# Artificial Urinary Sphincter Mechanical Failures—Is it Better to Replace the Entire Device or Just the Malfunctioning Component?

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**Purpose:** We evaluate the characteristics of artificial urinary sphincter mechanical failures and compare outcomes based on the surgical revision strategy, replacing only the failed component or the entire device.

**Materials and Methods:** A total of 1,802 male patients with stress urinary incontinence underwent artificial urinary sphincter procedures from 1983 to 2011 at our institution, of which 1,082 were primary placements. Of these patients 125 experienced mechanical device malfunction. Multiple clinical and surgical variables were evaluated for a potential association with device malfunction. In addition, we evaluated for predictors of failure of the revised device, including time from primary artificial urinary sphincter to revision surgery and surgical revision strategy (single component vs entire device), with failure defined as any tertiary surgery.

**Results:** At a median followup of 4.2 years (IQR 0.8, 7.9) 125 patients experienced device malfunction. The urethral cuff was the most common component failure (46.1%), followed by abdominal reservoir (22.6%), tubing (21.7%) and pump (9.6%). There was no association of time from primary surgery to revision for mechanical failure (HR 0.89, p=0.33) or revision strategy (HR 0.47, p=0.15) with the risk of tertiary surgery. Additionally, as there was no significant interaction between these variables (HR 1.11, p=0.39), no cutoff could be identified at which one revision technique produced significantly improved device survival compared to another. However, there was a trend toward improved 3-year device survival after replacement of the entire device vs a single component (76% vs 60%, p=0.11).

**Conclusions:** No cutoff in time to mechanical failure could be identified to guide decision making in the management of mechanical artificial urinary sphincter failure. Likewise, it is unclear if replacing the entire device, rather than the single malfunctioning component, alters device survival. As such, further studies are needed. However, given the current trend toward improved overall device survival, the limited additional risk and the lack of adequate clinical predictors for tertiary surgery, we would advocate for replacement of the entire device when possible.

**Key Words:** urinary sphincter, artificial; equipment failure; male; urinary incontinence; treatment outcome

**Abbreviations and Acronyms**

AUS = artificial urinary sphincter

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While artificial urinary sphincter placement is associated with excellent outcomes in the surgical management of severe male stress urinary incontinence, it is prone to failure with time.[1–3] Typically device

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failure is identified secondary to the development of recurrent incontinence, which may be secondary to mechanical device malfunction with leakage of fluid from the closed system, urethral atrophy, device infection or urethral erosion.[1,4–6] For those cases of device malfunction (ie from leaking of the instilled fluid) there is a paucity of data to support surgical management decisions.[5,7–9]

Given the limited data available on the surgical management of AUS mechanical failure, significant heterogeneity exists in the recommendations in the current literature.[5,7–11] For instance, it has been suggested that the entire device be removed if it malfunctions after being in place for 3 to 5 years, which is largely based on the median time to device malfunction.[5,7–9] This approach attempts to balance the risks of device infection, increased cost and longer recovery from more extensive surgery with the risk of repeat malfunction secondary to a component left in situ. Conversely, others argue for replacing the entire device in all cases.[10,11] Notably there are no reported predictors of device malfunction that could be used to guide decision making.[9,12] Therefore, we evaluated the predictors and management of mechanical AUS failure, comparing revision of a single component to replacement of the entire device, while accounting for time to failure of the primary device.

## MATERIALS AND METHODS

After obtaining institutional review board approval we identified 1,802 male patients who underwent AUS implantation at the Mayo Clinic (Rochester, Minnesota) from 1983 to 2011. Of those patients 1,082 were treated with primary implantations, and a subset (125) experienced mechanical device failure and underwent revision. Patients were excluded from analysis if they underwent primary AUS placement secondary to neurogenic bladder dysfunction, were less than 18 years old at AUS placement or declined research consent. Three surgeons performed the AUS implantations during the study and all implanted AUS devices were AMS 800™. The AUS components were filled with 22 cc iso-osmotic contrast, a water/contrast mix of 48 ml iohexol (Omnipaque™ 350) and 60 ml sterile water at the time of placement. In our practice a routine postoperative x-ray is performed to evaluate for contrast leak.

With regard to our approach to the evaluation of recurrent stress urinary incontinence after AUS placement, patients are evaluated with history and physical, cystoscopy (to rule out erosion, evaluate tissue quality and coaptation for urethral atrophy), uroflow with post-void residual and x-ray imaging (as contrast is instilled at the time of surgery in our primary placements). Device malfunction is confirmed by identifying loss of contrast from the system, as shown in figure 1. In terms of the revision surgery we typically use a combination of time from initial AUS placement, patient comorbidities and intraoperative findings to guide the replacement of a single component vs the entire device. That is, if the device has been in situ less than 3 years we will attempt to revise a single component, whereas with older devices we typically replace all 3 components. However, 24 of the 46 patients (52%) who underwent single component revision did so after this 3-year cutoff. Likewise, 10 of the 72 patients (14%) who underwent entire device replacement did so before this 3-year cutoff.

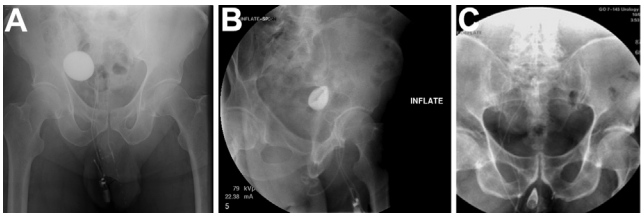


**Figure 1.** Fluoroscopic images demonstrating progressive loss of fluid (contrast) from AUS system, consistent with device malfunction, including immediate postoperative film with full abdominal reservoir (*A*), early AUS malfunction with deformation of abdominal reservoir (*B*) and late AUS malfunction with complete loss of fluid (*C*).

With regard to our surgical approach for revisions with the intention of single component replacement, we start with a repeat perineal dissection and intraoperative testing of the urethral cuff. If a leak is identified the cuff alone is replaced (fig. 2, *A*). If no leak is identified we proceed to evaluate for a leak in the reservoir. If a leak is identified the abdominal reservoir is exchanged and the scrotal pump left in situ (fig. 2, *B*). If no leak is found in the abdominal reservoir the remainder of the device is interrogated and exchanged. Notably any component that is removed and evaluated is replaced with a new component. Thus, even if one is attempting to revise only a single component, this may not be feasible depending on the intraoperative findings.

Individual charts were reviewed to evaluate pertinent clinical and surgical comorbidities, details of the primary and secondary devices, primary device outcome including time to failure, failed component, revision management strategy (single component vs entire device) and secondary device outcome (ie explantation for urethral erosion or infection, revision for device malfunction, urethral atrophy, tubing or pump complications). Given the retrospective study design the patients did not have standardized followup. Instead, after device placement the patients were evaluated 6 weeks postoperatively for device activation. Patients were then followed via office evaluation on an as needed basis as determined by their continence status or other device concerns. Additionally, the Mayo Clinic AUS Registry monitors outcomes periodically by correspondence with the patient. Details regarding device survival were obtained from the last office examination, any available subsequent operative report, or written or telephone correspondence.

Statistical analysis was performed using the SAS® software package. Continuous features were summarized