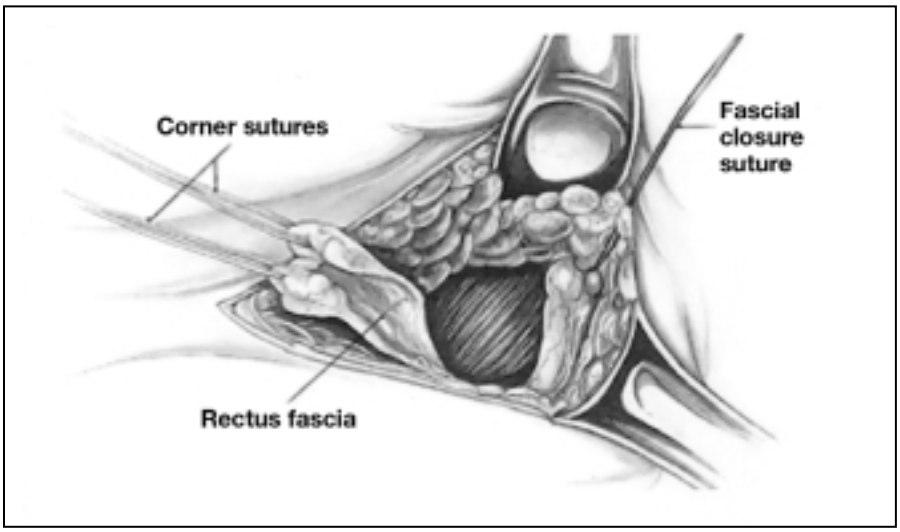


Figure 6. *Rectus fascial harvest: A fascial closure suture is placed where the fascia is mobilized laterally in order to assist in closure of the residual defect. Corner sutures on the harvested fascia assist in the mobilization of the strip and are used later in passage from the vaginal to the abdominal site. Reprinted, with permission, from Brubaker L.* Oper Tech Gynecol Surg. *1997;2:44-50.*[9]

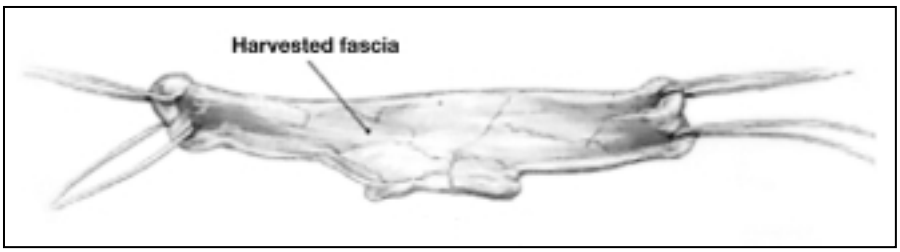


Figure 7. *Harvested rectus fascia strip measuring 2 cm in width by 8 cm in length. Reprinted, with permission, from Brubaker L.* Oper Tech Gynecol Surg. *1997;2:44-50.*[9]

Table 1
Allograft Fascia Lata

Source (Trade Name)	Sizes (cm)	Comments
LifeNet, Virginia Beach, Va	3X6; 3X15; large	Freeze-dried, γ-irradiated; viral inactivation
Bard, Covington, Ga (Fas Lata)	4X7; 2X12; 4X12; 8X12	Freeze-dried, γ-irradiated
Mentor, Santa Barbara, Calif (Suspend®)	4X7; 6X12; 2X18; 6X8	Solvent-dried, γ-irradiated (Tutoplast®-processed)
UroMed Corp, Norwood, Mass (Allo Sling)	2X4; 2X15; 2X18	Freeze-dried, γ-irradiated
Community Tissue Services Dayton, Ohio	4X13; 3X20; 1.5X20	Freeze-dried, γ-irradiated
American Red Cross Tissue Banking, St. Paul, Minn	<6; 6-12; >12	Freeze-dried, γ-irradiated

Adapted from Singla AK. *BJU Int*. 2000;85:264-269.[16]

by the American Association of Tissue Banks.

The other allograft material is dermis (AlloDerm®, Repliform™, LifeCell Corporation, The Woodlands, Tex), which is donated human tissue that is processed to remove all epidermal and dermal cells while preserving the remaining biologic dermal matrix. The tissue is freeze-dried without damaging components essential for revascularization and repopulation by the recipient's normal cells.[18] It comes in sizes comparable to cadaver fascia lata products. One study evaluated the maximum load, maximum load per width, and stiffness and found that autologous rectus fascia, solvent-dehydrated cadaveric fascia lata, and dermal grafts have similar values, whereas freeze-dried cadaveric fascia lata was inferior to all three.[19]

Xenografts have increasingly been used in sling procedures, mainly because of ready access to materials. Those commonly employed include porcine dermis[20] (Pelvicol®, C. R. Bard, Inc., Murray Hill, NJ), bovine pericardium (Veritas™ Collagen Matrix, Synovis Life Technologies, St. Paul, Minn), and porcine small intestinal lining[21] (Stratasis®, Surgisis®, Cook Ob/Gyn, Spencer, Ind).

Because of the time and morbidity associated with fascial harvest, the search for the perfect implant material for suburethral slings has for a long time included numerous synthetic materials.[13] Those used include polyethylene strips and gauze (Mersilene),[22,23] polypropylene mesh (Marlex),[24,25] Silastic band,[26] polytetrafluoroethylene[27] (Gore-Tex® soft tissue patch), and various types of modified polypropylene mesh with greater porosity (Prolene, Ethicon, Inc, Somerville, NJ; GyneMesh, Gynecare, Somerville, NJ). The significant aspects of the mesh material include type of weave, pore size, width, and weight, and the mechanical properties

Table 2
Synthetic Materials for Suburethral Sling Procedures

Mesh	Trade Name	Multi-/ Mono-filament	Pore Shape	Relative Stiffness	Relative Peak Load
Polyethylene (polyester)	Mersilene	Multi	Hexagonal	1	1
Polytetrafluoro-ethylene (patch)	Gore-Tex®	Multi	Node and fibrils	2.5	1.6
Polypropylene	Marlex	Mono	Irregular	–	–
	Prolene	Mono	Diamond	0.5	1
	TVT	Mono	Diamond	0.25	1.2

of some of these synthetic materials have also been studied (Table 2).[28]

Methods

There are 3 basic lengths of sling material. The first is a full-length sling that passes from underneath the urethra on either side, all the way to the point of fixation, where it is secured with sutures. Typically, the material is attached to the rectus fascia with sutures, and the ends of the material protrude through small openings in the rectus fascia. Some of the materials will not reach because of inadequate length, and often the surgeon will cut the strip of material longitudinally from one end to a point 3 cm from the opposite end, and then overlap one of the narrow arms of material to almost double the original length of the sling. This method is often used for harvested fascia lata or for prepared cadaveric or xenograft tissues, which may be 20 cm or less in length when removed from the package. In order to avoid tension on the sling, the length should be approximately 30 cm.

The second length of material is a half sling (7 cm or longer) that extends into the retropubic space above the perineal membrane (urogenital diaphragm) and has sutures applied to the tails to suspend the material to the appropriate fixation site, usually the rectus fascia.

The third length of material is a patch sling of only several centimeters, in which the tails do not enter the retropubic space but are attached to sutures that extend through the retropubic space to the attachment site. Alternatively, the sling may be attached by shorter lengths of suture secured by bone anchors into the pubic bones. There is also an adjustable type of patch sling (Remeex, Neomedic, Barcelona, Spain) in which the sutures extend to the abdominal rectus fascia, where they are secured to a device that allows tightening to control stress incontinence or loosening of the suture arms to allow voiding without obstruction.

Abdominal dissection. The abdominal dissection follows the harvest of the fascia lata if that technique is used. The incision need only be 4 cm in length (unless the patient is obese) and is usually placed 2 cm above the symphysis pubis, but not in the crease of the panniculus. In cases of rectus fascia harvest, the subcutaneous tissues are dissected widely to expose an 8- to 10-cm area of rectus fascia. A stabilizing suture is placed at each lateral extent of fascial harvest to allow proper fascial closure after harvest. The 2-cm by 8- to 10-cm strip of material is removed sharply and placed in sterile saline or antibiotic solution. Permanent sutures are placed at each corner, at either end of the strip. The strip may be lengthened by incising longitudinally, leaving 2 to 3 cm intact at one end and overlapping one of the longitudinal arms. The fascial incision is closed, and the fascia is cleared of fat below the site of the closure to allow for sling fixation.[9] If rectus fascia is not harvested, the incision may be 3 to 4 cm and is opened down to the rectus fascia. The fascia is cleared of fat and subcutaneous tissue at sites 2 cm above the symphysis and 2 cm lateral to the midline, where the sling arms or sutures will be passed through the fascia. If an instrument is used to grasp the sling or suture tails (as opposed to a needle passer technique using Pereyra or Stamey needles), then a small 0.5- to 1.0-cm incision is made in the full-thickness rectus fascia.

Vaginal dissection. The approach through the vagina to the retropubic space follows the same basic pathway in all instances. After a Foley catheter has been placed, an inverted U or midline incision is made. The dissection may thoroughly dissect pubocervical fascia away from the vaginal epithelium, allowing for plication of the fascia prior to laying the sling over it, or the fascia may be left attached to the epithelium, with minimal dissection other than sharp or blunt entry into the retropubic space. The retropubic space is entered sharply or bluntly, directing the instrument or finger toward the ipsilateral shoulder (Figure 8). Some surgeons do not enter the retropubic space when placing a sling, though most like to use a finger to guide the instrument as it is passed from the abdominal to the vaginal incision, and this is the

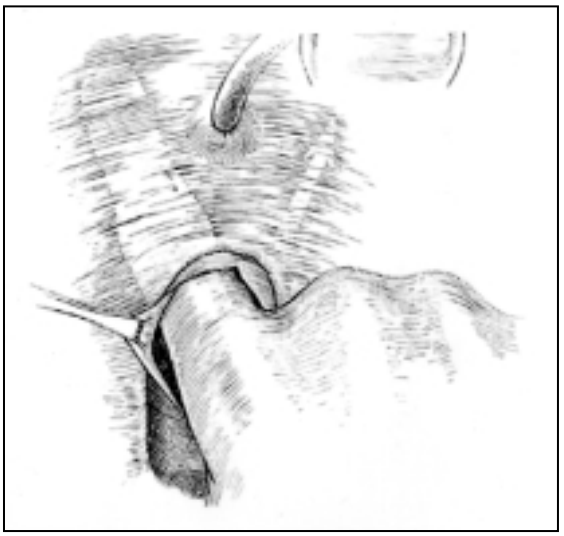


Figure 8. *Dissection lateral to the midline of the anterior vaginal wall into the space of Retzius under the descending pubic ramus. Reprinted, with permission, from Wheeless CR Jr.* Atlas of Pelvic Surgery. *1997:125-133.*[8]

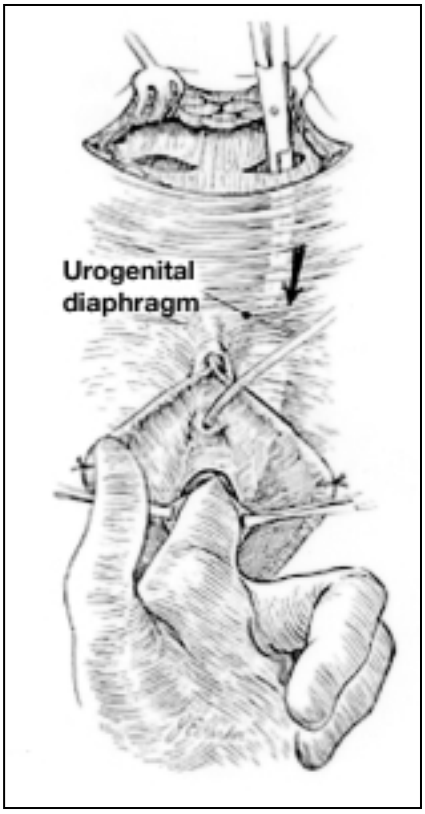


Figure 9. *Abdominal instrument passed behind the symphysis pubis to meet the vaginal finger extending into the space of Retzius. Reprinted, with permission, from Wheeless CR Jr.* Atlas of Pelvic Surgery. *1997:125-133.*[8]

recommended technique. The pubocervical fascia may or may not be plicated. The instrument passed from the abdominal to the vaginal site (uterine dressing forceps, long Kelly clamp, or needle-suspension ligature carrier) clears a small opening in the rectus fascia and then is directed toward the back of the symphysis pubis. Meanwhile, a finger is placed in the vaginal opening into the retropubic space and reaches up to meet the advancing clamp or needle (Figure 9). There should only be 1 cm or so of blind passage of the instrument before reaching the vaginal finger. The sling or suture arms are pulled from the vaginal site to the abdominal site on each side (Figure 10). Cystoscopy should then be performed to ensure that there has been no bladder perforation, and it is usually prudent to observe ureteral function. The sling body is usually sutured to the pubocervical fascia under the mid- to proximal urethra to prevent movement from the placement site. The placement site is guided by the Foley catheter bulb, which is the marker for the bladder neck (Figure 11).[9,13]

Placement location. The position of the sling historically had been to override the bladder neck and proximal urethra. Gradually, this position migrated distally until the sling position of optimum function was thought to be the proximal urethra (Figure 12). Since the introduction of the tension-free tape procedures at the mid-urethra, a number of surgeons have also moved the traditional suburethral sling placement even more distally to override the mid-urethra. A broad-based sling is considered preferable to a narrow band of material.

Fixation points. The purpose of the fixation site is to provide stability to the sling arms, allowing the urethra to be supported and compressed by the suburethral portion of the sling during increased intra-abdominal pressure. From early on, the fixation site was the rectus fascia, which is still the most prominent site. The arms of the sling may be sutured together loosely over the rectus fascia without actually being sutured to the fascia. Likewise, suspending sutures may be tied together over the rectus fascia. If a lower abdominal incision is used and the retropubic space opened, Cooper's ligament can also be used to support the sling arms. Bone anchors were introduced to allow alternative fixation to a solid structure, though there is no evidence that rectus fascia attachment is a cause of procedure failure. The back of the symphysis or the underside of the pubic ramus could be used for bone anchor placement from either the vaginal or abdominal approach. This is not a commonly used technique and adds expense to the procedure, as well as the potential for osteomyelitis.

Tension. In the early reports of fascia lata sling procedures, it was not uncommon for patients to have voiding function delay for almost a month.[29] Many methods have been used to help determine sling tension, including Q-tip angle, endoscopic view of the bladder neck, intraoperative urodynamics, and looseness of the sling or sutures at the abdominal rectus site. It is considered unusual

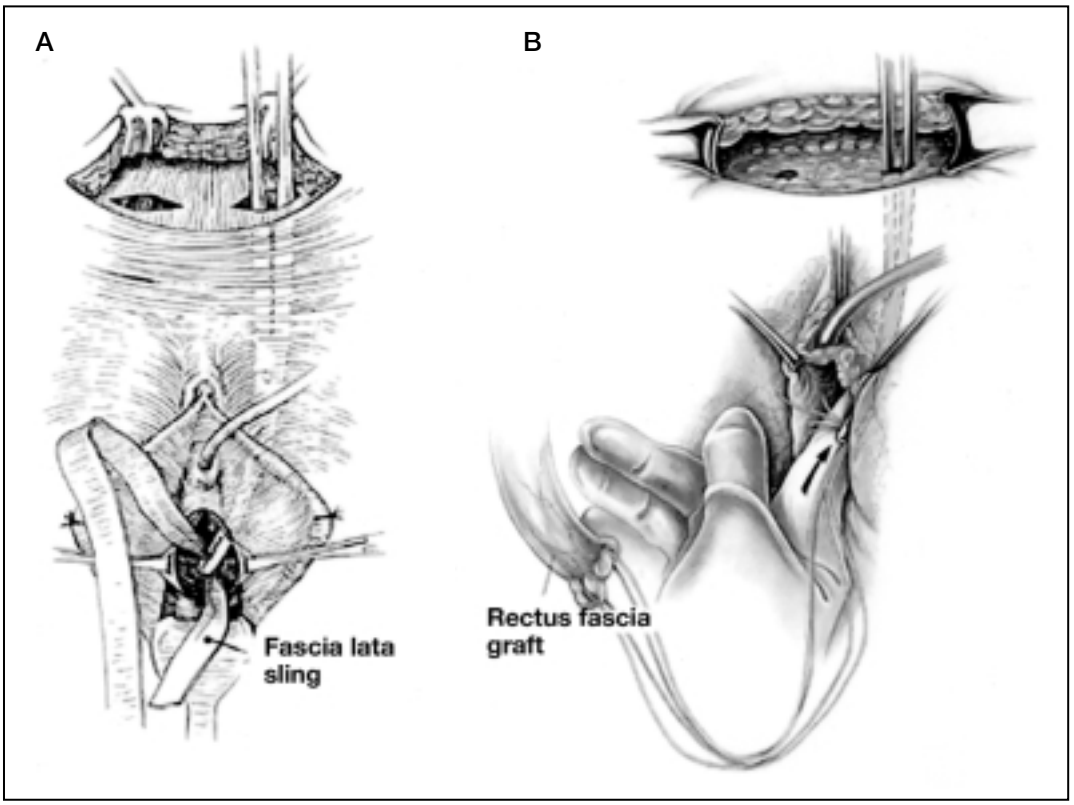


Figure 10. *Passage of sling material through the space of Retzius from the vaginal to the abdominal site:* (A) *Fascia lata full-length sling. Reprinted, with permission, from Wheeless CR Jr.* Atlas of Pelvic Surgery. *1997:125-133.*[8] (B) *Rectus fascia partial sling with attached sutures. Reprinted, with permission, from Brubaker L.* Oper Tech Gynecol Surg. 1997;2:44-50.[9]

to have the sling too loose, and if the sling is thought to be tight, it usually is. The sutures or sling tails are placed through the fascia and tied, with 1 to 3 finger breadths between the tissue and the sutures or sling. The sling tails or sutures may be tied together over the fascia before or after tying to the fascia itself, though either can be done separately. The object is to leave the sling loose. A spring device has been used to adjust tension intraoperatively, though it has not been well tested or accepted. One of the patch slings using polypropylene (Remeex) has sutures placed through an adjustable device implanted just above the rectus fascia, allowing increases or decreases in tension to ensure continence and avoid voiding dysfunction.

Postoperative care. Bladder drainage techniques include suprapubic catheter, Foley catheter, or intermittent self-catheterization. The trend has been to avoid suprapubic catheter use, because slings are placed with less tension and time to void is greatly shorter than in the past. Older and obese patients, who may have difficulty with eventual self-catheterization, may be candidates for suprapubic catheter drainage. Most often, a Foley catheter is left overnight and then removed the following day, allowing the patient the opportunity to void. Postvoid residual urine determinations are made by bladder scan or catheterization. If voiding is inadequate, the Foley may be reinserted or self-catheterization may be utilized or taught if the patient has not been previously instructed. Physicians determine the amount of residual urine that is acceptable, which may vary with patient age and should take into consideration the amount of urine voided.

Hospital length of stay is variable but is often only 1 day. Outpatient surgery may also be performed, particularly if there is no fascial harvest. The usual instructions and restrictions are employed at discharge. Typically, patients can drive when they no longer have pain requiring narcotic use. There is no information on length of time to remain off work or to avoid various activities. Most healing is complete at 3 months, and scar revision occurs for 2 years. The majority of patients should be able to perform normal activities at 2 to 3 weeks, with the exception of exercise, heavy lifting (>25 lb), housework, and yard work. The patient's return to work depends on the type of duty that she performs and her motivation to work at home or on a limited basis. This time frame needs to be mutually agreed upon by the physician and the patient. Often, the patient will return to work part time after 2 or 3 weeks and full time after another week. For those with more active duties, such

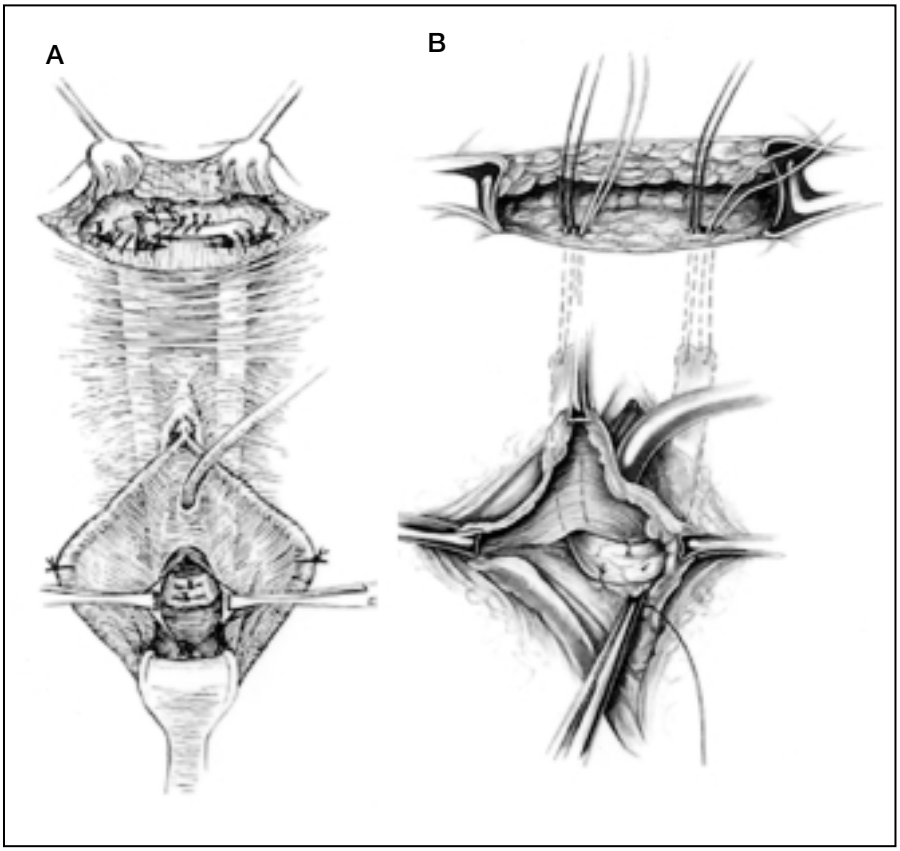


Figure 11. *Sling position under the bladder neck and at the rectus fascia fixation site:* (A) *Fascial lata full-length sling sutured to the rectus fascia. Reprinted, with permission, from Wheeless CR Jr.* Atlas of Pelvic Surgery. *1997:125-133.*[8] (B) *Rectus fascia sling suspended by sutures ready to be secured to the rectus fascia. The harvest site is noted 2 cm above the site of penetration of the rectus fascia by the suspending sutures. Reprinted, with permission, from Brubaker L.* Oper Tech Gynecol Surg. *1997;2:44-50.*[9]

as lifting, prolonged standing, walking, or other physically strenuous jobs, work return should most likely be around 6 weeks. All patients should avoid strenuous exercise and heavy lifting for 3 months. Intercourse and vaginal inserts should be avoided until there is good vaginal healing, which occurs some time after 4 weeks. There is no need for restriction of showers or shallow tub baths, and sitz baths may be utilized at the physician's direction.

Office follow-up is advised at 1 to 2 weeks, 6 weeks, 3 months, and 1 year. This schedule allows an opportunity to recognize complications such as infection, voiding dysfunction, and symptoms of detrusor overactivity at the early visits, as well as long-term detrusor overactivity or failure of procedure at the later visits.

Complications

Complications associated with conventional suburethral slings are outlined in Table 3.[13,30] The usual intraoperative complication of surgery is bleeding. Most local bleeding is recognized and controlled by pressure, cautery, or suture ligation. There may be large veins just under the descending pubic ramus where the dissection proceeds into the space of Retzius, and these are usually entered during the vaginal portion of the procedure and not in passing the sling from the abdomen to the vagina. The large vessels of the pelvis are seldom penetrated by instruments or sling. The sling may be passed through the bladder, so it is important to examine the bladder and ureteric function by cystoscopy after the sling has been passed. If there is sling through a portion of the bladder, the sling material is removed and re-passed. On rare occasions, the sling or a suprapubic catheter may be placed through a portion of bowel, though recognition of this complication can be delayed.

The immediate postoperative period should include the continued use of compression stockings, early mobilization, and use of an incentive spirometer to help avoid complications of deep venous thrombosis and respiratory problems. It is the usual practice to provide broad-spectrum antibacterial coverage intravenously just prior to the start of the procedure. Slings are often soaked in an antibiotic solution before placement. In the early postoperative period, an elevation of temperature may occur, caused by cystitis, pyelonephritis, bowel injury, pneumonia, or wound infection. Hematoma of considerable size may occur in the retropubic space, even if the patient shows no signs of volume compromise. This may be detected by a drop in hematocrit and diagnosed by clinical examination and ultrasound or other imaging modality. Voiding function and possible bladder overdistention must be monitored carefully. Bowel function should also be monitored; however, these patients are typically home within 1 or 2 days and the first bowel movement often occurs after hospital discharge.

Short-term complications include continued voiding difficulty and the potential need for self-catheterization. These complications may be associated with bladder infection, high postvoid residual urine volume, or overactive bladder symptoms. A wound seroma or infection may occur at either the

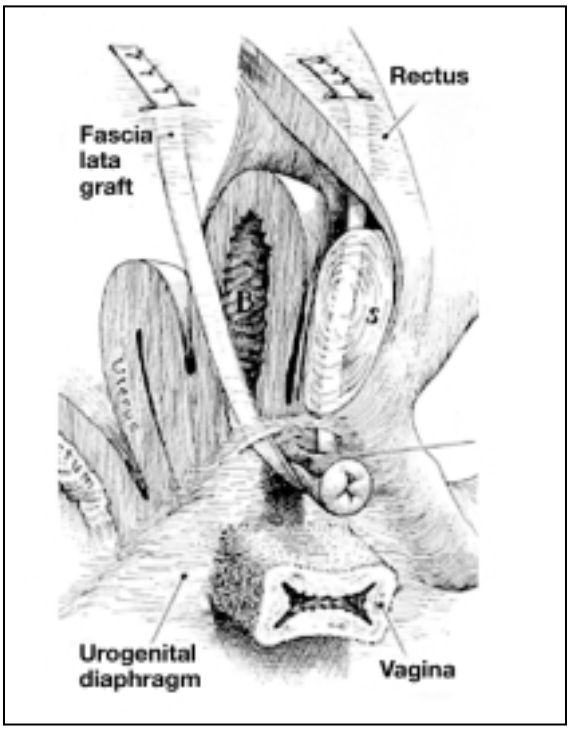


Figure 12. *Sling positioned at the proximal urethra, extending through the space of Retzius, and fixed to the rectus fascia. Reprinted, with permission, from Wheeless CR Jr.* Atlas of Pelvic Surgery. *1997:125-133.*[8]

Table 3
Complications of Conventional Suburethral Slings

Complication	Frequency, %	Resolution
Bleeding with vaginal dissection	20	Pressure, cautery, suture, packing
Retropubic space bleeding	5-10	Spontaneous absorption
Bladder perforation	1-2	Replace sling, leave catheter 2-3 days
Infection/wound	<5	Eventual healing
Wound seroma, leg or abdomen	3-5	Closed drainage
Infection, urine	20	No long-term sequela
Retropubic space hematoma	2	Slow resorption
Retropubic space abscess	Infrequent	Drainage: open vs imaging technique
Blood clot (DVT)	2-30	Aggressive treatment, prevention
Respiratory problem	2-5	Incentive spirometer, physiotherapy
Vaginal breakdown over sling	1-2	Soaks, local irrigation, antibiotics
Mesh erosion	5-25	Local excision, revision, and resuture
Voiding dysfunction	2.5-24	Patience, self-catheterization, medication
Obstructed voiding	1-2	Sling release
De novo urge incontinence	3-23	Bladder retraining, medication
Persistent urge incontinence	26-60	Bladder retraining, medication
Urethral erosion	Rare	Sling removal, probable surgical repair

DVT, deep venous thrombosis.

abdominal incision site or at the fascia lata harvest site. If a significant hematoma has occurred in either the abdominal incision or retropubic space, abscess formation may follow. Vaginal healing may be compromised by slough of the anterior vaginal wall, persistent oozing or bleeding from the suture sites, or failure of the incision to close properly over the sling. The patient should be checked for respiratory function and venous thrombosis.

Long-term complications associated with conventional slings include voiding dysfunction and a continued need for catheterization, overactive bladder symptoms, and procedure failure. In some cases, the sling has to be incised to allow voiding, although this is generally avoided for 6 weeks if possible, unless the patient has not voided at all by 3 weeks or requests intervention after appropriate counsel. An overactive bladder may persist or develop after surgery. Lastly, the procedure may not have corrected the original problem, and a different therapeutic recourse is indicated. The occurrence of vaginal erosion is usually a delayed event and has been reported mostly with the use of synthetic materials; it is uncommon with autologous and heterologous tissues. This area of incomplete healing may be difficult to resolve.

Pros and Cons

The cure rate for sling procedures is greater than 80% for all procedures, primary and repeat.[31] The usual quotation for cure in primary cases is 85%. The major points favoring use of a suburethral sling procedure are long-term durability, effectiveness in cases with impaired urethral sphincter function or restricted mobility of the bladder neck, and applicability to primary cases, with minimal risk of complications. The sling should extend beyond the perineal mem-

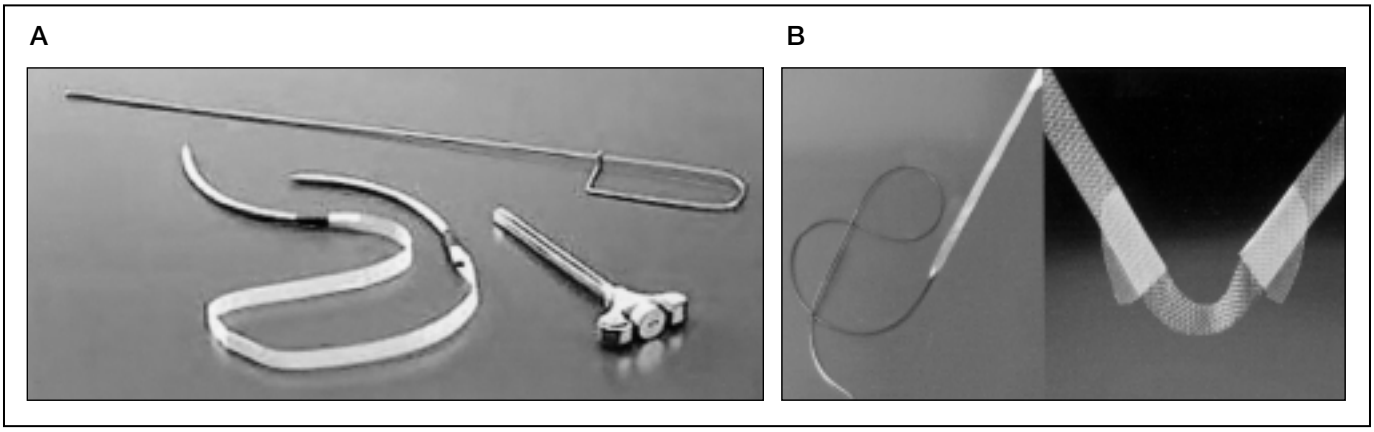


Figure 13. *Vaginal approach for the tension-free vaginal tape (TVT) procedure:* (A) *Gynecare TVT tension-free support for incontinence. Courtesy of Gynecare, a division of Ethicon, Inc.* (B) *Uretex: Bard Urological Division tension-free support system.*

brane into the retropubic space to allow stabilization with scarring of the sling in situ. Autologous materials are the safest to use, without fear of rejection or immunologic degradation. The disadvantages quoted for suburethral slings include the need for general or regional anesthesia, length of hospital stay, time required for harvest of autologous materials, voiding dysfunction, and incidence of postoperative detrusor overactivity.

The preferred method of suburethral sling is to use autologous rectus fascia or fascia lata placed as a full- or half-length sling into the retropubic space beyond the perineal membrane, attached loosely to or over the rectus fascia. Alternative methods alter only the material, with use of allograft (cadaveric solvent-dehydrated fascia lata),[16] xenograft (porcine dermis or bovine pericardium), or synthetic material (polypropylene mesh).

Procedure Settings

The usual setting for suburethral sling procedures is the hospital operating suite. The free-standing ambulatory surgery centers are seldom equipped with personnel, materials, or instruments for this type of surgery. The procedure is performed under general or regional anesthesia.

Concomitant Surgery

Sling surgery is often combined with other operative procedures, whether performed during hysterectomy or at the time of prolapse surgery. There is no concern for wide anterior dissection because the pubocervical fascia (fibromuscular layer) is reapproximated before laying the sling over it and the sling is sutured into position over the proximal to mid-urethra. If there is an obliterative procedure performed, the vaginal dissection and placement of the sling must be completed prior to complete vaginal closure. In the case of multiple procedures, it is most common to perform the hysterectomy first, followed by posterior dissection and vault suspension, and the anterior dissection last. The sling arms should not be secured until the remaining portions of the prolapse repair or hysterectomy have been completed and the vaginal epithelium has been closed. A sling procedure may also be performed with abdominal surgery as a combined technique. In this case, dissection may be performed in the space of Retzius, making the passage of sling material under direct vision, with tactile contact between the abdominal and vaginal surgeons. The alternate abdominal procedure is completed first; the sling is then positioned and the vaginal incision is closed; and the sling arms are then secured in the usual fashion and the abdominal incision is closed.

Sling surgery may be performed either before or after bulking procedures. It is not the usual intent to combine the 2 procedures; however, in general, if there is a decision regarding options in surgical approach, especially in the elderly or infirm, the bulking procedure would be performed initially. Bulking procedures may also be performed for failures of sling surgery and are especially effective when the bladder neck has been rendered immobile.

Tension-Free Sling Procedures

Tension-free slings refer to one of a group of surgical procedures using a polypropylene mesh to support the mid-urethra without tension. This is reported to result in fewer voiding problems in the postoperative period, while maintaining an efficacy of 85%, which is similar to the best of other operative procedures. A 5-year follow-up of one of these slings was recently reported.[32] A new approach to tension-free surgery using a transobturator approach has been published,[33] but the number of patients studied is insufficient to recommend the proce-

Table 4
Tension-Free Polypropylene Mesh Products

Trade Name	Company	Location
TVT	Gynecare (Ethicon, Inc.)	Somerville, NJ
Obturator system	Gynecare (Ethicon, Inc.)	Somerville, NJ
Sparc™	American Medical Systems	Minneapolis, Minn
Uretex®	C. R. Bard, Inc.	Covington, Ga
IVS Tunneller™	Tyco (US Surgical)	Norwalk, Conn
Remeex	Neomedic	Barcelona, Spain
ObTape™	Mentor	Santa Barbara, Calif
Monarc™	American Medical Systems	Minnetonka, Minn

dure without appropriate study. In spite of minimal clinical data, the transobturator approach has been approved for use by the Food and Drug Administration (FDA) and is being marketed in the United States.

Materials

Following a number of trials of other materials, polypropylene mesh was eventually settled on as the material of choice for tension-free sling procedures (Figure 13).[34] However, different properties of polypropylene mesh, such as pore size, type of weave, width, and weight, have led to several different products made from this material (Table 4).

Methods

The initial methods described for tension-free sling procedures were vaginal. However, because of an extensive urologic experience in passing instruments from the abdominal to the vaginal site for both needle and sling procedures, an abdominal approach was also devised. Both of these approaches are tension-free vaginal tape (TVT) procedures, although there are several companies competing with slightly different meshes placed in slightly different ways. Prophylactic preoperative antibiotic therapy is recommended. Postoperative antibiotic treatment is not recommended, unless there has been a bladder perforation.

Abdominal. A Foley catheter is placed, and the mid-urethral location is identified. The procedure begins with a 1.5- to 2.0-cm vaginal incision over the mid-urethra. The dissection proceeds superficially laterally to create bilateral 2-cm tunnels under the vaginal epithelium toward the descending pubic rami. The abdominal needle passer is then passed through a small incision on either side of the midline just above the symphysis pubis and is guided along the back of the symphysis until it passes under the descending pubic ramus, comes into contact with the vaginal finger, and is guided to the vaginal incision site. This has been the technique used for needle suspension procedures (ie, Stamey, Raz, Pereyra), performed in so many cases in the 1980s and 1990s. Cystoscopy is performed to ensure that the needle passers have not penetrated the bladder.

The mesh is attached to the needle passers and pulled through the retropubic space to the abdominal site. Sling adjustment is then performed by placing an instrument between the urethra and the sling and tightening the sling against it. The sheath is pulled off the tape, keeping the original loose position under the urethra. The vaginal incision is closed. The sling arms are cut flush with the abdominal incision sites, which are then closed with glue or suture.

Vaginal. The vaginal approach commences with infiltration of local anesthetic with or without a vasoconstrictor. One suggestion is the use of 30 mL of 1% lidocaine with 1/100,000 concentration of epinephrine. This is mixed with 100 mL of sterile saline to provide 130 mL of a 0.25% lidocaine solution. Using a 22-gauge spinal needle on a 20- or 30-mL syringe, 30 mL of the 0.25% solution is injected on each side of the midline retropubically, starting at the site of the planned suprapubic skin incisions, infiltrating the fascia, and then depositing the remaining portion of the solution along the back of the symphysis pubis and into the space of Retzius. A subepithelial injection of 2 to 4 mL is placed over the mid-urethra, and 20 mL is injected on each side vaginally by advancing the spinal needle to the descending pubic ramus and then under it. The total solution injected is 120 to 130 mL.

A Foley catheter is inserted. A 1.0- to 1.5-cm mid-urethral incision is made with a #15 scalpel blade, and the vaginal epithelium is separated from the underlying tissues on either side of the incision. Using scissors, shallow lateral tunnels 2 cm in length are created on either side toward the descending pubic rami. The Foley catheter is removed and replaced by a rigid catheter guide within an 18 French catheter, which is used to deflect the bladder away from the side of the needle insertion. The vaginal needle passer is placed in the tunnel, directed toward the

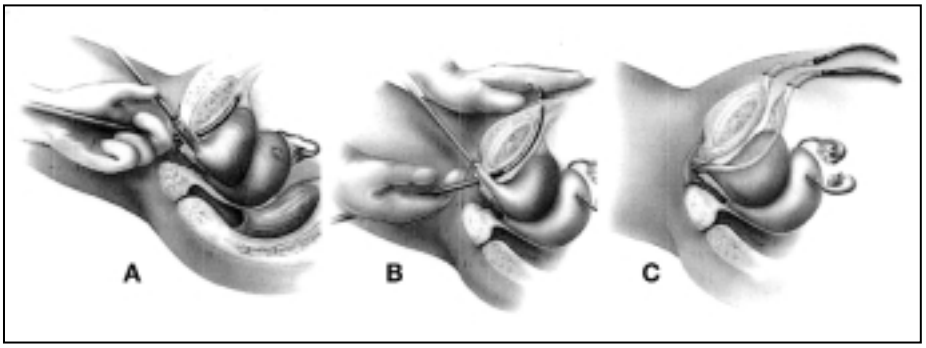


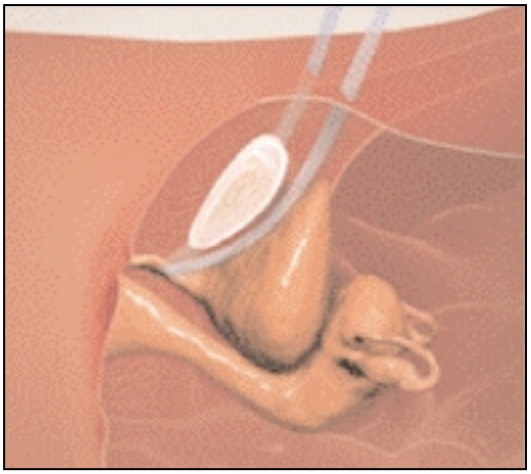
Figure 14. *Insertion of tension-free vaginal tape:* (A) *Vaginal guidance of needle under the descending pubic ramus along the back of the symphysis.* (B) *Pressure over the skin of the abdomen to allow the needle to penetrate the abdominal skin.* (C) *Both needles passed through the retropubic space and resting on the abdomen. Reprinted with permission from Klutke J, Klutke C.* Contemp Urol. *2000;10:59-73.*[57]

ipsilateral shoulder, and pressed firmly into the underside of the descending pubic ramus. The index finger of one hand helps to guide the needle under the pubic ramus while the curve of the needle rests in the palm of that hand (Figure 14A). The other hand works the handle of the needle passer, applying pressure as the endopelvic fascia is penetrated, and the posterior surface of the symphysis is contacted and followed until the needle approaches the resistance of the abdominal wall fascia and then the abdominal skin, where the vaginal hand now is moved abdominally to guide the needle through the skin (Figure 14B). The needle exits the abdominal skin 2 cm lateral to the midline, just at the level of the symphysis. Small incisions may be made initially for the needles at the time of skin penetration, or the needles may be passed without a skin incision. Cystoscopy is performed after each needle or both needles are passed, to ensure bladder integrity.

The needles with tape attached are pulled through on each side; this is best performed while observing cystoscopically, in case the needles were not initially observed in the bladder wall when, in fact, they had passed through a small portion of bladder (Figure 14C). The amount of fluid in the bladder should be 250 mL, and the patient is wakened from her sedation and asked to cough. Sling tension is adjusted with the patient coughing so that a few drops of fluid leakage are permitted during coughing. If the patient cannot cough effectively, the physician may press firmly on the suprapubic area, mimicking a sudden cough. Otherwise, an instrument such as a scissors, clamp, or dilator is placed between the tape and the urethra, leaving approximately 1 cm of space. The sheaths of the tape are then removed by pulling almost straight upward a small amount on alternate sling arms until the sheath releases from the tape. It is vital that the operator keep firm tension against the tape under the urethra to resist any further tightening. The sling arms are cut flush with the abdominal skin. The vaginal and abdominal incisions are closed as described above (Figure 15).

Transobturator. This is a newer version of tension-free sling popularized in Belgium and France and recently approved in the United States.[35] A randomized study[36] comparing 30 transobturator procedures with 30 TVT procedures has demonstrated the utility and safety of the transobturator approach compared with the standard vaginal TVT. An incision is made in the vaginal epithelium overlying the mid-urethra. Tunnels in which a finger may be placed are created through sharp and blunt dissection to the underside of the ischiopubic ramus. The index finger is placed in the tunnel on one side of the ischiopubic ramus, and the thumb of the same hand grasps the outline of the ramus in the genitofemoral fold between the labium majus and the thigh. This level is opposite the clitoris, about 1 cm superior to the level of the urethra. This represents the upper, inner corner of

Figure 15. *Tension-free suburethral sling passage completed with needles and sheath removed. Courtesy of Bard Urological Division.*



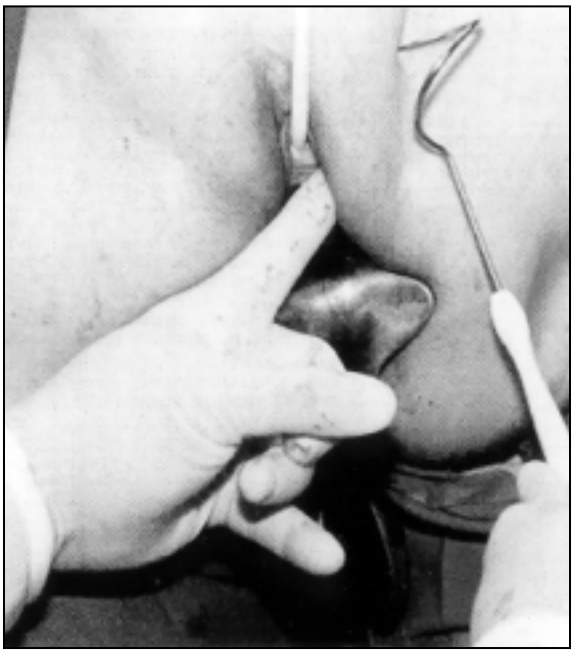


Figure 16. *Transobturator tension-free tape approach: The finger is placed in the vaginal dissection into the space of Retzius while the thumb hooks the tissue at the genital-crural fold. The specialized needle is passed from outside to inside or vice versa, and the tape is attached and pulled through the space. Reprinted, with permission, from Pelosi MA 2nd, Pelosi MA 3rd.* OBG Manage. *2003;15(9).*[35]

the obturator foramen. An incision is made at this level, and the introducer needle (Figure 16) is inserted perpendicularly and guided with the thumb until it penetrates the obturator membrane and muscle. The needle is then rotated under the pubic ramus, and the vaginal index finger guides it to the vaginal incision.

The tape is pulled along the tract of the needles from the vaginal site to the skin incisions over the obturator area. The needles are removed and the sheath is pulled free from the tape while the surgeon holds an instrument between the urethra and tape, as outlined above, to maintain a tension-free placement. Excess tape is cut at the skin surfaces, and the incisions are closed. Cystoscopy is optional with this technique. The position of the transobturator is more horizontal than that of the TVT (Figure 17).

Postoperative care. The patient should be able to be discharged from the day surgery area a few hours postprocedure, after ensuring that she is able to void or can utilize self-catheterization to check postvoid residuals or empty her bladder if unable to void. Alternatively, the patient may be admitted overnight for a 23-hour stay, with a Foley catheter inserted. The catheter is removed later the same day or early the next morning, and the patient's voiding function is checked by bladder scan or straight catheterization. She can be discharged home after making certain that she is voiding adequately or with the knowledge of self-catheterization.

The patient is asked to rest at home for several days, without working at home or at her usual job. She is encouraged to walk and restricted only from activities that make her tired. Intercourse is to be avoided for 2 to 4 weeks, until the incisions are healed. Most patients can return to work in 2 weeks, unless their job involves heavy lifting. Vigorous activity and lifting should be avoided for at least 6 weeks.

Complications

The most serious complications based on the first 500,000 TVT procedures are shown in Table 5. There were 7 deaths, 5 of which occurred after undiagnosed bowel perforation, 1 from uncontrolled bleeding in the retropubic space in a woman with a bleeding disorder, and 1 after a bowel perforation in which no additional information could be obtained. Major vascular injury may be prevented by avoiding hip flexion greater than 60° and using universal Allen stirrups. The insertion needle must not stray

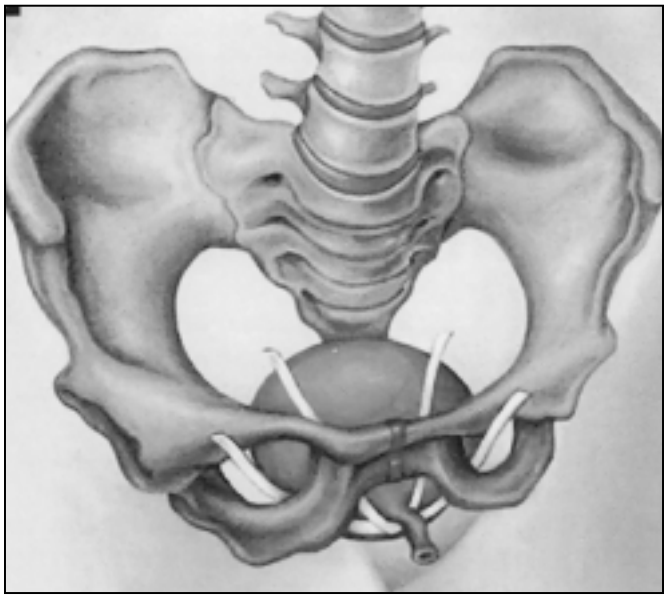


Figure 17. *Comparison of retropubic tension-free vaginal tape (TVT) and transobturator tape: note the lateral positioning of the transobturator sling compared with the lift underneath the TVT. Reprinted, with permission, from Pelosi MA 2nd, Pelosi MA 3rd.* OBG Manage. *2003;15(9).*[35]

Table 5
Reported Major Tension-Free Vaginal Tape Complications Based on 500,000 Cases*

Complication	US, n	Outside US, n	Total, N	%
Vascular injury	7	37	44	.009
Vaginal mesh exposure	43	17	60	.012
Urethral erosion	20	0	20	.004
Bowel perforation	16	12	28	.006
Nerve injury	3	1	4	.0008
Urinary retention	48	45	93	.019
Hematoma formation	4	16	20	.004

*Gynecare report to the Food and Drug Administration as of September 26, 2003. Seven deaths have been reported, 6 associated with bowel perforation.

laterally. Smaller venous channels are frequently penetrated, and these are usually controlled with direct pressure for 5 minutes or placement of a vaginal pack. Moderate bleeding may be controlled with a Foley catheter with 50 mL in the balloon to tamponade the bleeder against a pack in the vagina. Occasionally, a retropubic space hematoma will develop, but it is self-limited, and the usual treatment is observation.

Bladder perforation occurs 2% to 4% of the time and is usually managed by withdrawal and reinsertion of the needle. A Foley catheter is recommended for 1 or 2 days, and antibiotic coverage should be provided. Bladder perforation may be prevented by infiltration of the dilute local anesthetic in large volume amounts, keeping the bladder empty and directing the bladder away from the operative site with the rigid catheter guide. Bowel perforation may be prevented by imaging prospective patients who have had prior retropubic surgery and who may have bowel adherent in the cul de sac in close proximity to the retropubic area.

The more usual complications include urinary retention, urgency, and urinary tract infection (Table 6).[37-39] Eighty percent of patients will void by the time of discharge from surgery or the hospital. There is a 2% to 5% persistent urinary retention rate, and these patients may require cutting of the sling. This is best performed within the first 6 weeks after surgery, and continence is usually maintained. Urinary tract infection may be prevented by preoperative antibiotics and should be watched for closely in the postoperative period. There is still a 7% to 8% incidence of urinary tract infections in the first 2 months postoperatively. Urgency is not uncommon postoperatively, and although it usually resolves in 6 weeks without need for other treatment, as many as 10% to 12% of patients will have persistent symptoms requiring intervention. Mesh erosion is usually a delayed complication, occurring in only 1% of patients, and, much of the time, can be managed by excision of the exposed mesh and resuture of the vagina.

The transobturator tape does not have a retropubic passage and therefore avoids the major complications of retroperitoneal vascular injury, bowel injury, and bladder perforation. There remains the possibility of damage to the obturator vessels and nerve during passage of the needle, but this has been avoided by following the procedure as described. In spite of these attributes, there have been isolated reports of bladder perforation,[40] and it may be appropriate to carry out cystoscopy at the end of the procedure, especially in women with significant prolapse. The incidence of postoperative voiding dysfunction is lower with the transobturator approach.[36] There are still the same complications of bleeding, dysuria, urgency, and bladder infections as with TVT.

Pros and Cons

Although there is an implied suggestion that voiding dysfunction, bladder

Table 6
Complications in 1455 Tension-Free Vaginal Tape Cases in Finland

	Incidence	
Complication	No. per 1000	%
Minor voiding difficulty	76	7.6
Urinary tract infection	41	4.1
Bladder perforation	38	3.8
Postoperative urinary retention	23	2.3
Retropubic hematoma	19	1.9
Wound infection	8	0.8

Data from Kuuva N, Nilsson CG. *Acta Obstet Gynecol Scand.* 2002;81:72-77.[51]

perforation, and damage to bowel or significant pelvic vessels occur less frequently with the transobturator method than the other tension-free procedures, there is not enough evidence to support long-term efficacy or claims regarding complications. There are no data to recommend the transobturator approach at this time.

As far as comparison of tension-free techniques (TVT) and sling procedures, there is good evidence that efficacy is comparable in cases of primary stress incontinence and some evidence that there may be equal efficacy in difficult cases, such as intrinsic sphincter deficiency. The advantages of time and patient recovery greatly favor the tension-free procedures, although major complications are more commonly reported, perhaps because of the number of cases performed. The tension-free techniques allow the procedure to be performed under local anesthesia and sedation, perhaps opening the way for surgery in medically compromised or elderly patients, who might not otherwise undergo a surgical procedure.

Procedure Settings

Tension-free slings are designed for outpatient surgery. Patients in whom no other surgery is performed at the time of the sling procedure can be managed with local anesthesia and intravenous sedation. The ambulatory surgical center is the ideal place for these procedures. Patients can be discharged home in a few hours with appropriate instructions, especially regarding voiding adequacy, though it is strongly recommended that they be seen in the office on the following day. Some patients prefer to spend the first night in the hospital, in which case voiding trials are conducted prior to discharge. It is also important to ensure the absence of any adverse events in higher-risk patients, such as elderly or medically compromised patients, by close observation before discharge. The procedures can be performed under regional or general anesthesia and are routinely done in combination with other procedures, in which case the patient does not participate in the tensioning of the sling.

Table 7
Injectable Agents Available in North America

Trade Name	Company	Approval
Contigen®	C. R. Bard Inc, Atlanta, Ga	1993
Durasphere™	Boston Scientific, Boston, Mass	1999
Uryx®	Genyx Medical, Inc., San Diego, Calif	FDA submission[52]
Macroplastique®	Uroplasty, Minneapolis, Minn	FDA trials ongoing[53]
Zuidex™	Q-Med, Uppsala, Sweden	FDA trial starting[54]
Coaptite®	Genesis Medical Ltd., London, UK	FDA trials ongoing[55]

Concomitant Surgery

Karram and colleagues[38] performed 55% of their 350 TVT procedures in conjunction with other vaginal surgery. It is advised to reserve a separate incision for the placement of the tape so that it does not move out of the desired position. With respect to the order in which surgeries are performed, the tape can be placed initially and left within the sheath until the remainder of the surgery is completed, and the tension can then be adjusted as described above and the sheaths removed from the tape. The only difficulty with this technique occurs when there is disruption of small or large retropubic vessels, which would normally be controlled with a pack or counterpressure with a large Foley in the bladder or just filling the bladder to maintain pressure against a pack. This could disrupt the remaining planned surgery. The other technique is to perform the dissection and repair of anterior, posterior, and apical compartments, followed by the tape procedure. The exception occurs with obliterative procedures (colpocleisis) in which the vagina must not be completely closed prior to placing the tape or there is no room to palpate the appropriate structures.

Bulking Procedures

The following review focuses on the implantation methods of bulking procedures, as opposed to the indications or properties of the various materials or their relative efficacy. In the United States, the major breakthrough in bulking agents occurred in 1993 when the FDA approved the use of Contigen® (C. R. Bard, Inc, Covington, Ga).[41] In July 1994, Medicare approved payment for the service, based on a number of criteria. Initially, a periurethral method was employed, which then shifted to favor a transurethral technique. More recently, implanter devices have been developed for Macroplastique® (Uroplasty, Geleen, The Netherlands) and for a new preparation, Zuidex™ (Q-Med AB, Uppsala, Sweden) that recently commenced FDA-approved trials in the United States and Canada.

Materials

The ideal bulking material is biocompatible, nonimmunologic, and hypoallergenic. It retains its bulking characteristics for a prolonged interval and therefore does not biodegrade or migrate. The material should be

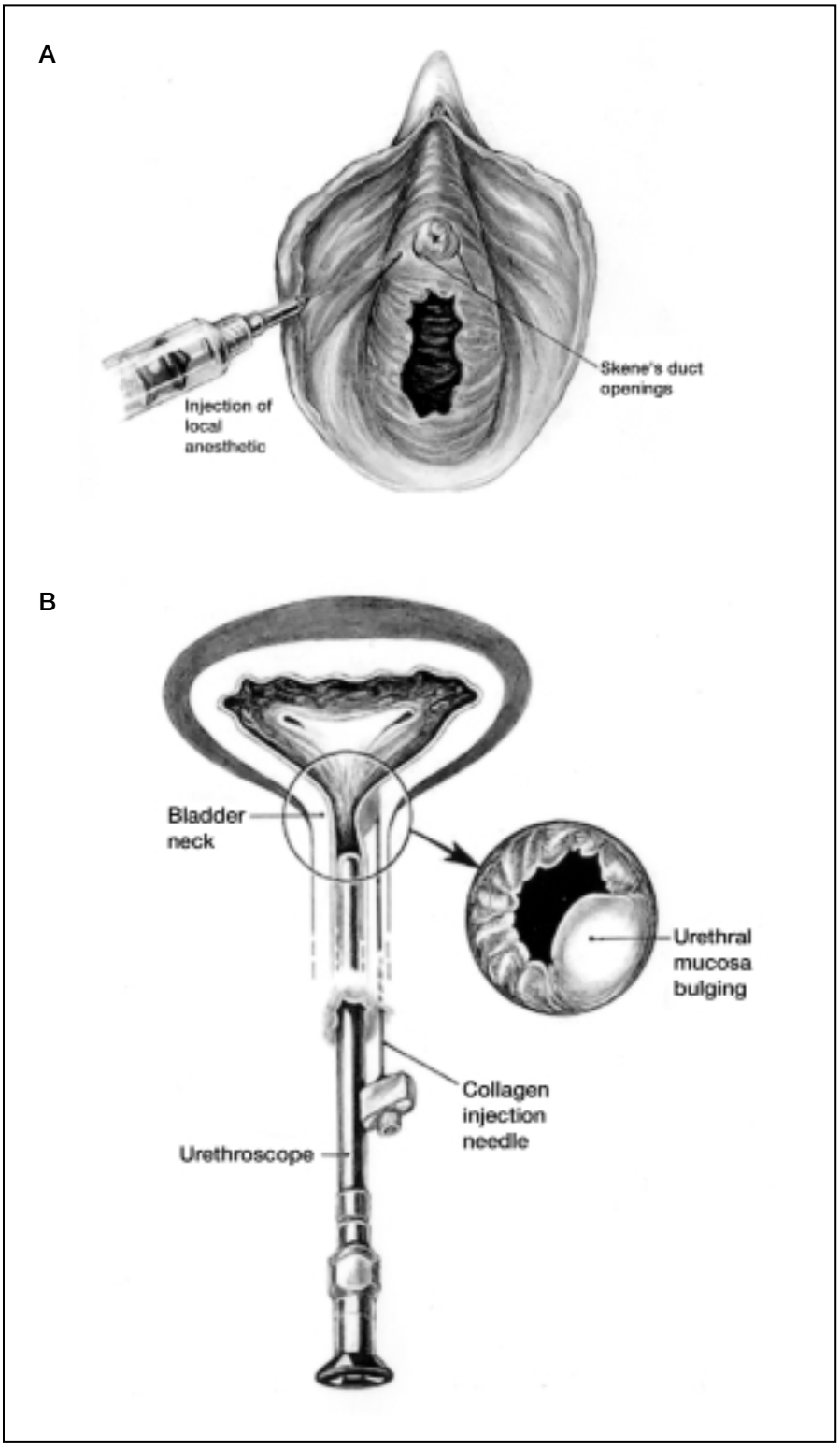


Figure 18. *Periurethral bulking technique:* (A) *Injection of local anesthetic at the Skene's duct openings.* (B) *Urethroscopic-guided periurethral injection of collagen 1 cm distal to the bladder neck. Reprinted, with permission, from Bent AE.* Oper Tech Gynecol Surg. *1997;2:51-55.*[44]

easy to prepare and inject.[42,43] Table 7 lists bulking materials approved for use or currently being studied.

Methods

The methods described relate to their use with current bulking materials. In some cases (Macroplastique), a special delivery device is needed. In most cases, however, the materials are injected through spinal needles, disposable injection needles that fit the operating channel of a cystoscopic setup, or through a special channel in an operating sheath and bridge set. The amount of material injected is usually much greater for periurethral techniques. There is a limit to the amount of some materials injected, such as Uryx, which is restricted to 2.5 mL per session. There are a variety of injection sites transurethrally, including just the 3 and 9 o'clock positions, the 4, 8, and 12 o'clock positions, or the circumferential techniques using material at 3, 6, 9, and 12 o'clock positions.

Periurethral. The patient empties her bladder and is placed in the lithotomy position.[42,44] The sites for injection of local anesthesia are selected at the level of the Skene's ducts opening on either side of the urethra. Using a 30-gauge needle, 0.5 to 1.0 mL of lidocaine solution is injected 0.5 to 1.0 cm from the urethral meatus (Figure 18A). The urethroscope or panendoscope with 0° lens is inserted into the urethrovesical junction and then withdrawn to observe the proximal urethra. A 5-mL syringe with 1% lidocaine solution and an attached 22-gauge spinal needle with or without a small amount of indigo carmine to stain the tissues is inserted at the selected injection site and guided paraurethrally and parallel to the urethra while it is directed slightly medial. The scope is used to observe the advancing needle as small amounts of local anesthetic are

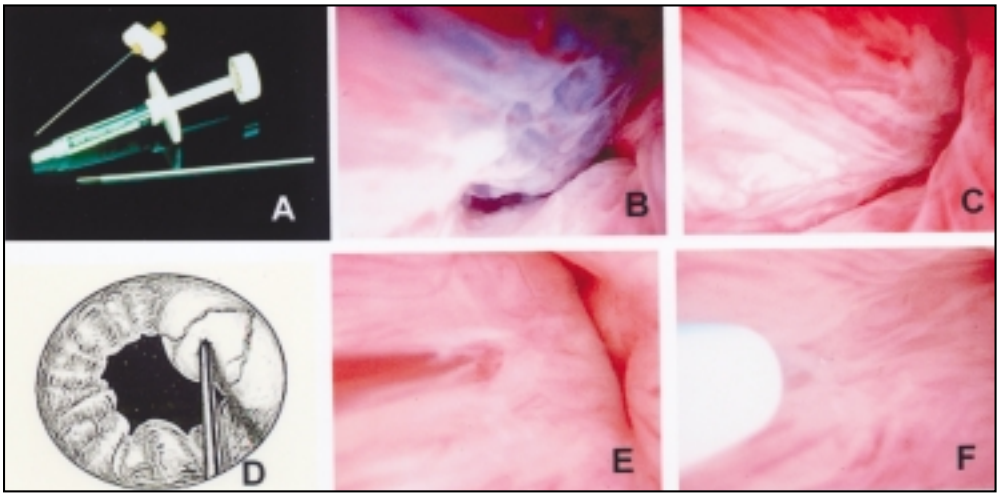


Figure 19. *Bulking procedures:* **(A)** *Contigen syringe with needles.* **(B)** *Periurethral injection of indigo carmine has stained the urethral submucosa.* **(C)** *Bulking in place at the proximal urethra after the periurethral injection has been completed.* **(D)** *Transurethral needle placement in the urethral submucosa.* **(E)** *Transurethral needle partially advanced and* **(F)** *advanced to the hub for transurethral bulking. Reprinted, with permission, from Bent AE.* Oper Tech Gynecol Surg. *1997; 2:51-55.*[44]

injected en route to the eventual placement site at the proximal urethra (Figure 18B). The syringe is periodically moved in short strokes to allow the needle to move the tissues without further advancement until the needle tip can be seen under the tissue at the proximal urethra and injection of the indigo carmine–stained local anesthetic causes the submucosa of the urethra to stain blue and to bulge. The syringe is replaced with a syringe of bulking agent, and the material is injected until the entire syringe has been injected and there has been adequate effect noted with urethral bulking (Figures 19A-C). The process is repeated on the opposite site, which is always more difficult because of the distortion of the proximal urethra caused by the initial injection. The amount of Contigen averages 3.75 mL for each of the 2 sites.

Transurethral.[42,44] The transurethral method normally has required the use of a cystoscope with a 12° or 25° lens with the appropriate sheath (21 French with no fenestration) and operating channel to allow the passage of a 5-French thermoplastic injection catheter and beveled 22-gauge disposable injection needle. Alternatively, some physicians use a 0° or 30° lens, but this makes simultaneous viewing of the needle puncture site and impact of the injection difficult. The disposable thermoplastic injection catheter holds 0.4 mL of solution and can be prefilled with 1% lidocaine solution. The collagen syringe is then attached to the needle, and the cystoscope with injection needle in position is placed into the bladder. The scope is withdrawn to observe the bladder neck and then withdrawn gradually, approximately 2 cm. The needle is advanced into the urethral submucosa, and the injection of material is preceded by the small amount of local anesthetic solution (Figures 19D and 19E). The needle is advanced almost to the hub, and the collagen material is injected (Figure 19F). Usually, 2.5 mL is injected at each of 2 sites. One can flush the injection needle at the first site to completely empty the collagen from the injection needle while at the same time pre-filling it again with lidocaine solution. The second site is selected opposite the first without passing the scope through the bladder neck again. The first part of the injection at this site deposits the local anesthetic followed by the collagen material.

In some instruments (Karl Storz, Tuttlingen, Germany; Richard Wolf Medical Instruments Corporation, Vernon Hills, IL), there is a built-in needle delivery system and the delivery mechanism is spring loaded to allow advancement of the needle into the urethral submucosa for shallow or deep injection with removal of the needle by releasing the thumb-operated mechanism. The various materials for injection may dictate injection systems, such as the pressure gun required for injection of Macroplastique. On the other hand, materials like Uryx can be injected through a 25-gauge needle. Other systems have been developed, each with its own injection style and technique, and there are various other injection aids and devices available.

Figure 20 depicts the effect of the injection techniques in diagram fashion in anterior and lateral views.

Insertion devices. There is an insertion device for Macroplastique, currently on protocol use in North America (Figure 21A).[45,46] There is also a device for Zuidex™ (Q-Med AB, Uppsala, Sweden), a bulking material recently approved for FDA trials in the United States. The latter device is called an implacer and allows transurethral injection without visualization of the injection site. The device has 4 angled ports for 4 needles and, after measurement of the urethral

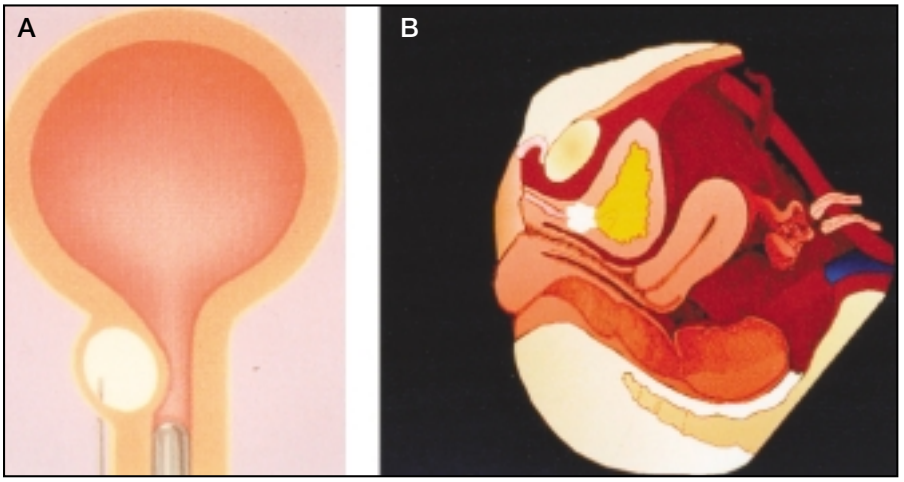


Figure 20. *Bulking location:* **(A)** *The periurethral technique shows Contigen deposited in the proximal urethra while the surgeon observes with the urethroscope.* **(B)** *The lateral pelvic view shows Contigen deposited in the proximal urethral location, approximately 1 cm distal to the bladder neck. Courtesy of Bard Urological Division.*

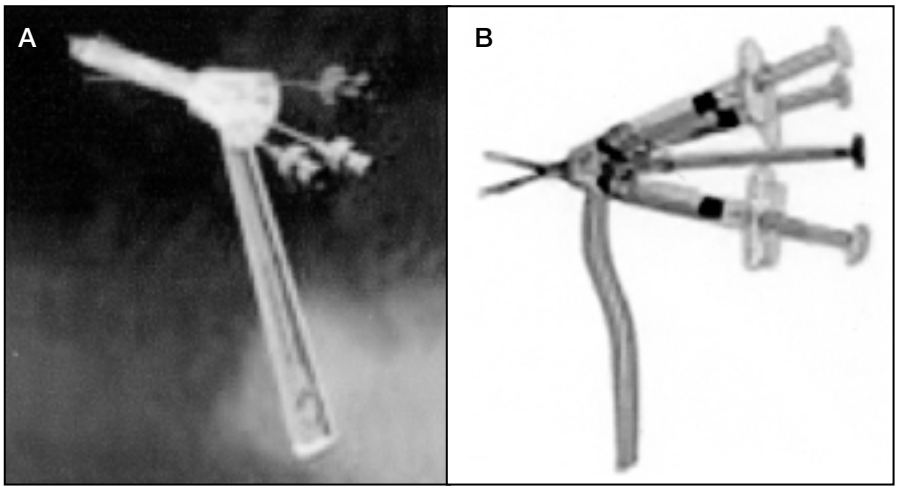
length, is positioned to allow placement of the material at the desired submucosal depth in the mid-urethra (Figure 21B).

Postinjection follow-up. Immediately after injection, the patient should have no pain. She may have urethral burning with urination, which lasts for only part of a day and can be controlled with phenazopyridine. Antibiotics are not mandatory but are usually given immediately before or 1 or 2 days after injection, because the rate of urinary tract infection is high. The patient is allowed to void after the injection, and she should be prepared to stay in the clinic area for 1 to 2 hours postprocedure to allow the initial swelling from the injection to diminish enough to allow voiding. If voiding does not occur or is associated with high residual urine (>200 mL as determined by bladder scan, ultrasound, or straight catheter), the patient needs to be instructed in self-catheterization or have an 8 to 10 French Foley catheter placed using no more than 5 mL in the balloon. One technique is to teach all patients self-catheterization before the injection; however, with this method, as many as 70% to 80% of patients are taught unnecessarily. Therefore, one may resort to teaching those who need self-catheterization after the injection. The other alternative is to insert a small Foley catheter (8-10 French) for 48 hours and have the patient return for voiding assessment. Those who utilize self-catheterization should do so after attempts at voiding 4 or 5 times a day. There is no longer a need to perform self-catheterization after voiding commences and residual urine amounts are less than 100 mL. This usually resolves within 12 hours. Patients should be called the day following the injection to ensure that there is no continuing problem. A follow-up appointment should be made for 1 to 4 weeks postprocedure. At that time, in addition to obtaining a patient history, the physician assesses the patient with regard to her voiding function, possible urinary tract infection, and the suburethral injection site. The effectiveness of the injection is also assessed, and overactive bladder symptoms are addressed, if appropriate.

Complications

The main advantage of injectables is their safety profile, even in very ill patients.[30,42,47] The most common complication during the procedure is pain during the injection. For patients undergoing the procedure in a clinic or office setting, pain can be minimized with intraurethral topical anesthetic gel and/or injection of 0.4 to 0.8 mL of local anesthetic, such as 1% lidocaine solution, into the submucosal injection site. This can be accomplished by preloading a disposable 22-gauge injection needle, which

Figure 21. *Implantation devices:* **(A)** *Macroplastique implantation system. Courtesy of Uroplasty BV, Geleen, The Netherlands.* **(B)** *Implacer device. Courtesy of Q-Med AB, Uppsala, Sweden.*



holds 0.4 mL of solution. Another complication is extrusion of material during injection. This can be avoided by submucosal placement of the needle approximately 1 cm into the tissue and observation of the injection effect on the urethral lining. If the injection is too superficial and the lining distends rapidly, an alternative site should be selected. A small amount of bleeding may occur at the injection site, or the material may start to extrude from the puncture site; if so, when using a disposable needle, pressing the hub against the lining of the urethra will usually control the situation. After injection, a small amount of material may leak from the site. This is seldom a problem unless the material used is Uryx, in which case the extruded material needs to be removed, as it is permanent and will lead to recurrent irritative voiding and infections.

After the injection, the most common complications in the immediate period are urinary retention and voiding dysfunction. It is important to assess voiding after the injection is complete. This can be accomplished by comparing the amount voided to the amount of fluid infused during the procedure using a bladder scanner or placing a straight catheter. In most cases, if 200 mL is placed during the procedure and the patient is able to void 100 mL or greater within an hour after injection, there is little concern regarding retention. Voiding discomfort occurs in some patients. The rate of urinary tract infection is as high as 10%; not only should antibiotic treatment be given after the injection, but the urine should be checked at the initial postoperative visit.

There are few delayed complications of bulking procedures. A rare one is formation of a suburethral abscess.[48,49] This is associated with increasing voiding dysfunction with or without pain. A more common problem is recurrent urinary tract infections requiring prophylactic antibiotics. Cystoscopy may be required to be certain that there is no bulking material resting in the urethra.

Pros and Cons

Contigen remains the bulking agent of choice, at least in the United States. This is because of a good safety profile demonstrated over the 10 years that it has been in use, the ease of injection, and its effectiveness in providing relief of symptoms in a large proportion of patients. The ideal bulking material has not been identified and, in spite of a prolonged search, nothing financially feasible appears to be better than the available agents. Autologous injection of muscle cells or collagen may offer improvement, but this option remains a long way off.

Procedure Settings

The ideal setting for injection is the office or clinic. No preoperative sedation is required, and patients and family members can observe the procedure on a monitor. Costs are contained by avoiding the operating suite and systemic drugs. The injection is performed in a sterilized field, using a no-touch technique. The patient is immediately able to get up and attempt voiding, or she may wait in the waiting area.

Neither an operating room nor systemic anesthesia is required for the procedure, both of which would represent an unnecessary expense and inconvenience to the patient. In some

Main Points

- Autologous materials in current use for suburethral slings include fascia lata, rectus fascia, and vaginal wall.
- There are 3 basic lengths of sling material: the full-length sling, the half sling, and the patch sling.
- The major points favoring use of a suburethral sling procedure are long-term durability, effectiveness in cases with impaired urethral sphincter function or restricted mobility of the bladder neck, and applicability to primary cases, with minimal risk of complications.
- Tension-free slings are reported to result in fewer voiding problems in the postoperative period while maintaining an efficacy of 85%, which is similar to the best of other operative procedures.
- The initial tension-free sling procedures were vaginal; however, because of an extensive urologic experience in passing instruments from the abdominal to the vaginal site for both needle and sling procedures, an abdominal approach was also devised.
- The ideal material for bulking procedures is biocompatible, nonimmunologic, and hypoallergenic. It retains its bulking characteristics for a prolonged interval and therefore does not biodegrade or migrate. The material should be easy to prepare and easy to inject.
- The main advantage of injectables is their safety profile, even in very ill patients. The most common complication during the procedure is pain during the injection. After the injection, the most common complications in the immediate period are urinary retention and voiding dysfunction.

situations, an ambulatory surgical area may prove more satisfactory to the physician.

Combination Therapy

It is generally agreed that certain patients respond better to periurethral bulking. However, should the procedure provide no relief after 2 injections, it is generally futile to try subsequent injections. A suburethral sling can be performed after periurethral bulking without concern for residual material. It may be preferable to use a nonsynthetic sling in patients who have bulking agents that do not biodegrade, although there has been no study to show this. If an antiincontinence procedure or other pelvic floor surgery has been performed first and stress incontinence persists or occurs, there is no contraindication to using a bulking agent, which is often highly effective in these cases. This may be done as early as 6 weeks after surgery.

In general, bulking agents are not indicated for patients with urethral hypermobility,[50] although this is not universally agreed upon. There have been situations in high-risk patients in which a pessary has provided excellent control of pelvic organ prolapse and there has been some temporary stabilization of bladder neck mobility. Periurethral bulking may be used in these patients, because when the prolapse is reduced by the pessary, the masking effect of the prolapse on the urethra is removed and stress incontinence may result. The results of periurethral bulking after radiation therapy have not been encouraging. ■

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