Original Article on Surgical Management of Stress Urinary Incontinence in Men

# Characterizing the biofilm of artificial urinary sphincters (AUS)

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**Background:** There is a paucity of data regarding the bacterial colonization on artificial urinary sphincter (AUS) devices following revision surgery. We aim to evaluate the microbial compositions of explanted AUS devices identified on standard culture at our institution.

**Methods:** Twenty-three AUS devices explanted were included in this study. During revision surgery, aerobic and anaerobic culture swabs are taken from the implant, capsule, fluid surrounding the device, and biofilm, if present. Culture specimens are sent to the hospital laboratory for routine culture evaluation immediately upon case completion. Differences in number of microorganism species detected across samples (richness) against demographic variables were determined through backwards selection of all variables using analysis of variance (ANOVA). We assessed the prevalence (how many times each species occurred) of microbial culture species. Statistical analyses were performed using the statistical package in R (version 4.2.1).

**Results:** Cultures reported positive results in 20 (87%) cases. Coagulase-negative staphylococci were the most commonly identified bacteria among explanted AUS devices (n=16, 80%). Among two of the four infected/eroded implants, more virulent organisms such as *Escherichia coli* and fungal species such as *Candida albicans* were identified. The mean number of species identified amongst culture positive devices was 2.15±0.49. The number of unique bacteria identified per sample was not significantly associated with demographic variables including race, ethnicity, age at revision, smoking history, duration of implantation, etiology for explantation, and concomitant medical comorbidities.

**Conclusions:** The majority of AUS devices removed for non-infectious reasons harbor organisms on traditional culture at the time of explantation. The most commonly identified bacteria in this setting is coagulase-negative staphylococci, which may be a result of bacterial colonization introduced at the time of implant. Conversely, infected implants may harbor microorganisms with higher virulence including fungal elements. Bacterial colonization or biofilm formation on implants may not necessarily equate to clinically infected devices. Future studies with more sophisticated technology, such as next-generation sequencing or extended cultures, may evaluate microbial compositions of biofilm at a more granular level to understand its role in device infections.

**Keywords:** Culture; biofilm; artificial urinary sphincter; stress urinary incontinence

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## Introduction

Treatment options for male stress urinary incontinence (SUI) include pelvic floor physical therapy, urethral slings and urethral bulking agents. However, the American Medical Systems (AMS) 800 artificial urinary sphincter (AUS) remains the gold standard for patients with severe SUI symptoms. Overall, experiences from high-volume centers have demonstrated favorable long-term durability and functional outcomes with the AUS, with appreciable complications including device infection, erosion, urethral atrophy or mechanical malfunction which may necessitate AUS revision (1,2).

Currently, there is a paucity of data regarding the bacterial colonization on AUS devices following revision surgery. In 1995, an analysis by Licht *et al.* demonstrated positive bacterial cultures in 8 of 22 (36%) AUS devices explanted for non-infectious reasons (3); however, this was prior to the introduction of the AMS 800 InhibiZone coating in 2008. When extrapolating data from penile prosthesis (PP), another common genitourinary implant device, one can also obtain insights on the biofilm composition of explanted AUS devices. Historically, coagulase-negative staphylococcus used to be the predominant species identified on the cultures and biofilms of genitourinary prosthetics such as PP and AUS (4,5). However, with the advent of antibiotic-coated devices or hydrophilic dipping solutions and improved surgical techniques, there has been a paradigm shift towards more virulent organisms such as *Escherichia coli*, *Pseudomonas aeruginosa* and even Candida species for PP (6,7). Herein, we aim to evaluate the microbial compositions of explanted AUS devices identified on standard culture data at our institution in a modern cohort.

### Highlight box

**Key findings**

- AUS devices removed for non-infectious reasons often harbor microorganisms at the time of explantation from bacterial colonization or biofilm formation.

**What is known and what is new?**

- Coagulase-negative staphylococci and commensal skin flora such as Cutibacterium species are the most commonly identified bacteria among explanted AUS devices.
- Devices explanted for infectious indications may harbor microorganisms with higher virulence, including fungal elements.

**What is the implication and what should change now?**

- It is important to differentiate between the concept of bacterial colonization or biofilm formation on AUS devices and true clinically infected implants. Future studies should be aimed at evaluating the microbial composition of biofilm using more sophisticated technology, such as next-generation sequencing or extended cultures, to better understand its role in AUS device infections.

## Methods

### *Patient population*

Institution review board approval was received to retrospectively review patients undergoing AUS revision surgery between June 2015 and June 2019 at a single institution. Indications for revision surgery included mechanical malfunction, erosion or infection. All patients undergoing revision surgery underwent preoperative evaluation with a routine history, physical exam and urinalysis, and if positive, a urine culture. Patients with positive urine cultures were treated with 5–7 days of culture-specific preoperative oral antibiotics. A threshold of >10,000 organisms/mL was the threshold to be considered as a positive urine culture. Peri-operative intravenous antibiotics were administered according to the American Urological Association (AUA) Guidelines. In addition, patients were treated post-operatively with 7 days of oral antibiotics (8). In order to decrease the risk of prosthetic infection, our institutional protocol when implanting AUS includes the use of the AMS 800 implant which has an antibiotic-impregnated coating (InhibiZone), with rifampin and minocycline. We also use one liter of saline irrigation mixed with vancomycin and gentamicin to the surgical bed for primary implants and two liters for revision cases. Also, all operative personnel (surgeon, assistant, scrub nurse) are instructed to change sterile gloves intraoperatively prior to handling of the implant.

### *Intraoperative sample collection*

Upon entering the pump or AUS cuff space, aerobic and anaerobic culture swabs are taken from any fluid surrounding the device. If a capsule or biofilm is present, these are also dislodged from the tissue and implant and sent as a separate specimen. The surface of the explanted AUS device is vigorously scraped with a gauze and sent as a separate specimen together with cut fragments of the prosthesis. Culture specimens and the removed implant are sent to the hospital laboratory for routine culture evaluation immediately upon case completion. Typically,

 

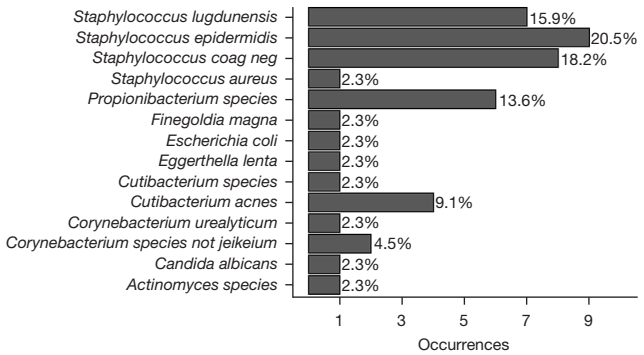


**Figure 1** Prevalence of microbial culture species identified on explanted artificial urinary sphincter devices (n=20).

all components of the AUS are removed, but in select cases, an individual component was exchanged. To avoid contamination of specimens or the AUS implant, strict sterility protocol is maintained. The implant space is irrigated with normal saline-based antibiotic (vancomycin and gentamicin) solution, unless clinically contraindicated. Reimplantation is performed based on the clinical scenario.

### *Data collection and statistical analysis*

Demographic data were abstracted for each patient. Culture results were tabulated as "yes" for positive growth, or "no" for negative growth. Microorganism species identification was documented for patients with positive growth. The organisms were identified by matrix-assisted laser desorption/ionization-time of flight (MALDI-TOF) mass spectrometry analysis which was developed, and its performance characteristics determined by Thomas Jefferson University Hospital Microbiology Laboratory. Differences in number of species detected across samples (richness) against demographic variables were determined through backwards selection of all variables using ANOVA. We also assessed the prevalence (how many times each species occurred) of culture species. Statistical analyses were performed using the statistical package in R (version 4.2.1).

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by institutional ethics board of Thomas Jefferson University (IRB# 20E.509) and individual consent for this retrospective analysis was waived.

## Results

### *Demographic data*

A total of 23 men, with a mean age of 69.2±9.6 years and a mean BMI of 29.0±4.0 kg/m$^2$, were included in our analysis. Of these 23, 18 (78%) were Caucasian while the rest were African American. Twenty (87%) of these men had previously undergone a radical prostatectomy for history of prostate cancer, four of which also underwent adjuvant or salvage radiotherapy. The mean time from AUS implant to explant was 42.6±40.5 months. At the time of analysis, seven (30%) patients had undergone one previous revision, while 3 (13%) others had undergone two previous revisions. Nineteen (83%) patients underwent revision surgery for device mechanical malfunction, while 4 (17%) underwent revision for an eroded or infected implant. At the time of revision surgery, 5 (22%) patients did not undergo reimplantation of a new AUS device, four of which had their devices removed due to infectious etiologies. Six (26%) patients did not undergo revision of all three components of the AUS, with 3 (13%) only undergoing revision of one component of the AUS. Of the six patients, 5 (83%) underwent cuff revision, 3 (50%) underwent revision of the scrotal pump, and only 1 (17%) underwent revision of the pressure regulating balloon. Our surgical approach includes a perineal incision for the cuff placement with a counter incision in the lower abdomen for placement of the scrotal pump and pressure regulating balloon. We do not perform a penoscrotal approach for our AUS placements or revisions. Five (22%) patients had a concomitant PP implant, three of which were placed at the time of initial AUS implantation. However, at the time of explantation, only one patient required simultaneous removal of both his PP and AUS implant for infectious indications.

### *Culture data and analysis*

Cultures reported positive results in 20 (87%) cases. There was a total of 44 occurrences of identified microbial species in these 20 devices. *Figure 1* highlights the prevalence of microbial culture species identified on explanted AUS devices. Coagulase-negative staphylococci species, including *Staphylococcus lugdunensis* and *Staphylococcus epidermidis*, were the most identified bacteria among explanted AUS devices (n=16, 80%, 24 occurrences). This is followed

 

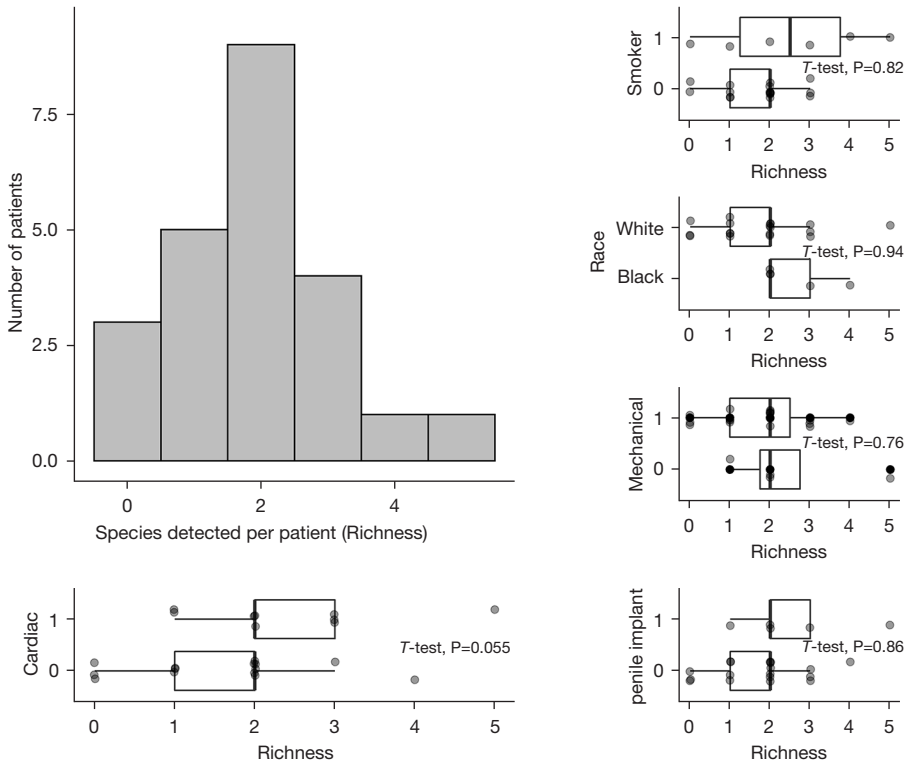


**Figure 2** Top five variables affecting richness (differences in number of species detected across samples) against demographic variables through backwards selection of all variables using ANOVA. ANOVA, analysis of variance.

by common commensal skin flora such as Cutibacterium species, including *Cutibacterium acnes* and *Propionibacterium species* (n=10, 50%, 11 occurrences). Although sample size is small, there was evidence of more virulent organisms such as *Escherichia coli* and fungal species such as *Candida albicans* identified once among two of the four infected/eroded implants. The mean number of species identified amongst culture positive devices was 2.15±0.49. The number of unique bacteria identified per sample was not significantly associated with demographic variables including race, ethnicity, age at revision, smoking history, duration of implantation, etiology for explantation, and concomitant medical comorbidities. *Figure 2* displays the top five variables affecting richness (all P>0.05).

## Discussion

Among our cohort of 23 patients, only four devices were explanted for infectious reasons, but majority (87%) of devices still resulted with a positive culture. The most common species identified was the coagulase-negative staphylococci species (n=16, 80%, 24 occurrences), followed by common commensal skin flora such as Cutibacterium species (n=10, 50%, 11 occurrences). While some of the cultures resulted more broadly as coagulase-negative staphylococci, some go more in-depth to identify these microbial species which usually results as *Staphylococci epidermidis* (n=9) or *Staphylococci lugdunensis* (n=7). Traditionally, coagulase-negative staphylococci species have been the primary organism responsible for prosthetic device infections among both PP and AUS (3,4,9). The introduction of these bacteria is thought to occur at the time of implantation or via hematogenous spread. These bacteria, including staphylococci species, can adhere and colonize the implant space via the formation of biofilm which can protect these bacteria against the host immune system and prophylactically administered antibiotics. Occasionally, planktonic bacteria are released from these biofilms and can cause symptoms of clinically apparent infection (10).

Due to the detriment and burden of this complication towards patients and the healthcare system, there has been significant efforts geared towards decreasing such risk for device infection. Meticulous attention to intraoperative

 

sterile technique, implementation of antimicrobial adjuncts such as use of broad-spectrum intravenous antibiotics, irrigation lavage, and even use of antibiotic-impregnated AUS devices has been developed to decrease the risk of biofilm formation (11,12). Specific to revision procedures, studies from PP research by Henry *et al.* have previously documented the importance of performing a thorough and vigorous washout of the implant space with antiseptic irrigation to dislodge any pre-existing biofilm that may have been sequestered during the initial implantation (13,14). Despite these changes, bacterial colonization rates remain high, although it is less clear whether this necessarily translates to clinically apparent device infections (9). Interestingly, we have noticed a paradigm shift for the types of microorganisms identified on devices explanted for various indications. While most of these data are extrapolated from PP research, majority of organisms explanted from mechanically malfunctioning devices are coagulase-negative staphylococcus, while implants removed for infectious reasons were more virulent gram-negative organisms or even fungal species (10). A multicenter study published by Gross *et al.* assessing cultures of 227 infected PP found that E. coli was the most common isolate (18%), while Candida species were the third most common (11%) (6). Although our sample size of infected explants was small, we found that the only devices that speciated *E. coli* and *Candida albicans* were two of the four clinically infected devices. Overall, while the predominant organism on GU implants are still staphylococcus species on standard culture, analysis with emerging technology, such as next-generation sequencing, may suggest otherwise (15). For example, our team previously demonstrated that while *Pseudomonas aeruginosa* and *Staphylococcus epidermidis* were the most common microbes for infected and eroded PP, respectively, *Escherichia coli* was actually the most common for malfunctioning devices (7). This is distinct from our findings in this study on culture data for AUS implants. Further comprehensive evaluation in a larger cohort is required to describe this finding.

Historically, implantation of the AUS requires two incisions—one in the perineum for cuff placement, and the other in the suprapubic region for the pressure regulating balloon and pump placement. In 2003, Wilson *et al.* described a novel surgical technique for AUS placement via a single penoscrotal incision (16). Overall, operative time is reduced, and this also allows for easier implantation of concomitant PP placement. However, outcomes with regards to continence rates, device infection or erosion rates are still controversial (17-20). At this time, we still perform the traditional two-incision approach for AUS placement. We highlight this fact as there is a possibility that different locations of AUS placement and surgical incisions may results in different microbial composition. This needs to be taken into account and evaluated in further detail.

While prosthetic surgeons highly emphasize the importance of sterility and antiseptic techniques, there has been several studies published questioning the utility of perioperative antibiotic use around the time of AUS implantation. For example, the AMS 800 implant has an antibiotic-impregnated coating (InhibiZone), with rifampin and minocycline. While this technology has shown increased efficacy in reducing infectious complications among PP implants, a recent retrospective analysis found no significant impact on infections or explantation rates in their multicenter cohort of 305 patients (12,21). A study by Adamsky *et al.* also found that routine use of postoperative oral antibiotics does not reduce the odds of AUS explantations, and this practice should be reconsidered in the era of increasing bacterial resistance (22). Next, although preoperative negative urine culture and treatment of UTIs are encouraged prior to device placement, another study by Kavoussi *et al.* demonstrated that there was poor correlation between preoperative urine culture results to the bacteriology of infected devices (23). They also found that there was no difference in infection rates among patients with negative urine cultures and patients with untreated asymptomatic positive cultures. In our practice, we still choose to treat all preoperative urine cultures with culture-specific antibiotics should they return positive for UTIs, especially if they are undergoing revision surgery. Our cohort had three patients with preoperative positive cultures and these patients were all treated with trimethoprim-sulfamethoxazole. Intraoperatively, we administer a combination of vancomycin and gentamicin, unless clinically contraindicated, which appears to broadly cover the most associated microorganisms found on infected prosthetics (6).

Aside from clinically significant infections, device erosions are also a common indication for AUS replacements. There have been some pre-established risk factors that may predispose patients to device failure. Some of these include the presence of urethral stent, perioperative anticoagulation use, and double-cuff or smaller (3.5 cm) cuff placement (9,24,25). By far, the most reported factor that may shorten overall device survival is the exposure to radiation therapy to the pelvis (9,26-30). In our cohort, four patients had received adjuvant radiation for localized

 

prostate cancer and all four of them underwent device explantation for device erosion or worsening urinary incontinence secondary to urethral atrophy. Radiation causes small vessel endarteritis that results in localized changes such as tissue necrosis, fibrosis and atrophy, leading to compromise of the urethral blood supply and tissue healing (27). This may portend an increased risk for device erosion or urethral atrophy. A recent meta-analysis of 18 studies on AUS outcomes indicated that radiation therapy not only reduces the odds of achieving complete continence after AUS placement, but also significantly increases the risk for revision surgeries, urethral erosions and subsequently, explantations (31). Recent multicenter studies echo the same conclusions. Mann *et al.* demonstrated that the "fragile" urethra (history of urethroplasty, radiation, prior AUS) were strong predictors for earlier erosion with radiation history providing the highest hazard ratio when compared to the other risk factors (HR =2.36; 95% CI: 1.52–3.64; P<0.01). AUS survival rates for "fragile" urethras were also much shorter at 1-year (76.5% *vs.* 44.1%) and 5-year (50.0% *vs.* 14.8%) survival when compared to "non-fragile" urethras (P<0.0001) (32). In patients with first replacement AUS, Huang *et al.* also found that a history of pelvic radiation was associated with a shorter time to device failure and was specifically associated with a seven-fold increase risk of device erosion (33). They suggest that in order to allow for optimal tissue healing, AUS replacement should be delayed after removal of an eroded device, which can leave patients incontinent for extended periods of time. Hence, adequate patient counseling is necessary in light of these risk factors to set reasonable postoperative outcomes and expectations regarding continence and complication rates.

Our study is not without limitations. First, the study design is based on a small sample size from a tertiary referral center and analysis for AUS removal for infectious and non-infectious etiologies were analyzed together. This precludes any powered statistical analysis and establishment of generalizable conclusions as it may not be representative of smaller volume practices. Techniques for sampling of biofilms on explanted AUS devices are still under development as mere swabbing of implants may not be enough to dislodge all microbes and its associated biofilms. There is also a possibility that the characterization of biofilm may be affected by preoperative and intraoperative administration of antibiotics. Ongoing follow-up and larger sample size with AUS explanted for various indications is also necessary to better correlate the findings of detected microbiota and its significance for clinically relevant prosthetic infections.

## Conclusions

The majority of AUS devices removed for non-infectious reasons harbor organisms on traditional culture at the time of explantation. The most commonly identified bacteria in this setting is coagulase-negative staphylococci and commensal skin flora such as Cutibacterium species, which may be a result of bacterial colonization introduced at the time of implant. Conversely, infected implants may harbor microorganisms with higher virulence including fungal elements, however larger cohort studies from infected devices are necessarily to confirm this. We hope that these findings can expand the literature on microbial composition among AUS devices which will subsequently allow for appropriate tailoring of culture-specific antibiotics in this era of increasing bacterial resistance, subsequently improving patient outcomes. It is important to differentiate between the concept of bacterial colonization or biofilm formation on AUS devices and true clinically infected implants as the management for these two may differ. Future studies should be aimed at evaluating the microbial composition of biofilm using more sophisticated technology, such as next-generation sequencing or extended cultures, to better understand its role in AUS device infections.

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## Footnote

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