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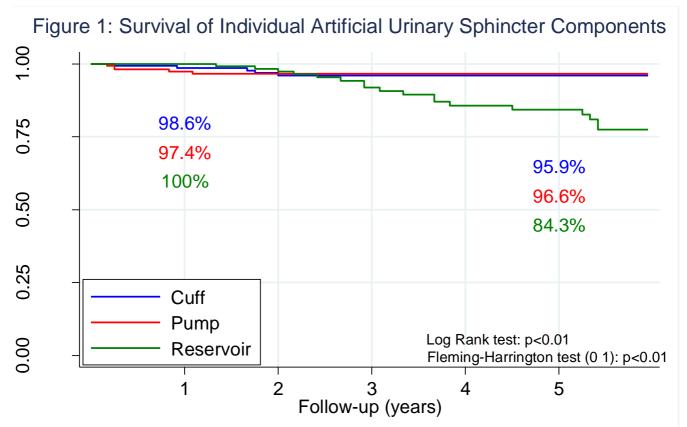
# ARTIFICIAL URINARY SPHINCTER FAILURE: CHARACTERIZING THE CAUSES OF FAILURES AND INDIVIDUAL DEVICE COMPONENT SURVIVAL

#### Hypothesis / aims of study

Stress urinary incontinence (SUI) occurs in 60% of men after radical prostatectomy, with 5% requiring surgical treatment. The artificial urinary sphincter (AUS), which offers excellent control of their post-prostatectomy SUI, contains 3 parts: the pump, urethral cuff, and pressure regulating balloon reservoir. Despite the effectiveness of AUS, up to 50% of patients require surgical revision after initial placement due to recurring SUI. Thus far, literature is heterogeneous regarding the causes of mechanical AUS failure and appropriate surgical management. Our study aims to tabulate the most common reasons of AUS failure requiring surgical revision and measure the differential survival of each AUS component.

### Study design, materials and methods

We report a series of 168 patients who received AUS placement and/or revision by one surgeon from 2008 – 2016. Explant or revision due to AUS malfunction or loss of efficacy was the event of interest. Upon presenting for revision, intraoperatively, the surgeon systematically evaluated the device for failure of the cuff, pump, and reservoir as well as the urethra, for signs of erosion or atrophy. In patients not requiring revision all device components were presumed functional. We conducted retrospective chart review to collect baseline characteristics, intraoperative findings, and post-operative outcomes. Survival rates for cuffs, pumps, and reservoirs were measured using Kaplan Meier estimates and compared using log-rank and Fleming-Harrington test statistics. Cox proportional hazards models were used to identify predictors of all-cause failure and mechanical failure.



### Results

168 patients were studied with median follow up of 2.7 years (IQR: 1.1, 5.9). All patients received an AMS 800 device with a 61-70mL reservoir filled with 27cc of isotonic contrast or saline. Cuff sizes ranged from 3.5 to 5.5cm, with 4.5cm selected in 119/168 cases (75.0%). 63 of the patients required AUS correction (37.5%). Loss of reservoir porosity and reservoir leak constituted 36.5% (23/63) of failures, followed by urethral atrophy (22.2%), and urethral erosion (19.0%), with few cases of pump (5) or cuff (5) failure. Among patients requiring revision, median time to AUS failure was 3.7 years (IQR: 2.7, 5.4) for reservoir causes and 1.1 years (IQR: 0.25, 2.5) for non-reservoir causes. Survival rates at 1 and 5 years for the reservoir, cuff, and pump are illustrated in Figure 1.

#### Interpretation of results

Our study identifies reservoir malfunction as the most common cause of AUS failure, particularly in patients presenting between 3 and 5 years after initial placement. For such patients, interrogating the reservoir first can decrease infection risk and surgical morbidity as it avoids manipulation of the urethral cuff. Furthermore, simply replacing lost fluid saves cost and allows for immediate reactivation of the AUS device.

### Concluding message

Reservoir fluid leak is the most common cause of AUS failure, particularly when patients present for revision several years after initial placement. Understanding this, initial interrogation and replacement of the reservoir may reduce surgical morbidity and costs for patients requiring AUS revision.

#### **Disclosures**

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