

# Long-term (> 5 years) outcomes of patients implanted with artificial urinary sphincter: A single-center experience

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## Abstract

**Introduction:** This study is conducted to evaluate the long-term outcomes, including effectiveness and complications, of artificial urinary sphincter (AUS) implantation in men with primarily stress urinary incontinence.

**Materials and Methods:** Consecutive patients with complete data sets and a continuous follow-up with the device in place for 5 years or more were included. We analyzed effectiveness through pads per day use, and complications were assessed based on device revisions and explantations. Various risk factors for revisions were evaluated and revision free-survival at 15 years was estimated.

**Results:** Thirty-four male patients were implanted and followed for a mean of 116.5 months (range: 60–285). Mean pads per day use was significantly decreased from 3.6 at baseline to 0.6 at 1 year, 1.1 at 5 years, and 1.06 at last visit ( $P < 0.0001$ ). During follow-up, 12 patients (35%) required between 1 and 3 device revisions and 1 (3%) required 5. The device revision-free survival was 76% (confidence interval [CI] 58%–87%) at 5 years and 56% (CI 32%–75%) at 15 years. A higher mean number of dilations or incisions for bladder neck contractures was a statistically significant risk factor for revisions in univariate analysis (odds ratio 1.8; 95% CI 1.02–3.2). No other significant risk factors for revisions were found. Explantations were performed in four patients for device erosion at 60, 69, 153, and 200 months.

**Conclusions:** The AUS provides excellent long-term outcomes with continued improvement in continence rates and <50% of patients requiring revisions at 15 years. The previous history of bladder neck contractures and dilations may predispose to an increased rate of revisions.

**Keywords:** Artificial urinary sphincter, follow-up studies, incontinence pads, prostatectomy, stress urinary incontinence, urinary incontinence

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## INTRODUCTION

Urinary incontinence is a common urological problem with an overall prevalence in men close to 17% and related annual costs in the United States of \$20 billion dollars.<sup>[1-3]</sup> Since its introduction in 1973, the artificial urinary sphincter (AUS) remains one of the most effective and commonly

performed surgical treatments for postprostatectomy male stress urinary incontinence (SUI) with more than 150,000 implantations worldwide.<sup>[4-6]</sup> Results show high effectiveness for continence with improved or dry mean rates of 79%, ranging between 59% and 100%, and high patient satisfaction, leading to a widespread use as well as

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to a grade B recommendation in the current European Association of Urology guidelines for moderate to severe SUI.<sup>[7,8]</sup> However, the device is also associated with repeat interventions, including revisions or explantations, in 26%–53% of the patients after mechanical failure, urethral atrophy, infection, or erosions.<sup>[5,8-10]</sup> Most data on AUS come from older retrospective studies with few trials showing long-term functional outcomes.<sup>[5,8]</sup> Thus, the main objective of this study is to report on a long-term follow-up (>5 years) of outcomes evaluating effectiveness and complications in male patients with primarily SUI who had AUS implantation at our institution.

## MATERIALS AND METHODS

After receiving Institutional Review Board approval, we analyzed records of patients with SUI or mixed incontinence after prostate cancer treatment that required AUS implantation for continence control at the Beth Israel Deaconess Medical Center in Boston, Massachusetts. All patients had to have a continuous minimum follow-up after device implantation of 5 years. All implantations were done with a classic two-incision technique using a single AMS 800™ (Boston Scientific, Marlborough, MA) cuff with bulbar urethral placement. The patients received broad-spectrum prophylactic antibiotics before the incision, antibiotic irrigation during the procedure, and postoperative antibiotics with cephalexin or ciprofloxacin for 7 days. Most of them were seen at 6 or 8 weeks for device activation. We recorded baseline characteristics such as age, body mass index (BMI), American Society of Anesthesiologists physical classification system (ASA), comorbidities, baseline diagnosis, etiology, severity, previous treatments for SUI, history of bladder neck contractures, cystoscopy findings, and treatment received for prostate cancer. Urodynamic results were available for 21 out of 34 patients. Early postoperative complications were recorded through Clavien-Dindo classification, and patients were followed yearly afterward with symptoms assessment and pads per day use. The effectiveness of the device was measured through the use of pads per day at year 1, 5, and last visit. The dry rate was defined as 0 pads per day, and improved rate was defined as 1 pad per day. Rates and causes for revisions and explantations including infection, erosion, urethral atrophy, device malfunction/migration, or persistent symptoms were recorded. Device revision-free survival which was defined as the absence of a second related surgery during follow-up was estimated using Kaplan–Meier curves. Hazard ratios were calculated with 95% confidence intervals (CIs). We searched for significant risk factors for revisions based on uniform data set (UDS) findings, prior history of bladder neck

contractures and dilations, history of radiotherapy, ASA, BMI, and presence of comorbidities such as diabetes mellitus, cardiovascular disease, and hypertension. We checked normal distribution and used *t*-test for normally distributed continuous variables or Wilcoxon rank-sum test if not to assess significance. Chi-square test was performed for categorical binary variables. Logistic regression analysis was used to include multiple variables and assess for potential risk factors.  $P < 0.05$  is to determine significance with a two-tailed. Calculations were made through Stata® 15 software (StataCorp. LLC, College Station, TX, USA).

## RESULTS

Thirty-four consecutive patients had complete data sets and a continuous follow-up with the device in place for 5 years or more. All of them had a previous history of prostate cancer treated with radical retropubic prostatectomy (RRP) in 70%, RRP + radiation in 21%, radiation alone in 3% while the remaining 6% included cryoablation and robotic-assisted laparoscopic prostatectomy. Pure stress incontinence was the main complaint in 76% of the patients and mixed incontinence in 24%. The mean age at implantation was 68 years/old with a mean follow-up after implantation of 116.5 months (range: 60–285). Other baseline characteristics and details about AUS implantation are included in Table 1. Prior medical history included bladder neck contractures in 44% with a mean number of dilations or incisions of 3.7. Baseline mean pads per day use was 3.6 (range: 1–10) and 1 patient was using, in addition, a Cunningham clamp for continence control. UDS was performed in 21 patients showing intrinsic sphincter deficiency (ISD) alone in 16 patients and ISD + detrusor overactivity (DO) in 5. The mean leak point pressure was 53 cm water (range 25–100), bladder capacity 293.4 ml (range 125–550), and Q max of 11.2 ml/s (range 5–24).

After implantation, one patient presented with a scrotal hematoma requiring drainage classified as a Clavien-Dindo IIIB complication. During follow-up, 12 patients required between 1 and 3 device revisions and 1 patient required 5 with a total number of revisions in the cohort of 26. The median time to the first revision was 19 months (interquartile range: 7–70 months). The cause for revisions was persistent incontinence, generally due to cuff related urethral atrophy or device malfunction in 65%, erosions in 19%, trauma causing the pressure regulating balloon to burst in 12%, and infection in 4%. The device revision-free survival was 76% (CI 58%–87%) at 5 years and 56% (CI 32%–75%) at 15 years [Figure 1]. A higher mean number of dilations for bladder neck contractures was a statistically significant

**Table 1: Baseline patient characteristics and implanted AUS details**

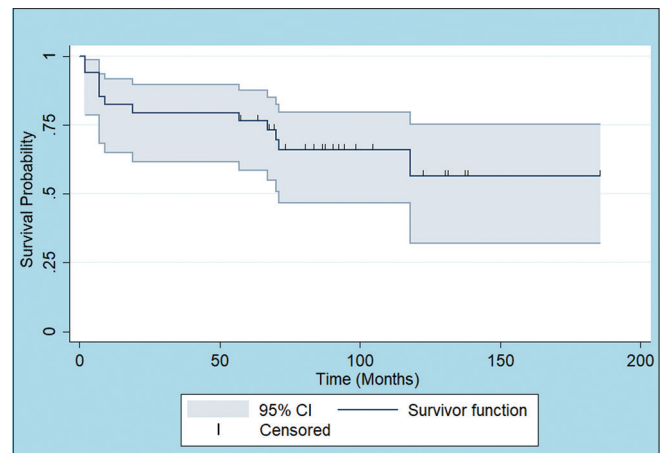
Total Male Patients	34
Incontinence Type (%)	
Pure Stress	76
Mixed Incontinence	24
Mean±SE BMI	26.7±3.7
Comorbidities (n)	
Hypertension	22
Dyslipidemia	10
Diabetes	8
Cardiovascular disease	6
Depression	3
Chronic Obstructive Pulmonary Disease	2
Hypothyroidism	2
Mean±SE of Urethral Dilations	1.5±3.6
Previous Treatment for SUI (n)	
Collagen	8
Medications	1
Sling	1
Mean±SE Age at Implantation	68±8.2
Year of Implant (%)	
<2000	20
2000-2010	76
>2010	3
Cuff Size (%)	
4 cm	53
4.5 cm	44
5 cm	3
Pressure (%)	
51-60 cmH <sub>2</sub> O	24
61-70 cmH <sub>2</sub> O	52
71-80 cmH <sub>2</sub> O	24

risk factor for revisions in univariable analysis (odds ratio 1.8; 95% CI 1.02–3.2). Patients who received radiotherapy did not show statistically significant differences in revisions ( $P = 0.9$ ), and there was no statistically significant difference either between patients with ISD + DO versus ISD alone ( $P = 0.06$ ). Other possible risk factors such as higher ASA ( $P = 0.2$ ), or higher BMI ( $P = 0.9$ ) were not statistically significant. Explantation after 5 years was carried out in 4 patients for device erosion at 60, 69, 153, and 200 months.

Mean pads per day use as a measure of continence was significantly decreased from 3.6 pads to 0.6 pads at 1 year, 1.1 at 5 years, and 1.06 at last visit ( $P < 0.0001$ ). In addition, two patients with recurrent bladder neck contractures required clean intermittent self-catheterization to keep the bladder neck open. At the end of the follow-up, 29 patients had the device activated and functioning properly while the device was explanted in 4. The remaining patient had the device deactivated because of decreased dexterity secondary to underlying dementia.

## DISCUSSION

This is one of the longest studies reporting results in AUS implanted patients. We analyzed outcomes with

**Figure 1: Device revision-free survival estimates**

the device in place during a mean follow-up of more than 9 years in patients primarily with postprostatectomy incontinence. In this cohort of 34 men, AUS device effectiveness was similar to other reports with 82% of the patients requiring 1 or fewer pads per day during the 1<sup>st</sup> year and 35% of them achieving dryness.<sup>[8,10-13]</sup> Furthermore, significantly improved continence was maintained for 5–15 years.

Considering early postoperative complications, one study of 57 patients with a median follow-up of 15 years showed this type of complications in 6 implanted patients with the majority being Clavien-Dindo I and II.<sup>[14]</sup> This contrasts with our series where only one patient presented a postoperative complication. Regarding overall complications, device revisions were needed in 38% of patients with the most of them requiring between 1 and 3 revisions. This is consistent with one pooled analysis of 12 studies that showed a reoperation rate of 26% (14.8%–44.8%).<sup>[8]</sup> Our findings showed recurrent symptoms, mainly because urethral atrophy, as the main cause for revisions which is similar with several studies.<sup>[5,10,15]</sup> However, other authors have reported infections or erosions as the main causes for revision.<sup>[8,9,11]</sup> The device revision-free survival has been described previously, and we estimated that after 15 years, 56% of patients will be free from revisions which is better than the series reported by Léon *et al.* where only 15% was revision free by 15 years.<sup>[14]</sup> Different risk factors for revisions and explantations have been evaluated, and there is conflicting data for previously irradiated patients. While some authors have reported worse outcomes in this subpopulation, others have not found statistically significant differences.<sup>[5,6,9,10,14-18]</sup> Although in this series we only had a small number of radiated subjects, patients with radiation did not show an increased rate of complications.

We identified an increased revision rate in patients with a previous history of bladder neck contracture and dilations. Due to their need for urethral manipulation and instrumentation, they may be at higher risk of complications such as erosions, but further studies are needed to confirm this finding.

There were no definitive associations between any UDS parameters and increased adverse outcomes in this population. These findings are also expected and similar to what other investigators have found.<sup>[19]</sup> However, patients with poorly compliant bladders may have been excluded for device implantation based on their urodynamic findings.

There was a total of 4 explants between 5 and 15 years in our cohort. All were due to cuff or pump erosion with 2 occurring just after 5 years and the other 2 between 10 and 15 years. This is interesting and consistent with findings in other studies where explantation most commonly occur in 2 peaks around 5 and 10 years after implantation.<sup>[14]</sup>

Our results show overall excellent outcomes for continence after AUS placement with the majority of patients achieving dryness or significantly improved continence rates. These results were maintained over time with very acceptable benefit/risk duration for up to 15 years. The main causes for revisions were the return of symptoms due to atrophy under the cuff or device malfunction. However, infections or erosions were much less commonly seen, and this may be due to careful aseptic technique and appropriate use of antibiotics.<sup>[20]</sup>

This study has several limitations. First is the retrospective observational nature of the study and the resultant biases. Second is the small sample size with a related loss of power. Third is the absence of a proper control. Nevertheless, this study does provide further important information useful for both urologists and patients. The continuous follow-up for at least 5 years and device revision-free survival curves for up to 15 years after implantation further increases the knowledge about long-term effectiveness and complications of this device and help the patients to make a more informed decision. Our next step will be to focus on satisfaction and quality of life as most of the patients referred satisfaction with the device.

## CONCLUSION

The present study shows that the AUS provides excellent long-term outcomes with overall improved continence rates

and revisions in <25% at 5 years and in <50% at 15 years. Although the numbers are relatively small, radiated patients did not show worse outcomes, but the previous history of bladder neck contracture and dilations may predispose to an increased rate of revisions.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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