Stress Urinary Incontinence

Slings, Single-Incision Slings, and Nonmesh Approaches

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KEYWORDS

• Sling • Stress urinary incontinence • Urethral bulking • Colposuspension
• Fascial sling

KEY POINTS

- Midurethral sling surgery offers a minimally invasive approach for the treatment of stress urinary incontinence in women.
- Retropubic and transobturator slings demonstrate comparable efficacy, though with unique adverse event profiles.
- Single incision slings may optimize patient experience through decreased pain and faster return to normal activity.
- Surgical treatments of stress urinary incontinence not requiring the use of synthetic mesh include urethral bulking, retropubic colposuspension, and the autologous sling.
- Although synthetic slings have quickly become the standard of care for stress urinary incontinence, nonmesh therapies are well-established and offer favorable cure rates for the complex or mesh-averse patient.

SYNTHETIC MIDURETHRAL SLINGS

Since the introduction of the tension-free vaginal tape (TVT) by Ulmsten and Petros in 1995, the most common surgical treatment for symptomatic stress urinary incontinence has been the midurethral sling. The midurethral sling has largely replaced nonmesh alternatives, including the Burch retropubic urethropexy and the autologous pubovaginal sling, owing to the minimally invasive approach of the midurethral sling. Given comparable efficacy, along with decreased surgical time and recovery, the synthetic midurethral sling is considered the standard of care for the surgical treatment of stress urinary incontinence.[1] With more than 250,000 procedures performed annually in the United States, and a 27% increase in the number of procedures performed in the last decade, the prevalence of sling surgery continues to increase.[2–4]

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Important material properties of synthetic midurethral slings include a macroporous pore size, weave, and appropriate elasticity. Integration of the device requires collagen in-growth and capillary permeability. The device must allow permeability of both bacteria and host defense cells, including macrophages and lymphocytes, to prevent infection. Optimal material properties of the device must discourage long-term complications and maintain efficacy.

BACKGROUND

Ulmsten and Petros postulated that stress urinary incontinence occurred because of the pubococcygeal muscle's inability to elevate the anterior vaginal wall, resulting in a lack of urethral closure against the pubourethral ligament.[5] They referred to this mechanism of continence and resulting incontinence as the integral theory. The first described midurethral sling procedure (TVT, Gynecare, Ethicon, Somerville, NJ) was hypothesized to strengthen the interface between the pubococcygeal muscle and the anterior vaginal wall at the midurethra, thereby addressing the Integral Theory.

Although the originally described device involved the passage of synthetic tape from a vaginal route through the retropubic space, subsequent modifications in technique showed similar efficacy via a transobturator approach. Initially described by Delorme in 2001,[5] the transobturator approach was designed to avoid the inherent risks of retropubic hematoma formation and bladder perforation associated with trocar passage through the retropubic space. As opposed to passage through the retropubic space, the transobturator trocar was designed to pass from the outside-in, through the groin and obturator foramen. In 2003, the technique was further modified to an inside-out approach by de Leval.[6] The transobturator approach was associated with an increased rate of groin pain as compared with the retropubic approach.[7]

RETROPUBIC SLING

As originally described, the TVT device was placed in a bottom-up fashion, beginning with trocar passage through the bilateral periurethral tunnels, subsequently through the retropubic space, and finally exiting through the abdominal fascia and bilateral suprapubic skin incisions[8] (**Fig. 1**). The initial outcomes were first defined in a prospective multicenter study of 6 sites in which patients underwent the procedure under local anesthetic. Patients were followed for 1 year and 119 of the 131 treated patients met the definition of cure.[9] Two hematomas and 1 bladder perforation were noted perioperatively, and no mesh extrusion was noted at 1 year.[8] The authors concluded that the retropubic midurethral sling was safe and effective for the minimally invasive treatment of stress urinary incontinence.

After the introduction of the TVT, longer term follow-up at 7 years was published by Nilsson and associates.[8] In a multicenter, prospective, observational cohort design of 90 patients, the authors reported an 81.3% objective and subjective cure rate at a mean of 91 months. Although urinary tract infection (7%) and de novo urinary urgency (6.5%) were somewhat frequent, no other significant complications were noted in the long-term follow-up.[8]

A subsequent modification to the originally described TVT included placement of a retropubic sling through a top-down approach from the suprapubic region through the retropubic space with an exit in the vagina. In a meta-analysis by Ford and colleagues,[9] the bottom-up approach to top-down comparison favored a bottom-up

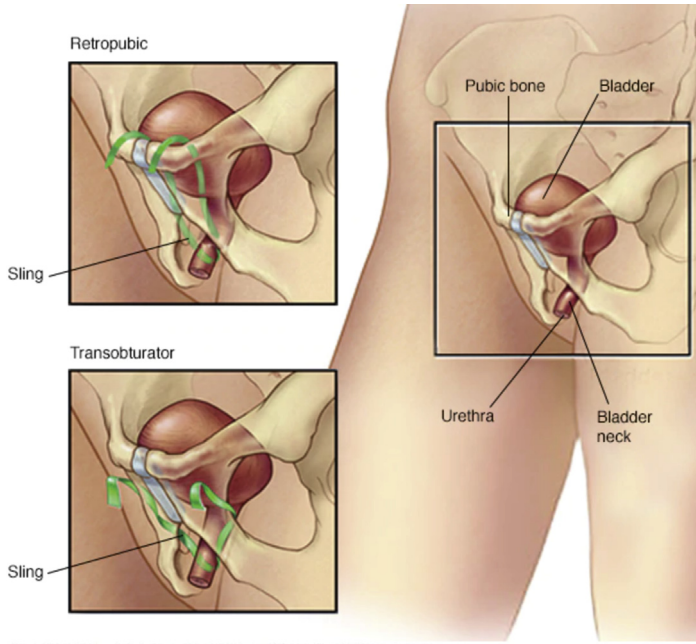

Fig. 1. Retropubic and transobturator slings. (*From* Mayo Foundation for Medical Education and Research; with permission).

approach, citing a higher subjective cure rate, less voiding dysfunction, fewer bladder perforations, and fewer mesh extrusions.

TRANSOBTURATOR SLING

In 2001, Delorme[5] published the results of a case series of the 40 women who underwent sling placement via a transobturator route. Although patients in the series were treated for stress urinary incontinence alone as well as stress urinary incontinence at the time of prolapse repair, 39 of 40 patients were deemed to be continent after the surgery. The most common adverse event was dysuria, which occurred in 5 patients. The authors concluded that the procedure was both safe and effective.[5]

A subsequent modification to the transobturator sling was the direction of trocar passage. Although the procedure was designed to pass the trocar from the outside-in, through the groin and obturator foramen and finally into the vaginal tunnel, de Leval modified the approach in 2003 to traverse inside-out from the vaginal tunnel through the obturator foramen and finally out through the groin (see **Fig. 1**).

de Leval published his perioperative findings on 107 women who underwent this approach using the transvaginal tape obturator inside out.[6] With a mean operative time of 14 minutes and no bladder or urethral perforations, the authors determined the procedure to be feasible.[6] Interestingly, the results were used to discourage the need for urethral evaluation with cystoscopy at the time of transvaginal tape obturator inside out placement, because the urethra and bladder were considered free from risk of injury.[6] Subsequent studies have confirmed that the transobturator approach carries a risk of injury to the urethra and bladder, and cystoscopy is recommended at the time of any midurethral sling placement. Multiple comparative

studies have shown similar subjective efficacy between the inside-out and outside-in approaches. However, vaginal perforations were noted to be fewer with an outside-in approach.[9,10]

RETROPUBIC VERSUS TRANSOBTURATOR SLING

Clinical Outcomes

Recent comparative efficacy data were compiled in 55 trials in the 2017 Cochrane Database of Systematic Review's midurethral sling operations for stress urinary incontinence in women.[9] Most trials reported on outcomes at 1 year, although 5 trials reported 1- to 5-year outcomes. Only 1 trial reported the comparative efficacy at more than 5 years. There was no difference in subjective cure at any time point, with subjective cure rates of 62% to 98% in the transobturator sling group and 71% to 97% in the retropubic sling group at 1 year. Overall, subjective cure was maintained with both sling approaches at 5 years. At short, medium, and long-term follow-up, defined by the intervals described elsewhere in this article, no difference in objective cure rates by route of sling placement were observed. At 1 year, the objective cure rate was 85.7% in the transobturator group and 87.2% in the retropubic sling group.[9,10]

Quality-of-life outcomes have been reported inconsistently in comparative trials between retropubic and transobturator slings. Ford and colleagues noted variable outcome measures reported in 33 of 55 comparative trials using 16 different validated measurement tools. In all measures, condition-specific quality of life improved significantly postoperatively, with no difference between groups. At 6 to 24 months, sexual function improved significantly with no difference between groups. Although the quality-of-life outcome reporting continues to be heterogeneous, more recent trials have more consistently reported on condition-specific symptom and sexual function outcomes.[9]

Complications and Concerns

The adverse event profile for midurethral slings depends on the route of sling placement. Although there are some adverse events that occur independent of sling route, there are many important differences. Retropubic placement is associated with an increased risk of bleeding and major vascular injury, bladder perforation (4.5 vs 0.6%), and postoperative voiding dysfunction.[10–12] Interestingly, do novo urgency (8%) and mesh extrusion rates (2%–3%) seem to be similar between groups. Groin pain is significantly greater in patients undergoing transobturator sling placement (6.5% vs 1.5%).[10]

SINGLE INCISION SLING

Although the transobturator approach was initially developed to decrease morbidity, a high rate of groin and hip pain, up to 12%, as well as a 1% reoperation rate encouraged the development of the single incision sling.[13] Both retropubic and transobturator approaches were developed. The sling incision sling was designed to use a much smaller mesh length placed into the obturator internus muscle or obturator membrane, using the transobturator approach, or to anchor into the retropubic space without transversing it. By avoiding the extent of the obturator foramen and groin structures, this less invasive approach was thought to decrease complications, including groin pain, visceral injury, and vascular injury.

Discussion

One early single incision sling, the TVT-Secur (Gynecare, Bridgewater, NJ), was widely studied and shown to be inferior to traditional full-length midurethral slings in several

randomized studies. In 4 of 5 randomized trials comparing the single incision sling TVT-Secur with bottom-up retropubic slings, women were more likely to have persistent urinary incontinence after single incision sling surgery. The device was thus withdrawn from clinical use.[14] Nonetheless, Nambiar's Cochrane review of single incision slings noted that TVT-Secur was inferior to full-length midurethral slings, but that single incision slings with an obturator approach may be more cost effective than full-length transobturator slings based on 1 year of follow-up.[14]

Summary

Clinical outcomes

Subsequent single incision slings with anchors have demonstrated comparable efficacy to transobturator slings. Recent publications comparing transobturator slings with single incision slings have shown similar objective and subjective cure rates ranging from 81.6% to 96.4% for transobturator slings and 67% to 87% for single incision slings at a mean of 18.6 months.[14] Mostafa and colleagues[15] noted that, when 10 trials involving TVT-Secur were excluded from 26 available trials comparing single incision slings with standard midurethral slings, no significant difference in patient-reported cure (relative risk, 0.94; 95% confidence interval, 0.88–1.00) or objective cure (relative risk, 0.98; 95% confidence interval, 0.94–1.01) were observed. Recent results of the 522-study, a postmarket surveillance study required under Section 522 of the Food, Drugs and Cosmetics Act, comparing the single incision sling Solyx with the transobturator sling Obtryx II (Boston Scientific, Marlborough, MA) noted no difference in treatment success at 36 months (90.4% to 88.9%; $P = .93$).[16]

No differences in quality-of-life measures in 13 comparative trials or in sexual function measures in 5 comparative trials were found between the single incision slings and full-length slings.[14] Perioperative data showed that single incision slings were associated with shorter operative times with a mean difference of 17.33 minutes when compared with retropubic slings.[14] When compared with a transobturator sling, women undergoing single incision sling surgeries also have lower rates of postoperative pain (6% after single incision sling, 23.9% after transobturator sling).[14] Women undergoing single incision sling surgery have been reported to return to normal activities 5 days earlier and to work 7 days earlier than women undergoing standard midurethral sling surgeries.[15]

Complications and Concerns

Differences in complication rates between single incision slings and traditional midurethral slings are varied. However, after excluding TVT-Secur studies, lower urinary tract injury, voiding dysfunction, extrusions, do novo urinary urgency, and worsening of preexisting urgency do not differ between the groups.[14] In a 2020 prospective study comparing the single incision sling Solyx with the transobturator sling Obtryx II, mesh-related complications were similar between groups at 36 months of follow-up (mesh exposure, 2.8% vs 5.0%; $P = .38$). Serious adverse events including pain during intercourse (0.7% vs 0%; $P = 1.00$), pelvic pain (0.7% vs 0%; $P = 1.00$), and urinary retention (2.8% vs 4.3%; $P = .54$) were also similar between groups.[16]

Although the use of synthetic mesh for stress urinary incontinence surgery has remained the source of controversy in the recent decade, as evidenced by worldwide practice patterns including the removal of synthetic mesh slings from the market in the UK in 2018 and increased postmarket surveillance requirements in the United States, the midurethral sling remains a germane option for women seeking a surgical solution to stress urinary incontinence.[2–4]

CLINICS CARE POINTS

- Synthetic midurethral slings placed either via the retropubic or transobturator route are highly effective for the treatment of stress urinary incontinence in women.
- Full-length retropubic slings are associated with a significantly higher risk of bladder perforation and postoperative voiding dysfunction, whereas full-length transobturator slings are associated with a higher incidence of groin pain.
- Women undergoing single incision sling placement have less pain and a quicker return to activity, with similar subjective outcomes as women undergoing other types of midurethral sling placement.

CLINICAL CASE

A 47-year-old G1P1 presents to clinic with complaints of bothersome urinary incontinence, primarily during running and high-impact exercise. She notes that, since the birth of her child 6 years ago, she has been unable to run during the daylight hours, for fear that her leakage will be obvious to those around her. She has no significant past medical or surgical history. On examination, she has a stage 2 anterior vaginal wall prolapse with a positive empty supine stress test during minimal cough. She has a postvoid residual of 5 mL. She strongly desires sling surgery for treatment of her stress urinary incontinence.

1. What type of sling surgery would you recommend and why?
   Given leakage on examination with minimal effort, the patient likely has poor urethral closure pressure. Subjective and objective cure rates would be similar should she desire to undergo either a retropubic or transobturator approach. However, retropubic sling placement may optimize outcomes in patients with urethral sphincter compromise.
2. How would you counsel the patient on the need for urodynamic testing before sling placement?
   With demonstrable leakage during increased abdominal pressure, as well as a normal postvoid residual, there is no need for urodynamic evaluation before surgery. In the ValUE randomized trial, completing urodynamic evaluation in women with demonstrable stress urinary incontinence did not result in any alteration to the surgeon's treatment plan.[17]

NONMESH APPROACHES

Other surgical treatment options for stress urinary incontinence include autologous fascial slings, retropubic colposuspension and urethral bulking. Patients who are not candidates for surgical treatment with synthetic mesh may consider one of these extensively studied and effective nonmesh surgical approaches.

AUTOLOGOUS SLING

History

The first fascial suburethral sling was described by Price in 1933,[18] with a strip of fascia lata (deep fascia of the thigh) passed beneath the urethra and fixed to the rectus muscles. Aldridge[19] published his modification of the technique in 1942, which involved the transfer of fascial strips from the external oblique aponeurosis (rectus fascia) through the rectus abdominis muscle to the vaginal incision, where they were sutured together to allow for elevation of the urethra and bladder neck. This technique

was the most popular for fascial sling for stress incontinence for many years. The method has since undergone multiple modifications, including transition to a combined abdominovaginal approach with the introduction of perioperative antibiotics, the use of a single continuous portion of rectus fascia, complete detachment of the fascia from both ends before passage under the urethra, and the use of a permanent suture bridge on both ends of a fascial sling.[20] Various attachment points of the autologous sling, including the rectus fascia and the pubocervical and periurethral ligaments, have also been suggested.[20] The most popular modern technique was introduced by McGuire and Lytton in 1978.[21]

Discussion

Today, autologous slings are typically harvested from either the rectus fascia (abdominal) or fascia lata (thigh). Rectus fascia harvest may be accomplished via a Pfannenstiel incision, with final fascial strip measurements reported between 1.5 and 2.5 cm in width and 7 and 16 cm in length.[19,22,23] A permanent suture is attached to both ends of the portion of the harvested fascia. A vaginal incision is made over the bladder neck and tunnels are developed with posterolateral dissection to the level of the endopelvic fascia with entry into the retropubic space. The fascial sling is then passed around the urethra at the level of the bladder neck; the permanent sutures are passed through the rectus fascia just above the symphysis pubis using Stamey needles. Cystourethroscopy is performed to rule out bladder or urethral injury, and may also be used to confirm adequate urethral coaptation with sling placement. The ends of the permanent suture tails attached to the fascial sling are then attached to one another in the midline, avoiding tension under the bladder neck, and the abdominal incision is closed (**Fig. 2**). The sling may also be attached to the periurethral fascia using delayed absorbable sutures before closing the vaginal incision.[23,24]

Alternatively, patients may be placed in the lateral decubitus position for harvesting of the fascia lata via an incision on the lateral aspect of either thigh, 4 cm above the knee. A comparison of fascia lata and rectus fascia slings found no difference in

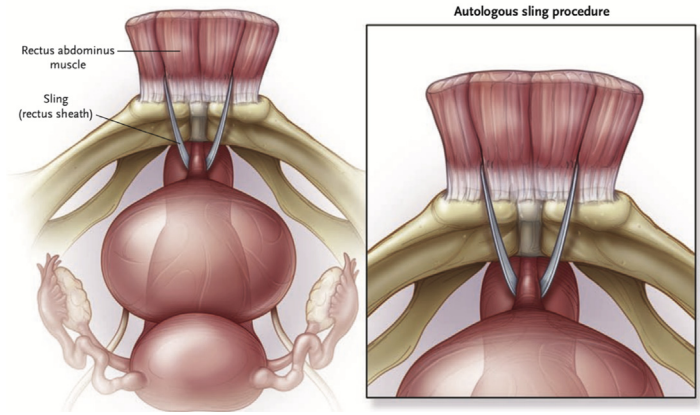

Fig. 2. Autologous sling. (*From* Albo ME, Richter HE, Brubaker L, et al. Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence. *N Engl J Med*. 2007;356:2143-55; with permission)

functional outcomes at 1 year postoperatively, with no statistically significant increase in perioperative adverse events.[25] This practice may be preferable in an obese patient, or in the setting of multiple prior abdominal surgeries.[26] A similar width of 1.5 to 2.0 cm and an increased length of 18 to 22 cm may be obtained, often with the aid of a fascial stripper device.[27] The fascia lata is not reapproximated before multilayer incision closure with compression dressing application. The fascial sling is then placed using the technique described elsewhere in this article.

Autologous fascial slings may be considered for women with severe stress urinary incontinence and a fixed urethra, those with a concurrent urethral diverticulum, urethral fistula or history of prior mesh complications, or a patient who strongly desires a nonmesh sling.[28]

Clinical Outcomes

The reported efficacy of the autologous sling for stress urinary incontinence varies in the literature with definition of objective cure. In patients undergoing autologous sling with rectus fascia, 3-year cure rates of 75.6% and patient satisfaction as high as 84.7% have been reported.[23] A randomized controlled trial comparing retropubic colposuspension with autologous slings, which included women with a history of prior anti-incontinence surgery found a similar 5-year patient satisfaction of 83%.[29] Despite this high satisfaction, strictly defined continence (no symptoms on a 3-day bladder diary, no self-reported incontinence and no surgical retreatment) was found to be low at 30.8% after fascial sling.[29] Long-term follow-up at a single institution likewise reported a cure rate of 45% as measured by a 24-hour voiding diary, 24-hour pad test, and patient questionnaire.[26] Patient satisfaction remains high regardless of route of fascial harvest; at the 4-year follow-up after a fascia lata autologous sling surgery, 85% of patients reported being cured or significantly improved.[27]

Patient-reported satisfaction after an autologous fascial sling surgery is high. Validated quality-of-life questionnaires administered to patients 5 years after an autologous sling procedure found a decrease in symptom bother, with no significant difference when compared with patients 5 years after retropubic colposuspension.[29] Clinically important improvements in sexual function have also been reported at 12 and 24 months after autologous fascial sling and did not differ significantly when compared with women undergoing transobturator sling, retropubic sling, or a retropubic colposuspension procedures.[30] A smaller study found no significant postoperative changes in sexual function.[31] Data on sexual function after autologous sling are otherwise scarce.

Complications and Concerns

Intraoperatively, there is a risk of bladder injury of approximately 3.3%; this risk may increase with scarring owing to prior anti-incontinence procedures.[32] Postoperative risks include urinary tract infection (1.1%–11.4%),[31,32] de novo urgency (11%–18.5%),[23,27] de novo urgency incontinence (7.2%),[27] and urinary retention ($\leq$20%).[22] Observation and self-catheterization for at least 3 months postoperatively in anticipation of gradually decreasing sling tension is recommended for the initial management of urinary retention, after which time urethrolysis may be considered.[22] Finally, there is a reported 6.0% to 7.7% risk of wound infection after an autologous sling procedure, which may account for a more significant proportion of complications after rectus fascia harvest as compared with fascia lata.[24,32] Overall, the reoperation rate after autologous sling is reported at 6%.[32]

RETROPUBIC COLPOSUSPENSION

History

A retropubic colposuspension was first described by Dr John C. Burch in 1961 and is today known as the Burch procedure.[33] Although Dr Burch originally published the attachment of paravaginal fascia to the tendinous arch of the fascia pelvis, this process was later modified to attach the paravaginal fascia to Cooper's ligament.[34] In 1978, Dr Emil Tanagho[35] published a further modification of the procedure to include the placement of paravaginal fascia sutures more lateral to the urethra and under less tension, thus describing the current approach to the Burch colposuspension. The procedure was considered the gold standard of stress urinary incontinence treatment before the introduction of the midurethral sling.[34] The Marshall–Marchetti–Krantz procedure was described by Drs Marshall, Marchetti, and Krantz in 1949, involving the fixation of the bladder neck to the symphysis pubis periosteum.[36] There is a risk of osteitis pubis associated with this procedure, and in 2009 the International Consultation on Incontinence Committee determined that there was no evidence for continued use of the Marshall–Marchetti–Krantz procedure.[37]

Discussion

Historically, retropubic colposuspension was performed using an open abdominal incision; in more recent years, a laparoscopic approach has gained popularity. Regardless of the surgical route, the first step is a careful dissection of the retropubic space, followed by the identification of the bladder neck. With the bladder deviated to one side, 2 to 4 stitches are placed in the paravaginal fascia 2 to 3 cm lateral to the urethra from the level of the bladder neck to the proximal one-third of the urethra (**Fig. 3**). These stitches are then anchored to the ipsilateral Cooper's ligament and tied off tension, aided by the elevation of the vagina by an assistant.[38]

Ideal candidates for a retropubic colposuspension include women who strongly desire to avoid synthetic mesh in surgical repair of their stress urinary incontinence, and for whom fascial harvest for autologous sling is not favorable.[28]

Clinical Outcomes

As one of the oldest established surgical procedures for stress urinary incontinence, the success rates and long-term complications of retropubic colposuspension are

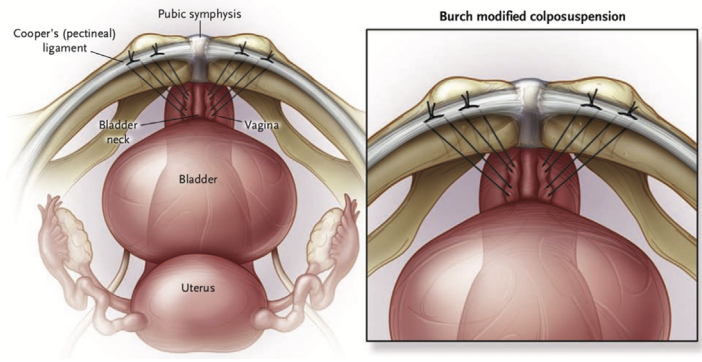

Fig. 3. Retropubic colposuspension. (*From* Albo ME, Richter HE, Brubaker L, et al. Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence. *N Engl J Med*. 2007;356:2143-55; with permission)

well-described in the literature. Fifty-five trials involving open retropubic colposuspension with a total enrollment of 5417 women were included in the most recent Cochrane review, which reported an overall cure rate of 68.9% to 88.0%.[39] A Cochrane review of 26 trials involving laparoscopic retropubic colposuspension and a total of 2271 woman found similar cure rates, with decreased morbidity, shorter hospital stays, and fewer postoperative complications given the minimally invasive approach.[40] The efficacy of both open and laparoscopic retropubic colposuspension is reported to decrease from 90% at 1 year to 70% at 10 years.[40] Given the similar reported efficacy of the laparoscopic approach and the minimally invasive midurethral sling procedure, the retropubic colposuspension procedure has been performed less frequently in recent years; however, it may still be offered to index patients undergoing surgery for stress urinary incontinence.[41]

The most recent Cochrane Reviews of both open and laparoscopic retropubic colposuspension encourage future studies of quality-of-life outcomes for patients undergoing these procedures, because data are lacking. Studies that collected validated quality-of-life questionnaires generally reported improvement in patient-reported symptoms or no change when compared with alternative stress urinary incontinence treatment.[39,40] One randomized controlled trial of midurethral sling and colposuspension found that patients undergoing colposuspension reported less improvement in some quality-of-life measures at 6 months and 2 years; however, there was no difference at 5 years of follow-up.[42] Sexual function after retropubic colposuspension is inconsistently reported in the literature, with conflicting results. Coital incontinence is likely to be cured or improved postoperatively,[43] and the addition of colposuspension to sacrocolpopexy in a randomized controlled trial did not adversely affect sexual function.[44] Conversely, a small prospective study comparing colposuspension and midurethral sling found statistically significant decreases in multiple domains of sexual function.[45]

Complications and Concerns

Perioperative complications associated with retropubic colposuspension are listed in **Table 1**. The reported rates of postoperative voiding dysfunction vary widely based on definition; however, up to 25% of patients experience immediate postoperative voiding dysfunction[34] and 22% of patients noted voiding difficulties in a 10- to 20-year postoperative follow-up.[46] De novo detrusor instability may also occur in 5% to 27% of patients.[38] Despite this finding, reoperation after a retropubic colposuspension is reported to be low at 4.2 per 1000 woman-years.[47] An association of retropubic colposuspension with future development of prolapse has been noted with rectocele formation in 11% to 25% and enterocele formation in 4% to 10% of patients, although direct causation has not been demonstrated.[46]

Table 1
Perioperative complications of retropubic colposuspension

Complication	Rate of Occurrence (%)
Bleeding owing to injury of paravaginal veins	2
Bladder injury	0.4–9.6
Ureteral injury	0.2–2.0
Urinary tract infection	4–40
Wound infection	4.0–10.8

Data from Sohlberg EM, Elliott CS. Burch Colposuspension. *Urol Clin North Am*. 2019;46(1):53-59.

Table 2
Currently available urethral bulking agents and year of introduction or approval

Generic name	Brand Name	Year
Carbon-coated zirconium oxide beads	Durasphere	1999
Calcium hydroxyl apatite	Coaptite	2001
Polydimethylsiloxane elastomer	Macroplastique	1991
Polyacrylamide hydrogel	Bulkamid	1996

Data from Hussain SM, Bray R. Urethral bulking agents for female stress urinary incontinence. *Neurourol Urodyn* 2019;38:887-92.

URETHRAL BULKING

History

Urethral bulking was first described at the end of the nineteenth century by Austrian surgeon Dr Robert Gersuny, who pioneered the use of paraffin as an injectable material in a variety of clinical settings, including breast augmentation.[48] In 1914, renowned American gynecologist Dr Howard Kelly cautioned against the use of periurethral paraffin injections, citing the risk of emboli formation with only temporary symptomatic improvement.[49] The use of sclerosing agents in the treatment of stress urinary incontinence was first described by the British obstetrician Dr Bryan Murless in 1938 when he injected sodium morrhuate in the anterior vaginal wall of 20 women. The agent achieved its intended goal by resulting in periurethral tissue scarring.[50] In 1963 Sachse, a German physician, published on the periurethral use of a sclerosing agent named Dondren. Although the treatment was moderately successful, several patients developed pulmonary emboli and Dondren use was halted.[51] A later alternative of polytetrafluoroethylene (Teflon) was introduced in the 1970s, but failed to gain approval from the US Food and Drug Administration owing to reports of granuloma and periurethral abscess formation, with only an 18% 5-year cure rate.[52]

Since the historical use of paraffin and Dondren, a wide variety of materials have since been tested for use in urethral bulking agents, including autologous fat, ethylene vinyl alcohol, and hyaluronic acid. All of these agents were found to have various increased risks, including the reabsorption of fat resulting in pulmonary embolism, urethral erosion (ethylene vinyl alcohol), and sterile abscess formation (hyaluronic acid) and are no longer available for use.[53] The most successful historical urethral bulking agent was glutaraldehyde cross-linked bovine collagen. Collagen was introduced in 1993 with cure rates ranging from 40% to 60%, and rate of both improvement and/or cure as high as 68% to 90%.[54] Although production was discontinued in 2011, these promising reported success rates made collagen the gold standard in the development of new urethral bulking agents.[55]

Discussion

Today, urethral bulking is accomplished with 1 of 4 available urethral bulking agents, each of which optimize cure rates while minimizing adverse events as compared with previous agents (**Table 2**). Insufficient data exist to determine the superiority of one urethral bulking agent over another.[56] Regardless of the material selected, all urethral bulking agents are injected in the clinical setting with the goal of improving urethral mucosal coaptation.[56] The agent of choice is typically injected into the periurethral tissue at the level of the bladder neck and proximal urethra, although at least 1 trial has compared this practice with a midurethral injection and found no significant difference

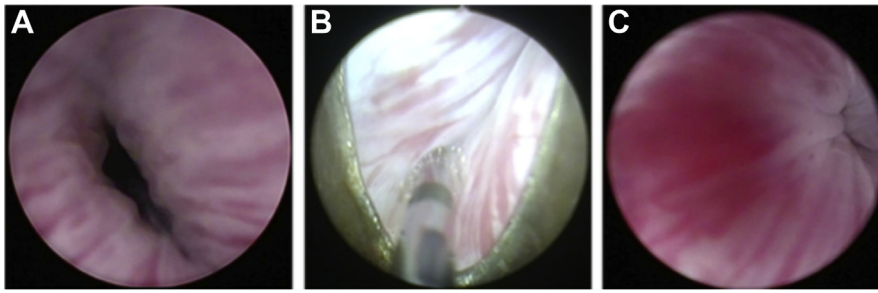

Fig. 4. *A*) A patient with previous urethral injection is noted to have incomplete coaptation of the urethra with residual bulge on the left side of the urethra. (*B*) After injecting the right side of the urethra, (*C*) coaptation is noted. (*From* Li H, Westney OL. Injection of Urethral Bulking Agents. *Urol Clin N Am*. 2019;46:1-15; with permission).

in cure rate.[57] The proceedure may be accomplished with either transurethral or periurethral injection. Urethral bulking is most often performed under direct cystoscopic visualization, although ultrasound guidance and the use of an implantation device have also been used.[58]

In transurethral injection under direct cystoscopic visualization, an injection needle is introduced via cystoscope and used to inject lateral to the urethral meatus, typically at the 3 and 9 o'clock positions. This technique is illustrated in **Fig. 4**. A limited volume of 0.5 mL or less is injected in each site given the limitations of the submucosal space.[55] If performed without or with minimal systemic anesthesia, local anesthetic solution may be injected before injection of urethral bulking agent to enhance patient comfort during injection.

Periurethral injection is also performed under direct cystoscopic visualization and may result in less urethral trauma.[53] In this technique, the injection needle is placed periurethrally through the vaginal epithelium.[56] Urethral insertion devices may be

Fig. 5. Syringe adaptor and uroplasty injection needle. (*From* Li H, Westney OL. Injection of Urethral Bulking Agents. *Urol Clin N Am*. 2019;46:1-15; with permission)

used to deliver both silicone and dextronomer preparations of urethral bulking agents to the periurethral tissue, as pictured in **Fig. 5**. The urethral length is first measured to ensure that the device is placed at the appropriate depth before injection. The device allows for passage of 4 needles for injection. Repeat injections are not recommended less than 12 weeks after the prior procedure.[55] Based on gradually diminishing efficacy over time, it is generally accepted that women undergoing urethral bulking will require future repeat injection. Current studies' length of follow-up have not allowed for an established an interbulking interval, although many trials have limited the number of repeat injections to between 3 and 5.[56,59]

The ideal candidates for urethral bulking include women with bothersome stress urinary incontinence who would prefer to avoid the use of synthetic mesh and the need for general anesthesia. The procedure may also be considered in patients who have failed to achieve adequate symptom improvement with surgery, those without urethral mobility, or those who have previously experienced mesh-related complications.[30]

Clinical Outcomes

The reported improvement and objective cure rates vary between types of urethral bulking agents. A meta-analysis of polydimethylsiloxane elastomer (Macroplastique) reported a short-term (<6 months) improvement rate of 75% and long-term (>18 months) 64% improvement.[60] This rate was significantly higher than the cure rate, which ranged from 43% in the short term to 36% in the long term.[60] Carbon-coated zirconium (Durasphere) has reported improvement rates as high as 80% at 1 and 2 years in 2 randomized controlled trials,[61,62] and as low as 21% after 36 months in a prospective cohort study.[63] A multicenter randomized trial involving calcium hydroxyl apatite (Coaptite) reported a 63.4% improvement and 39% cure rate at 12 months.[64] Finally, polyacrylamide hydrogel (Bulkamid) was found in a multicenter prospective cohort study to have a 64% improvement at 2 years after injection.[65] Although these results are promising, the most recent Cochrane review of urethral bulking maintains that there is an unsatisfactory basis for practice, and that bulking cannot be recommended for women who are appropriate candidates for other surgical procedures.[56]

Table 3
Complications of urethral bulking

Complication	Rate of Occurrence (%)
Urinary retention	8.4
Urinary urgency/Urgency incontinence	7.0
Pain with injection	6.4
Urinary tract infection	5.5
Transient hematuria	3.4
Pseudocyst/Periurethral mass formation	0.7
Urethral erosion	0.3

Data from Li H, Westney OL. Injection of Urethral Bulking Agents. *Urol Clin N Am*. 2019;46:1-15; and Ghoniem G, Boctor N. Update on urethral bulking agents for female stress urinary incontinence due to intrinsic sphincter deficiency. *J Urol Res*. 2014;1:1009; and de Vries AM, Wadhwa H, Huang J, Farag F, Heesakkers J, Kocjancic, E. Complications of Urethral Bulking Agents for Stress Urinary Incontinence: An Extensive Review Including Case Reports. *Female Pelvic Med Reconstr Surg*. 2018;24(6):392-8.

Trials investigating the use of various urethral bulking agents have demonstrated modest improvements on validated quality-of-life measures.[56] Although improvement from baseline quality of life scores is reported by the studies highlighted in the most recent Cochrane review, most demonstrated no significant difference when compared with groups receiving alternative therapies.[56] The only noted exception is a comparison between Macroplastique and home pelvic floor exercises in which patients receiving Macroplastique injections had statistically significant improvement in the Urinary Incontinence Quality of Life Scale.[56] Outcomes specific to sexual function after urethral bulking have not been reported.

Complications and Concerns

Known complications of urethral bulking are listed in **Table 3**. Urethral bulking is generally considered a low-risk procedure, because only 3% of complications require invasive treatment such as abscess incision and drainage or periurethral mass removal.[66] Most complications are managed conservatively with oral antibiotics, anticholinergics, clean intermittent catheterization, an indwelling catheter, or watchful waiting.

SUMMARY

Traditional surgical techniques for the management of stress urinary incontinence are nonmesh approaches, including autologous slings, retropubic colposuspension, and urethral bulking. Autologous slings involve increased morbidity owing to fascial harvest, and are ideal in patients who have failed alternative therapies for stress incontinence or who are not candidates for a synthetic mesh. Retropubic colposuspension is a well-studied technique that may be performed via an open or a laparoscopic approach, with a high reported cure rate. By increasing urethral coaptation with injection of synthetic bulking agents, urethral bulking results in improvement in stress incontinence symptoms without the need for general anesthesia.

CLINICS CARE POINTS

- Autologous slings may be harvested from the rectus fascia (abdominal) or fascia lata (thigh) for placement at the level of the bladder neck in patients with a fixed urethra, a concurrent urethral diverticulum, or with a history of mesh complications.
- Retropubic colposuspension was long considered the gold standard for stress urinary incontinence treatment with high reported improvement and cure rates, despite an increase in postoperative voiding dysfunction.
- Urethral bulking agents may be ideal in the medically frail patient with stress urinary incontinence.
- Although patient satisfaction with urethral bulking is high with few adverse events, efficacy gradually diminishes over time and is low when compared with alternative therapies.

CASE STUDY: MS L

An 87-year-old G1P1 presents with complaints of bothersome urinary incontinence, requiring her to wear briefs as well as 2 to 3 pads daily. Her medical history is significant for atrial fibrillation, chronic kidney disease, congestive heart failure, coronary artery disease and hypertension, with prior cardiac stent ×2. On examination, she has

no significant prolapse and a normal postvoid residual volume, with a positive stress test of large volume of urine. She is interested in surgery to manage her incontinence.

3. What type of surgery would you recommend and why?
   This patient is an ideal candidate for a urethral bulking procedure, because it may allow her to avoid general anesthesia in the setting of multiple medical comorbidities.
4. The patient returns 1 year later with the complaint of recurrent urinary incontinence, and requests repeat urethral bulking. Can this be safely offered to her?
   Yes; although there are limited data on a recommended interval of urethral bulking, efficacy has been noted to gradually decrease over time. The need for repeat injections should be included in the preoperative counseling for urethral bulking.

DISCLOSURE

L. Caldwell.: nothing to disclose. A.B. White: Boston Scientific: investigator (522 Solyx), consultant.

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