Long-Term Device Outcomes of Artificial Urinary Sphincter Reimplantation Following Prior Explantation for Erosion or Infection

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Abbreviations and Acronyms

AUS = artificial urinary sphincter

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Purpose: We evaluated clinical outcomes in patients treated with artificial urinary sphincter reimplantation after artificial urinary sphincter explantation for erosion or infection.

Materials and Methods: We identified 704 consecutive artificial urinary sphincter implantation procedures performed at our institution from 1998 to 2012, including 497 (71%) as primary implantation and 138 (20%) as revision surgery for device malfunction. A total of 69 patients (10%) had undergone at least 1 prior artificial urinary sphincter explantation secondary to urethral erosion and/or device infection, of whom 36 (52%) were treated with 2 to 5 prior reimplantation procedures. Patient followup was performed through office examination, or written or telephone correspondence.

Results: Patients treated with artificial urinary sphincter reimplantation had a median age of 78 years (IQR 72, 80) and a median followup of 34 months (IQR 5, 61). Artificial urinary sphincter reimplantation was done a median of 9 months (IQR 6, 13) after explantation. Patients treated with reimplantation after erosion or infection were more likely to require repeat explantation than those with primary implantation (13 of 69 or 19% vs 32 of 497 or 6.4%, $p = 0.002$). However, when evaluating repeat procedures, the 5-year device survival rate after reimplantation due to erosion or infection vs primary implantation was 68% vs 76% ($p = 0.38$).

Conclusions: Our findings suggest that artificial urinary sphincter reimplantation after explantation for urethral erosion and/or device infection is associated with an increased rate of recurrent erosion/infection requiring repeat explantation. However, in appropriately selected and counseled patients clinically acceptable long-term device use can be achieved.

Key Words: urinary bladder; urinary sphincter, artificial; urinary incontinence, stress; male; replantation

SINCE it was originally described in 1973, AUS implantation has been considered the gold standard for moderate to severe male stress urinary incontinence.[1] Multiple reports of primary implantation showed excellent long-term AUS durability and patient satisfaction.[2–4] Notably, in the setting of primary AUS implantation several large series revealed an overall 25% to 50% revision rate and a 0.46% to 9.5% infection/erosion rate.[2,3,5–8]

Also, multiple studies of the outcome of revision AUS surgery showed similar infection and erosion

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rates for primary and secondary procedures.[4,9] However, these series included a conglomeration of secondary operations, including those for mechanical and nonmechanical failure, ie device malfunction, urethral atrophy, erosion or infection. A few small series of patients who underwent secondary device implantation after explantation for erosion or infection showed decreased device survival and increased recurrent erosion rates compared to primary AUS implantation.[9–12] However, these studies were done in small cohorts with limited followup and typically lacked a comparative primary implantation group.[9–12]

Thus, in a large series with long-term followup we compared AUS durability and the frequency of erosion or infection events in patients treated with primary AUS implantation and those who underwent secondary AUS reimplantation after prior explantation for device erosion or infection.

METHODS

After obtaining institutional review board approval we reviewed the records of 704 consecutive patients who underwent AUS placement at our institution from October 1998 to January 2012. We identified 69 men previously treated with device explantation due to erosion or infection in circumstances that we refer to as salvage AUS placement. Determination of the reason for device explantation was based on clinical presentation, cystoscopy, radiographic imaging and/or intraoperative findings. Erosion was defined as perforation of the urethral cuff into the urethral lumen. Device explantation was considered due to infection if suggested by clinical presentation, in addition to a lack of evidence of erosion on cystoscopic and/or radiographic evaluation. In all cases the entire device (cuff, reservoir, tubing and pump) was removed at explantation.

After AUS explantation a waiting period of at least 3 months (median 9, IQR 6, 13) was used to allow tissue healing before salvage reimplantation. Healthy urethral tissue was confirmed via cystoscopy and physical examination before proceeding with reimplantation. The decision to proceed with reimplantation was at treating surgeon discretion after thorough consultation with the patient.

All implanted AUS devices were an AMS 800®. All urethral cuffs were placed around the bulbar urethra with cuff size and type (tandem vs single and/or transcorporeal) at treating surgeon discretion. Recorded clinical variables included patient age, incontinence etiology, number of prior implantation procedures, body mass index, diabetes mellitus, coronary artery disease, hypertension and pelvic radiation history. Patients were excluded from analysis if they were female, younger than 18 years or had the cuff implanted at the bladder neck.

The retrospective nature of this study precluded a standardized followup protocol in all patients. Rather, patient followup regarding device survival and function was performed by last office examination, or written or telephone correspondence.

Followup duration was compared using the Wilcoxon rank sum test. AUS explantation and revision rates were compared by chi-square analysis and the Fisher exact test (revision rate). Device survival was estimated as time from AUS implantation to subsequent explantation or revision using the Kaplan-Meier method. Statistical analysis was performed using JMP®. All statistical tests were 2-sided with $p < 0.05$ considered statistically significant.

RESULTS

We identified 704 consecutive AUS implantation procedures performed at our institution from 1998 to 2012, of which 497 (71%) were primary implantation and 138 (20%) were revision surgery for mechanical failure or urethral atrophy. A total of 69 patients (10%) had undergone prior AUS explantation secondary to urethral erosion and/or device infection. In 32 of the 69 men (46%) with salvage AUS placement the most recent prior AUS device was placed at our institution.

Table 1 lists clinical features of all 69 patients with a median age of 77.5 years (IQR 71, 80) who underwent salvage AUS implantation after explantation for erosion or infection at a median of 8 months (IQR 6, 13). These men had been treated with a median of 2 prior device placements (range 1 to 5). Those treated with salvage AUS reimplantation were a median of 78 years old (IQR 72, 80) and had a median followup of 34 months (IQR 5, 61). The most common etiologies of stress urinary incontinence were radical prostatectomy in 61% of cases, radiation therapy in 9% and radical prostatectomy plus radiation therapy in 24%. Comorbid medical conditions were highly prevalent, such as obesity, hypertension and diabetes mellitus.

Table 1. *Clinicopathological features of patients with AUS reimplantation after previous erosion or infection event*

	No. Devices Reimplanted (%)
Explantation etiology:	
Erosion	53 (77)
Infection	16 (23)
Incontinence etiology:	
Transurethral prostate resection	3 (4)
Radical prostatectomy	43 (62)
Radiation therapy	5 (7)
Transurethral prostate resection + radiation therapy	1 (1)
Prostatectomy + radiation therapy	17 (25)
Body mass index greater than 25 kg/m^2	56 (81)
Diabetes mellitus	16 (23)
Hypertension	37 (54)
Coronary artery disease	23 (33)
Prior pelvic radiation therapy	22 (32)
Surgical cuff placement:	
Single bulbar	45 (65)
Tandem	3 (4)
Transcorporeal	18 (26)
Tandem transcorporeal	3 (4)