

# The Artificial Urinary Sphincter is Superior to a Secondary Transobturator Male Sling in Cases of a Primary Sling Failure

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## Abbreviations and Acronyms

AUS = artificial urinary sphincter  
BMI = body mass index  
PPSUI = post-prostatectomy stress urinary incontinence  
UDS = urodynamics  
VLPP = Valsalva leak point pressure

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**Purpose:** We compared continence outcomes in patients with post-prostatectomy stress urinary incontinence treated with a salvage artificial urinary sphincter vs a secondary transobturator sling.

**Materials and Methods:** We retrospectively reviewed the records of patients undergoing salvage procedures after sling failure from 2006 to 2012. Post-operative success was defined as the use of 0 or 1 pad, a negative stress test and pad weight less than 8 gm per day. We performed the Wilcoxon test and used a Cox regression model and Kaplan-Meier survival analysis.

**Results:** A total of 61 men presenting with sling failure were included in study, of whom 32 went directly to an artificial urinary sphincter and 29 received a secondary sling. Of the artificial urinary sphincter cohort 47% underwent prior external beam radiation therapy vs 17% of the secondary sling cohort ( $p = 0.01$ ). Average preoperative 24 hour pad weight and pad number were higher in the artificial urinary sphincter cohort. Median followup in artificial urinary sphincter and secondary sling cases was 4.5 (IQR 4–12) and 4 months (IQR 1–5), respectively. Overall treatment failure was seen in 55% of patients (16 of 29) with a secondary sling vs 6% (2 of 32) with an artificial urinary sphincter (unadjusted HR 7, 95% CI 2–32 and adjusted HR 6, 95% CI 1–31).

**Conclusion:** In this cohort of patients with post-prostatectomy stress urinary incontinence and a failed primary sling those who underwent a secondary sling procedure were up to 6 times more likely to have persistent incontinence vs those who underwent artificial urinary sphincter placement. These data are useful for counseling patients and planning surgery. We currently recommend placement of an artificial urinary sphincter for patients in whom an initial sling has failed.

**Key Words:** urethra; prostatectomy; urinary incontinence, stress; suburethral slings; urinary sphincter, artificial

STRESS urinary incontinence is common after transurethral and radical resection of the prostate. The incidence of incontinence ranges from 1% to 3% after benign resection<sup>1,2</sup> and from 5% to 90% after radical resection for prostate cancer.<sup>3,4</sup> PPSUI, which can greatly affect quality of life, represents a major economic burden<sup>5</sup>

with 6% to 9% of patients seeking surgical treatment for PPSUI.<sup>6</sup>

The male transobturator sling is a minimally invasive treatment option for PPSUI with reported success rates ranging from 76% to 91% at 12 to 27-month followup.<sup>7</sup> In case of a failed primary sling many surgeons offer a variety of salvage therapies, including

ProACT™, an AUS, excision and replacement of transobturator slings, and repeat transobturator slings while leaving the original sling in place.<sup>8–13</sup> However, to our knowledge there are no published head-to-head comparisons of salvage therapies for the management of transobturator sling failure.

Our objective was to assess the success of a secondary transobturator sling compared to AUS implantation in the management of primary sling failures for patients with PPSUI.

## METHODS

### Patient Selection

We performed an institutional review board approved, retrospective review of all patients who underwent placement of a transobturator sling at our institution from January 2006 to December 2012. We used our institutional data portal DEDUCE (Duke Enterprise Data Unified Content Explore) to identify these patients. DEDUCE is an online research tool that provides Duke University Medical Center investigators with access to clinical information collected as a byproduct of patient care.

### Data Collection and Outcome Definition

We extracted demographic and followup data from clinic notes. Patients provided a 24-hour pad test to quantify incontinence after primary transobturator sling failure. We recorded 24-hour pad weights and the number of pads used by each patient after transobturator sling failure. We assessed functional bladder capacity from the patient 24-hour bladder diary as recorded prior to the first transobturator sling placement. A small portion of patients underwent repeat UDS after sling failure and we report the patient VLPP from these repeated studies. Time at outcome was calculated as the first time that a patient reported recurrent incontinence or the last recorded urology appointment when the patient was noted to be continent by the urologist. We defined post-operative continence as the use of 0 or 1 security pad per day, a negative stress test on examination and a pad weight of less than 8 gm per day.<sup>14</sup>

### Operative Technique

Each salvage procedure was performed by one of 3 surgeons (GDW, ACP or ACL) using the same technique. AUS placement was done through a perineal incision with the AUS cuff placed around the intercrustral bulbar urethra and distal to the sling. In all cases the sling was left in situ.<sup>10</sup> The salvage transobturator sling was also placed through a perineal incision without excising the indwelling sling.<sup>15</sup> All slings were AdVance™ transobturator slings.

### Statistical Analysis

Summary statistics are presented as the mean  $\pm$  SD for normally distributed variables and the median (IQR) for continuous variables that were not normally distributed. Frequency and percentages are presented for categorical variables. Missing data were assessed and less than 10% of the data set was missing. We used the Fisher exact test to statistically compare demographic variables that were

categorical, the Student t-test to compare normally distributed continuous variables and the Wilcoxon rank test to compare nonnormal continuous variables.

We applied the Wilcoxon test, a Cox regression model and Kaplan-Meier survival analysis to compare the likelihood of continence with time in patients who received an AUS vs a secondary transobturator sling. Statistical analyses were performed with STATA®, version 13.1.

## RESULTS

We identified 330 patients who underwent a transobturator sling procedure for PPSUI. By chart review we determined that 63 patients reported persistent incontinence after transobturator sling placement and elected to undergo a salvage procedure. Two patients were excluded from study, including 1 lost to followup after AUS placement and the other with a long protracted course that included placement and removal of an InterStim® sacral nerve stimulator. Of the 61 included patients 32 subsequently went directly to placement of an AUS and 29 received a secondary transobturator sling at a median of 10 (IQR 6–29) and 14 months (IQR 7–19) after primary surgery, respectively.

The table lists the baseline demographic characteristics of the 2 groups. The groups did not differ significantly by age, race, BMI or the prevalence of diabetes. Of the AUS cohort 47% had received prior external beam radiation therapy vs 17% of the secondary transobturator sling cohort ( $p = 0.01$ ). Of patients who went on to receive an AUS 28% had a history of a bladder neck contracture that had been treated with a bladder neck incision vs 3% who received a transobturator sling ( $p = 0.01$ ). Average daily pad use and 24-hour pad weight recorded after sling failure were higher in the cohort that underwent AUS placement (4 pads per day and 400 gm) vs the cohort that received a secondary transobturator sling (2 pads per day and 300 gm). UDS was routinely performed before placing the first transobturator sling but not always when managing treatment failure. Repeat UDS testing was done in 14 patients, of whom secondary transobturator sling recipients had a higher and more favorable median VLPP than those who underwent AUS salvage therapy.

Median followup for the AUS and the secondary sling cohorts was 4.5 (IQR 4–12) and 4 months (IQR 1–5), respectively. At 4 months 100% of salvage AUS patients were continent vs a median of 79% of secondary sling patients (95% CI 56–90). At 5 months median continence rates were 100% vs 43% (95% CI 20–64), respectively. At 10 months 100% of AUS patients remained continent vs 35% of secondary sling patients (95% CI 14–58). Overall treatment failure was seen in 55% of secondary sling cases (16 of 29) vs 6% of AUS cases (2 of 32)

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