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REVIEW PAPER

TRAUMA AND RECONSTRUCTIVE UROLOGY

Cuff downsizing in the treatment of non-mechanical persistent or recurrent stress urinary incontinence: narrative review

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Introduction Stress urinary incontinence (SUI) is a common complication following radical prostatectomy, affecting up to 60.0% of men. The artificial urinary sphincter (AUS) has been the gold standard for treating severe SUI since its introduction in 1973. Despite its efficacy, long-term complications such as device failure and recurrent incontinence are relatively common, often necessitating revision surgeries. This review focuses on cuff downsizing as a revision strategy for non-mechanical AUS failure.

Material and methods A literature review was conducted using PubMed/Medline, covering studies published between January 2000 and December 2023. Key words included: “artificial urinary sphincter”, “cuff downsizing”, “urethral atrophy”, “non-mechanical failure” and "male urinary incontinence revision”. Inclusion criteria were studies addressing cuff downsizing as a primary revision for non-mechanical failures. Only English-language studies were reviewed. We analyzed the timing of revisions, follow-up duration, and outcomes such as continence rates, complication rates, and device survival.

Results Six retrospective studies involving 206 patients were included in the present review. Cuff downsizing was performed as the sole intervention in 3 studies and in combination with other approaches in the remaining 3 studies. The median cuff size decreased from 4.5 cm preoperatively to 4.0 cm postoperatively, with 8.0–12.0% of patients receiving a cuff downsized by more than 1.0 cm. Across all studies, continence rates after revision surgery ranged from 52.0% to 90.0% based on patient-reported outcome measures (PROMs). Device survival rates varied from 64.0% to 95.0%, with infection and urethral erosion being the leading causes of device explantation.

Conclusions Cuff downsizing is a reasonable revision strategy for non-mechanical AUS failure, offering similar continence outcomes and complication rates compared to alternative techniques.

Key Words: AMS 800 ‹› artificial urinary sphincter ‹› stress urinary incontinence ‹› non-mechanical failure ‹› cuff downsizing

INTRODUCTION

Stress urinary incontinence (SUI) affects up to 60.0% of men after radical prostatectomy depending on the definition of urinary incontinence, the surgical technique used, and the duration of follow-up. One year after surgery for prostate cancer, 1 in 10 men report a moderate or severe urine leakage [1].

Since its introduction in 1973, the artificial urinary sphincter (AUS) has been recognized as the gold standard treatment for men with severe SUI [2, 3]. Although the device offers excellent continence outcomes, it is prone to failure over time, resulting in recurrent incontinence. Studies conducted on several large cohorts have reported device revision or explantation rates exceeding 25.0% in the long run [4]. In principle, only AUS infection and

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urethral erosion are absolute indications for reoperation involving device removal. In all other cases, a conservative approach may be considered, or appropriate interventions can be undertaken to facilitate improvement [5].

Upfront persistent urinary incontinence at the time of AUS activation can result from an improperly sized cuff (too loose), inadequate fluid pressure within the system, or incorrect device usage by the patient, potentially causing overflow or urgency urinary incontinence.

The recurrence of SUI may stem from factors such as inadvertent device deactivation, detrusor overactivity, improper pump handling, cuff erosion, mechanical failure, or fluid leakage from the system. Once these factors are excluded, persistent or recurrent SUI is likely attributable to non-mechanical failure which is defined by the persistence or recurrence of SUI despite a normally functioning device, with no signs of urethral erosion, infection, or fluid loss from the system [6].

In case of recurrent non-mechanical SUI after AUS implantation urethral atrophy was traditionally regarded as the primary cause of non-mechanical failure of AUS, but other hypothesis have recently been formulated such as fibrosis of the urethra of improper pressure generated by the device. In that context, cuff downsizing during revision surgery is often the favored option to improve continence in patients with non-mechanical AUS failure [7].

The aim of the present review was to analyze the outcomes of cuff downsizing for male AUS non mechanical failure.

MATERIAL AND METHODS

Evidence acquisition

A comprehensive search of the PubMed/MEDLINE database was performed for articles published from January 2000 to December 2023. The search strategy employed the following key words: "artificial urinary sphincter", "cuff downsizing", "urethral atrophy", "non-mechanical failure", and "male urinary incontinence revision". Studies were eligible for inclusion if they investigated cuff downsizing as the primary revision procedure for cases of non-mechanical device failure. The data search process is presented in the Table 1.

We analyzed the timing of revisions, follow-up duration, and outcomes such as continence rates, complication rates, and device survival. Additional interventions, including cuff repositioning, tandem cuff placement, and pressure-regulating balloon replacement, were also considered.

Evidence synthesis

Study characteristics

We identified 6 retrospective studies [8–13] that assessed the strategy of cuff downsizing in 206 patients with urethral atrophy as the etiology of recurrent stress urinary incontinence (Table 2). In 3 studies [8, 11, 13], cuff downsizing during revision surgery was the sole intervention. In the other 3 studies [9, 10, 12], the authors also employed additional treatment approaches, including implantation of a higher-pressure balloon, cuff repositioning, cuff replacement (placing a new cuff of the same size in the same position), and tandem cuff implantation.

The average time from the original surgery to revision was 40 months, with a follow-up period ranging from 2 to 6 years. The median cuff size before and after revision surgery was 4.5 cm and 4.0 cm, respectively. Data regarding downsizing of more than 0.5 cm were available in 4 out of 6 studies [8, 10, 11, 13], showing that 8.0–12.0% of patients received a final cuff that was at least 1.0 cm smaller than the original. The smallest cuff size of 3.5 cm was reported in 5 out of 6 studies [8–11, 13], with 2 studies [9, 11] reporting that 23.0–26.0% of patients received this cuff size, while the remaining 3 studies [8, 10, 13] did not report implantation of the smallest cuff size.

In 3 out of the 6 studies [8, 11, 13], cuff replacement was the only intervention during revision surgery. In 2 studies [11, 12], 35.0% and 70.5% of patients underwent reimplantation of all AUS components, while in one study, patients received a completely new device if the previous one was older than 5 years, though exact numbers were not provided [13].

Table 1. *Flowchart of data searching process*

Records identified through database searching (n = 34)
Records after duplicates removed (n = 34)
Records screened (n = 34)
Records excluded (n = 24)
Full-text articles assessed for eligibility (n = 10)
Full-text articles excluded, with reasons (n = 5)
Studies included in qualitative synthesis (n = 5)
Additional studies identified through manual search (n = 1)
Total studies included in final review (n = 6)

In addition to the electronic search, reference lists of relevant articles were manually screened. One important study (Saffarian et al., 2003 [8]) was identified through manual review, as it fulfilled inclusion criteria but was not retrieved through the database search due to possible indexing inconsistencies.

Among the 6 studies included in the analysis, 2 studies [8, 13] used patient-reported outcome measures (PROMs) to report functional outcomes, while 2 others [9, 12] employed the pad test as a method of assessing continence status. One study used both methods [11], and 1 study [10] did not report functional outcomes, focusing instead on device survival.

Despite these variations, final results showed that 23.5% to 69.5% of patients remained pad-free after revision surgery, with 52.0–90.0% reporting improvement in patient-reported outcome measures (PROMs).

Device survival was reported in all studies and ranged from 64.0% to 95.0% during the follow-up period, with infection and erosion being the primary causes of AUS explantation. In 1 study [13], previous SUI surgeries (e.g. sling) were identified as risk factors for explantation. Data regarding the influence of single-component replacement vs complete device replacement on device survival were consistent across 2 studies [11, 12]. One study [12] showed longer device survival in patients who underwent complete AUS exchange (82.2% vs 69.6%), while the other [11] reported 85.7% vs 69.0% in favor of only cuff replacement.

DISCUSSION

Recurrent SUI following AUS implantation remains a clinical challenge, particularly in the cases of non-mechanical failure. Several therapeutic options have been explored, including increasing system fluid, replacing the balloon with a higher-pressure reservoir, cuff downsizing, cuff repositioning, transcorporal cuff insertion, and tandem cuff placement [9, 12, 14].

However, a major limitation in this field is the lack of randomized controlled trials evaluating the efficacy of these approaches. Most data come from ret-

Table 2. *Studies assessing cuff downsizing as a treatment modality for recurrent stress urinary incontinence*

Study	Pts no	Other interventions	Time to rev (months)	Follow up (months)	Pre op cuff size	Post op cuff size	3.5 cuff	>0.5 cm change	All components replacement	Continence rate	Device survival (DS)
Saffarian et al. (2003) [8]	17	No	31 (5–96)	22 (1–64)	4,5	4,0	None	0	No	Satisfaction rate increase 15 – > 80% (PROMS)	DS – 95.0%
Eswara et al. (2015) [9]	19	Yes PRBR (18), CR (11) TCP (42)	26	29	4,25	3,9	5 (26.3%)	N/A	No	60.0% (Pad test)	DS – 15/19 (78,9%)
Linder et al. (2017) [10]	12	Yes TCP (50)	72	26	4,5	4	None	1 (8.3%)	No	Not reported	DS – 60.0%
Krughof et al. (2023) [11]	34	No	72	20	4,5	4	8 (23,5%)	4 (11.8%)	Yes when AUS older than 3 years 24 (70.5%) pts	93.0% improvement 23,5% – 0 pads (PROMS + Pad test)	Erosion – 12.0% DS – 69.0% in the complete replacement group DS – 85.7% in the cuff-only group
Cousin et al. (2023) [12]	99	Yes CR (10) TCP (13) CC (18)	42	80	4,5	N/A	N/A	N/A	Yes (35.0%)	0 pads – 69.6% Improvement – 30.4% (Pad test)	DS – 78,8%
Weis et al. (2024) [13]	25	No	N/A	52	5	4,5	None	3 (12.0%)	Yes when AUS older than 5 years	52% improvement in PROMS	DS – 64.0%
Total	206	3/3	40 (26–72)	38 (20–80)	4,5	4	23.5–26.3%	8.3–12.0%	3/6	50.0–90.0%	64.0–95.0%

CC – cuff change (the same cuff size in the same position); CR – cuff repositioning; PRBR – pressure-regulating balloon replacement; TCP – tandem cuff placement

rospective studies or prospectively maintained databases, which, while useful, provide variable results.

Replacing the pressure-regulating balloon (PRB) as a first step appears to be a straightforward procedure and thus a rational solution for patients with persistent or recurrent SUI. What's more, loss of turgor in the pressure-generating balloon has previously been identified as a potential cause of AUS dysfunction. Bergeson et al. [15] investigated pressure-regulating balloon fatigue and found that during revision surgery, 66.0% of PRBs failed to maintain the manufacturer's specified pressure ratings for the appropriate fluid volumes, potentially leading to reduced urethral coaptation.

Srivastava et al. [14] analyzed data from 168 patients who underwent AUS implantation. Over an average follow-up period of 2.7 years, 63 patients (37.5%) required reoperation due to AUS dysfunction. The most common reasons for revision were balloon failure (36.5%), urethral atrophy (22.2%), and urethral erosion (19.0%). Malfunction of the cuff or pump was diagnosed in 7.9% and 6.3% of patients, respectively. In the group of patients where AUS dysfunction was caused by the failure 1 of its components, the time to revision was twice as long as in patients who experienced urethral erosion or infection (4 years vs 2 years). Based on the study results, the authors developed a strategy for AUS revision that involves replacing only the balloon first, which they believe can reduce surgical trauma and decrease the number of complications in a significant number of patients [14].

However, this approach is often questioned due to the high complication rates reported in other studies. In the study by Moses et al. [16], among 22 patients who underwent PRB replacement with a higher-pressure balloon, the explantation rate was 45.0%.

Another recurrent SUI treatment modality, which may seem appealing due to its simplicity, is increasing the volume of fluid in the system. The proper functioning of the AUS is ensured by the PRB, which is filled with a radiopaque solution or saline during surgery, typically with a volume of 20.0–24.0 ml. Within the filling range of 16.0–24.0 ml, the balloon generates a consistent pressure. Therefore, adding additional fluid to the system may not achieve the desired result or could significantly increase the pressure, thereby raising the risk of urethral erosion [17].

Urethral atrophy is commonly considered the most frequent non-mechanical cause of recurrent SUI following AUS implantation. The reduction in the circumference of the urethra at the cuff site due to chronic compression provides a plausible rationale for the cuff downsizing concept. However, there are studies that question the concept of urethral atrophy. Subcuff urethral capsulotomy presents a challenge to traditional methods for addressing recurrent incontinence. Initially described by Bugeja et al. [7] and later supported by Pearlman and Terlecki [18], this technique involves a midline ventral incision of the capsule, followed by blunt dissection to "refresh" the urethra. This allows for the placement of a new AUS cuff of the same size as the original, along with a new pressure-regulating balloon with the same pressure rating.

Although these maneuvers appear to reduce the risk of urethral erosion, further multicenter studies with larger datasets are necessary to validate these findings.

An alternative approach involves the implantation of a second cuff in close proximity to the original one [19]. Tandem cuff placement has been reported to restore continence in up to 80% of cases. However, it may lead to similar issues at the new, typically more distal location. Additionally, an ischemic segment of the urethra may form between the two cuffs, increasing the risk of urethral stricture at this junction. Data comparing functional outcomes and complication rates between patients who underwent cuff downsizing and those who received tandem cuff placement suggest that both techniques can provide similar functional results with comparable risks of complications.

A study by O'Conner et al. [20] with a small cohort but long follow-up compared 25 men who underwent initial single cuff placement (74 months follow-up) to 22 men who had initial tandem cuff placement (58 months follow-up). The study found no significant difference in continence between the 2 groups, but a higher rate of complications requiring reoperation in the tandem cuff group (7 vs 12 cases) [20]. The length of follow-up may be a crucial factor in accurately capturing the number of complications, as in 2 of the 3 studies discussed above, the follow-up period did not exceed 2 years [9, 10].

Another option is cuff reposition to a more proximal or distal site [21]. However, this may not always be feasible if the remaining portion of the bulbar urethra is compromised or cannot be adequately mobilized. When placed distally, the thinner spongiosum increases the risk of cuff erosion. In cases where dissection around the urethra is not possible, transcorporal cuff placement is an alternative, although this carries a risk of bleeding and may contribute to erectile dysfunction [22].

The final, and perhaps most important, issue is whether to replace a single component of the AUS (such as the cuff) or the entire device. The first

approach may offer advantages such as reduced intraoperative trauma, shorter procedure and recovery times, and lower costs. However, replacing only one component carries the risk of treatment failure if the remaining "old" parts of the AUS malfunction. Additionally, considering the significant complication rate associated with AUS revision, which can reach up to 36.0%, it is reasonable to question whether it is worth exposing the patient to potential further surgical interventions.

The above analysis focuses on a single revision technique for patients who initially received the AMS 800™ Artificial Urinary Sphincter. This study does not address other types of sphincters, whose structural differences may allow for alternative approaches in managing persistent or recurrent SUI.

CONCLUSION

Although the AUS is considered the "gold standard" for surgical management of male SUI, it does not provide stabile long-lasting results for all patients. It is crucial for reconstructive urologist to well-understand all device-related issues and to know the available revision strategies. The aim is to achieve optimal outcomes for patients with the fewest possible interventions and complications.

Traditional revision techniques have limitations, highlighting the need for innovation. The available evidence supports cuff downsizing as a viable revision option for non-mechanical AUS failure, offering outcomes comparable to other techniques. However, patient-specific considerations and informed discussions regarding potential risks are essential.

As the treatment landscape continues to evolve, future efforts should focus on multicenter research collaborations and advancements in device design, particularly in refining the cycling mechanism and pressure regulation.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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ETHICS APPROVAL STATEMENT

The ethical approval was not required.

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