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TITLE

Dorsolateral fibro-muscular tissue preservation during artificial urinary sphincter cuff placement is associated with low infection and erosion rates

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DESCRIPTION

Dorsal fibro-muscular preservation for AUS

Key Words

Artificial urinary sphincter, stress incontinence, infection, erosion, prostatectomy

ABSTRACT

Objectives

To present a modified technique in artificial urinary sphincter (AUS) placement that is associated with low rates of erosion and infection in a high-risk population.

Material and Methods

After IRB approval, we identified patients who underwent primary AUS placement using the modified technique between January 2007 and November 2015. Our modification consists of preserving the dorsal fibro-muscular tissue surrounding the bulbar urethra and horizontally transecting the ventral bulbospongiosus muscle during urethral cuff placement. Preoperative variables such as radiation therapy and bladder neck contractures were recorded. Efficacy and complications including infections, erosions, and reoperations were recorded at follow-up.

Results

The new technique was used on 208 patients: 40% had a history of radiation therapy including 15% salvage radical prostatectomy; 26% had previous bladder neck contractures. No patients developed infection. Overall erosion occurred in 6 (2.9%) patients and spontaneous erosions occurred in 2 (0.9%) during the study period. Twenty-one patients underwent reoperation for device failure. The probability of reoperation for any reason was 7% (95% CI 4%, 12%) at 1 year. The 12-month social continence rate was 74% (95% CI 67%, 81%).

Conclusion

Preservation of dorsolateral fibro-muscular tissue for AUS placement is an effective means to achieve low risk for erosions. Our modified technique is safe with low infection and erosion rates while maintaining good functional outcomes despite a high-risk population.

Introduction

Since its introduction in the 1970s, the artificial urinary sphincter (AUS) has been the benchmark of the management of stress urinary incontinence, especially for men who had undergone radical prostatectomy. Its design has had incremental modifications since then. The most important of which was the introduction of the narrow-back cuff which led to significantly lower re-operative rates(1). More recently, the addition of an antibiotic coating has been thought to decrease infection rates, and the introduction of a smaller diameter cuff possibly thought to improve efficacy(2).

Despite these modifications, the cuff insertion technique has remained stable consisting of a midline perineal approach to the bulbar urethra(3). This is similar to the familiar dissection of a proximal urethroplasty; that is, midline division of the bulbospongiosus muscle with direct dissection on the urethral bulb to encircle it. While encircling the urethra, however, the surgeon encounters its dorsal aspect, which is the thinnest and at greatest risk of intraoperative urethral damage with possible later cuff erosion. In fact, early device infection is often associated with underlying - often unrecognized - cuff erosion. Erosion and infection lead to an additional operation to explant the device followed by a period of several months during which time the patient is incontinent, and finally an operation to place another device. This is distinctive to a device replacement for malfunction or inadequate continence, in which case the device can be removed and replaced in the same setting thereby reducing the time that the patient is incontinent and decreasing the number of operations the patient undergoes. Furthermore, AUS outcomes are worse in patients who have a history of erosion, and some men never undergo repeat AUS replacement because of newly formed urethral stricture. Therefore, our major focus in performing the AUS procedure is to decrease infection and erosion rates.

We changed our AUS surgical technique in 2007 because we hypothesized that we could mitigate the risk of erosion while maintaining efficacy by modifying our technique for placement of the urethral cuff. We use a dissection that avoids initial bisection of the urethral bulb away from the bulbospongiosus muscle. The dissection begins by encircling the entire bulbar urethra, the bulb, and the bulbospongiosus muscle and thereby avoids direct dorsal dissection of the urethra. This preserves the dorsolateral fibro-muscular tissue. We then dissect the ventral bulbospongiosus muscle away from the urethral bulb to allow closer apposition of the cuff to the urethra. The aim is to decrease complications, specifically erosion and infection while maintaining efficacy. Here we provide our results with this approach.

Methods

After obtaining Institutional Review Board approval, we queried our prospectively maintained database to identify all consecutive male patients who underwent primary insertion of an AUS at our institution. We excluded patients with prior history of male sling placement or those with previous artificial urinary sphincter placement. Patients who underwent transcorporal or tandem cuff placement were also excluded. There were 208 patients between January 2007 and November 2015 that met criteria for analysis.

We used Kaplan-Meier methods to estimate the rate of any reoperation and the rate of reoperation due to infection or erosion after AUS performed at MSKCC. Cox proportional hazards regression was used to assess whether prior radiation treatment or type of radiation treatment (primary or salvage) was associated with time to reoperation. Men were considered continent at one year if they reported using one or fewer pads per day at 9 to 15 months post-operatively, and not continent if they reported using two or more pads a day or required a re-operation within 12 months of insertion. All analyses were conducted using Stata 13.0 (StataCorp, College Station, TX).

Surgical Technique

All procedures during the study period were undertaken using our 'modified technique' for cuff placement. Patients had preoperative video urodynamics (as per ICS standards) cystoscopy to exclude urothelial pathology, aberrant anatomy or anastomotic strictures(4). If an anastomotic stricture was discovered, it was dilated, incised or resected until stable prior to insertion of the AUS. This step-wise management of bladder neck contractures has been previously described elsewhere(5). There were no patients that underwent treatment of anastomotic stricture simultaneously with AUS placement. All patients received peri-operative antibiotics with vancomycin 1gm x 2 doses and gentamicin 3mg/kg unless with renal insufficiency in which case vancomycin was renally dosed and gentamicin was substituted with ceftazidime 2mg IV.

Our modified technique involves placing a 14-french urethral catheter with a drainage bag already attached followed by a standard midline perineal incision. Sharp dissection is continued *outside* the bulbospongiosus muscle until the corporal bodies are encountered (Figure 1), which are then dissected free from the bulbospongiosus muscle to the level of the inferior pubic ramus. Here, the bulbospongiosus muscle (bulbar urethra contained within) and fibro-muscular layers of the perineal membrane is encircled under vision with the use of a right-angle clamp (Figure 2). The muscle is then *transversely* divided at its ventral aspect (Figure 3) to expose the urethral bulb ensuring that the dorsal bulbospongiosus muscle is intact and the fibro-muscular layers of the perineal membrane is included (Figure 4A and 4B). The urethral circumference is then measured using the measuring tape (Figure 5) and the cuff is placed (Figure 6A and 6B) around the ventral bulbar urethra whilst including dorsolateral fibro-muscular layers. After cuff placement, the ventral bulbospongiosus muscle is re-approximated over the secured urethral cuff with a running suture.

A sub-rectus space is created via a counter incision for the ectopic placement of the pressure-regulating balloon (Figure 7). Placement of the scrotal pump and connection of the tubing is per standard techniques. The cuff is left open and in the locked position after confirming proper cycling.

The urethral catheter is removed on post-operative day 1, and the patient is discharged following successful void trial. If post-operative retention is noted, a 12F Foley is gently reinserted and a further void trial is undertaken approximately 2 days later. The patient is discharged with analgesia and appropriate prophylactic antibiotics.

The patient is seen at 2 weeks post-op for wound review and the device is activated at 6 weeks post-op. Longer term follow-up is at 3 months, 6 months, 12 months, and yearly thereafter. At any time during the follow up if there was a change in symptoms or recurrence of incontinence, a work up would be initiated including cystoscopy to identify problems such as erosion.

Results

The study cohort included 208 patients with AUS insertion procedures performed by a single surgeon. There were 58 reoperations for any reason. The median follow-up time after first AUS for patients with no reoperation was 2.4 years (IQR 1.0, 4.3). The majority of patients had a previous radical prostatectomy (84%) and 40% of patients had radiation to the prostate before their first AUS procedure. Notably, 32 patients (15%) had radiation therapy prior to prostatectomy (Table 1).

Reasons for reoperation were categorized as due to erosion in 6 (2.9%) patients, device malfunction/mechanical issues in 21 patients and other reasons, which included decreased efficacy or residual incontinence or recurrent anastomotic stricture, in 31 patients. Among the 6 reoperations due to erosion, two were due to skin erosions: a tubing erosion in the scrotum in a patient on androgen depravation therapy and a scrotal pump erosion in a patient that underwent scrotal surgery for an unrelated condition. Two were due to erosion after instrumentation, one after catheterization and one after cystoscopy and two were presumably spontaneous urethral erosions. There were no AUS infections in the study cohort, and therefore no reoperations for infection. The probability of reoperation for any reason was 7% (95% CI 4%, 12%) at 1 year and 17% (95% CI 12%, 23%) at 2 years. For reoperation due to erosion or device malfunction, the probability was 2% at 1 year (95% CI 1%, 6%) and 6% at 2 years (95% CI 3%, 11%). Kaplan-Meier estimates for time to reoperation due to infection, erosion or device malfunction are presented in Figure 8. Using a Cox proportional hazards model, we found no evidence of an association between history of prior radiation or type of radiation and time to reoperation for any reason (Table 2).

While AUS failure was considered a complication that required re-operation, six patients had other complications that did not require re-operation within 30 days of surgery, with one case each of pulmonary embolus, bladder neck contracture, scrotal hematoma, abdominal hematoma, post-operative fever and urinary retention due to difficulty using the device. Furthermore, there were 22 patients (out of 208, 11%) who had self-limited postoperative urinary retention that resolved spontaneously after a further 2 days of catheterization.

Men were considered socially continent at 12 months post-operatively if they reported using one or fewer pads per day, and were considered not socially continent if they reported using more than one pad a day or required a re-operation within that 12 month period. At 12 months after the AUS, the probability of being socially continent was 74% (95% CI 67%, 81%) among 170 patients with continence outcomes available.

Discussion

We describe a technique in which the dorsal dissection of the urethra remains outside the bulbospongiosus muscle, whilst including dorsolateral fibromuscular tissue in the cuff placement. We report low rates of reoperation and excellent long-term continence.

Roth et al. describe placement of the cuff around the entire bulbospongiosus muscle(6). This involved a similar initial dissection, but was associated with increased revision rates likely due to muscle atrophy under the cuff. More recently, Collado Serra et al. reported their results using a bulbospongiosus muscle preserving technique that included dorsal urethral dissection similar to our technique(7). They reported their results on 82 patients over an 11 year period, demonstrating a 77% dry rate at one year and, notably, only one erosion during the time period. Our technique differs in that while the initial dissection is similar, we transect the ventral portion of the bulbospongiosus muscle overlying the thickest part of the urethral bulb, to allow better sizing of the cuff. This in turn allows for optimized efficacy of sphincter coaptation and minimizing erosions by preserving the dorsal layer of fibromuscular tissue. Erosions are devastating complications especially in high risk populations (I.E. radiated patients), and maneuvers to prevent this are extremely useful.

Guralnick et al. popularized placement of transcorporal cuff in order to avoid dissection of the dorsal urethra, especially in revision surgery particularly after a previous cuff erosion(8). This technique is associated with increased rates of erectile dysfunction and hematomas due to the corporotomies and relies on using a part of the urethra distal to the normal perineal location because the cuff has to be placed at a location where the corpora have not bifurcated. Other techniques for cuff placement, including tandem cuffs and penoscrotal approaches, have been described but these do not protect the dorsal urethra(9). At our institution, transcorporal or tandem cuff placement is not done at the time of initial AUS placement and therefore these patients were not included in the study cohort.

Gousse et al. reported long-term patient-reported outcomes and noted an infection rate of 1.4% and erosion rate of 4% (10). While our median follow up time without requiring reoperation is 2.4 years, past large series demonstrated that infections and erosions rate tend to occur earlier. Lai et al. reported their results with AUS placement in 218 high-risk patients over 13 years, 28% of whom had previous radiation therapy, and noted an infection rate of 5.5% and an erosion rate of 6%. Infections in their series occurred at a median of 3.7 months and erosions at a median of 19.8 months(11). We think that the prevention of urethral cuff erosion is paramount during AUS surgery. This is not only because of the increased burden of urgent secondary surgery to remove the AUS, but also because of the three to six month period of incontinence that these patients have to endure. Furthermore, results of revision surgery after erosion are worse than those with primary surgery(12) and in some series less than 50% of patients ultimately receive a secondary AUS after erosion(13). The overall erosion rate in our series was 2.9%, but the incidence of spontaneous urethral cuff erosion was extremely low in our series (2 of 208, 0.9%, of all primary AUS cases). There were two cases with erosions associated with documented instrumentation of the urethra. This is not surprising considering the main strength of our technique is to protect the dorsal urethra during dissection. It also reminds us that further education of health professionals regarding the risk of careless catheterization of an activated AUS. We have previously advocated the use of 'medical alert' bracelets for AUS patients to help in this regard(14).

We had no infections in our series. This is likely due to use of meticulous surgical technique, ensuring no breaks in the sterility, and using appropriate perioperative antibiotics, but also due to the fact that we had no early erosions or unrecognized urethral injuries. Erosion is often also associated with infection. In fact, some authorities believe that early erosion will present as an infection. We suspect that this is the main reason we had no cases of infection in our cohort – specifically, early or "technical" erosion rates are decreased by including the dorsal fibro-muscular tissue within the urethral cuff. This is in comparison to published infection rates of 3-16%(15).

Our study population is a complex group of patients. Many had been referred from outside institutions with the majority having had attempts at urethral bulking and some with known metastatic prostate cancer on androgen blockade. Approximately 40% of our patient cohort had been irradiated and more than 25% required prior surgery for bladder neck contractures. Of note, 15% of our patients had a salvage prostatectomy – prostatectomy for local recurrence often many years after primary radiation therapy. This subset of patients is known to have high rates of urinary incontinence and anastomotic stricture(16). These more complex patients did not require the alteration of our technique, which is a significant advantage.

Similar to other published studies(15,17,18), prior radiation does not appear to adversely affect continence outcomes or increase complications. This may be an advantage of our technique in that the initial wide dissection avoids the chance of damaging the urethra. The dissection also is more within avascular tissue planes and involves relatively minimal bleeding.

The main reason for an AUS is to improve urinary continence. While different measures have been used to measure urinary continence (pad numbers, pad weight, specific questionnaires, entirely dry), social continence – use of one or less pad per day - is considered technical success by most authorities and used to compare different techniques. Our series had a 74% continence rate at one year after AUS placement. Patients who required re-operation within 1 year were considered to be and included in "not socially continent" group. This rate of continence is similar to published series which are reported to be between 61 to 100%(19). Meta-analysis in published series reports a continence improvement in 88% and total continence of 74% but with urethral erosion and infection rates of 12% and 4.5% respectively using traditional surgical approach(20). More recently, O'Conner et al demonstrated in a series of 33 elderly men over 75 a success rate of 72% using 1 pad or less, and device removal for erosion in 2 (11%) patients(21). None of those patients receiving the AUS had salvage prostatectomy which again is considered high-risk for perioperative complications. Our study with the modified technique has a low erosion rate and at the same time allows for good efficacy in a population of high risk patients where complications like erosions and infections are devastating morbidities.

The major limitation of this study is the retrospective nature of the analysis, and thus may have inherent selection bias. Nevertheless, the analysis is on consecutive patients undergoing primary sphincter placement while excluding any patients that had prior SUI procedures. Additionally, outcomes are cases from a single center and a single surgeon which may limit reproducibility. The learning curve for AUS placement has been shown to be steep and significant (25 up to 200 cases)(22,23). Furthermore, there are no head-to-head comparisons of AUS cuff placement techniques in the literature(24). It is extremely difficult to perform such a comparison given the limited number of AUS cases performed each year, even at high volume centers.

Conclusion

Our modified technique is safe with low infection and erosion rates with functional outcomes comparable to contemporary series, despite our relatively high risk population. The low rate of infection and erosion is particularly notable because of the high burden on patients who suffer these complications –two additional operations and lower success rate than in patients without infection or erosion. Our technique can be used across a wide variety of patients, including those with a history of radiotherapy and bladder neck contracture.

Conflicts of Interest: Dr. Sandhu reports personal fees from Boston Scientific, outside the submitted work. No other conflicts exist.

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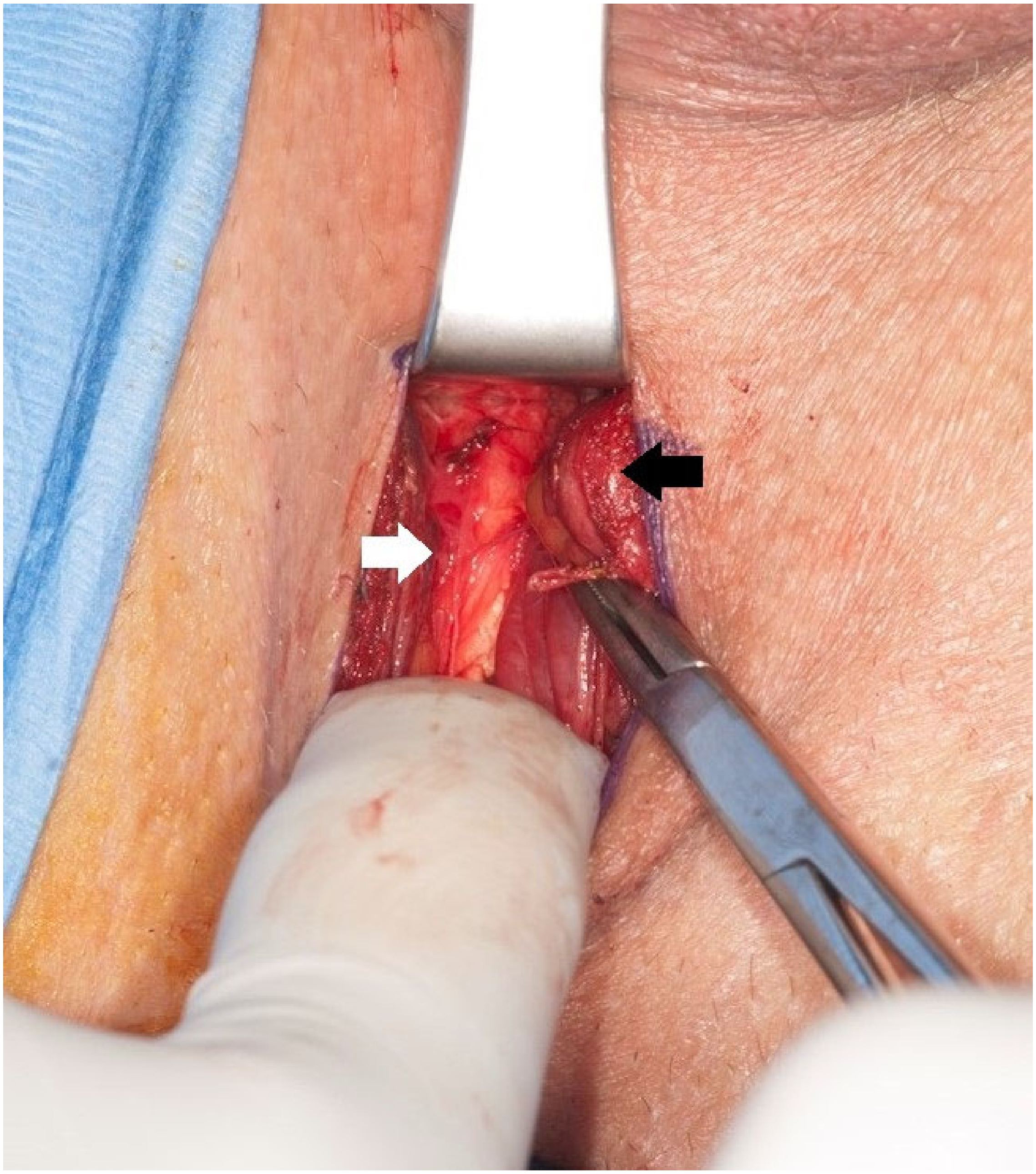
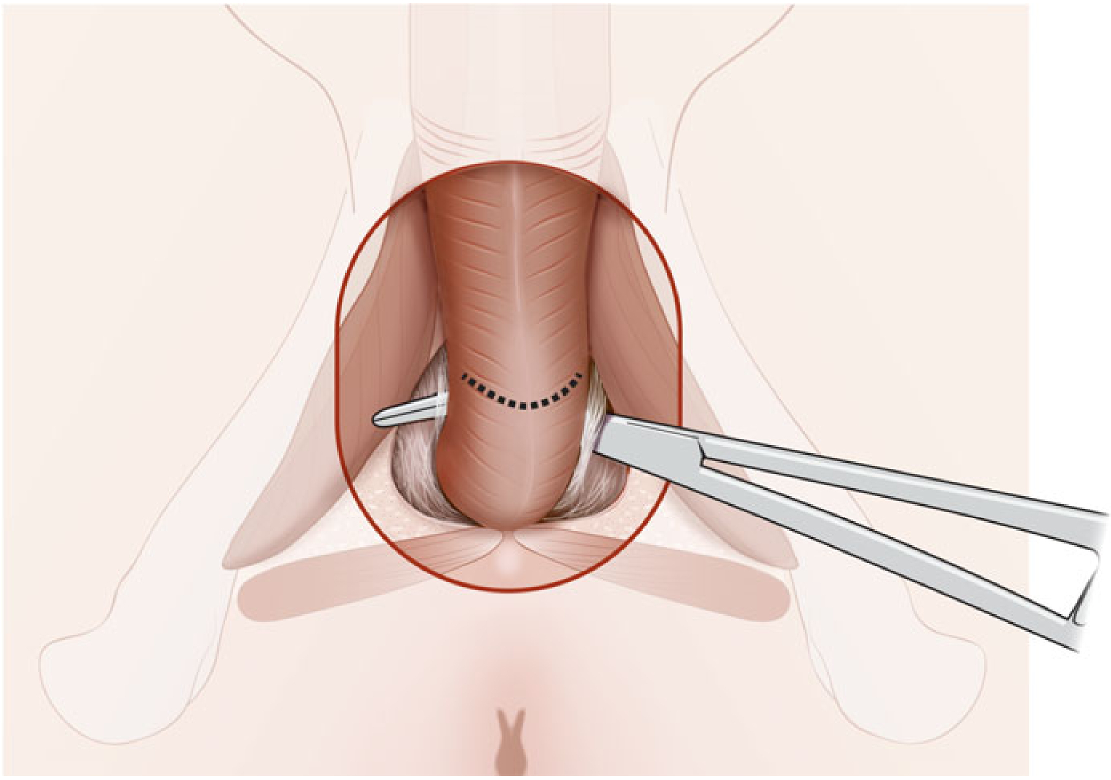
Table 1. Patient characteristics at first AUS procedure, N=208. All data are median (IQR) or frequency (%).

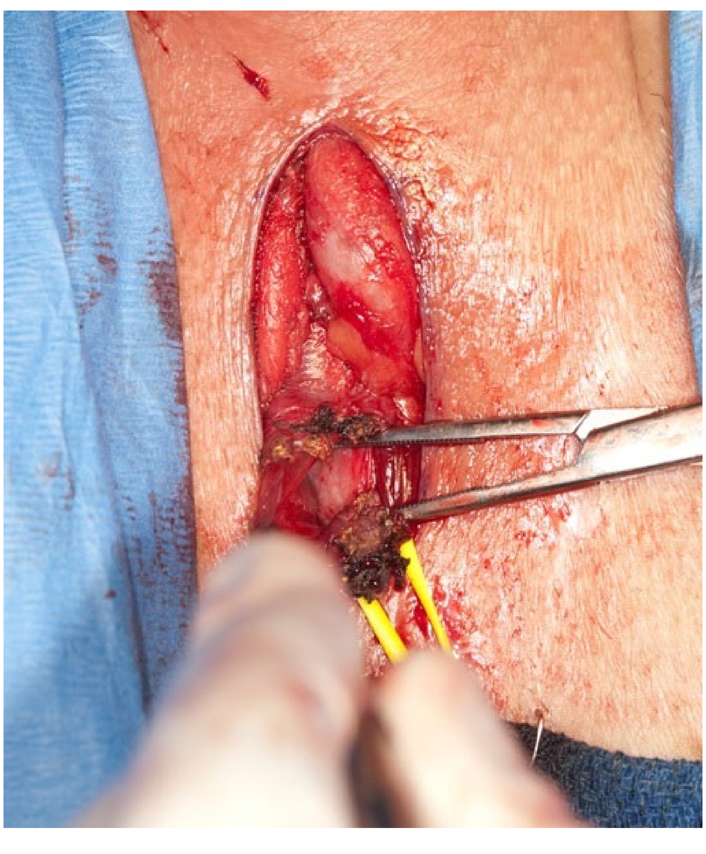
Age at first AUS procedure	67 (62, 71)
Type of pre-AUS radiation	
None	125 (60%)
Primary	34 (16%)
Salvage	31 (15%)
Other	2 (1.0%)
Pre-AUS radiation, type unknown	16 (7.7%)
Prior Operation Type	
Radical Prostatectomy	74 (36%)
Laparoscopic Radical Prostatectomy	30 (14%)
Robotic Radical Prostatectomy	28 (13%)
Salvage Radical Prostatectomy	25 (12%)
Salvage Laparoscopic Radical Prostatectomy	3 (1.4%)
Salvage Robotic Radical Prostatectomy	4 (1.9%)
Cystoprostatectomy	10 (4.8%)
TURP	13 (6.3%)
Other	1 (0.5%)
None	20 (10%)
History of bladder neck contracture	
Yes	54 (26%)
No	154 (74%)

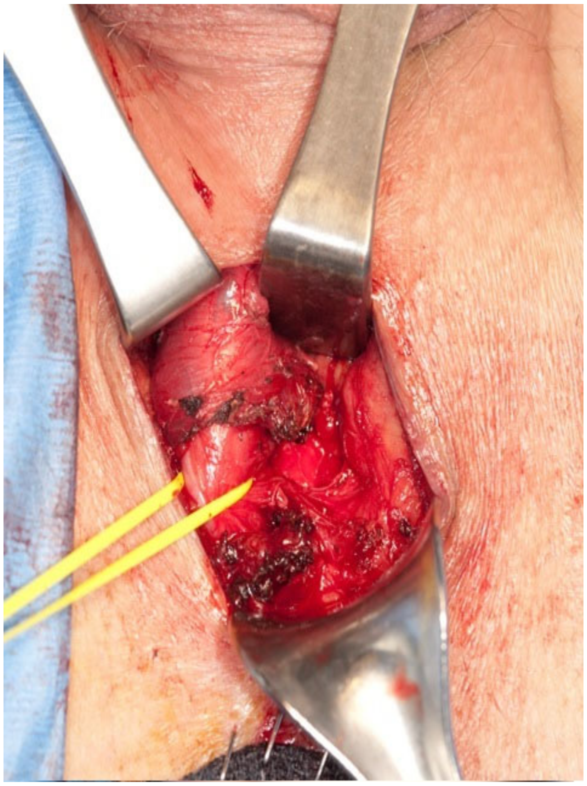
Table 2. Cox proportional hazards models for time from AUS procedure to reoperation for any reason and reoperation due to erosion or device malfunction, for any history of prior radiation and type of prior radiation.

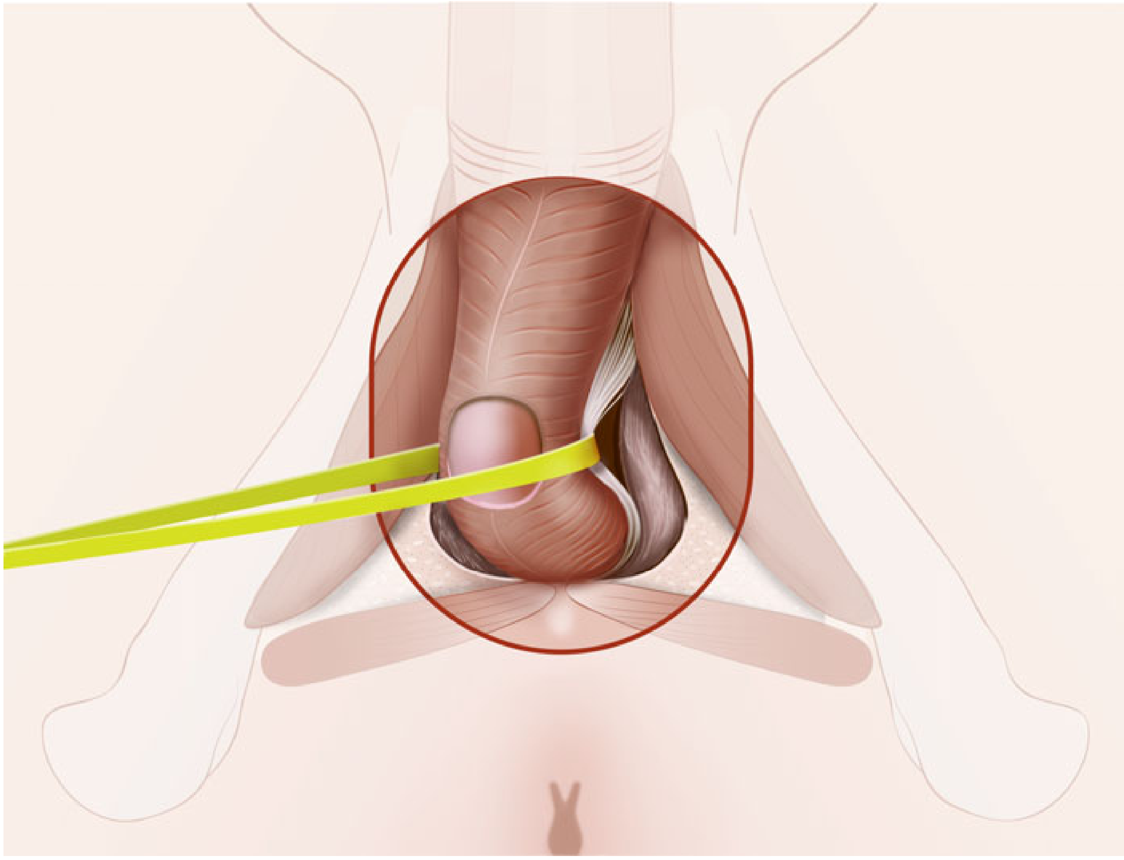
	Reoperation – Any Reason			Reoperation – Erosion and Device Malfunction		
	HR	95% CI	p value	HR	95% CI	p value
N=208						
No prior radiation	Ref.	-	0.2	Ref.	-	0.8
Prior radiation	0.72	0.42, 1.22		0.91	0.43, 1.96	
N=190						
No prior radiation	Ref.	-	0.4	Ref.	-	0.7
Prior primary radiation	0.60	0.29, 1.21		0.63	0.23, 1.76	
Prior salvage radiation	0.86	0.40, 1.86		0.84	0.24, 2.92	

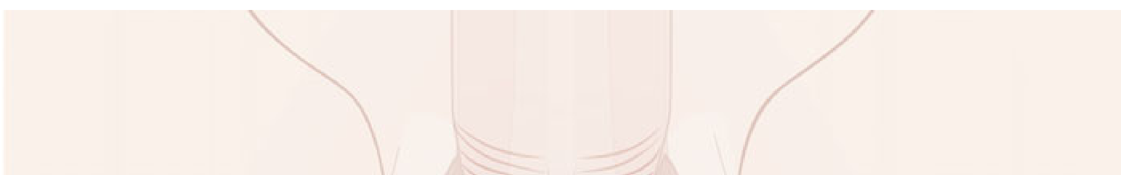












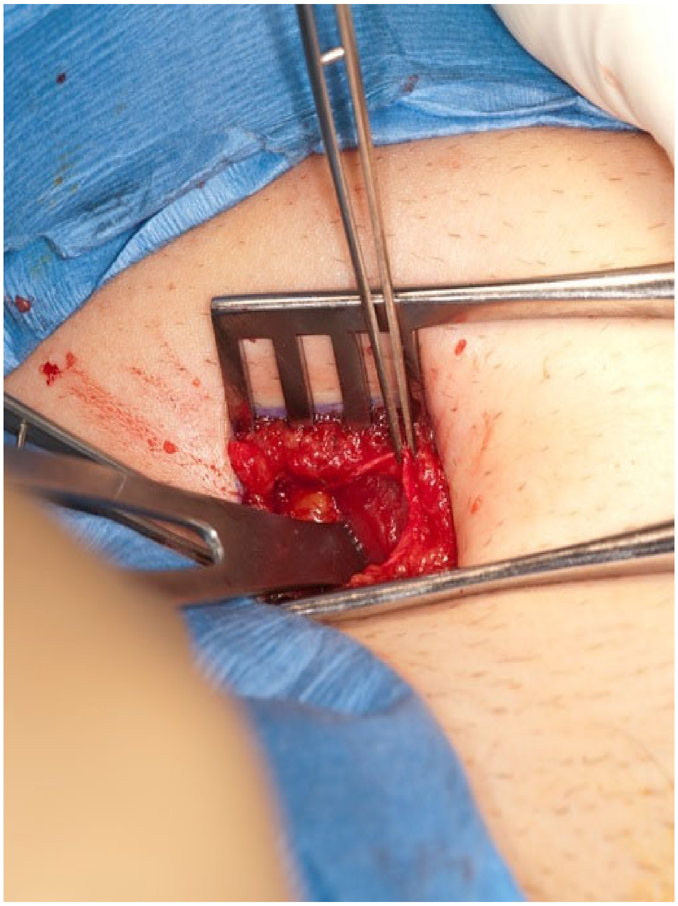


Figure 8. Kaplan-Meier estimates for time from AUS insertion to reoperation due to infection, erosion or device malfunction, with 95% confidence interval.