Review Article

The fragile urethra: what to do next?—a narrative review

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Background and Objective: Although the artificial urinary sphincter (AUS) has demonstrated successful outcomes in treating male stress urinary incontinence (SUI) for the past five decades, this procedure also carries inherent risks, including recurrent SUI, device malfunction, local tissue compromise, and infection/erosion, all of which may require revision surgery with or without device replacement. Patients that are at the highest risk for such untoward events often possess unhealthy urethral tissue (termed a "fragile urethra") that is compromised and unable to provide optimal cuff coaptation and continence. Accordingly, there are several techniques to address recalcitrant SUI in the setting of a fragile urethra to afford an improved chance of return to continence. Here, we review characteristics of patients that are at higher risk for an untoward outcome following AUS implantation and further define strategies to promote optimal success with device implantation. The aim of this paper is to review the available literature and describe surgical options for male SUI in patients with known or anticipated urethral tissue compromise.

Methods: A thorough literature review was completed by querying PubMed for relevant articles. Search terms included artificial urinary sphincter, failure, recalcitrant, urethral atrophy, fragile urethra, revision, radiation, cystectomy, incontinence, and/or urethroplasty published between 1975 and 2022.

Key Content and Findings: Options for management of the fragile urethra include cuff relocation, cuff downsizing, tandem cuff placement, transcorporal cuff placement, pressure regulating balloon exchange with increased or decreased pressure, bulbospongiosus preservation, sub-cuff ventral capsulotomy, urethral wrapping with graft, and in select cases, urinary diversion, or complete device removal with a return to stress urinary incontinence. Proper patient selection is paramount to optimize outcomes. Advantages and disadvantages of each strategy are reviewed.

Conclusions: Numerous techniques are viable options for patients with recalcitrant SUI in the setting of a fragile urethra, but high-quality evidence with reproducible outcomes for many of these strategies remain limited. Proper patient selection as well as adequate counseling by experienced implant surgeons may help optimize outcomes. Further multi-institutional investigations with longer term outcomes are needed to improve patient selection and counseling with shared decision-making prior to any intervention.

Keywords: Artificial urinary sphincter (AUS); stress urinary incontinence; fragile urethra

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Introduction

Since its introduction in 1972, the artificial urinary sphincter (AUS) has become the definitive and perhaps most studied intervention for male stress urinary incontinence (SUI) with numerous prior works demonstrating excellent outcomes (1-8). However, device placement is not without its risks, including recurrent SUI, device malfunction, local tissue compromise, urethral atrophy, and device infection/

erosion (1).

The basic principle of the AUS is a pressurized cuff which compresses the urethra, resulting in coaptation of the circumferential urethral mucosa providing a barrier to SUI. Optimal continence is achieved with a functioning cuff around the corpus spongiosum, which is at its largest diameter in the proximal bulbar urethra, diminishing in thickness distally (9,10).

Previous work has established dry rates of up to 85.7%, with improvement rates of 61–100% (11). In the overall population, explantation due to erosion and/or infection has various reported rates from 3.3–27.8% (11). Unfortunately, several patient factors may result in a urethra that is compromised (termed as a "fragile urethra") that is at perhaps the highest risk for subsequent failure on the index case or revision cases (12-16).

Ultimately, tissue ischemia is the primary mechanism for contributing to fragile urethra, with a multitude of etiologies. The blood supply of the urethra comes from the bulbourethral artery and dorsal penile artery (9,17) and various insults can thus result in tissue compromise. Care should be taken to avoid damaging the bulbourethral artery, as the branching collaterals are sacrificed dorsally at the site of dissection for the placement of the cuff. Urethral atrophy and subsequent erosion can result from local ischemia due to pressure directly by a previously placed cuff, with patients reporting increased incontinence or pad usage. There are some investigations calling urethral atrophy into question, as there is suggested restoration of urethral circumference with capsulectomy (18,19). Nevertheless, these patients have been shown to have worse outcomes compared to the general population. Patients with prior urethral compromise (e.g., history of prior radiation, urethroplasty, and/or previous AUS) have higher failure rates (defined as non-functioning device, erosion, or infection) with more pronounced risk with increasing number of prior procedures performed (16). Another risk factor for poor blood supply is hypogonadism, under the premise that androgens contribute to urethral homeostasis and stability (20). Although some may suggest there are ways to delay urethral atrophy such as nocturnal deactivation of the cuff, the need for revision or further procedures is high (21). Patients with prior pelvic radiation may have a 5 and 10-year revision-free survival rate of 72.6% and 56.4%, respectively (22). Patients who have had prior AUS erosion are also at increased risk for higher rates of subsequent explantation (23-25). Therefore, understanding the various techniques in management of the fragile urethra is paramount as these patients will more than likely need revision.

Prior to surgical intervention for patients with fragile urethra and recalcitrant SUI, appropriate workup is imperative. Patients must demonstrate correct technique for activation and deactivation. A device that questionably cycles could have the pressure-regulating balloon (PRB) interrogated by ultrasound to ensure adequate fluid volume (26). Cystoscopy with device cycling should be completed to demonstrate failure of coaptation, and a cough stress test with a full bladder can confirm recurrent SUI. In our practice, urodynamics is reserved for any patient with recurrent SUI who is deemed to have tight cuff coaptation on cystoscopy along with no demonstrable cough-induced incontinence upon evaluation.

We review the available literature and describe surgical options for male refractory SUI in patients with known or anticipated urethral tissue compromise. We present this article in accordance with the Narrative Review reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-22-798/rc).

Methods

A thorough literature review was completed by querying PubMed for relevant articles and is summarized in *Table 1*. Search terms included artificial urinary sphincter, failure, recalcitrant, urethral atrophy, fragile urethra, revision, radiation, cystectomy, incontinence, and/or urethroplasty published between 1975 and 2022. Boolean operations were utilized to optimize the search results. Specifically, this was queried as "artificial urinary sphincter" AND (failure OR recalcitrant OR "urethral atrophy" OR fragile OR revision OR radiation OR urethroplasty). This search strategy yielded 643 results. Next, abstracts were screened, and articles included were systematic reviews, meta-analyses, case reports, retrospective case series, prospective case series, and review articles. Duplicate articles, editorial comments on prior publications, and articles published in a language other than English were excluded, thus narrowing the initial search to 77 results. Full-text manuscript queries were then performed, and articles were excluded if subject matter was unrelated to the specific question as determined by mutual two-co-author consensus. Specifically, subject matter had to report on techniques addressing a fragile urethra with perioperative outcomes. This yielded 39 results. Additional articles found through sources cited on full-text article reviews were included if relevant, for an additional 17 results. A separate query was run for articles

Table 1 Search strategy utilized for present review assessing options for management of recurrent stress urinary incontinence following prior artificial urinary sphincter surgery in men with urethral compromise (e.g., "fragile urethra)

Items	Specification
Date of Search	8/3/22
Databases and other sources searched	PubMed
Search terms used	Query 1: "Artificial urinary sphincter" AND (failure OR recalcitrant OR "urethral atrophy" OR fragile OR revision OR radiation OR urethroplasty)—643 results
	Query 2: Cystectomy AND incontinence AND benign NOT neobladder—29 results
Timeframe	1975–2022
Inclusion and exclusion criteria	Inclusion: systematic review, meta-analyses, retrospective analyses, prospective analyses, review articles, English
	Exclusion: duplicate, editorial comments, irrelevant subject matter
Selection process	One co-author independently reviewed abstracts of search results for relevance—Query 1: 77 results; Query 2: 8 results
	Full-text review of the results for eligibility was completed with mutual two-co-author consensus—Query 1: 39 references; Query 2: 4 references
Any additional considerations	Additional relevant cited material from initial references were included for an additional 17 references

regarding simple cystectomy (SC) due to limited overlap with other AUS publications. Search terms for urinary diversion included cystectomy, incontinence, and benign. Boolean operations were utilized again to optimize search results. This was queried as cystectomy AND incontinence AND benign NOT neobladder. This yielded 29 results. Using the above criteria to review abstracts, this was narrowed to 8 results. Full-text reviews were performed as above and yielded 4 results.

Key content and findings

Options for fragile urethras include cuff relocation, cuff downsizing, tandem cuff placement, transcorporal cuff placement, PRB exchange with increased pressure, use of lower pressure PRB, preservation of bulbospongiosus muscle, sub-cuff ventral capsulotomy, urethral wrapping with graft, and in extreme cases urinary diversion or return to stress urinary incontinence. Proper patient selection will help to optimize outcomes. Advantages and disadvantages of each strategy are reviewed below.

Cuff relocation

Cuff relocation can be performed if other areas of healthy urethra are present. Proximally, the urethra has the most robust supportive spongiosum, which is the ideal site for index placement (10). Over time, this primary site may atrophy, resulting in an alternate location with more robust spongiosum. The rationale for cuff relocation to this area with healthier urethral tissue is that coaptation will improve and the patient regains continence, but there are still some considerations. If the primary AUS cuff was placed as proximally as possible, this relegates a revised cuff location to an area more distal with possibly poorer surrounding spongiosum. Theoretically, atrophy and erosion can be hastened, and patients may be limited in any future number of revisions. A cadaveric study of distal relocation showed a maximum of four sites for AUS placement in the average patient (27). In some cases, the AUS can be replaced proximally if the index placement was suboptimal. In either case of relocation, repeated dissection disrupts urethral blood supply further which may worsen outcomes so the bulbourethral artery should be preserved. Additionally, there is risk for cuff migration particularly if the relocation site is in continuity with the previous site (27).

Couillard and colleagues reported early though limited data that five of six patients who underwent proximal cuff repositioning achieved one pad per day or less, while no revisions were required at median one-year follow up (28). In a multi-center study by Eswara and associates, however, eleven patients who underwent repositioning tended to have higher

rates of incontinence compared to 79 patients who underwent other revision techniques, with a hazard ratio of 6.03, but this failed to reach statistical significance (P=0.10) (29). The largest retrospective study comparing primary to secondary AUS implantation included repositioned cuffs in patients without prior infection or erosion. Of 119 patients undergoing a total of 142 revisions (seventeen cases were excluded as no cuff was replaced), 52 devices were placed distal to the original position and 15 proximal, while 75 were placed at the index site. Pooled outcomes after revisions showed only a slight increase in repeat revision rate from 17.9% to 23.5% with only a modest drop in continence from 90% to 82%, though reported outcomes by site of relocation were not described (23).

Cuff relocation is ultimately an ideal choice if a more proximal segment of urethra is available due to a sub-optimally located index cuff placement. Literature does support good continence outcomes and a similar revision rate as index operations. Limitations of this strategy include the need for further urethral dissection, as well as achieving a potentially finite number of revisions using this technique.

Cuff downsizing

Cuff downsizing reduces the aperture of the cuff when inflated, thereby facilitating closer urethral coaptation. This may be performed in isolation or in combination with other revision techniques. Currently the smallest cuff commercially available is the 3.5 cm cuff, limiting this option to patients with initial 4.0 cm or larger cuff placement (30). The role of the 3.5 cm cuff in reducing 4.0 cm cuff downsizing was appreciated soon after the release of this cuff size (31). Early failure to achieve continence may indicate a suboptimal cuff measurement necessitating downsizing. In the setting of the fragile urethra, subsequent atrophy prevents complete coaptation. Paradoxically, due to the increased local pressure and resultant pressure ischemia from a small cuff that is distributed over already atrophied tissue, downsizing may hasten subsequent atrophy and necessitate revision sooner. Brant and colleagues reported in a prospective multi-institutional trial that placement of a 3.5 cm cuff was an independent risk factor for primary AUS explantation, with 7 of 44 patients undergoing 3.5 cm cuff placement requiring explantation at mean follow up of 2.3 years (P=0.04) (24). Notably, these patients may even have had urethral wrapping or transcorporal cuff placement utilized per the surgeon's best judgment.

The increased risk of failure with use of a 3.5 cm cuff was further characterized by Loh-Doyle and colleagues. The investigators evaluated mechanical failure rates in 993 surgeries, 465 of which were primary implantations with median follow up of 31.5 months and found 16 of 166 (9.64%) 3.5 cm cuffs mechanically failed, with a hazard ratio of 7.313 (P<0.0001) compared to larger-sized cuffs (32). Given this emerging work, we rarely utilize 3.5 cm cuffs in our practice. The benefits of downsizing, however, include obviation of the need for further dissection and disruption of the urethral blood supply (27). As such, this may be a suitable option for patients with isolated urethral atrophy and compromised vasculature.

Early retrospective studies that demonstrated proof of concept showed improvement in 17 patients with regards to social continence rates with decreased average daily pad use from 3.9 to 0.5, as well as improved patient satisfaction from 15% to 85% (P=0.01) (33). Importantly, these studies were completed prior to the development of the 3.5cm cuff. Linder and colleagues had a comparative retrospective study showing no difference in three-year device survival with downsizing compared to tandem cuff placement, with survival of 60% and 76% respectively (P=0.94) (34). However, this was underpowered with only nine patients in the downsizing arm against 56 tandem placements, and no continent or patient satisfaction outcomes were reported.

Ideal candidates for downsizing include sub-optimally sized index cases, or severe urethral atrophy with resultant decreased urethral diameter. This management strategy can often be planned when cystoscopy in a patient with recurrent SUI shows poor cuff coaptation. The concept has been supported since the introduction of the 3.5 cm cuff with decreased rate of 4.0 cm revisions, and additional benefits include minimal dissection with maximal preservation of the existing blood supply. Due to no cuff size available under 3.5 cm (presumably due to concerns regarding increased urethral pressure and erosion risk), downsizing past 3.5 cm will likely never be an option for men with the smallest cuffs. Importantly, downsizing may hasten need for revision in men with already atretic urethras and this point should be incorporated in counseling discussions with patients prior to revision surgery (35).

Tandem cuff

Tandem cuff or double cuff placement uses the rationale that one cuff may not completely attain continence, so placement of a second cuff either distal or proximal should

theoretically increase resistance enough to minimize SUI in the absence of complete coaptation of either moiety. This technique though does require further dissection that can further compromise vascular supply (27).

Maurer and colleagues performed a prospective trial of salvage tandem cuff placement versus transcorporal, which demonstrated similar continence rates of 88% and 72% (P=0.37) respectively with no significant difference with respect to infection, erosion, or explantation (36). However, studies have shown tandem cuff placement to have increased rates of failure (16) as well as erosion (37), so tandem cuff placement has fallen out of favor. Additionally, tandem cuffs have not been shown to improve leakage (38).

Even though the theoretical rationale for tandem cuff placement is to increase total resistance to flow, clinical and cadaveric studies have not demonstrated efficacy. Several of these have reported worse outcomes necessitating explantation, which obviates the benefits with this approach.

Transcorporal cuff (TC)

TC placement is the most well described approach to AUS in the fragile urethra, having initially been described in 1986 by Nelson (39). By incorporating the ventral wall of the corpora, the dorsal urethra is padded from the corporal bodies and tunica albuginea, to help minimize erosion and provide extra tissue for improved coaptation. After dissection, bilateral corporotomies are made with perforation of the septum. This portion is incorporated into measurement for the AUS cuff, and corporotomies are closed around the cuff. This allows a cuff to be placed around an atrophic urethra and helps if distal placement is necessary due to prior surgery or poor tissue quality at the cuff placement site. It can also be completed in combination with other techniques such as cuff relocation (40).

In a comparative study of 26 patients with prior treatment for prostate cancer, 18 underwent a standard approach while 8 underwent TC placement with mean follow up of 31 months. Retrospective analysis showed TC placement clinically tended to outperform standard approach in rates of continence (89% *vs.* 61% respectively), though those of erosion were comparable (11% *vs.* 13% respectively). However, statistical significance was limited due to low subject enrollment (41). A more recent study by Hoy and Rourke of 13 TC and 17 standard placements supported TC placement as a viable option, though not necessarily superior to standard placement in the fragile urethra as statistical significance was not reached. For patients who underwent TC placement versus standard, the reported continence rate was 85% *vs.* 71% (P=0.43), patient satisfaction rate was 85% *vs.* 94% (P=0.56), and explantation rate was 15% *vs.* 0% (P=0.18) respectively (42).

Another study focusing on patients with prior pelvic radiotherapy undergoing first time AUS showed TC did outperform the standard approach regarding major complications including explantation and revisions, with rates of 14.8% and 56% respectively (P=0.01) as well as continent functional outcomes, with one pad per day *vs.* three, respectively (P=0.019) (43).

One drawback of the TC technique is the risk for deterioration of erectile function and corporal violation that would complicate future penile prosthesis placement. This strategy should be predominantly offered to patients with poor erectile function and those unlikely to desire surgical treatment such as penile prosthesis implantation. As such, the first studies were performed in men with pre-operative poor erectile function. In a study of 31 patients at a mean follow up of seventeen months, 9 achieved complete continence, while 17 required one or fewer pads, and 25 men reported satisfaction with their level of continence (40). In this group, one patient had preoperative erectile response to intra-urethral alprostadil which diminished post-operatively, while one patient with satisfactory erectile function had no change in function. Wiedemann and colleagues reported mostly good post-operative erectile function in a study of seventeen men, six of whom were sexually active pre-operatively. Five men maintained their level of erectile function and sexual activity, while only one patient progressed to bothersome post-operative erectile dysfunction (44). Outcomes of placement of a TC cuff in a patient with an already existing penile prosthesis have yet to be reported.

Another drawback particularly for atrophic urethras is incomplete buttressing of the urethra, as the ventrolateral urethra is not supported by the corpora. Ortiz and colleagues studied the most common sites for erosion comparing TC and the standard approach (45). Out of 723 cases among 611 patients, 54 (7.5%) cases of erosion were noted. The cohort with TC placement did have significantly more compromised urethras particularly with radiation history, prior AUS, and prior cuff erosion. Therefore, it is unsurprising that a higher rate of erosion occurred in TC (15/82, 18.3%) *vs.* standard (39/641, 6.1%) cohort (P<0.05). Notably though, most erosion events occurred ventrally in both groups, with 79% of standard *vs.* 67% of TC (P=0.4), with lateral erosion in 20.5% of standard *vs.* 33% of TC

(P=0.3). Interestingly, dorsal erosion was the lowest in both groups at 5% standard and 20% TC (P=0.1). This questions the benefit of the dorsal padding in the TC approach, given no significant difference in the map of erosion in either group, with low rates of dorsal erosion regardless of technique.

Vasan and colleagues describe a "gullwing technique" that may circumvent the erectile side-effects and difficulty with future penile prosthesis implantation, while also providing circumferential support. By creating bilateral flaps or "gull-wings" of tunica albuginea, these can be wrapped around the ventrolateral urethra providing circumferential buffer (46). Additionally, the corporal size is theoretically not compromised, as they do not need to be cinched together with the closing stitch. No long-term data is presently available with regards to functional outcomes (46).

Due to the nature of the technique, TC cuff placement is ideally suited for men with poor baseline erectile function without significant desire for further sexual activity. Transcorporal cuffs have demonstrated satisfactory continence outcomes, but studies are mixed with regards to erectile function outcomes as these have also predominantly been performed in men without satisfactory erectile function (40-44). The introduction of the gullwing modification may provide an opportunity to maintain erectile function or maintain eligibility for a future penile prosthesis, not enough literature supports this (46). Furthermore, the benefit of protection from future dorsal erosion may be overstated, given the findings of predominantly ventral and lateral erosion noted in large contemporary investigations (45).

Pressure-regulating balloon exchange with increased pressure

Another proposed method to improve urethral coaptation in the fragile urethra is to increase the pressure of the PRB. The standard PRB is designed for 61–70 cmH_2O. By replacing the standard PRB with a higher-pressure system, typically 71–80 cmH_2O, there is more resistance to flow, and continence may be restored. This technique minimizes urethral dissection, theoretically preserving blood supply and allowing for same day device usage following revision surgery. However, this does raise concern for hastening erosion, due to increased pressure on the urethra.

Moses and colleagues identified 22 men who underwent PRB exchange with higher pressure, and evaluated continence and erosion rates. With median follow up of 22.4 months, exchange was found to decrease continence pad use from 4±3 pads per day to 1±1.6 pads per day (P=0.01) (47). Erosion was noted in three patients (14%), all of whom had a prior history of radiation (P=0.04).

Loh-Doyle and colleagues retrospectively reviewed 55 revisions with higher pressure PRB for recurrent SUI with a median follow up of 26.4 months (48). 13 out of 33 patients surveyed at follow-up were completely dry while 14 used one or less pad per day, and four patients (7.5%) ultimately developed urethral erosion with a median time of ten months to erosion. Interestingly, in contrast to Moses' study, radiation was not found to be a significant risk factor for erosion.

This management strategy has been shown to demonstrate some efficacy at 1–2 year follow up, with acceptable erosion and explantation rates comparable to the general index AUS (11). It also offers the benefit of requiring no urethral dissection thus theoretically preserving the blood supply (47,48). Further research is warranted with longer-term outcomes to evaluate if erosion risk is dramatically increased in practice compared to other revision techniques.

Use of the lower pressure pressure-regulating balloon

There has been suggestion of using a lower pressure PRB (51–60 cmH_2O) in patients who have had pelvic radiation. However, this was described in only one study. To decrease risk of erosion, Singla and Singla have described their use of the lower pressure PRB preemptively in the radiated urethra, coupled with delayed activation at 6 weeks (21). The authors did not specifically describe how their outcomes differed in patients who underwent this technique from those who did not.

Bulbospongiosus preservation

During standard urethral dissection, the bulbospongiosus muscle is opened midline and retracted laterally as the posterior urethra lies just deep to this structure (11). Given its anatomic relation with the urethra, it has been hypothesized that preserving this muscle by mobilizing it laterally preserves urethral blood flow, minimizing risk of ischemia (49). Roth and colleagues retrospectively analyzed 21 men who underwent muscle-sparing AUS placement that were identified as high-risk due to a history of pelvic radiation or prior AUS erosion. Fifteen patients completed questionnaires over a mean follow up time of 35.8 months with 10 of 15 considering themselves "cured" or "greatly

improved," with no erosions reported (49).

A prospective cohort study by Serra and colleagues was performed evaluating muscle-urethral complex AUS placement (50). 82 patients with a history of prostatectomy, 23 of whom underwent salvage radiotherapy were evaluated with a median follow-up period of 46 months. Overall, 63 (76.8%) patients reported cure and 76 (92%) patients met criteria for social continence at initial follow-up, though by the end of the study eighteen (28%) of the initially cured patients lost continence. Of these eighteen patients, six were found to have inadequate coaptation on cystoscopy presumed due to urethral atrophy, though no patient underwent revision.

These studies have demonstrated good outcomes with regards to continence, and low rate of erosion. However, neither have a comparative arm demonstrating superiority against muscle-dividing techniques, and further studies are needed to determine if there is benefit for the fragile urethra.

Sub-cuff capsulotomy

Sub-cuff capsulotomy is a demonstrated technique to restore urethral circumference to optimize same-site replacement, based off the idea that urethral atrophy may not be ischemic in nature but rather a property of the resultant pseudo-capsule and resultant fibrosis following initial placement. Immediately after cuff removal, the resultant ventral fibrotic band is released, avoiding dorsal dissection and subsequent full capsulectomy, allowing the urethra to expand, facilitating replacement without proximal or distal dissection to avoid downsizing or the need for TC cuff placement.

Pearlman and colleagues describe a retrospective cohort study of seven patients who underwent sub-cuff capsulotomy while profiling the pressures of the PRB intra-operatively. Intra-operatively, the mean urethral circumferential increase was 1.1 cm, ranging from 0.5 to 2.5 cm after capsulotomy while the PRB was replaced. Five of these patients underwent the same or larger cuff size, while two patients required downsizing by 0.5 cm. Objective continence rates of one or less pad per day at mean follow up of 11.8 months was 71.4%, and no complications were reported (19). Four out of six PRB's were noted to be lower than the rated 61–70 cmH_2O, ranging from 53.0 to 74.8 cmH_2O, and all were replaced with standard PRBs.

Sub-cuff capsulotomy is an emerging concept with little supportive data and no further multi-institutional data at present. It has the benefit of being a low-risk attempt at a salvage procedure at the index site. If careful dissection to avoid urethrotomy is maintained, this technique also circumvents further urethral dissection and the disruption of blood supply (19). Perhaps the largest risk is quick reversion to atrophic urethra necessitating replacement with an alternate technique. Accordingly, this technique may be an adjunct in a patient with urethral circumference of 3.5 cm or less to optimize coaptation if transcorporal cuff placement is not suitable. Given the lack of multi-institutional data or larger scale studies confirming the initial findings, we have not yet adopted this strategy regularly in our treatment algorithm for patients presenting with recurrent SUI at our center.

Urethral wrapping

Urethral wrapping is a form of external urethral bulking. Studies have evaluated use of small intestinal submucosa (SIS), rectus fascial autologous graft, as well as collagen fleece wrap for circumferential external urethral bulking in patients with a history of multiple revision AUS surgeries. Buttressing the atrophic and eroded urethra theoretically allows for extra supportive layers of tissue and improved coaptation, with the AUS cuff placed overtop the supporting layers.

Surgisis® from Cook Group Incorporated (Bloomington, IN) is a porcine-derived acellular matrix which dissolves cellular material while retaining supportive connective tissue biomolecules. One cohort study of five patients with recurrent SUI after initial AUS or male sling surgery underwent external urethral bulking with SIS to allow for a subsequent 4.0 cm cuff which was the smallest available at the time (51). At a mean follow up of eleven months, all patients achieved continence of one or less pad per day, except for one patient who reported 1–2 pads per day. More recently in a larger cohort study, three of eight patients achieved total continence at two-year follow up, though the remaining five had complications, three necessitating explantation at 4–8 weeks and one with revision and resultant return to total incontinence (52).

TachoSil® manufactured by Takeda Pharmaceutical Company Limited (Tokyo, Japan) is an equine-derived collagen sponge coated with human coagulation factors. Although marketed as a hemostatic agent, it has been used in reconstruction as a graft. In a study of sixteen patients, twelve of whom had 1–4 prior AUS surgeries, two patients achieved complete continence while nine

were able to use only one pad per day, though data was limited to three month follow up with 75% reporting their condition as much or very much improved. One patient developed erosion and another one pump malfunction, both necessitating revisions. Unfortunately, long-term data with external validation is lacking with regards to efficacy (53).

More recently, rectus fascia autologous grafts have been studied. Gani and colleagues performed a prospective study evaluating 23 patients, all with prior pelvic radiotherapy, with a prior male sling in eight patients and an AUS in one patient. At a median follow up of 32 months, seventeen patients achieved complete continence while five achieved one pad per day. One patient did develop erosion and required explantation at three month follow up (54).

Ultimately, urethral wrapping with synthetic or autologous tissue has benefits of external bulking without reliance on native tissue that may have been violated numerous prior times with prior AUS surgery. Availability of synthetic materials and surgeon graft harvest are likely the biggest hindrances to regularly incorporating this technique due to extra cost and operative time. As with many techniques described, longer-term data with external validation is lacking. Additionally, some data has demonstrated poorer efficacy, making this a controversial technique that we do not actively recommend at present.

Permanent urethral ligation (PUL)

PUL is a last resort option for the end-stage urethra that avoids major abdominal surgery. This relegates patients to rely on a catheterizable or non-catheterizable vesicostomy or suprapubic tube (SPT) for bladder drainage but has the potential to restore complete continence. The largest retrospective study examined 20 men who underwent PUL with concurrent SPT, with fifteen men dry at median follow-up of 27.5 months (55). The most common complications were bladder spasms attributed to the SPT, though four patients required repeat PUL due to recanalization, while one elected for perineal urethrostomy and a return to SUI. Notably, urethrocutaneous fistula developed in two men and ultimately four men eventually proceeded to SC due to refractory post-operative complications. These findings were corroborated in a subsequent study where six of seven patients achieved total continence after PUL with SPT, while one was pending work up at the time of publication (56).

PUL is a seldom utilized last resort for the end-stage urethra. While it may afford a small chance at regaining continence, it is associated with, though not significantly, complications including urethrocutaneous fistula. A notable proportion of patients may proceed to an alternative long-term solution including cystectomy (55,56). Although the populations this has been studied in may intrinsically bias toward poorer outcomes, it has not proven a robust option for management of SUI alone, and as such, we do not recommend its routine use except in rare and challenging scenarios.

Simple cystectomy

A rare but important consideration remains SC with cutaneous urinary diversion. Although much rarer than malignant indications, benign indications include severe refractory SUI. The decision to proceed relies on shared decision-making after recurrent symptoms, morbidity from urinary tract infections (UTI), and numerous alternatives that have been exhausted in surgical candidates who are motivated to undergo definitive treatment. In patients with severe SUI who are good surgical candidates, SC affords the opportunity to significantly improve quality of life as a definitive continence procedure in the well-counseled patient (57). Specific data on patient satisfaction after SC for SUI is limited due to its rare indication, but several studies have shown improvement in health-related-quality of life (HRQOL). Al Awamlh and associates studied HRQOL after SC using a standardized questionnaire, and found significant improvement in multiple HRQOL factors, including mean social functioning scores 52/100 to 80.9/100 ($P<0.01$), though only one patient was treated for incontinence (58). Another such report corroborated by Volz and colleagues evaluated HRQOL after salvage SC for benign conditions. Although not specific to recurrent SUI, 54 patients underwent salvage SC, eight of whom had prior AUS and two of whom had bothersome SUI without prior AUS. Social function improvement peaked, with improvement from 40.2/100 to 69/100 at three months post-operatively, though decline was observed at 36-month follow up to 41.7/100 ($P=0.027$). A limitation of the findings was that only two patients with prior AUS or SUI had pre-operative and post-operative survey results (59).

SC for benign indications is not without its risks. Morbidity and mortality can be high and must be weighed against the patient's goals of care. Cohn and associates studied 26 patients who underwent SC for benign disease, finding 38% experienced a minor Clavien I-II complication and 35% a major Clavien III-V complication, including one mortality within 30 days and a 73% 30-day morbidity rate ($P=0.04$). Patient satisfaction and HRQOL outcomes

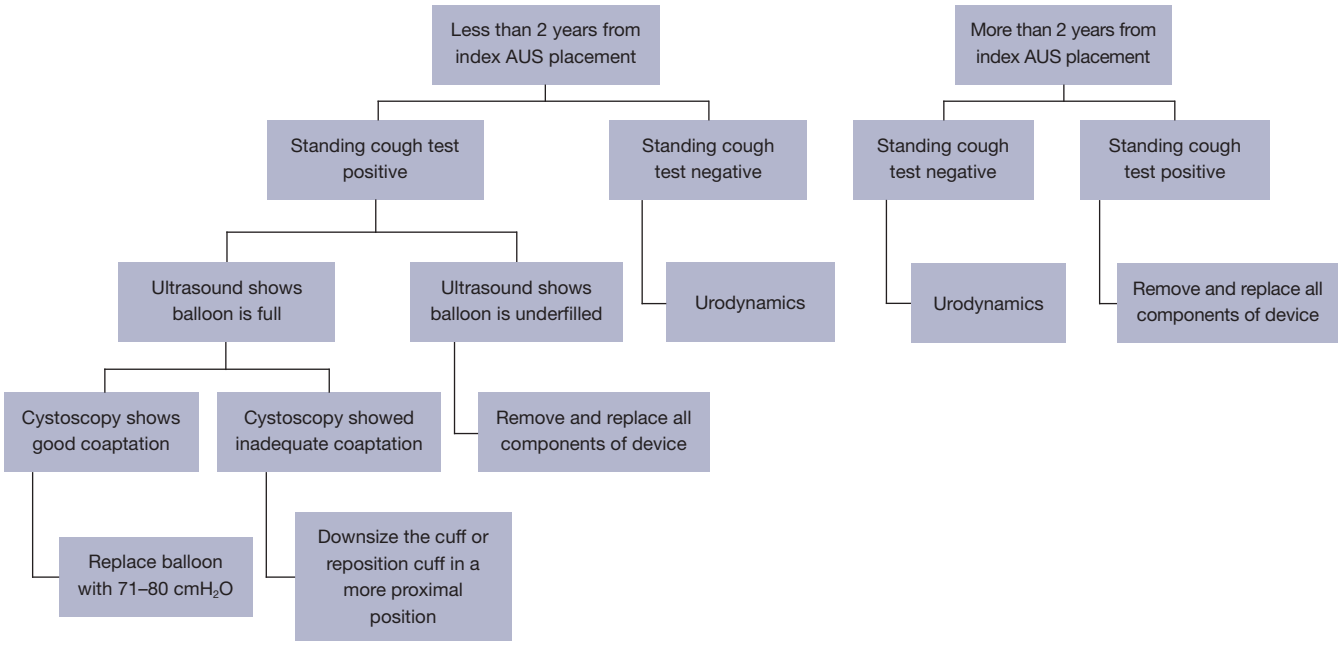

Figure 1 Our center's management strategy of recurrent stress urinary incontinence in a patient with prior artificial urinary sphincter in place.

were not studied. Ultimately physicians may be reluctant to pursue such an aggressive treatment for benign disease, but the debilitation of the underlying condition must be considered in concert with the motivation of the patient to improve their respective HRQOL (60).

SC for refractory SUI is an uncommonly performed surgery for management of the persistently incontinent male that has failed numerous prior anti-incontinence measures but one that could be considered and with reserved judgment. There is limited data due to the rarity of its presentation and SC can be a highly comorbid operation. Nevertheless, patients with severe debilitation from symptoms should be well counseled and offered the option if they are an appropriate surgical candidate.

Non-operative management

In any case of recalcitrant SUI, non-surgical management with chronic or intermittent urinary catheterization, SPT, external catheter, penile clamp, or return to SUI with incontinence pad(s) should remain an option and be offered as alternatives (61). The modality utilized in such refractory situations primarily depends on the patient's lifestyle preferences. These have the benefit of flexibility and lower risk, as any non-surgical management can easily be interchanged depending on available resources and patient preference.

While non-operative management for recalcitrant SUI may relegate a patient to a poor quality of life, it can be offered at any point in time or if the patient's competing medical risks makes any surgical intervention prohibitive. Specifically, surgery may offer a high reward of continence at high risk for further deterioration of quality of life due to potentially devastating complications of primary or repeated prosthetic surgery. It is important to ensure care options are explored in earnest, and not to shy away from aggressive management if the appropriately counseled patient chooses so in the shared decision-making process with a prosthetic/reconstructive urologist.

Summary

For patients who present with urinary incontinence and a current AUS, our initial step to management begins with a thorough history and physical to assess the etiology of incontinence. The timing from their most recent AUS insertion factors into the evaluation and management. *Figure 1* highlights the algorithm we recommend in evaluating such patients. Office evaluation should include a standing cough test. If we are not able to reproduce stress incontinence, we recommend evaluation with urodynamics.

Table 2 Advantages and disadvantages of the various reported strategies utilized previously for the management of recurrent stress urinary incontinence following prior anti-incontinence surgery in men

Technique	Advantages	Disadvantages
Relocation	Suboptimal distally located initial cuff (28), atrophic urethra at initial site (27)	Urethral dissection (27), limited if index operation site optimized
Downsizing	Minimal urethral dissection (27)	Limited to 4.0cm or larger (30), erosion progression (24), mechanical failure (32)
Tandem cuff	None (38)	Urethral dissection (27), high complication rate (16,37)
Transcorporal cuff	More protective tissue layers (40)	Erectile dysfunction, interference with current or future penile prosthesis (42,43)
Pressure-regulating balloon exchange with increased pressure	Minimal urethral dissection (47,48)	Erosion progression (47,48)
Pressure-regulating balloon exchange with decreased pressure	None (21)	Unclear benefit (21)
Bulbospongiosus preservation	Preservation of blood supply, more protective layers of tissue (49,50)	Unclear long-term benefit (49,50)
Urethral wrapping	None (53)	Requires graft, urinary retention (52)
Capsulotomy	Minimal urethral dissection (19)	Unclear longer-term benefit as decreased urethral circumference due to capsule can reform
Permanent urethral ligation	None	High complication rate with persistent need for indwelling suprapubic tube catheterization (55,56)
Simple cystectomy	Definitive continence procedure (57)	Major abdominal operation with extensive morbidity, urostomy management (60)
Non-operative management	Minimal risk, flexible to patient needs (61)	Low patient quality of life

If stress incontinence is reproduced in a patient whose AUS was placed more than two years prior, the patient often undergoes complete device removal and replacement.

In a patient whose AUS was placed less than two years ago, we determine if the device is functioning appropriately by evaluating the reservoir with ultrasound and then coaptation of the cuff with real-time cystoscopy. PRB exchange with a higher pressure 71–80 cmH_2O balloon rating can be offered for patients who have reasonable coaptation seen on cystoscopy with a full PRB on ultrasound. If inadequate coaptation is seen, we often utilize cuff downsizing (but not to 3.5 cm for reasons already stated) and/or cuff repositioning to a more proximal location, if feasible. If the cuff cannot be downsized, it is often relocated with a more proximal position targeted. We do not recommend tandem cuff placement. Detailed counseling is imperative, as well as setting expectations that long-term outcomes beyond 2–3 years are not available given that most studies lack statistical significance. Urodynamics is often reserved for patients that have conflicting examinations in the office (e.g., recurrent SUI complaints but unable to demonstrate SUI in the office, etc.).

For patients who have had prior urethral surgery such as urethroplasty with urethral transection, prior AUS erosion, or 3.5 cm cuff, we recommend transcorporal placement, but counsel patients on progressive erectile dysfunction risk given the nature of the surgical cuff placement. For patients with severe recalcitrant SUI in the end-stage urethra that is not amenable to surgical revision by any other techniques, we recommend shared decision-making regarding pursual of SC, with appropriate counseling of risks, benefits, and goals of surgery. We also reserve permanent urethral ligation for extremely select cases. Data supporting urethral wrapping, decreased pressure PRB, and bulbospongiosus preservation is controversial, and accordingly, we do not advocate for its routine use until further work with longer-term outcomes is completed. *Table 2* shows a summary of the advantages and disadvantages of each technique described in this narrative review.

Recalcitrant SUI in the high-risk urethra is particularly difficult to study due to the nature of the disease course. As

such, much of the data available are retrospective and/or non-comparative in nature. Further research is needed with long-term outcomes of each technique, and larger sample sizes to better quantify perioperative outcomes.

Conclusions

Relocation, tandem cuff placement, cuff downsizing, TC cuffs, PRB exchange with increased or decreased pressure, bulbospongiosus preservation, and sub-cuff ventral capsulotomy are reported options for patients with recalcitrant SUI. In select circumstances, SC can alternatively be employed. Patients who are not surgical candidates or those who do not opt for surgery can be offered a multitude of treatment strategies including chronic catheterization, SPT placement, and penile clamps. Evidence supporting urethral wrapping is mixed and cannot be recommended for routine use at this time. Similarly, tandem cuff placement is not advised due to its low efficacy and high complication rate. Due to the nature of the disease course, high-quality evidence is lacking, and any selected approach requires experienced judgment. Proper patient selection as well as adequate counseling by expert implanters may optimize techniques and outcomes if appropriate expectations are set. Future work with longer term outcomes is needed to improve patient selection and counseling for shared decision-making between the patient and treating urologist.

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Footnote

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