

# **The Treatment of Iatrogenic Male Incontinence: Latest Results and Future Perspectives**

**Guest Editors: Claudio Antonio Giberti, Drogo K. Montague, Ricarda M. Bauer, and Wilhelm A. Hübner**





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## Contents

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**Male Stress Urinary Incontinence: A Review of Surgical Treatment Options and Outcomes**, Landon Trost and Daniel S. Elliott

Volume 2012, Article ID 287489, 13 pages

**Post-Radical-Prostatectomy Urinary Incontinence: The Management of Concomitant Bladder Neck Contracture**, Thomas King and Y. Zaki Almallah

Volume 2012, Article ID 295798, 7 pages

**Comparison between Two Different Two-Stage Transperineal Approaches to Treat Urethral Strictures or Bladder Neck Contracture Associated with Severe Urinary Incontinence that Occurred after Pelvic Surgery: Report of Our Experience**, A. Simonato, M. Ennas, A. Benelli, A. Gregori, F. Oneto, E. Daglio, P. Traverso, and G. Carmignani

Volume 2012, Article ID 481943, 6 pages

**New Artificial Urinary Sphincter Devices in the Treatment of Male Iatrogenic Incontinence**, Ioannis Vakalopoulos, Spyridon Kampantais, Leonidas Laskaridis, Vasileios Chachopoulos, Michail Koptsis, and Chrysovalantis Toutziaris

Volume 2012, Article ID 439372, 6 pages

**Artificial Urinary Sphincter: Long-Term Results and Patient Satisfaction**, Drogo K. Montague

Volume 2012, Article ID 835290, 4 pages

## Review Article

# Male Stress Urinary Incontinence: A Review of Surgical Treatment Options and Outcomes

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*Introduction and Objective.* Iatrogenic male stress urinary incontinence (SUI) affects a percentage of men undergoing urologic procedures with a significant impact on quality of life. The treatment of male SUI has evolved significantly with multiple current options for treatment available. The current paper discusses preoperative evaluation of male SUI, available surgical options with reported outcomes, and postoperative complication management. *Methods.* A PubMed review of available literature was performed and summarized on articles reporting outcomes of placement of the artificial urinary sphincter (AUS) or male slings including the bone anchored sling (BAS), retourethral transobturator sling (RTS), adjustable retropubic sling (ARS), and quadratic sling. *Results.* Reported rates of success (variably defined) for BAS, RTS, ARS, and AUS are 36–67%, 9–79%, 13–100%, and 59–91% respectively. Complications reported include infection, erosion, retention, explantation, and transient pain. Male slings are more commonly performed in cases of low-to-moderate SUI with decreasing success with higher degrees of preoperative incontinence. *Conclusions.* An increasing number of options continue to be developed for the management of male SUI. While the AUS remains the gold-standard therapy for SUI, male sling placement is a proven viable alternative therapy for low-to-moderate SUI.

## 1. Introduction

Urinary incontinence is estimated to affect 12–17% of US males, with increasing prevalence associated with aging [1, 2]. Stress urinary incontinence (SUI) as a subtype has been defined by the International Continence Society as the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing [3]. Although any surgical or radiotherapeutic manipulation of the external urinary sphincter may result in SUI, radical prostatectomy (RP), transurethral resection of the prostate (TURP), and radiation therapy are most commonly associated with RP accounting for the majority of iatrogenic etiologies. The true prevalence of SUI following RP is unknown with widely varying estimates reported from 2 to 43%, which is likely reflective of differing surgical techniques, methodology, definitions, and followup performed, among others [4–9]. External beam radiation therapy and TURP are less commonly associated with SUI, with reported outcomes ranging from 1 to 16% and 1 to 3%, respectively [10–12]. Given that prostate cancer is the most

commonly diagnosed malignancy in US males, the true scope and impact of iatrogenic male SUI on quality of life (QOL) is likely significant.

The treatment of male SUI has continued to improve since the introduction of the first externally worn urethral cuff by Foley in 1949. Subsequent modifications of an internally placed prosthesis by Kaufman in 1973 (Kaufmann III) and an internal reservoir by Rosen in 1976 led to the first completely internalized artificial urinary sphincter (AUS). Despite initial enthusiasm with the procedure, significant complications arose including urethral erosions and fistulae secondary to the continuously elevated urethral occlusion pressures. Subsequent advancements by American Medical Systems (AMS, Minnetonka, Minnesota) with the AS 721 led to reported success rates of 79% among 34 patients treated by Scott and colleagues [13]. Further improvements were later introduced including automatic cuff closure, cuff deactivation, and modifications to the narrow-backed cuff, all of which have continued to improve outcomes while decreasing complication rates. Currently, the most commonly utilized

AUS is the AMS 800 (AMS, Minnetonka, Minnesota) which consists of a pump, reservoir, and urinary cuff. Since its popularization, the AUS has remained the gold-standard treatment for male SUI.

Beginning in the late 1990s, the male sling was introduced as a surgical alternative to the AUS for patients with low volume incontinence (1–3 pads). Among other factors, one notable difference with male slings compared to the AUS is the lack of mechanical components, which reduces the potential for device failure. Although several variations on sling design exist, the most commonly published series available report on three specific designs, the suburethral bone-anchored slings (BAS), retourethral transobturator slings (RTS), and adjustable retropubic slings (ARS).

With an increasing number of options available for the treatment of male SUI, it is important for treating clinicians to be aware of available therapeutic options, comparative outcomes, and associated complications. The current paper is outlined to review the clinical evaluation of males presenting with SUI, discuss the male sling and AUS as treatment options, review reported outcomes on therapies, briefly discuss management of common postoperative complications, and highlight potential future perspectives.

## 2. Clinical Evaluation

Males presenting with stress urinary incontinence should undergo a complete history and physical examination to include reviewing the underlying etiology and duration of the incontinence, current and prior urinary symptoms, history of genitourinary pathology (ex, nephrolithiasis, urothelial carcinoma), urinary tract infections, the degree and subjective bother of incontinence, and a review of prior procedures including radiation. Additional quantitative measures which may be employed include obtaining pad weights and standardized QOL questionnaires [14–16]. Patients should further undergo a genitourinary examination and be assessed as to their physical and mental capacity to function a potential AUS device.

Further testing may be individualized based on results obtained during the history and physical examination. All patients should undergo a routine urinalysis and postvoid residual to rule out concurrent infection and any degree of urinary retention. Additional testing may be obtained as clinically indicated including imaging (ex, history of nephrolithiasis, urothelial carcinoma), urine cytology (ex, irritative voiding symptoms, history of urothelial carcinoma), and PSA. Urodynamics studies are not routinely performed and are predominantly reserved for cases of suspected elevated bladder pressures or indeterminate/multifactorial etiologies for incontinence [17]. It is the author's practice to perform a cystoscopy on all patients considering surgical treatments for SUI to rule out anatomic abnormalities (ex, stricture, bladder neck contracture). Additionally, this permits filling of the bladder with saline followed by direct observation of the degree of stress urinary incontinence experienced.

Surgical candidates desiring a male sling or artificial urinary sphincter should be 6–12 months out from the

initial event resulting in SUI as this permits resolution of concomitant urinary symptoms and allows sufficient time for spontaneous recovery of continence. Additionally, patients should ideally have a normal bladder capacity and compliance, have isolated SUI without significant urgency, be free of intraurethral and/or intravesical pathology, have sufficient physical and mental capacity to function a potential device, and be able to maintain his activities of daily living without need for assistance. Although none of these factors would preclude surgical intervention, each should be weighed in the clinical decision so as to reduce potential future complications. Patients with prior histories of urothelial carcinoma, nephrolithiasis, urethral stricture disease, and bladder neck contractures, among others should demonstrate a sufficient period of disease stability prior to consideration of sling/AUS placement to reduce the risk of erosions resulting from repeated interventions.

## 3. Treatment Options

Although numerous treatment options for male SUI exist, including penile clamps, transurethral bulking agents, or catheters (condom or indwelling), the most commonly utilized surgical therapies performed include placement of a male sling or AUS.

*3.1. Male Sling.* Since its initial introduction, the male sling has become increasingly utilized in cases of low-to-moderate volume (1–3 pads/day) incontinence. Although several variations of the male sling are currently available, the three subtypes with the most reported series available include the BAS, RTS, and ARS.

Bone-anchored slings result in compression to the bulbar urethra through placement of a synthetic or organic mesh which is secured to the inferior pubic ramus using six titanium screws. Sutures are subsequently secured to the screws and mesh material and tightened to result in appropriate tensioning. Following initial reports of degradation of organic materials, synthetic mesh (InVance; AMS, Minnetonka, Minnesota) has become the most commonly utilized material with the BAS [18]. See Figure 1 for graphical representation of BAS placement.

A second category of available male slings includes the RTS, with the AdVance (AMS, Minnetonka, Minnesota) and I-Stop TOMS (CL Medical, Lyon, France) slings most commonly employed. In contrast to the BAS which utilizes anchored sutures, the RTS is self-anchored with bilateral polypropylene mesh arms placed in a transobturator fashion. The sling portion is secured at the proximal bulbar urethra with continence achieved through subsequent elevation of the urethra.

Several reports have examined preoperative characteristics, surgical techniques, and postoperative management principles which have been associated with improved outcomes with RTS placement [29–31]. Preoperative characteristics found to be predictive of worsened outcomes include weakened residual sphincter function, incomplete sphincter closure, and lack of elongation of the coaptive sphincter

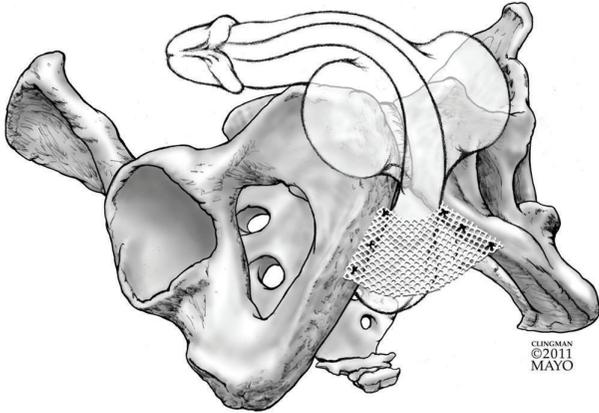


FIGURE 1: Graphical representation of the bone-anchored sling.

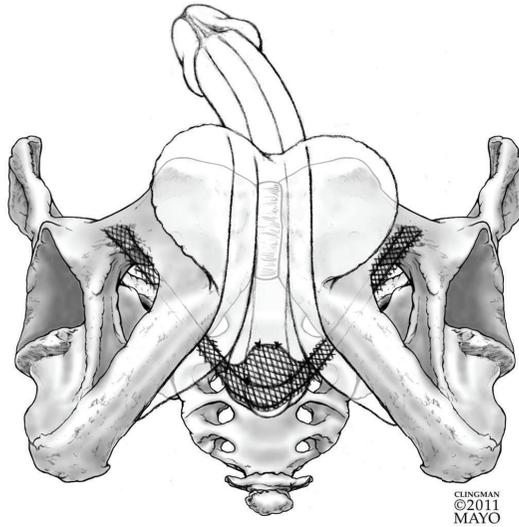


FIGURE 2: Graphical representation of the retrourethral transobturator sling.

zone. Intraoperative and postoperative factors associated with improved outcomes include tunneling of the sling arms into subcutaneous tissues to improve fixation, placing five or more stitches, using nonabsorbable stitches, and minimizing postoperative activity to reduce dislodgement. See Figure 2 for graphical representation of RTS placement.

Similar to RTS, ARS (Reemex, Neomedic International, Terrasa, Spain; and Argus, Promedon SA, Cordoba, Argentina) are surgically placed at the proximal bulbar urethra, with traction sutures placed retropubically. The sutures are then tensioned at the level of the rectus fascia utilizing either a “veritensor” (Reemex) device or silicone columns and washers (Argus) to provide an appropriate level of urethral compression. See Figure 3 for graphical representation of ARS placement.

A fourth category of sling which has recently been introduced is the quadratic sling (Virtue, Coloplast, Humlebaek, Denmark). The sling consists of a broad-based mesh material placed over the bulbar urethra similar to the BAS. It is

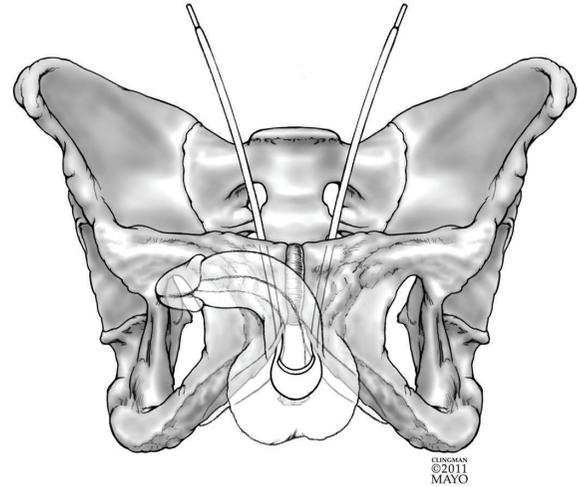


FIGURE 3: Graphical representation of the adjustable retropubic sling.

then self-secured with four mesh arms which are placed in both a transobturator (two arms) and prepubic (two arms) manner. The limbs may then be further secured to create additional points of fixation as needed. See Figure 4 for graphical representation of quadratic sling placement.

The hypothesized mechanism for improved continence with the various sling designs varies and is not thoroughly understood. Bone-anchored slings likely achieve direct compression of the bulbar urethra with subsequent increases in outflow resistance. In contrast, the mechanism for the RTS is based on the hypothesis that mild/moderate SUI results from compromise of periurethral supporting structures [32]. Through proximal placement of the mesh material, the dynamics of the bulbar urethra are modified to result in functional extension of the membranous and angulation of the bulbar urethra. The mechanisms for improved SUI with the ARS and quadratic sling are currently unknown and may result from a combination of urethral compression and angulation.

**3.2. Artificial Urinary Sphincter.** Since its popularization in 1978, the AUS has arguably remained the gold-standard therapy for SUI. The currently available model, AMS 800 (AMS, Minnetonka, MN), consists of a pump, pressurized reservoir, and sphincter cuff. Cuff sizes range from 3.5 to 14.0 cm, and the reservoir is available in five pre-set pressures (41–50, 51–60, 61–70, 71–80, and 81–90 cm H<sub>2</sub>O) to adapt to various patient requirements. When cycled, the pump functions to actively shunt fluid from the cuff to the reservoir via a unidirectional valve, which additionally prevents uncontrolled retrograde transmission of fluid to the cuff. A refill-delay resistor maintains the cuff in an open state to permit voiding and subsequently permits transfer of fluid from the reservoir to the cuff. The pump also contains a deactivation button which permits the cuff to be placed in a locked “open” state when needed or to potentially

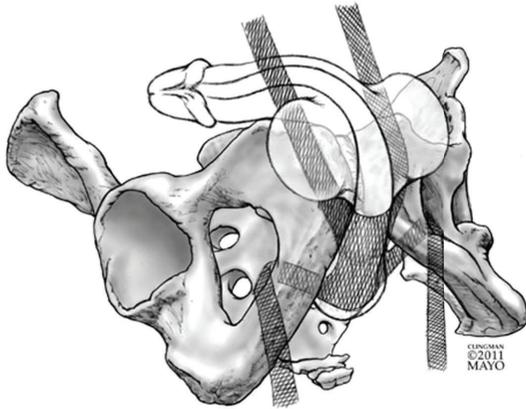


FIGURE 4: Graphical representation of the quadratic sling.

reduce urethral atrophy [40]. See Figure 5 for graphical representation of AUS single cuff placement.

Placement of the AUS is performed via a similar dissection to that of male sling insertion. The proximal bulbar urethra is identified, isolated, and measured, and an appropriately sized cuff is placed circumferentially. The reservoir is placed deep to the rectus sheath, and the pump is located in the inferior hemiscrotum. Contrast may be instilled in lieu of saline to permit future trouble shooting of the device, and the device is connected and cycled. Variations to placement of the AUS are frequently utilized in cases of recurrent incontinence following prior AUS placement, urethral atrophy, or prior device erosions/infections. In these settings, an AUS may be placed in “tandem” with an existing AUS and secured to the reservoir and pump with a Y-connect device [41]. See Figure 6 for graphical representation of AUS tandem cuff placement. Alternatively, a transcorporeal dissection of the proximal bulbar urethral may be performed or alternative materials may be placed around the urethra including porcine small intestinal submucosa at the time of AUS cuff placement to provide additional tissue bulk [42–44].

In patients presenting with persistent incontinence following prior sling placement, an AUS may be placed, with dissection performed similar to a primary AUS procedure. In cases where the prior mesh is encountered, this may be incised without need for complete excision, and the cuff placed in the standard fashion.

#### 4. Results

Multiple series are currently available reporting outcomes of the various male sling techniques and AUS implantation. However, given the nature of the studies performed and methodology for reporting, outcomes should be interpreted with caution. There is currently no accepted standard method for reporting pre- and postoperative degrees of incontinence or any consistent method for defining success with treatment. The majority of studies have poorly or undefined inclusion/exclusion criteria with significant heterogeneity of the patient population including inconsistent inclusion of

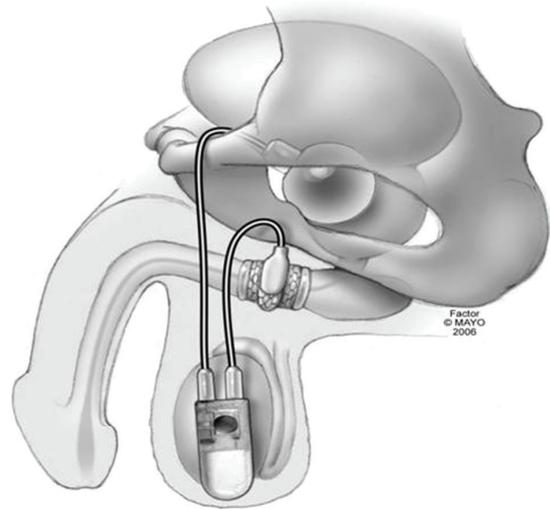


FIGURE 5: Graphical representation of the single-cuff artificial urinary sphincter.

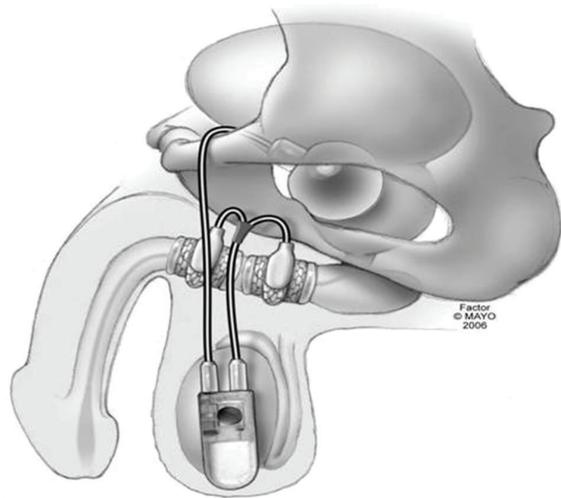


FIGURE 6: Graphical representation of the tandem-cuff artificial urinary sphincter.

patients with varied etiologies for SUI or prior radiation therapy. These factors, among others, limit the ability to draw comparisons between studies and techniques.

**4.1. Male Sling.** As the BAS has been available and utilized for a longer period of time than other slings, more studies are currently available for review with longer mean/median follow up periods. For the purposes of the current review, studies were included if they were published within the past 10 years and examined synthetic sling placement only, as organic sling material is no longer commonly employed.

Overall results of the BAS demonstrated cure rates ranging from 37 to 67% with improvement noted in an additional 10–40% [19–28]. The wide range of results is likely secondary to surgical method, definitions for continence utilized and

also may be due to a migration of case complexity. More recent reports have included an increased number of patients with prior radiation therapy and those with more severe preoperative incontinence. Several studies have noted significance in the association of preoperative continence and postoperative success rates with conflicting reports on the impact of radiation on overall success. Complications commonly reported include infection (2–15%), erosion (0–3%), de novo urgency/overactivity (0–14%), pain (0–73%) which typically resolves within 4 months, and sling removal (0–13%). See Table 1 for comparison of outcomes among patients undergoing BAS placement.

Results from placement of the RTS have similarly demonstrated resolution or improvement in males with mild-to-moderate SUI in 9–62% and 16–46% of patients, respectively [33–39, 58]. With the notable exception of Cornel and colleagues who reported a success rate of 9% and failure rate of 46% among 35 patients, other studies report higher cure rates of 52–74% with improvements noted in and additional 16–27%. Complications reported with the RTS include temporary urinary retention <2 weeks (0–24%), urethral injury (0–3%), pain (0–34%), need for sling removal (0–4%), and dysuria (0–14%).

It is notable that four studies examining RTS were prospectively designed, with three accruing over 110 patients [33, 34, 38, 58]. As with the BAS groups, improved outcomes were noted among patients with decreased preoperative incontinence, with a trend towards increased failures noted among patients with preoperative radiation therapy [38].

Two studies of interest investigated the role for RTS as a salvage technique in cases of recurrent incontinence following prior anti-incontinence surgery. Christine and colleagues reviewed 19 patients undergoing RTS in patients with recurrent incontinence following prior AUS placement [35]. Patients had self-reported pre-op pad usages of 2–5 ppd. Following RTS placement, 15/19 (79%) reported requiring 0 ppd, with the remaining 4/19 (21%) describing improvement. Approximately half of the patients did not require reactivation of the sphincter.

Similarly, Soljanik and colleagues reported on 29 patients undergoing RTS following a previously failed sling procedure with preoperative mean pad requirement of 4.3 ppd. At 17 months followup, results demonstrated resolution of incontinence in 10/29 (35%) with improvement noted in an additional 16/29 (55%). These studies highlight the potential role for male sling placement as a potential adjunctive/salvage treatment; however, further validation is required prior to its consideration as a routine salvage measure. See Table 2 for comparison of outcomes among patients undergoing RTS placement.

A third category of currently available slings includes the ARS, with the Argus (Promedon SA, Cordoba, Argentina) and Reemex (Neomedic International, Terrasa, Spain) slings most commonly utilized. Results of initial and longer-term followup demonstrate success rates of 13–100% with larger series reporting rates of 54–79% [45, 47–52]. Patients required adjustments in 10–100% of cases, many of which required repeated anesthesia. Complication rates were noted to be significantly higher compared to other sling categories

with infections (5–7%), erosion (3–13%), explantation (2–35%), bladder perforation (5–29%), retention (35%), and perineal pain (4–38%) most commonly reported. See Table 3 for comparison of outcomes among patients undergoing ARS placement.

One study of interest conducted by Tuygun and colleagues retrospectively compared the Argus (Promedon SA, Cordoba, Argentina) sling to the AMS 800 (AMS, Minnetonka, Minnesota) AUS [46]. A total of 16 patients with prior AUS erosions were treated with either ARS ( $n = 8$ ) or repeat AUS ( $n = 8$ ). Results demonstrated cure rates of 5/8 (63%) versus 1/8 (13) and improvement rates of 2/8 (25) versus 1/8 (13) for the AUS and sling, respectively.

A more recently released sling is the Virtue quadratic sling (Coloplast, Humlebaek, Denmark) with minimal data available on initial outcomes. The only currently published study was performed by Comiter and colleagues who reported initial outcomes of 22 patients undergoing sling placement with pre- and postoperative retrograde leak point pressures tested [59]. Results demonstrated improvements in the leak point pressure from preoperative  $33 \pm 9$  to  $69 \pm 6$  cm H<sub>2</sub>O. Although these results are an encouraging proof of concept, further data is currently pending.

**4.2. Artificial Urinary Sphincter.** Multiple series have reported on long-term AUS outcomes [53–57]. As the AUS has been available for use for a longer period of time than the male slings, mean follow-up periods are greater and range from 3 to 7.7 years. Similar to the reports on male slings, the definition for postoperative continence varies by study, with the most commonly utilized definition of 0–1 pads as being “continent.” Results demonstrate overall continence rates of 59–91% with the two studies which included over 100 patients reporting 69% and 82% success [54, 56]. Kim and colleagues reported on the long-term durability of the AUS and noted that patients with <4 years of follow-up experienced continence rates of 76% which increased to 89% in those with >8 years followup. This result appeared to correlate with the finding that the far majority of surgical revisions required were performed in the first 36–48 months with an overall, long-term mechanical failure rate of 36% noted at 10 years [54].

Similarly, Lai and colleagues reported on 270 patients with a mean followup of 3 years including some patients with >12 years followup [56]. Mean preoperative and postoperative pad use was 5.3 and 1.1 ppd, respectively. Thirty-four percent (60/176) of patients who presented with postprostatectomy incontinence (PPI) had undergone prior radiation therapy, with 34% and 43% of all PPI patients demonstrating detrusor instability and decreased bladder compliance on urodynamic studies, respectively. Patients who had previously undergone peri-urethral bulking agent administration or male sling placements did not demonstrate a decreased success rate compared to those who had not undergone similar procedures. Twenty-two percent (59/270) of patients ultimately required repeated surgical intervention secondary to complications at a median time of 14.4 months.

TABLE 1: Comparison of results of bone anchored sling placement in adult males with SUI.

Study	Pts (No.)	Mean/med f/u (mo)	Pre-op continence (mean/med)	Success def	Success (%)	Improved (%)	No improvement (%)	Complications (%)	Notes
Cespedes and Jacoby [19]	58	6			26 (45)	11 (19)	21 (36)	None	
Ullrich and Comiter [20]	36	25	≥3 ppd	0 ppd	24 (67)	9 (25)	3 (8)	None	Mean pads decreased from 4.6 to 0.64
Comiter [21]	48	48	≥3 ppd	0 ppd	31 (65)	10 (21)	7 (15)	Infection 1 (2), erosion 1 (2), perineal pain × 3 months 7 (16), 2 (4) screw dislodgement	Mean pads decreased from 4.6 to 1.0
Castle et al. [22]	38	18		≤1 ppd	15 (40)			Infection 3 (8), erosion 1 (3), majority with significant perineal pain × 3-4 mo	
Gallagher et al. [23]	31	15		≤1 ppd	18 (58)			Infection 2 (6), Sling removal 4 (13)	3 pts lost to f/u, 4 pts w/sling removal
Fischer et al. [24]	62	15	Pad wt 352 g ± 43	PGI-I 1 question	36 (58)	6 (10)	26 (42)	Infection 3 (5), erosion 1 (2), pain >5 months 5 (8), total 13 (21)	Prospective study; 71% chance of success if preop pad weight <423 g
Guimarães et al. [25]	62	28		0 ppd	40 (65)	14 (23)	8 (13)	Infection 2 (3), pain 12 (19), bone anchor dislodgement 1 (2)	3 year f/u w/21/30 (70), 4 year 8/12 (67) successful
Giberti et al. [26]	40	35		pad weight 0-1 g	22 (55)	5 (13)	13 (33)	Infection 6 (15), de novo detrusor overactivity 2 (5), pain 29 (73)	
Athanasopoulos et al. [27]	43	24	See notes	≤1 ppd	22 (51)	8 (19)	13 (30)	Infection 5 (12), ne novo urgency 6 (14), pain 1 (2)	Pre-op incontinence: 1-2 pads in 6/43 (14), 3-5 pads in 23/43 (53), and ≥6 pads in 14/43 (33)
Carmel et al. [28]	45	36		0 ppd	16 (36)	18 (40)	11 (24)	Infection 1 (2), pain ≤ 3 months 10 (22)	12 pts (27%) w/preop radiation

Common complications following AUS placement include urethral atrophy resulting in recurrent incontinence (4–10%), erosion (4–10%), infection (1–14%), and mechanical failure (0–29%). See Table 4 for comparison of outcomes among patients undergoing AUS placement.

Numerous additional studies have reported on salvage therapies available for prior AUS failures including tandem cuff placement, cuff downsizing, transcervical cuff, and the use of biologic materials as a urethral bulking agent [41–43, 60–62]. Although a formal review of salvage therapies

TABLE 2: Comparison of results of retrourethral transobturator sling placement in adult males with SUI.

Study	Pts (No.)	Mean/med f/u (mo)	Pre-op continence (mean/med)	Success def	Success (%)	Improved (%)	No improvement (%)	Complications (%)	Notes
Rehder et al. [33]	118	12	2.3 ppd	≤1 ppd	87 (74)	20 (17)	11 (9)	Retention 6 (5), perineal pain 23 (20)	Prospective
Cornel et al. [34]	35	12		0 ppd, <2 g urine loss/day	3 (9)	16 (46)	16 (46)	Removal 1 (3), retention 1 (3), mod-severe pain <3 months 12 (34)	Prospective, 2-center study
*Christine and Knoll [35]	19	13		0 ppd	15 (79)	4 (21)	0 (0)	None	Pts w/recurrent incontinence after AUS placement
*Soljanik et al. [36]	29	17	4.3 ppd	0 ppd	10 (35)	16 (55)	3 (10)	Urethral injury 1 (3), retention <2 wks 9 (24)	Pts previously failed sling placement
*Bauer et al. [37]	24	18	4.5 ppd	≤1 ppd	6 (25)	6 (25)	12 (50)	Removal 1 (4)	All patients with RP and adjuvant radiotherapy
Cornu et al. [38]	136	21	2.1 ppd	0 ppd	84 (62)	22 (16)	30 (22)	Pain 14 (10), dysuria 19 (14)	Prospective study; failure ass'd w/24-hr pad >200 g, trend toward radiation therapy
Bauer et al. [37]	126	27	4.9 ppd	≤1 ppd	65 (52)	30 (24)	31 (25)	Removal 2 (2), retention <10 wks 19 (15), persistent pain 1 (1)	Prospective study; 17 pts (14%) with pre-op radiation
Berger et al. [39]	26	22	5.6 ppd	0 ppd	16 (62)	7 (27)	3 (12)	Pain ≤4 weeks 5 (19)	

\* Salvage patient populations.

and outcomes is beyond the scope of the current review, one recent study with long-term followup examined primary single versus double cuff AUS placement and found no statistical difference in continence outcomes between treatment groups [55]. This would argue against the routine placement of tandem cuffs as a primary treatment modality. Similarly, the above procedures are predominantly reserved for use as a salvage technique rather than primary therapy.

Many studies have reported significant improvements in quality of life measures with both the male sling and AUS [28, 37, 39, 49, 63]. This likely highlights the significant impact that SUI has on overall quality of life as well as the improvements noted with its treatment. It is also important to note that with either male sling or AUS placement, it is uncommon to experience a complete resolution of incontinence with a return to preexisting baseline continence levels. As such, it is important to appropriately counsel patients

as to reasonable postoperative expectations and potential complications.

## 5. Complications

Complications resulting from either male sling or AUS implantation may be categorized as occurring intraoperative, early postop (<90 days) or late postop (>90 days). Intraoperative complications may include urethral injury occurring at the time of urethral dissection or passage of a trocar for male sling placement. If a small injury is recognized, placement of the AUS/male sling may continue at a separate site to prevent subsequent erosions. A large urethral injury should be repaired primarily with the procedure aborted and a catheter placed. Bladder injuries occurring during trocar passage may be managed with repassing of the trocar and subsequent

TABLE 3: Comparison of results of adjustable retropubic sling placement in adult males with SUI.

Study	Pts (No.)	Mean/med f/u (mo)	Pre-op continence (mean/med)	Success def	Success (%)	Improved (%)	No improvement (%)	Complications (%)	Notes
Romano et al. [45]	48	45		0 ppd	31 (66)	6 (13)	10 (21)	Infection 3 (6), erosion 6 (13), removal 9 (19), pain 2 (4)	Argus sling; adjustment required in 5 (10)
*Tuygun et al. [46]	8	10	6.8 ppd	0 ppd	1 (13)	1 (13)	6 (75)	Pain 3 (38)	Argus sling; pts w/prior AUS erosion; study compares AUS to sling as salvage option
Bochove-Overgaauw and Schrier [47]	95	27	See notes	≤1 ppd	51 (54)	17 (18)	27 (28)	Infection 6 (6), erosion 3 (3), removal 11 (12), total 55 (58)	Argus sling; Pre-op continence: 1-2 ppd in 13/100, 3-5 ppd in 46/100, and 6-10 ppd in 41/100
Dalpiaz et al. [48]	29	35	5 ppd		5 (17)			Infection 2 (7), erosion 3 (10), bladder perforation 3 (10), retention 10 (35), removal 10 (35), significant pain 8 (27)	Argus sling; Dissatisfied with clinical outcome 21 (72)
Hübner et al. [49]	101	25		≤1 g 20-min pad test	80 (79)			Bladder perforation 5 (5), infection 5 (5), erosion 13 (13), removal 16 (16), pain <3 wks 15 (15)	Argus sling; adjustment required in 39 (39)
Sousa-Escandón et al. [50]	51	32		≤1 ppd	33 (65)	10 (20)	8 (16)	Infection 3 (6), removal 1 (2), bladder perforation 5 (10), majority with perineal pain	Remeex sling; multicenter study; adjustment required in 51 (100)
Verdejo et al. [51]	5	15	5-8 ppd	≤1 ppd	5 (100)				Remeex sling
Parra et al. [52]	15	19			5/12 (42)	4/12 (33)	3/12 (25)	Removal 3 (21), readjustment 12 (86), bladder perforation 4 (29), retention 5 (36)	Remeex sling

PPD: pads per day; PGI-I: Patient Global Impression of Improvement; RP: radical prostatectomy; RLPP: retrograde leak point pressure.

\*Represents specialized/salvage patient populations.

TABLE 4: Comparison of results of single-cuff AUS placement in adult males with SUI.

Study	Pts (No.)	Continence def (pads/day)	Mean follow-up (yr)	Success (%)	Explantation (%)	Complications	(%)
Arai et al. [53]	58	≤2	4.2	91.4	20.3	Mechanical failure	6.5
						Infection	14
						Erosion	4.7
Kim et al. [54]	124	0-1	6.8	82	36 (incl revision)	Mechanical failure	29
						Infection	7
						Erosion	10
O'Connor et al. [55]	25	0-1	6.2	61	16	Mechanical failure	0
						Infection	8
						Erosion	8
						Atrophy	4
Lai et al. [56]	218	0-1	3	69	27.1 (incl revision)	Mechanical failure	6
						Infection	5.5
						Erosion	6
						Atrophy	9.6
Gousse et al. [57]	71	0-1	7.7	59	29 (incl revision)	Mechanical failure	25
						Infection	1.4
						Erosion	4

catheterization for a period of several days postoperatively. Given the relative incidence of bladder injury with retropubic sling placements, patients undergoing these procedures should undergo intraoperative cystoscopy to rule out bladder perforation.

Early postoperative complications include urinary retention, infection and/or erosion, perineal pain, and de novo detrusor overactivity. Urinary retention typically occurs secondary to postoperative edema and resolves spontaneously in the majority of cases. Persistent retention lasting >8 weeks may indicate inappropriate sizing of the sphincter cuff, overtensioning of the sling, or sling malposition. Retention is typically managed with in-and-out catheterization with suprapubic tube placement required in rare cases. In the case of AUS placement, it is the authors' preference to avoid indwelling catheters and to use a small (12 F) straight catheter when required in the postoperative period to reduce the risk of development of catheter-related erosions.

Infections of the AUS device or sling material may be secondary to unrecognized urethral erosion versus intraoperative contamination. Preoperative patient factors including repeated device placements, prior erosions, and radiation therapy all predispose patients towards a higher rate of postoperative infections. The most commonly isolated organisms with infection include *S. aureus*, *S. epidermidis*, Enterococcus, Methicillin resistant *S. aureus*, and gram-negative bacilli [64]. Infections occurring beyond 90 days may be related to

hematogenous spread of bacteria at the time of additional procedures.

Urethral erosions occurring early in the postoperative period are likely secondary to unrecognized urethral injury occurring at the time of surgical implantation. Device erosions require explantation, even in the absence of infection, with possible repeat AUS/sling placement performed several months later pending sufficient recovery and absence of urethral stricture development.

Postoperative perineal pain is more common with male sling placement than AUS, with some authors noting pain in 100% of male sling patients for periods up to 4 months. Patients may additionally develop de novo detrusor overactivity, which may be managed with anticholinergic therapy as indicated.

Mechanical failure is unique to AUS devices and has been shown in one long-term followup of 100 patients undergoing AUS to have 5- and 10-year device failure-free rates of 74.8% and 70.1%, respectively [53]. Additional studies with follow-up periods >5 years confirm similar findings of device failure rates of 25–34% [54, 57, 65].

## 6. Patient Stratification

The decision as to which procedure to perform in males presenting with stress urinary incontinence is based on several factors. Most commonly, male slings are offered in

cases of lower-volume incontinence (1–3 pads/day), or in the setting of complicating patient factors including inability to function the AUS pump. Placement of an AUS may be performed with any degree of SUI and may be employed in the setting of prior male sling failures.

There is currently no universally accepted standard by which patients are stratified into receiving a male sling versus AUS. Similarly, there are no currently accepted objective measures by which men are formally evaluated for stress incontinence. Evaluating clinicians may elect to stratify patients based on subjective reporting of pad usage, objectively obtained 24-hour pad weights, or by the degree of SUI visualized on examination. This lack of consensus on the clinical evaluation of males with SUI is mirrored in the available published literature which similarly lacks an accepted method of standard reporting.

Additionally, there are currently no publications which directly compare results for the various treatments of male SUI, and as such, it is not possible to directly compare reported outcomes between studies. Based on the reported literature available, it is not possible to definitively identify one sling procedure as superior over another.

In general, available data on the various male slings have shown a reduction in overall efficacy in patients with pre-surgical, higher volume incontinence (discussed further in Section 4), and therefore AUS is typically chosen in these cases. Alternatively, male slings may be preferred in cases of diminished hand and/or cognitive ability, regardless of degree of incontinence as this may avoid potentially serious complications of urinary retention and its sequelae. Given the lack of data and guidelines, the decision as to whether to perform a male sling versus AUS depends on several factors including patient preference, surgeon comfort, and experience with the available procedures, and knowledge of the currently available outcomes and complications of each procedure.

Regardless of the treatment selected, it is important to review with patients appropriate immediate and long-term expectations following the procedure as well as potential complications and need for additional procedures.

## 7. Future Perspectives

The treatment of male SUI has evolved significantly over the past 40 years, with numerous improvements made to the AUS and multiple variations of the male sling developed in a relatively short period of time. And given the prevalence of prostate cancer with need for ongoing treatments, there will likely remain a significant need for treatment of iatrogenic SUI for the foreseeable future. It is anticipated that there will be ongoing improvements to the AUS to increase device longevity, reduce infectivity, and to better cater to patients with limited manual/mental capability. It is similarly expected that new variations and improvements to the existing male slings will continue to be developed, with further studies performed providing additional and longer-term followup on previously installed slings.

Novel techniques and materials will emerge to meet the ongoing need for alternative, minimally invasive, and adjustable options for management of low-to-moderate volume incontinence. This is particularly relevant in the setting of the recent FDA announcement in July of 2011 regarding utilization of mesh in pelvic organ prolapse. This may directly or indirectly impact the utilization of mesh material in other applications, including male sling placement.

More recently, investigators have examined the potential use of stem cell therapy to directly treat the underlying disease process. Several investigators have reported on the successful creation of muscle- or adipose-derived stem cells and hypothesized their potential use as a regenerative treatment for iatrogenic injury to the native rhabdosphincter [66–69]. Yamamoto and colleagues reported the use of adipose-derived stem cell injection into the periurethral tissues of two men with SUI following RRP performed at least two years prior [70]. With limited followup at 12 weeks, both men experienced significant improvements in measured pad weights over a 4-day period. Although this study has significant limitations including the lack of a control group treated with periurethral bulking injection with adipose tissue alone, findings such as these will likely lead to additional research on the potential for stem cell therapy.

Similar to stem cell therapy, additional investigations continue in identifying alternative bulking agents for use as a periurethral injectable material [71]. Watanabe and colleagues recently reported improved objective findings in rats treated with adipose-derived mesenchymal stromal cells compared to those treated with standard collagen injections [72]. Although these treatments remain in the early stages of research, they offer potential significant advantages over currently available surgical therapies given their minimally invasive approach without need for synthetic material/device implantations.

## 8. Conclusions

Iatrogenic male stress urinary incontinence remains a significant problem impacting a large number of patients with resultant impairment of quality of life. Patients presenting with SUI should undergo a thorough history and physical examination with additional studies obtained as indicated. Several therapies are currently available for the treatment of low-to-moderate volume incontinence including the AUS and several variations of male slings (BAS, RTS, ARS, and quadratic sling). Patients with large-volume incontinence are best managed with AUS when found to be an appropriate surgical candidate. Complications of sling/AUS placement include temporary retention, perineal pain, infections, erosions, de novo urinary symptoms, and device malfunction. Patients desiring surgical management of SUI should be counseled as to expected outcomes as well as potential complications.

## Abbreviations

ARS:	Adjustable retropubic sling
AUS:	Artificial urinary sphincter
BAS:	Bone-anchored sling
PPD:	Pad(s) per day
PPI:	Postprostatectomy incontinence
SUI:	Stress urinary incontinence
RP:	Radical prostatectomy
RTS:	Retrourethral transobturator sling
TURP:	Transurethral resection of the prostate.

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## Review Article

# Post-Radical-Prostatectomy Urinary Incontinence: The Management of Concomitant Bladder Neck Contracture

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Urinary incontinence postradical prostatectomy is a common problem which adversely affects quality of life. Concomitant bladder neck contracture in the setting of postprostatectomy incontinence represents a challenging clinical problem. Postprostatectomy bladder neck contracture is frequently recurrent and makes surgical management of incontinence difficult. The aetiology of bladder neck contracture and what constitutes the optimum management strategy are controversial. Here we review the literature and also present our approach.

## 1. Introduction

Despite advances in surgical technique in recent years, urinary incontinence remains a relatively common complication following radical prostatectomy [1]. The true incidence of postprostatectomy incontinence (PPI) is difficult to ascertain owing to the lack of a single definition of what actually constitutes continence after radical prostatectomy. EAU guidelines define continence following radical prostatectomy as either total control with no leakage or pad usage, no pad use but loss of a few drops of urine, or use of up to one “safety” pad per day [2]. Nevertheless radical prostatectomy does represent the commonest cause of stress urinary incontinence in men [3], and it has been estimated that 14–20% of men who undergo radical prostatectomy will use absorbent pads on the long term to manage incontinence [4]. With the increasing number of radical prostatectomies currently performed, the incidence of PPI is also likely to rise [1].

PPI can have devastating effects on quality-of-life patients treated for prostate cancer and may result in considerable psychological morbidity [5]. PPI itself can be difficult to treat, and concomitant bladder neck contracture (BNC) presents an even more challenging clinical problem. The presence of a BNC itself may impact upon continence, and persistent contractures complicate the surgical management

for PPI. In addition, treatment for recurrent and intractable BNC may result in de novo incontinence which then needs to be addressed.

Controversy exists as to both the underlying aetiology of bladder neck contracture and also how best to manage it. In this article we paper the literature and present our approach.

## 2. Aetiology of Bladder Neck Contracture

Bladder neck contracture, bladder neck stenosis, and anastomotic stenosis are synonymous terms and constitute a well-recognised complication following radical prostatectomy with a reported incidence of 0–32% [6–10]. Various technical and patient-based factors have been found to be associated with the formation of bladder neck contracture. However, few factors are reported with consistency between different studies and the precise aetiology remains to be firmly established.

Of the technical factors thought to play a role, the surgical approach seems to be of particular importance. Minimally invasive laparoscopic and robot-assisted laparoscopic techniques have a lower reported incidence of BNC when compared to open surgery [10–12]. Indeed in a recently published series of 4592 patients, Sandhu et al. reported surgical

approach to be the strongest predictor for subsequent development of BNC with a hazard ratio of 0.11 for laparoscopic versus open surgery ( $P < 0.001$ ) [13]. Better visualisation whilst carrying out the anastomosis allowing more accurate mucosal apposition, a continuous suturing technique, and overall reduced intraoperative blood loss have all been cited as possible reasons for the difference seen between open and laparoscopic techniques [11, 14].

Other technical factors reported to be associated with development of BNC include degree of blood loss and haematoma formation [7, 8, 13, 15], calibre of the reconstructed bladder neck [15], and early urinary retention following catheter removal [16]. Urinary extravasation has been reported as important in several studies [7, 8, 13]; however, others have found that the degree of urinary extravasation is unrelated to BNC development provided a urinary catheter is left in place until extravasation is seen to resolve on cystography [15].

Borboroglu et al. have reported significantly higher rates of post-radical-prostatectomy BNC in smokers, those with ischaemic heart disease, hypertension, and diabetes [17] prompting the hypothesis that its development may be a manifestation of microvascular disease. Similarly, a multivariate analysis by Sandhu et al. found that age, body mass index, and comorbidity in particular preexisting renal disease were predictive for formation of BNC [13]. In contrast, in a series of 650 robot-assisted laparoscopic radical prostatectomies, Msezane et al. found no difference in age and body mass index between those who developed BNC and those who did not [14]. Other patient-based factors cited as contributory include previous TURP [7, 8] and a propensity to undergo hypertrophic scarring [18]. Tumour stage [8] and Gleason score [15] do not appear to be significantly associated with BNC development.

Clearly development of BNC following radical prostatectomy is not due to one single factor but is a result of an undoubtedly complex interplay between baseline patient characteristics and technical factors. However, the surgical aim of creating a tension-free, watertight anastomosis with good mucosal apposition and minimal devascularisation of the bladder neck must be seen as the best starting point for minimizing its occurrence.

### 3. Presentation and Effect of Bladder Neck Contracture on Urinary Continence

BNC typically presents with lower urinary tract symptoms in particular reduced stream shortly following radical prostatectomy or ultimately retention of urine. Retrospective series have reported that the majority of BNCs present within 6 months following prostatectomy [18, 19]. In a series with prospective followup, Giannarini et al. reported development of BNC at a median time of 3.8 months after radical prostatectomy [20]. Investigations usually reveal a reduced Qmax and an obstructive pattern on uroflowmetry following which the diagnosis is typically made at urethroscopy with the finding of a narrowed bladder neck which will not admit a flexible cystoscope.

Alternatively bladder neck contracture may present with or come to light during the workup for PPI. Indeed in multivariate analysis, development of bladder neck contracture has been shown to be an independent risk factor for urinary incontinence following radical prostatectomy [21]. The effect of bladder neck contracture on urinary incontinence may be several fold. Firstly, bladder outflow obstruction due to a contracture may aggravate overactive bladder symptoms and thus worsen any component of urge incontinence contributing to the patients overall symptoms. Secondly, it has been suggested that, in determining the rigidity of the anastomotic region, presence of a bladder neck contracture may impair the ability of even a preserved external sphincter contraction to close the bladder outlet efficiently [20]. Conversely by virtue of causing bladder outlet obstruction, a bladder neck contracture may mask the severity of incontinence due to sphincteric deficiency. Thus treatment for BNC can have a positive or detrimental effect on urinary continence depending on which of the above aspects is predominant in the individual patient and what procedure is used. However, the outcome in terms of continence should largely be predictable.

### 4. The Management of Concomitant BNC and PPI

The optimum treatment for bladder neck contracture is controversial, and various authors have advocated differing strategies. Often success is reported differently between studies, and direct comparison of outcomes is difficult. Overall, treatment should be considered in light of the planned strategy for dealing with PPI. Where there is no plan to intervene for PPI, the ideal treatment for BNC would be minimally invasive and have no adverse effects on continence. In this situation simple transurethral procedures are most appropriate although, owing to the recurrent nature of the problem, repeat intervention may be required. Ramchandani et al. have advocated transurethral balloon dilatation and reported a success rate of 59% after initial treatment [22]. Park et al. reported a 92% success rate at 12 months with dilatation using the Nottingham dilators followed by a 3 month self catheterisation protocol; however, 27% required more than 2 procedures [18]. The findings of Surya et al. [7] illustrate the recurrent nature of bladder neck contracture; in their series, patients were managed initially with dilatation using either the Van Buren sounds or filiform bougies and followed with those requiring dilatation more than once every 6 weeks going onto having either cold knife incision or incision with electrocautery. Only 28% were managed with dilatation alone whilst only 62% responded to a single cold knife incision with the remainder of patients requiring additional periodic dilatation. In addition this study reported de novo incontinence in all patients whose contracture was treated with electrocautery. In contrast Popken et al. reported no adverse effects on continence with their strategy of endoscopic resection using electrocautery [6]. Yurkanin et al. have used cold knife incision at 4 o'clock and 8 o'clock and report a low retreatment rate of 17%

TABLE 1: Endoscopic management of postprostatectomy bladder neck contracture.

Authors	Year	<i>n</i>	Technique	Results
Surya et al. [7]	1990	18	Dilation with sounds followed by cold knife incision unsuccessful after 6 months	28% managed with dilation alone Single CKI effective in 62%
Ramchandani et al. [22]	1994	27	Transurethral balloon dilation	Successful in 59%
Popken et al. [6]	1998	15	Electrocautery resection	53% required >1 procedure
Yurkanin et al. [23]	2001	36	Cold incision at 4 and 8 o'clock	Repeat procedure required treatment in 17%. 92% managed with
Park et al. [18]	2001	26	Dilation over wire followed by CISC for 3 months	successfully 27% require $\geq 2$ dilations in 12 months
Giannarini et al. [20]	2007	43	Dilation followed by cold incision at 4, 8 and 12 o'clock	7% managed with dilation only 26% recurrence after incision
Eltahawy et al. [24]	2008	24	Holmium laser incision at 3 and 9 o'clock + steroid injection	83% patent bladder neck at 24 months 29% require 2nd procedure
Vanni et al. [25]	2011	18	Cold incision + mitomycin injection	72% patent at 12 months after single procedure

[23]. Giannarini et al. also used cold knife incision and were able to demonstrate a positive effect on continence following treatment of BNC in 90% of patients as assessed by one-hour pad testing. Of the 21 originally incontinent men in their series, 11 had become continent (less than one gram increase in pad weight) and 8 had improved on pad testing at one month following incision of their contractures [20].

As well as self-catheterization protocols and repeat dilatations, novel strategies to mitigate contracture recurrence have been described. In a series of predominantly recurrent contractures, Eltahawy et al. report a success rate of 83% at 24 months followup using holmium laser incision followed by steroid injection [24]. Vanni et al. who describe radial incision with cold knife followed by injection with mitomycin C have found 72% success for bladder neck patency at 12 months following a single procedure [25]. Table 1 summarises the different strategies described for the endoscopic management of postradical prostatectomy BNC.

In the situation where definitive surgery for PPI in the form of artificial urinary sphincter (AUS) is planned, any BNC should be treated aggressively and a stable patent bladder neck ensured prior to AUS placement. This is to minimise the chance recurrence and the need for further endoscopic procedures which may damage the AUS once in situ or increase the chances of cuff erosion [26]. In addition, definitive treatment for a recurrent contracture may necessitate the sacrifice of continence to establish patency of the bladder outlet. As such, in these situations procedures to deal with the contracture are often combined with implantation of an AUS to restore continence.

Once again, multiple strategies have been described by different authors. Gousse et al. advocate a staged approach

where aggressive transurethral incision of the bladder neck contracture at three, nine, and twelve o'clock by Collings knife is followed by AUS placement 6–8 weeks later provided a check cystoscopy at 5 weeks confirms a patent bladder neck [27]. In contrast Mark et al. reported good results with synchronous Collings knife incision and AUS implantation in 26 patients [28]. Only one patient developed symptomatic BNC recurrence with the AUS in situ, and this was managed successfully with repeat incision at the time of sphincter revision. In a later paper, authors from the same institution reaffirm that a synchronous approach is successful in most situations but suggest that a staged approach may be required in patients with a history of multiple prior dilations or incisions or in the setting of long dense contractures [29]. Since BNC typically presents well before most urologists would consider surgical intervention for PPI, the majority patients with symptomatic BNC fall into the former group (having had prior procedures) by the time they are referred for surgical management of their incontinence, and, as such, practice in our tertiary centre is to carry out staged procedures (Figure 1).

Rarely, postprostatectomy BNC can be severe and entirely refractory to endoscopic measures, and these recalcitrant contractures combined with postprostatectomy incontinence represent a formidable challenge in terms of management. Essentially two strategies have been proposed to avoid long-term catheterization or urinary diversion: placement of a UroLume stent combined with AUS or open surgery to reconstruct the bladder neck again combined with AUS to restore continence.

Elliott et al. reported good results using UroLume stents followed, after a 3 month interval, by AUS placement in a

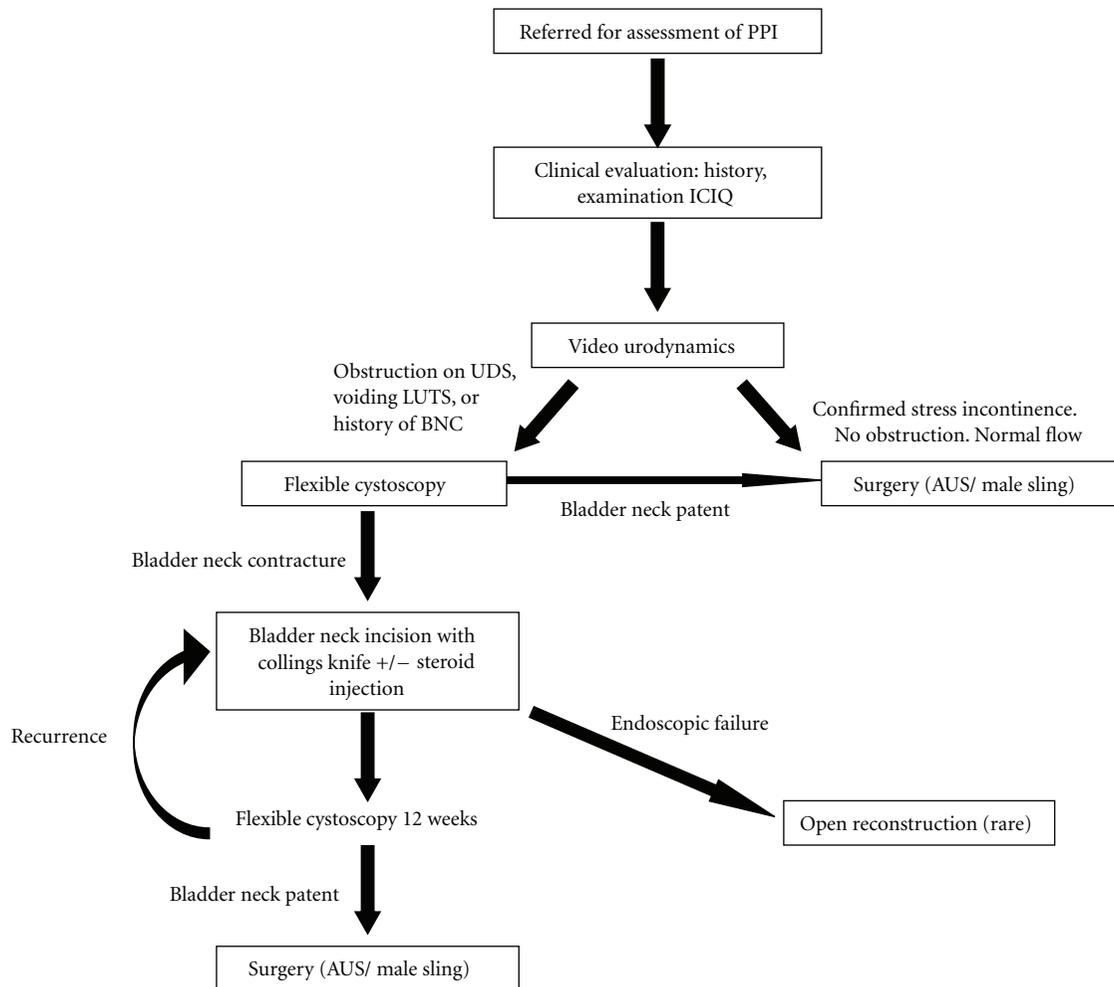


FIGURE 1: Our approach to management of PPI with concomitant BNC.

series of 9 patients with recurrent contractures and severe stress incontinence. 88% were satisfied with the procedure, mean pad use declined from 6.5 to 0.7 per day, and within the 17.5 month followup no reoperations were required on the AUS [30]. One patient did, however, develop stent ingrowth which required placement of second overlapping stent. Anger et al. have also used this strategy following the failure of endoscopic management but proposed a shorter interval between stent placement and AUS implantation of only 4–6 weeks in order to minimise the period spent with total incontinence. In their series of 8 patients, stent obstruction due to ingrowth occurred in two patients at 4 and 6 months, respectively, and was successfully managed using a flexible ureteroscope and holmium laser resection of the hyperplastic tissue [29]. However, in a later study from the same institution with longer followup, Borawski and Webster report that 50% of patients managed with UroLume stent combined with AUS required an average of 2.25 procedures for stent ingrowth over 37 months. In addition 11 patients (27.5%) required a total of 18 AUS uncouplings to facilitate endoscopic treatment, and the risk of cuff erosion was higher

(35% versus 10%) in those requiring treatment for stent ingrowth [26].

It has been reported that the rate of symptomatic tissue ingrowth with urethral stents in general approaches 25% [31]. In the setting of recurrent postradical prostatectomy BNC, the 5-year cumulative incidence of treatment failure following insertion of a single stent has been estimated at 50% [32]. This, together with other problems such as haematuria, stent migration, encrustation, and perineal pain, means that the role of stents must be seen as extremely limited in a setting where additional procedures to deal with stent complications are themselves compounded by the presence of an artificial urinary sphincter.

The alternative to UroLume stents in fit patients with good life expectancy and cancer control is open surgery to excise the stenosed bladder neck together with adjacent scar tissue and fashion a new anastomosis; again this is normally combined with AUS implantation to restore continence. Various approaches have been described including perineal [33] and combined abdominoperineal [34] with synchronous [34] or delayed [33] placement of AUS. Some

authors [35, 36] advocate pubectomy to facilitate exposure and allow for a tension-free anastomosis whilst others have found this unnecessary [33]. A variety of reconstructive techniques have been used with similar success; however, owing to the rarity of the need for such interventions, the numbers in all published series are necessarily small [33–37]. Indeed because these patients are complex, no single technique is likely to be applicable in all cases, and instead an individualised approach is required. This is illustrated by Wessells et al. who describe a series of four patients with obliterative contractures each requiring a different technique of reconstruction ranging from simple end-to-end anastomosis to onlay urethroplasty using full-thickness penile skin graft with rectus muscle flap for graft coverage [35]. In experienced centers, the long-term success from such procedures is around 70% [37].

## 5. Concomitant BNC and the Male Sling

The insertion of a synthetic suburethral male sling for the treatment of PPI is a relatively new procedure but is gaining worldwide popularity as a less invasive alternative to implantation of an AUS which also maintains spontaneous urethral voiding [38]. Sling devices seem to offer the best results in men with mild-to-moderate stress incontinence [39]. However, the global experience is still limited and more long-term results are awaited. Consequently experience of patients with concomitant BNC undergoing male sling is even more limited. Our standard practice is to attempt to identify patients with BNC prior to the insertion of a male sling. Patients with significant contracture will need bladder neck incision with Collings' knife with the possibility of upgrading their PPI. This itself may lead to a change in the overall management plan for their urinary incontinence. In our experience, patients with concomitant BNC who initially appear to be suitable for the insertion of male sling often need the AUS once their BNC has been treated. However, in patients with mild BNC, it can be argued that synchronous treatment of BNC with insertion of a male sling may be appropriate [40]. Treatment of mild bladder neck stenosis is unlikely to change the grade of PPI, and the possibility of those patients having significant recurrence of BNC, which will require treatment in the future, is likely to be small.

## 6. Our Approach

Our unit has ran a specialist service dedicated to the management of PPI for a number of years, and the framework of our basic approach is illustrated in Figure 1. All patients receive a thorough initial clinical evaluation in terms of history, clinical examination, and ICIQ scoring. Subsequent investigation centres on high-quality video urodynamic studies to demonstrate stress incontinence and assess bladder capacity, any coexistent detrusor overactivity, or evidence of bladder outflow obstruction. Following this, patients found to have evidence of obstruction on urodynamics; those with voiding LUTS or a history of prior bladder neck contracture precede to flexible cystoscopy for further assessment and

management as illustrated. Practically speaking almost all our patients undergo flexible cystoscopy as it also provides an opportunity to evaluate the sphincter condition; however, a small number with severe stress incontinence and no evidence of obstruction precede directly to surgery following urodynamic assessment.

## 7. Conclusion

The management of bladder neck contracture in the presence of PPI is challenging. Most patients can be successfully managed endoscopically, and cases requiring open excision and reconstruction are fortunately rare. Treatment of bladder neck contracture in the setting of mild PPI can be managed with conservative steps in the form of dilatation followed if necessary by intermittent self-catheterization to maintain patency. However, if the PPI warrants surgery, any concomitant BNC must be treated aggressively, and a stable, patent bladder neck should be ensured prior to placement of any prosthesis in order to avoid complicated recurrence.

## Abbreviations

PPI: Postprostatectomy incontinence  
 BNC: Bladder neck contracture  
 AUS: Artificial urinary sphincter  
 BNI: Bladder neck incision.

## Conflict of Interests

Y. Z. Almallah is an advisor for the National Institute for Health and Clinical Excellence (NICE) and the NHS Health Technology Assessment (HTA) Programme and user/trainer of various male anti-incontinence devices manufactured by the American Medical Systems.

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## Clinical Study

# Comparison between Two Different Two-Stage Transperineal Approaches to Treat Urethral Strictures or Bladder Neck Contracture Associated with Severe Urinary Incontinence that Occurred after Pelvic Surgery: Report of Our Experience

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**Introduction.** The recurrence of urethral/bladder neck stricture after multiple endoscopic procedures is a rare complication that can follow prostatic surgery and its treatment is still controversial. **Material and Methods.** We retrospectively analyzed our data on 17 patients, operated between September 2001 and January 2010, who presented severe urinary incontinence and urethral/bladder neck stricture after prostatic surgery and failure of at least four conservative endoscopic treatments. Six patients underwent a transperineal urethrovesical anastomosis and 11 patients a combined transperineal suprapubic (endoscopic) urethrovesical anastomosis. After six months the patients that presented complete incontinence and no urethral stricture underwent the implantation of an artificial urethral sphincter (AUS). **Results.** After six months 16 patients were completely incontinent and presented a patent, stable lumen, so that they underwent an AUS implantation. With a mean followup of 50.5 months, 14 patients are perfectly continent with no postvoid residual urine. **Conclusions.** Two-stage procedures are safe techniques to treat these challenging cases. In our opinion, these cases could be managed with a transperineal approach in patients who present a perfect operative field; on the contrary, in more difficult cases, it would be preferable to use the other technique, with a combined transperineal suprapubic access, to perform a pull-through procedure.

## 1. Introduction

Referring to prostate surgery, urinary incontinence and iatrogenic bladder neck/urethral strictures are devastating complications that strongly impair a patient's quality of life (QoL).

Iatrogenic late urinary incontinence following surgery for benign prostatic hyperplasia (BPH) is an uncommon complication occurring in less than 1% of cases, especially because of technical improvements during the last decade in performing a transurethral resection of the prostate (TURP) [1–3].

In a recent review of more than 50 papers, the weighted mean continence rate at 12 months after retropubic radical prostatectomy (RRP), laparoscopic radical prostatectomy (LRP) and robot assisted radical prostatectomy (RARP) was

79%, 84.8% and 92% respectively. However, persistent post-RP urinary incontinence in literature affects 2% to 5% of patients one year after surgery [4, 5]. This broad range of incidence is obviously influenced by different factors such as the surgeon's experience, surgical technique, selection of the patients and time of assessment relative to surgery [6].

Urethral strictures are the major late complication after TURP, ranging from 2.2% to 9.2% [6]; the range is from 0.6% to 14% considering also open simple prostatectomies (OSP) for BPH [7].

Anastomotic strictures following radical prostatectomy for prostate cancer are reported in about 1–8% of all patients [8].

Most of the strictures are managed with dilatation or endoscopic treatments. Eventual severe incontinence after

TABLE 1: Pre-operative patients features.

	Patient	Prostatic Surgery	Prior Urethrotomies	Prior TUR
Procedures with an end to end re-anastomosis	1	RRP	+	
	2	RRP	+	
	3	OSP		+
	4	OSP		+
	5	TURP		+
	6	RRP	+	
Procedures with the pull-through technique	7	LRP	+	
	8	RRP	+	
	9	RRP	+	
	10	RRP	+	
	11	LRP	+	
	12	RRP	+	
	13	RRP	+	
	14	LRP	+	
	15	RRP	+	
	16	RRP	+	
	17	RRP	+	

TUR: Transurethral Resection; RRP: Retropubic Radical Prostatectomy, LRP: Laparoscopic Radical Prostatectomy; OSP: Open Simple Prostatectomy; TURP: Transurethral Resection of Prostate.

incision of the stricture can be successfully managed by implantation of an artificial urinary sphincter (AUS) [9]. The treatment of strictures in incontinent patients after failure of transurethral procedures is controversial: a permanent stent or a urinary diversion (by catheters or major surgery) does not always achieve an optimal functional result, which is the combination of lumen patency and urinary continence [10]. Some authors advocate complex abdomino-perineal approaches to perform urethroplasty and AUS implantation in one or two stages [3, 11], whereas others perform a one- or two-stage implantation of prostatic stent and AUS [10, 12]. However, such procedures are complex, invasive, and potentially morbid.

In this paper we report our experience in the management of patients with combined urinary incontinence and urethral/bladder neck stricture after prostatic surgery; the surgical treatment of these patients is continually evolving and we made our choices and evaluations considering the individual patients, the surgeon's experience, and the available resources.

We approached the patients with two different two-step techniques; an open urethroplasty followed by AUS insertion after 7 months and an urethroplasty with a pull-through technique followed by AUS insertion after 8–10 months.

## 2. Materials and Methods

**2.1. Patients.** We retrospectively evaluated 17 patients, treated at our institution between September 2001 and January 2010 for a combination of severe urinary incontinence and posterior urethral stricture or bladder neck contracture after prostate surgery. Fourteen patients had an anastomotic bladder neck contracture following RP for localized prostate

cancer. The other 3 patients developed a posterior urethral stricture after prostatic surgery for BPH: 1 after TURP and 2 after OSP. Among these last 3 patients, 2 presented a type II prostatic urethral stricture and 1 a type III stricture according to the criteria of Pansadoro and Emiliozzi [7].

All the patients presented with erectile dysfunction. Two patients underwent adjuvant radiotherapy after RP, 2 patients suffered from diabetes mellitus and 1 from chronic hepatitis C. Before definitive treatment, all the patients underwent 4 or more internal urethrotomies or transurethral resections (Table 1) followed by recurrence of disease.

To exclude detrusor over-activity or compliance abnormalities, every patient was evaluated through physical examination and a diagnostic work-up including flexible urethroscopy, retrograde and voiding urethrogram, and urodynamic investigations, according to the methodology and definitions of the International Continence Society.

The patients were scheduled for a two-step approach: first they underwent urethroplasty and subsequently, the implantation of an AUS. Retrospectively we identified two subgroups: in the first one (group A) 6 patients underwent an anastomotic urethroplasty with removal of scar tissue and repetition of end to end anastomosis (13). In the second one (group B) 11 patients were subjected to urethroplasty with a pull-through technique following the Solovov-Badenoch principle. In group A the AUS were implanted after a follow up period of 6 months and in group B after 8–10 months.

**2.2. Surgical Technique: The First Step.** While the patient is on call to the operating room (OR), antibiotic intravenous prophylaxis is administered and the hair is removed from the surgical field in the OR just prior to surgery.

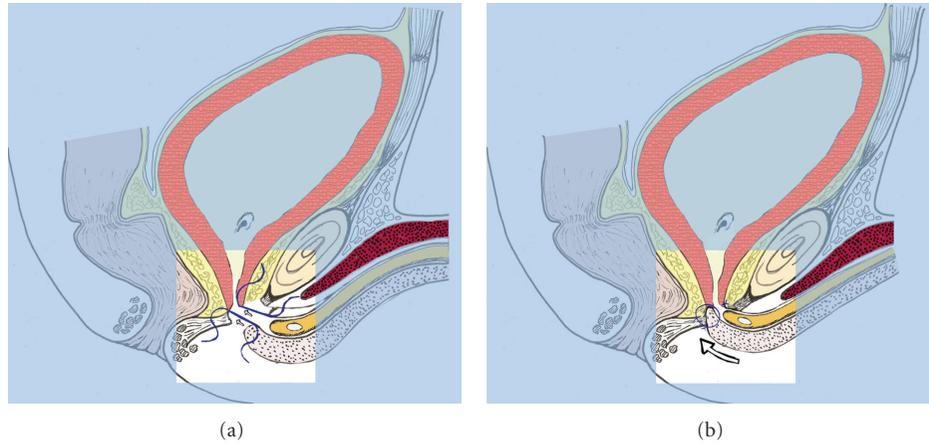


FIGURE 1: (a) Two 3–0 polygalactinin sutures are passed through the proximal edge of the urethra and the bladder neck. (b) The sutures are tied.

All the procedures are performed with the patients in the lithotomy position.

**2.2.1. Trans-Perineal Urethroplasty with End to End re-Anastomosis.** During a flexible urethroscopy a guide-wire is passed into the bladder. Then a reversed Y-shaped incision is made on the perineal skin; the layers below are opened, up to the bulbospongiosus muscles, which are separated in order to expose the bulbar urethra. After that a vascular loop is passed around the bulbar urethra.

A 24 Ch Catheter is passed into the urethra to recognize the distal edge of the stricture, so that we are able to remove dorsal scarring tissue of the stricture from the urethral lumen to the periphery, until healthy tissue is observed.

To obtain a tension-free anastomosis, the anterior urethra is largely dissected from the corporal bodies and the intercrural space is developed, starting from the bifurcation of the corporal bodies, with a wide mobilization. After that, we dorsally spatulate the anterior urethra and interrupted 3–0 polygalactin acid sutures are placed on the proximal mucosal edges; sutures are then placed in the distal segment of the urethra (Figure 1(a)) and tied after placement of a 18 Ch catheter (Figure 1(b)). Furthermore, four more interrupted sutures are placed between urethra and corporal bodies to better guarantee a tension-free anastomosis.

Finally, a non-absorbable suture is passed between urethra and corporal bodies as a landmark to identify the correct place to place the cuff at implantation of the AUS.

The incision is closed in layers, after which the bulbourethral muscles are reconstructed and the superficial perineal fascia is also closed.

A fourteen-day course of antibiotics is given and the catheter is removed at day 10 after a cystography.

**2.2.2. Repetition of the Vesico-Urethral Anastomosis with the Pull through Technique.** The procedure starts with a perineal reversed Y shaped incision and exposure of the bulbar urethra, separating the bulbospongiosus muscles; a vascular loop is then passed around the bulbar urethra. The distal

edge of the stricture is recognized with the help of a Nelaton urethral sound and then incised.

The bladder is then punctured suprapubically with a needle, a guide-wire is passed through and the tract is coaxially dilated until a 26 Ch Amplatz sheath is placed; through this, a flexible cystoscope is introduced into the bladder and a guide-wire is passed through the bladder neck to the stenosis and retrieved from the perineum. A 24 Ch Nelaton urethral sound is subsequently suprapubically passed through the guide-wire and introduced up to the bladder neck.

The dorsal scarring tissue of the stricture is proximally removed by pulling and following the Nelaton catheter, with whom the guide-wire moves in unison, until healthy tissue is observed (to create a large lumen for the vesico-urethral anastomosis). The anterior urethra is largely dissected from corporal bodies and the intercrural space is developed with a wide mobilization in order to obtain a tension-free anastomosis. The anterior urethra is then spatulated dorsally and interrupted polygalactin acid 3-0 sutures are placed on the proximal edges of the corpus spongiosus of the urethra to guarantee haemostasis.

Two mono-filament 0-0 sutures are placed at the proximal edge of the anterior urethra; afterwards they are passed through the Nelaton catheter from its tip until the proximal edge of the sound (Figure 2(a)). Therefore this is then carefully retrieved through the perineum into the bladder neck to pull the proximal stump of the urethra inside the bladder through the bladder neck. A gentle trans-perineal push of the urethra with the fingers helps to successfully complete the manoeuvre, so that we can define the procedure as a combined “pull through and push through technique”. Finally, the sutures exiting the Amplatz catheter are cut and pulled out of the bladder.

After placement of a 18 Ch catheter, interrupted polygalactin 3–0 sutures are then placed in the proximal segment of the urethra between the paraurethral fascia and the vesico-urethral anastomosis to achieve a watertight anastomosis (Figure 2(b)). At this point the urethra is evaluated to find

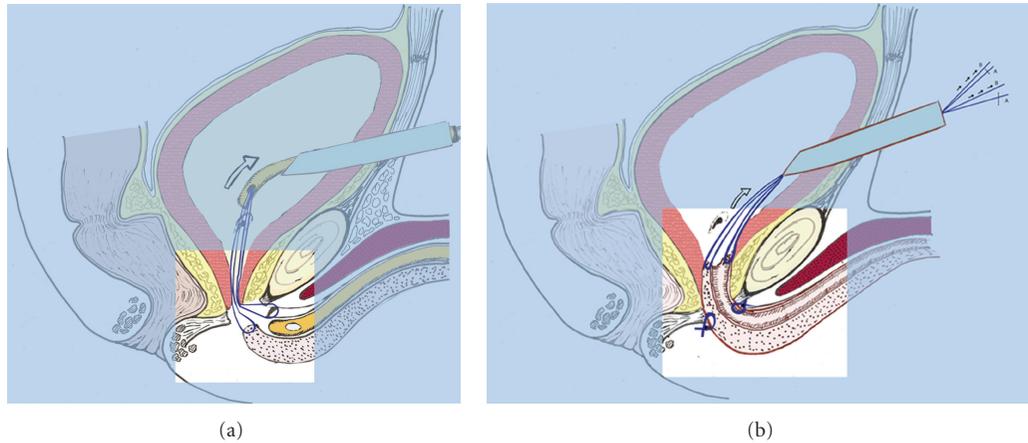


FIGURE 2: (a) Placing of 2 0-0 sutures at the proximal edge of the anterior urethra. They pass into the Nelaton supra-pubic catheter. (b) The proximal edge of the urethra is pulled through the pelvic floor and placed inside the Bladder. Polygalactinin 3-0 sutures are then placed in the proximal segment of the urethra between the para-urethral fascia and the vesico-urethral anastomosis. Afterwards the sutures exiting the Amplatz catheter are cut (A) and pulled out (B) of the bladder.

the suitable place to place the cuff of the AUS during the second surgery and a monofilament non-absorbable suture is passed as a future landmark. Four more sutures are placed between the corpus spongiosus of the urethra and the corporal bodies in order to obtain a better tension-free anastomosis; this manoeuvre is accomplished carefully to avoid the placement of the stitches where the cuff will be placed.

The bulbo-urethral muscles are reconstructed and the superficial perineal fascia is re-established. The incision is then closed in layers.

The two mono-filament 0-0 sutures placed at the proximal edge of the urethra are removed pulling a distal tail, after which a suprapubic 14 Ch catheter is placed.

A fourteen-day antibiotic course is given and ten days later, surgery patients undergo cystography in order to remove the urethral catheter; the suprapubic catheter is extracted three days later.

**2.3. Follow up after the First Step.** All patients were evaluated with urine cultures one, three and six months later. After six months a flexible urethroscopy was also performed.

If a stable patent urethral lumen was present and the patient was completely incontinent, he was scheduled for AUS placement (7 months after the first surgery in group A and 8 to 10 months after surgery in group B).

**2.4. Surgical Technique: The Second Step, Trans-Perineal AUS Insertion.** While the patient is on call to the operating room (OR), antibiotic intravenous prophylaxis (gentamicin sulphate plus vancomycin) is administered. The hair is removed from the surgical field in the OR just prior to surgery.

The elements of the system are immersed into an antibiotic solution.

The patient is placed in the lithotomy position and a vertical midline perineal incision is made. Then the

landmark suture placed during the previous surgery is located; it is useful to find the plane between the urethra and the corporal bodies. The urethra is circumferentially dissected off the corporal bodies for a length of 2 cm to accommodate the cuff of the sphincter. The circumference of the urethra is then measured for cuff size selection.

Afterwards, a small incision in the right iliac region is made, and a pocket bluntly created under the rectus muscle, extra-peritoneally, to allow the placement of the balloon reservoir. The reservoir tubing is brought out through a separate incision in the anterior rectus fascia to avoid scrotal violations.

The cuff tubing is grasped, and guided up into the abdominal wound passing through the bulbo-urethral muscles. Then a lateral subcutaneous hemi-scrotal pouch is created with Hegar dilators, to place the pump of the AUS. Before its placement the pump is carefully filled with saline solution.

All of the appropriate tubing connections are made and the device is tested and deactivated. The cuff placed around the bulbar urethra is 4-5 cm in length and a 61 to 70 cm H2O pressure-regulating balloon is used. Finally, the incisions are closed in layers.

A fourteen-day course of antibacterial therapy is given and the devices are activated 4 weeks after surgery.

**2.5. Follow up after the AUS Insertion.** Every three months for the first year and then annually, we carried out an examination and evaluated urine cultures and post-void residual urine.

### 3. Results

We did not observe intraoperative or early postoperative complications in either of the approaches, for any patient. Six months after the first step of the treatment 16 patients

(94%) were completely incontinent with no urethral strictures and complete anastomotic healing. One patient was retentive after the urethroplasty but he showed a pervious urethra lumen and continues to drain his bladder with self-catheterization.

All 16 patients underwent AUS implantation; 10 of them (58.8%), from group B, after an eight/ten-month follow up and 6 of them (35.3%), the entire group A, after a six-month follow up.

After a mean follow up of 50.5 months (range 18–111) 14 patients (82.4%) are continent without post-void residual urine and a perfectly functional device.

Only two of the 16 patients who had undergone AUS implantation needed a complete removal of the device due to urethral erosion. One of them was a previously irradiated patient who developed urethral erosion 6 months after AUS implantation; the other one was a patient with chronic hepatitis C who presented scrotal swelling and partial urethral erosion 2 months after device implantation; the former was part of group A and the latter of group B. However both of them are now completely incontinent with a pervious urethral lumen.

Therefore we achieved an overall success rate of 5/6 (83.3%) in group A and of 9/11 (81.8%) in group B.

The patient presenting chronic hepatitis underwent scrotal and abdominal ultrasonography which showed a low level of echogenicity around the pump and the balloon. The microbiological examination of the liquid obtained by the fine-needle aspiration revealed no bacterial contamination.

#### 4. Discussion

For both the anastomotic posterior urethroplasty techniques we achieved excellent results, with a specific success rate of 100% in group A and 91% in group B, similar to contemporary reported experiences concerning the trans-perineal approach [14]. Regarding AUS implantation, currently it seems to be the most effective treatment for severe urinary incontinence [15]. Having said this, in our opinion, in patients affected by recurrent urethral stricture caused by prostatic surgery, it is a reasonable approach to perform preliminary surgery to obtain a patent and stable lumen. The aim of this first step is to create a clinical and functional context of urinary incontinence which can be managed by the implantation of an AUS.

We believe that the first step of treatment would have to be a trans-perineal or combined trans-perineal-suprapubic (endoscopic) access; these approaches are less invasive and have a lower rate of perioperative morbidity than the open supra-pubic techniques [16, 17] as demonstrated by the absence of early post-operative complications in our series. Concerning the selection of surgical techniques to be performed as the first step of the procedure, we can explain the choices given by considering different anatomical and clinical aspects. End to end anastomosis is easy to perform when the bladder neck is joinable without particular problems due to favourable local conditions, that is, when the angle between the ischio-pubic ramus is wide and the

scarring tissue is poorly or moderately represented. On the contrary, when we encounter patients with acute angles between the ischio-pubic ramus or with too much fibrous tissue, we prefer to adopt the pull-through technique which plays on the Solovov-Badenoch principle [18, 19]. This technique was abandoned because of the low success rate, nevertheless we believe that those poor results were due to adverse operative and anatomical conditions: originally this approach was intended for the treatment of posterior urethral traumatic injuries, but repair of an unaligned urethra in these patients may be very difficult owing to extremely distant urethral edges (e.g., dislocated by a pelvic hematoma) and the addition of bone scarps in the surgical field. In our series, a wide dissection of the corpus spongiosus from the corpora cavernosa always allowed adequate mobilization of the distal urethra so that the surgeon encountered no problems in placing the proximal edge of the stump inside the bladder. To achieve this result, it is essential that the surgeon combine the endoscopic supra-pubic pull-through with a manual “push through” action from the trans-perineal access, thereby avoiding any eventual injury to urethral tissue. Furthermore, we took advantage of the development of advanced operative instrumentation such as the flexible fiber-optic cystoscopy [20] and new suture materials.

A nodal point regarding this technique and the whole urethral surgery is the “ischemic fragility” of the urethral mucosa which is the main cause of perioperative complications [21]; as we are aware of this problem, we prefer to wait at least six months before implanting the AUS, thus avoiding ischemic injuries to the proximal part of the distal urethra.

Two patients presented urethral erosion after the second surgical step, so we removed the devices. As they are completely incontinent with a patent and stable lumen, we could advise re-implantation of the AUS, but we feel this indication should be limited to the irradiated patient. Adequate strategies such as adopting alternative cuff sites or performing trans-corporal cuff implantation allow us to avoid a second AUS revision [22] in this kind of patient.

We are aware that there is an important disadvantage in our two-stage approaches, which is the requirement of a second operation, but we believe that this is balanced by obtaining the recovery of the urethral tissue before implanting the sphincteric device, minimizing the risk of perioperative complications.

#### 5. Conclusions

To treat patients that present urethral stricture or bladder neck contracture after prostatic surgery and failure of several endoscopic treatment, we advise performing a first-step surgery with a pure trans-perineal urethroplasty which is less invasive, easier to perform and has a lower operative time. If difficulties are encountered during the procedure, this may be switched to a combined trans-perineal/suprapubic approach. After six months, when a stable patent urethral lumen is obtained, the patient can undergo AUS implantation.

## Disclosure

The Authors have no conflict of interest to disclose.

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## Review Article

# New Artificial Urinary Sphincter Devices in the Treatment of Male Iatrogenic Incontinence

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Severe persistent stress incontinence following radical prostatectomy for prostate cancer treatment, although not very common, remains the most annoying complication affecting patient's quality of life, despite good surgical oncological results. When severe incontinence persists after the first postoperative year and conservative treatment has been failed, surgical treatment has to be considered. In these cases it is generally accepted that artificial urinary sphincter is the gold standard treatment. AUS 800 by American Medical Systems has been successfully used for more than 35 years. Recently three more sphincter devices, the Flow-Secure, the Periurethral Constrictor, and the ZSI 375, have been developed and presented in the market. A novel type of artificial urinary sphincter, the Tape Mechanical Occlusive Device, has been inserted in live canines as well as in human cadavers. These new sphincter devices are discussed in this paper focusing on safety and clinical results.

## 1. Introduction

In recent years, despite improvement in the surgical technique, the prevalence of Postprostatectomy Urinary Incontinence (PPUI) has increased due to rising number of radical prostatectomies performed annually [1]. Iatrogenic-induced sphincter incompetence is the reason of postoperative stress incontinence in 95% of cases. The reported PPUI rates vary from 5% to 48%. This large variation may be attributed mainly on the influence of the interviewing physician and a lack of a standardized definition of "post prostatectomy incontinence" [2].

Noninvasive therapy and particular pelvic floor muscle training is the first-line treatment for early incontinence following prostatectomy within the first 6 to 12 months [2]. Lifestyle interventions and pharmacotherapy (duloxetine) are also recruited in this attempt [3, 4]. Despite this conservative intervention, up to 10% of patients with PPUI exhibit a persistent and moderate-to-severe incontinence for more than one year postoperatively [5]. For these patients surgical treatment is recommended [2].

The Artificial Urinary Sphincter (AUS) 800 (American Medical Systems, Minnetonka, MN, USA), despite the new surgical treatment options (slings, injection of bulking agents, stem-cell therapy), remains the gold standard for persistent moderate-to-severe stress urinary incontinence due to Intrinsic Sphincter Deficiency (ISD) [1, 2, 6]. In effort to keep the good success rates and improve some disadvantages of AUS 800 (high cost, complications, and relative difficult insertion), four new devices have been developed in recent years [1]. We attempt to present technical characteristics and insertion procedures for these devices and to report safety and efficacy data, where they are available.

## 2. FlowSecure™ (RBM-Med)

The FlowSecure artificial urinary sphincter is a new prosthesis for the management of urinary incontinence due to ISD that has been designed and developed by Professors Craggs M. D. and Mundy A. R. at London's Institute of Urology and Nephrology, in 2006 [7]. Unlike AUS 800, this sphincter is



FIGURE 1: FlowSecure artificial urinary sphincter.

an adjustable prosthesis filled with normal saline without contrast. Plain X-rays cannot therefore be used for monitoring, and ultrasound scan is the adequate radiographic technique for evaluation. Except verifying prosthesis status, ultrasound also allows measuring of the postvoid residual volume and calculation of the urethral closing pressure [8]. Moreover, MRI can ensure the precise position and integrity of all components of the sphincter [9].

The FlowSecure sphincter is a one-piece device consisting of two reservoirs placed in the paravesical space, a cuff that surrounds the urethra and a control pump with a self-sealant port that is placed in patient's scrotum (Figure 1). The first reservoir regulates resting urethral pressure and the other relieves stress pressure during intra-abdominal increase. During bladder filling the cuff connected with the pressure regulating reservoir compresses and keeps the bulbar urethra closed at low pressure. When intra-abdominal pressure rises, the stress relief balloon provides additional pressure to the cuff to maintain continence. The fluid pressure of the prosthesis may be regulated by injecting or removing saline through the self-sealing port in the control pump located in patient's scrotum [10]. When the patient wishes to void he only has to press the control pump until a good urine flow is achieved. In this way the cuff is emptied by moving the fluid from it to the pressure-regulating reservoir. Redirection of fluid flow and filling of the cuff is recovered when compression on the pump stops [11].

Indications for implantation of the FlowSecure device in order of significance are postprostatectomy urinary incontinence, incontinence due to congenital abnormalities, neurogenic bladder with ISD, and women stress incontinence, where other surgical procedures have failed [9–12].

Both perineal and suprapubic access are needed for prosthesis implantation. Pressure-regulating and stress relief reservoirs are lodged in Retzius space through the suprapubic incision. The cuff is placed through the perineal incision around the bulbar urethra as it is designed to transmit direct pressure over the urethra. By blunt dissection a space is created between the two incisions to pass the tubing, as well as a subcutaneous space in the scrotum where control pump is placed. FlowSecure is accompanied by a plastic trocar and its obturator, which allows transposition of urethral cuff between Retzius space and perineum, and a tube of

glue for temporary fixation of the belt over the cuff when adjusting it [11]. The control pump should be used as soon as the scrotal edema disappears. In case of persistent urinary retention, patients must be taught to perform intermittent self-catheterizations until the problem resolves. It is important that, during the catheterizations period, the patient must use the control pump to empty the cuff, even if he cannot void. The patient should be reevaluated for continence status 2 to 4 weeks after discharge. If he maintains continence, the prosthesis does not need pressurization. In those patients, who do not regain continence, pressurization of the system must be carried out. Under strict aseptic conditions, local anesthesia is administered at the scrotal area where the control pump is located. Some saline is injected through the self-sealing port using an orange 25 G 15 mm needle and a 10 mL syringe. The needle must be inserted longitudinal to the pump, to avoid damaging the device. The prosthesis pressure is directly dependant on the injected volume, following a pressure/volume curve. Ideally, the first pressurization reaches between 40 and 50 cm H<sub>2</sub>O, which normally takes about 4 to 6 mL of saline. The patient is advised to be re-evaluated two weeks after initial pressurization. At this time, fluid can be added or removed from the system to accommodate to the patient's needs. It is not advisable, during subsequent pressurization, to add more than 2 mL of saline per session [9]. Proper device function must be monitored by free uroflowmetry, ultrasound scan, and clinical history [8].

Knight et al. presented 9 male patients (mean age 66 years) with urodynamically proven stress incontinence due to radical prostatectomy treated with implantation of FlowSecure sphincter. The patients were followed for a minimum period of 12 months. All 9 patients recovered well from surgery. Two devices had to be removed for technical reasons. The mean leakage for the remaining 7 patients prior to implantation was  $771 \pm 658$  mL corresponding to a continence index of 54%. Twelve months later the leakage had statistically significantly reduced to  $52 \pm 36$  mL ( $P < 0.05$ ) and the continence index increased to 97%. There was no significant difference in bladder capacity or flow rate. Four patients required additional pressurization to achieve optimal continence and this was carried out without complication [13]. In another study by Rodriguez et al. 100 patients with stress urinary incontinence of various etiologies underwent bulbar urethra (96%) or bladder neck (4%) implantation of a FlowSecure device. All patients had tried conservative treatments and also 59 patients had undergone unsuccessful surgical procedures (suburethral slings, bulking agents, Proact, and AUS-800). Nine patients had undergone previous pelvic radiotherapy. At implantation the sphincters' pressure was left at atmospheric level in all cases. Patients attended for initial pressurization 2–4 weeks postoperatively and were recalled at two-week periods for evaluation and repeat pressurization, if it was required. Overall, 3 pressurizations procedures were required to achieve socially satisfactory continence in 89 patients. The implanting procedure lasted in average 38–47 minutes. Mean inpatient stay was 4.3 days. 53 patients had postoperative self-limited scrotal hematoma. Implants had to be removed in

28 patients (28%) due to early infection (8%), late infection secondary to pressurization procedures (5%), perforation of the pump at pressurization (9%), and mechanical failure (6%). No erosions were noted [14].

The main advantage of FlowSecure device over AUS 800 is that while the latter exerts a high constant pressure over the urethra, the former increases pressure on the urethra instantly, only during stress increase of intra-abdominal pressure. During the deactivated position the cuff turns back to the initial low pressure not exceeding 40 cm H<sub>2</sub>O, thus minimizing danger for urethral erosion [11].

In conclusion, FlowSecure artificial urinary sphincter is easy to implant, with low risk of mechanical failure, and adjustable to the patient's continence needs. Its main purpose is to achieve total patient continence during periods of raised abdominal pressure while subjecting urethra to the lowest possible pressure during resting. Urethral ischemia potentially leading to atrophy and erosion is thus prevented [8]. Use of one-piece prosthesis also decreases the risk of infection due to intraoperative handling and minimizes the chance of mechanical failure derived from errors during assembly [13]. All these may predict a promising future. However, more time and studies will be needed to define the role of this sphincter in the management of stress incontinence resistant to other treatments.

### 3. Periurethral Constrictor (Silimed, Rio de Janeiro, Brazil)

The Periurethral Constrictor (PUC) was developed by Dr. Fabio Vilar in 1996. It was designed for implantation in pediatric patients to treat deficient bladder sphincter function [15]. The PUC is a one-piece, two-part device. It is comprised of a constrictor cuff linked by a 20 cm silicone tube to a valve, which is elliptical in shape and rounded at the edges (Figure 2) [16]. The adjustable cuff is implanted around the bladder neck through suprapubic approach or bulbous urethra through perineal incision [17]. The valve is placed in a space accessible by percutaneous puncture, usually in the subcutaneous space between the umbilicus and the iliac crest. The injection port is designed to accommodate a fine Huber needle [18].

The system works hydraulically by the injection of sterile saline solution through the self-sealing valve in order to promote a static occlusive pressure on the cuff. The activation of the PUC takes place 6–8 weeks after implantation surgery. This requires filling the bladder and then injecting further saline into the system for as long as the occlusive pressure obtained allows good urine flow without significant increase of the post void residual urine volume [16].

A limited number of studies with controversial results have been published for using PUC in PPUI, excluding studies focused in its use in pediatric population, especially for the treatment of neurogenic urinary incontinence due to ISD [15, 18, 19]. In a study performed by Simone et al. 43 patients with mild urinary incontinence following radical prostatectomy were treated by PUC implantation. Overall successful rate was 86%. Postoperative complications



FIGURE 2: The Periurethral Constrictor.

occurred in 6 patients (1 hematoma, 1 erosion, 2 infections, and 2 malfunctioning devices). Only the first two complications were managed by device removal [20]. Schiavini et al. retrospectively studied 30 patients with PPUI and PUC implantation for a mean period of 42.1 months. At the time of implantation the reported mean use of pads was 4.4 per day. In 22 patients (73.3%) the devices were functional leading to a good continence result. In 7 patients the device was removed because of cuff erosion (4 patients, 13.3%) and infection (3 patients, 10%). An eighth patient remained incontinent after the device reactivation because of detrusor hyper-reflexia [16]. On the other hand, Lima et al. presented a study with 82.2-month mean followup which reported a very high device removal rate 41.07% [17]. The average time between surgery and the removal of the device was 22.6 months. The most frequent complication was urethral erosion in 15 patients (26.78%). Comparing erosion rates of AUS 800, ranging from 1.7% to 4.5%, the present study presented higher rates [21]. Other complications were mechanical malfunction in 5 (8.9%), urethral stenosis in 3 (5.3%), urinary fistula in 2 (3.5%), infection in 2 (3.5%), and persistent urinary tract infection in 1 case (1.7%). In patients in whom the device was not removed (33), only 17 from them were continent, representing an overall success rate of 30.35% [17].

The above results, suggest that further studies are required to determine the safety and efficacy of this type of artificial urinary sphincter. However, simplicity and low cost of PUC are important characteristics in its favor comparing with AUS 800 [16]. The one-piece design makes the device easier to implant and the absence of connections reduces the chances for leakage and kinks [19]. The characteristics of the cuff allow spontaneous voiding and catheterization without the need of previous emptying the cuff. It can be deactivated, under activated or reactivated at any time by simply punctuating the subcutaneous port to add or subtract

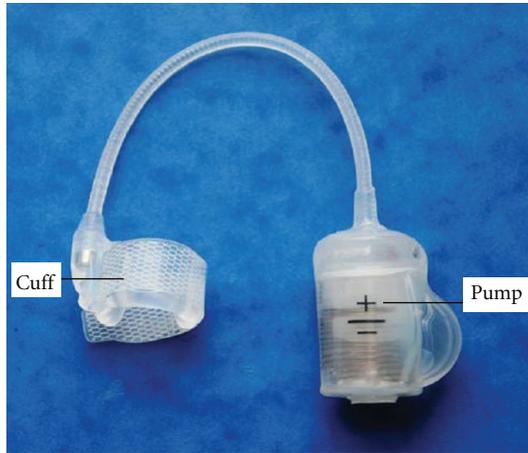


FIGURE 3: The ZSI 375.

fluid [18]. Based on these observations, more studies are needed to bring safer conclusions.

#### 4. ZSI 375 (ZEPHYR Surgical Implants, Swiss-French)

ZSI 375 is an artificial urinary sphincter produced by ZEPHYR Surgical Implants, a Swiss-French company. The system was designed and created by Dr. Christophe Gomez-Llorens and Raphael Gomez-Llorens in 2005 [22]. It is used to treat severe urinary incontinence due to ISD. The ZSI 375 is a one-piece medical device that can be implanted only in men. It is made by silicone elastomer and filled with sterile normal saline solution. It consists of an inflatable and adjustable cuff that fits around the urethra and a pump with an embedded pressure-regulating tank placed in the scrotum connected with the cuff by a 110 mm silicone tube (Figure 3). The maximal pressure in the cuff must not exceed 350 mbar. The ZSI 375 is filled by normal saline solution. There are two compartments in the device: a hydraulic circuit and a compensation pouch circuit separated by a piston. Spontaneously, the spring pushes the piston up and the piston pushes the saline solution of the hydraulic circuit into the cuff. The pressure in the hydraulic circuit is not the only factor of the cuff efficiency. To obtain a good continence result, the deflated cuff must compress the urethra. The ZSI 375 has the advantage to increase the issued pressure and give the chance to readjust the cuff [22].

Two incisions are needed for the implantation of the device. Through a perineal incision the cuff is placed around the bulbar urethra. The pump unit is placed in a subdartos pouch through an inguinal incision. Six to eight weeks later the device is activated by pressing an activation button. If necessary, it is possible to inject 1 or 2 mL of normal saline in the compensation pouch through the scrotum to increase the issued pressure [22].

The advantages of ZSI 375 over AUS 800 are reduced cost, the opportunity to adjust the issued pressure of the

device, and the possibility to re-adjust the cuff in case of postoperative urethral atrophy [22].

In a study performed by Sandul et al. 34 men with urine incontinence after treatment for prostate cancer were treated by ZSI 375. Thirty-two of them had radical prostatectomy, six of those also had adjuvant radiotherapy, and two had brachytherapy followed by TURP to relieve outlet obstruction. Eight patients had already undergone a male perineal sling operation. Initial sphincter closure pressure was elected to be 60–70 cm H<sub>2</sub>O. 60% of the patients needed further increase of the pressure, something which was performed as an office procedure. The interval for primary activation ranged from 4 to 6 weeks. With a maximum followup of 20 months, no surgical revision was necessary for mechanical malfunction. Infection of the device occurred in 2 (5.8%) patients requiring device removal. Overall, social acceptable continence was achieved in 94.2% (32 patients) [23]. Llorens et al. studied 17 men, after 1 year of implantation of the ZSI 375. 14 patients were incontinent after radical prostatectomy and 3 patients after TURP. All patients had tried previous conservative treatments without success. Total continence was defined as dry, and social continence was defined as a minimal leakage requiring at the most one pad daily with activity. All other results were defined as incontinence. In 14 patients the initial pressure adjusted to 60–70 cm H<sub>2</sub>O and in 3 patients to 70–80 cm H<sub>2</sub>O. Mean hospitalization duration was three days. Implantation and recovery were uneventful for 12 patients. Four patients in whom the pump unit was implanted through the perineal incision presented permanent scrotum edema making the manipulation of the pump difficult. This led to the reimplantation of the pump in a subdartos scrotal pouch through a scrotal incision. After reimplantation, one patient presented extrusion of the pump unit and the device had to be removed. Finally one patient presented infection leading to artificial sphincter removal five days after the procedure. None of the remaining 15 patients demonstrated bladder overactivity, chronic urinary retention, or any other adverse effect. According to the results the three patients implanted with 70–80 cm H<sub>2</sub>O issued pressure in the system were dry. For the 12 patients implanted with the 60–70 cm H<sub>2</sub>O issued pressure in the system, three became completely dry, three achieved social continence, and six were still incontinent using two to three pads per day. Eleven patients implanted with 60–70 cm H<sub>2</sub>O were initially satisfied with their continence results. However, after in-situ injection of one mL of saline solution in the compensation pouch, the issued pressure increased 10 cm H<sub>2</sub>O to 70–80 cm H<sub>2</sub>O and the patients improved or achieved social continence [22]. 70–80 cm H<sub>2</sub>O seems to be the most efficient issued pressure because the pressure-regulating system of ZSI 375 is not submitted to abdominal pressure.

The innovative features of the ZSI 375 are the following: it is a one-piece device thus facilitating preparation and implantation; it contains an adjustable cuff mounted in a curve to reduce creasing and fracture danger; it offers the possibility to increase the issued pressure of the device in situ achieving better continence results; finally, preparation and implantation of the ZSI 375 are technically simple and quick

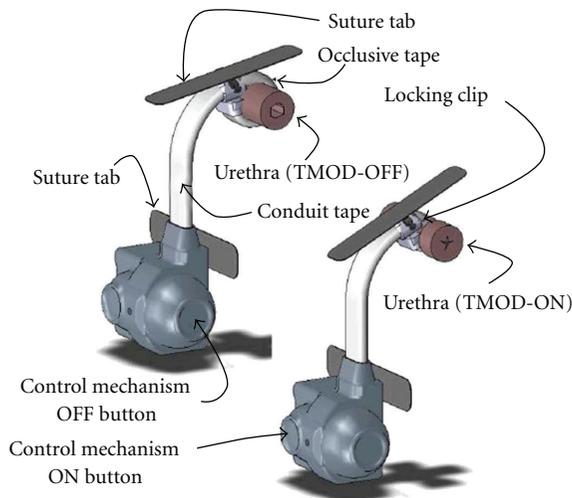


FIGURE 4: The Tape Mechanical Occlusive Device.

with no serious adverse events associated with the device [22].

## 5. The Tape Mechanical Occlusive Device (GT Urological, Minneapolis, MN)

A new type of artificial sphincter is being developed utilizing a spring-loaded mechanism for applying circumferential pressure in the urethra, which is easy to implant and simple to use. This artificial urinary sphincter is the Tape Mechanical Occlusive Device (TMOD) (GT Urological LLC, Minneapolis, MN), a one-piece device that is manually controlled by the patient through its ON/OFF buttons [24].

The TMOD is a totally implantable, one-piece artificial urinary sphincter (Figure 4) consisting of an occlusive tape and a conduit tape, connected to a control mechanism. The conduit tape originates at the control mechanism and the occlusive tape connects to the conduit tape. The conduit tape is of sufficient length to allow placement of the occlusive tape at the bulbous or penoscrotal urethra without creating undue tension on the conduit tape. The scrotally implanted control mechanism consists of a titanium casing, housing a three-metal alloy spring that applies tension to sutures running through the conduit and occlusive tapes. The control mechanism has ON and OFF buttons and is covered with a flexible silicone boot that prevents tissue ingrowth. The boot has a port for injection of saline into the device that displaces air and creates an isotonic interior. This same port is designed for antibiotic flushing per surgeon discretion. In the ON position, the occlusive tape contracts and is designed to apply radial pressure to the urethra of 50–80 cm of water. The degree of radial pressure was chosen from clinical experience with the AUS 800 in order to limit urine leakage while minimizing urethral perfusion. There is a locking clip that locks the occlusive tape to itself to form an annular occlusive ring around the urethra. This can easily be unclipped for tape removal if repositioning or removal of the TMOD is required. Suture tabs are attached to both the

control mechanism and occlusive tape to anchor the device in place and prevent migration [24].

In humans is anticipated to implant the occlusive tape in an open, deactivated condition, allowing it to remain in that condition for 6 weeks postoperatively to permit healing. The physician would then activate the device to apply pressure to the urethra by depressing the ON button through the intact scrotal skin. The patient can then depress the control mechanism OFF button to again remove occlusive pressure from the urethra and allow for unobstructed voiding or lock it in the deactivated position for voiding or nocturnal deactivation. To reactivate, the patient can push the ON button [24].

The TMOD has been implanted in canines to assess its functionality, occlusive efficiency, and biocompatibility and in human male cadavers to assess its occlusive efficiency and sizing, with encouraging results. Activation of the implanted TMOD resulted in intraurethral pressures within the desired range of 50–80 cm H<sub>2</sub>O. The device has proven to have no evidence of systemic toxicity. It has met the requirements for reliability and biocompatibility [24].

The TMOD seems to offer several advantages over the currently available AUS 800. It is a single piece device that does not require assembly reducing preparation time by operating room staff. It is nonhydraulic and requires no pressure-regulating balloon placement leading to less dissection. The reduced width of the tape minimizes the dissection around the bulbar urethra reflecting a lower risk of urethral injury during the operation. The simplicity of the ON/OFF button operation allows easier patient control. The TMOD has not been implanted in live human patients yet and human clinical trials should follow given the proof of technical feasibility, biocompatibility, and lack of systemic toxicity.

## 6. Conclusion

The first artificial urinary sphincter was introduced in 1973 to treat ISD [25]. After its introduction the basic device design changed to the fifth-generation model, the AUS 800, in 1983 [26]. Despite its good success rate, in order to decrease mechanical failure, numerous changes have been made to the various components of this device; however, its basic design and mode of operation have remained unchanged for over 20 years. Recently, new devices have been developed to overcome the disadvantages of AUS 800. The controversial results in success and complication rates emphasize that these new devices need to be implanted in greater numbers of patients and with longer follow-up periods. If this experience reveals that one or more of them present potential advantages, these new artificial urinary sphincters will become an important tool in the management of men suffering from PPUI owing to ISD.

## Conflict of Interests

The authors declare that they have no conflict of interests.

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## Review Article

# Artificial Urinary Sphincter: Long-Term Results and Patient Satisfaction

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The published evidence concerning the safety, efficacy, and patient satisfaction for implantation of the current model of the artificial urinary sphincter (AS 800) in men with post prostatectomy urinary incontinence was the objective of this review. A Pub Med English language literature search from 1995 to 2011 was performed. A majority of men who undergo AUS implantation for post prostatectomy urinary incontinence achieve satisfactory results (0 to 1 pad per day). Infection rates range from 0.46 to 7%, cuff erosion rates range from 3.8 to 10%, and urethral atrophy ranges from 9.6 to 11.4%. Kaplan-Meier 5 year projections for freedom from any reoperation were 50% for a small series and 79.4% for a larger series. Kaplan-Meier projections for freedom from mechanical failure were 79% at 5 years and 72% at 10 years. In another series 10 year projections for freedom from mechanical failure were 64%. Although the artificial urinary sphincter (AUS) is the gold standard for the treatment of this disorder, most men will continue to need at least one pad per day for protection, and they are subject to a significant chance of future AUS revision or replacement.

## 1. Introduction

There is a wide range in the reported incidence of postradical prostatectomy urinary incontinence coming from individual series presumably due to inconsistent definitions of incontinence and differing modes of assessment. When large populations of postradical prostatectomy patients are surveyed, however, a more consistent pattern is observed. In a series of 1291 postprostatectomy patients, significant urinary incontinence persisted in 8.4% of men at eighteen months [1]. In a more recent NEJM study of 557 men at 12 months after radical prostatectomy, 24% were using pads, and 8% classified this as a moderate or big problem [2]. Urinary incontinence occurs less often after transurethral resection of the prostate being a significant problem in only 0.5% of 3885 men 2 months following surgery [3].

The artificial urinary sphincter (AUS) is widely regarded as the gold standard for the treatment of post prostatectomy urinary incontinence [4]. This prosthetic device was first introduced in 1973 [5], and during the next 10 years there

were design changes resulting in 5 different models of the device [6]. The fifth model of the AUS, the AS 800 (American Medical Systems, Minnetonka, MN, USA) was introduced in 1983 and is still in use today. The AS 800 has 3 separate components: a cuff, a pressure regulating balloon, and a pump-control assembly (Figure 1). The components are implanted separately and connected by 2 tubing connectors. For post prostatectomy urinary incontinence, the cuff is placed around the bulbous urethra, the pressure regulating balloon is usually placed in the retropubic space, and the pump-control assembly is placed in the scrotum.

Since 1983 the basic design of the AUS has been unchanged; however, there have been numerous modifications to device components leading to both increased continence and longer device life. These component changes include narrow back cuffs for bulbous urethral use, smaller (3.5 and 4.0 cm) cuffs, surface-coated cuffs to reduce wear, kink-resistant tubing, tubing sleeves to reduce wear, and sutureless connectors to facilitate making connections and to reduce connector failures.



FIGURE 1: AS 800 (Used by permission of American Medical Systems, Minnetonka, MN, USA).

## 2. Materials and Methods

A PubMed English language literature search from 1995 through 2011 for keywords: artificial sphincter; urinary sphincter, artificial; prosthesis failure; prostatectomy/ae [adverse effects]; patient satisfaction; quality of life was performed. Thirteen articles were found where data relevant to patients with post prostatectomy incontinence could be separated from other AUS uses. These articles were examined to perform this paper.

## 3. Results

**3.1. Efficacy.** There is no standardization for reporting pre- and post-AUS levels of incontinence. In a study of 50 patients with a median followup of 23.4 months, the preoperative levels of incontinence were such that 70% wore an average of 6 diapers a day, and 24% wore an average of 7.4 pads per day [7]. After AUS implantation, 20% had complete continence. Of the remainder, 55% had leakage of a few drops, daily, and 22% had leakage of less than a teaspoonful.

In a study of 54 men with mean follow-up of 7.2 years, 54% were socially continent (0 to 1 pad per day). Mean pad score before AUS implantation was 2.75, and it decreased to 0.97 after AUS implantation [8].

In a group of 113 patients with mean follow-up of 73 months (range 20 to 170), 32% were pad free, 33% used 1 pad per day, 14% used 2 pads per day, 17% used 3 pads per day, and 5% used more than 3 pads per day [9].

In a study of 33 men aged 75 years or greater with an average follow-up of 5 years, mean pad use decreased from 6.7 pads per day (range 3–10) to 0.8 pads per day (range 0–2) [10].

In a study comparing 435 first time AUS implants to 119 repeat AUS implants, pad use of 0 to 1 day was noted in 90% of the primary implants and 82% of the secondary implants [11].

In 124 patients with a median follow-up of 6.8 years, 27.1% required no pads and 52.0% required 1 pad per day after AUS implantation [12].

In a cohort of 71 men with mean follow-up of 7.7 years (range 0.5–16), 27% used no pads, 32% used 1 pad, 15% used 1–3 pads, and 25% used more than 3 pads daily [13].

In a series of 40 men with mean follow-up of  $53.4 \pm 21.4$  months (range 27–132), pad count decreased from  $4.0 \pm 0.9$  to  $0.62 \pm 1.07$  per day, and on a visual analog scale the impact of the incontinence decreased from  $5.0 \pm 0.7$  to  $1.4 \pm 0.93$  [14].

**3.2. Cuff Erosion.** Cuff erosion (Table 1) occurring within the first few weeks or months following AUS implantation is usually due to injury to the urethra when is mobilized prior to cuff placement. Late erosion usually occurs after a catheter has been inserted for a prolonged period without proper deactivation of the AUS. Unfortunately, very few reports of cuff erosion rates make the distinction between early and late cuff erosion.

**3.3. Infection.** AUS infection (Table 1) occurring without cuff erosion is not common. Most cuff erosions will lead to infection unless the erosion is detected early, and the AUS is removed before infection occurs. Most reporting of AUS infection fails to distinguish between infection alone and infection occurring as the result of cuff erosion.

**3.4. Urethral Atrophy.** When men achieve a satisfactory level of continence following activation of their AUS (0 to 1 pad per day) and later a gradual increase in pad use occurs, an AUS trouble shooting protocol should be employed [16]. If other causes of increasing incontinence have been ruled out by this protocol and the number of pump cycles to completely empty the cuff has increased, then urethral atrophy under the cuff has occurred. Possible revision procedures for this problem include cuff down sizing [17], tandem cuff placement [18], or transcorporeal cuff placement [19].

Urethral atrophy rates are shown in Table 1.

**3.5. Mechanical Failure.** For penile prosthesis implantation the American Urological Association Erectile Guidelines Committee has recommended that freedom from mechanical failure be reported in terms of Kaplan-Meier projections [20]. This allows meaningful comparisons within a single series and among several series where individual patient follow-up is variable. A similar recommendation should be adopted for reporting mechanical failure and other complications of AUS implantation.

Kaplan-Meier reporting was used in one series where 66 AUS implantation patients were available for a mean follow-up of 41 months, The 5-year Kaplan-Meier projections for freedom from any reoperation was 50% and for freedom from any cuff revision was 60% [21]. In another series of 124 patients with median follow-up of 6.8 years, the 10 year Kaplan-Meier freedom from mechanical failure was 64% [12]. In a report of 530 men the 5 year Kaplan-Meier freedom from reoperation was 79.4%, for primary cases and 88% for revision surgeries [11]. In a fourth series of 39 men with bulbous urethral cuff AUS implantations, Kaplan-Meier

TABLE 1

Reference	N	Mean followup (months)	Infection (%)	Cuff erosion (%)	Urethral atrophy (%)	Device failure (%)	Removal/revision (%)
Lai et al. [15]	176	36.5	5.5	6.0	9.6	6.0	27.1
Kim et al. [12]	124	81.6	7	10		29	37
Raj et al. [11]	554	68	0.46	3.8	11.4	5.6	21.4
Gousse et al. [13]	71	92.4	1.4	4		25	29

freedom from mechanical failure at 5 years was 79% and at 10 years it was 72% [22].

Mechanical failure rates for the remaining studies are shown in Table 1.

**3.6. AUS Implantation after Radiation Therapy.** In one series, 58 men with AUS and no prior radiation (group 1) were compared to 28 with AUS after radiation therapy for prostate cancer (group 2) [23]. Mean follow-up was  $31 \pm 23$  months for group 1 and  $36 \pm 21$  months for group 2. Reoperation was required for 22.4% group 1 and 25% group 2. Urethral atrophy occurred in 14% in both groups. Urethral erosion occurred in 2% group 1 and 7% group 2. Infection occurred in 7% group 1 and none in group 2. None of these differences were statistically significant. The degree of continence (0-1 pad per day) was similar for both groups, 60% and 64%.

In another study, 76 men with AUS implantation and no radiation were compared to 22 men with AUS implantation after radiation [24]. Urethral atrophy, infection, and erosion were more common in the group with radiation (41%) compared to the group without radiation (11%).

**3.7. Patient Satisfaction.** Ideal satisfaction studies would be prospective and used standardized questionnaires administered pre- and post-operatively. In addition since incontinence may have a significant quality-of-life impact on the partner, including partners in these studies would be desirable. Unfortunately, nearly all studies are retrospective and use a variety of nonvalidated satisfaction scales.

In a study of 50 patients with a median follow-up of 23.4 months, 90% reported satisfaction, 96% would recommend AUS implantation to a friend, and 92% would have the AUS placed again [7].

In a study of 54 men with mean follow-up of 7.2 years, subjective improvement was 4.1, and overall satisfaction was 3.9 (scale 0 to 5) [8].

In a group of 113 patients with mean follow-up of 73 months (range 20 to 170), 28% were very satisfied, 45% were satisfied, 18% were neutral, 6% were dissatisfied, and 4% were very dissatisfied [9].

In 71 men with a mean follow-up of 7.7 years (range 0.5–16), 58% were very satisfied, 19% were satisfied, and 23% were unsatisfied [13].

#### 4. Conclusions

Significant urinary incontinence following radical prostatectomy which persists for more than one year occurs in as many

as 8% of men. Although the AUS is the gold standard for the treatment of this disorder, most men will continue to need at least one pad per day for protection, and they are subject to a significant chance of future AUS revision or replacement.

Current reporting of AUS implantation results is far from ideal. Freedom from mechanical failure and other complications should be reported in terms of Kaplan-Meier projections. Quality-of-life and patient satisfaction studies should be prospective, include partners, and use validated questionnaires.

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