

The “Minimal-Touch” Technique for Artificial Urinary Sphincter Placement: Description and Outcomes

ABSTRACT

Objective: The study aimed to describe “minimal-touch” technique for primary artificial urinary sphincter placement and evaluate early device outcomes by comparing it with a historical cohort.

Materials and methods: We identified patients who underwent primary artificial urinary sphincter placement at our institution from 1983 to 2020. Statistical analysis was performed to identify the rate of postoperative device infection in patients who underwent minimal touch versus those who underwent our traditional technique.

Results: 526/2601 total procedures (20%) were performed using our “minimal-touch” approach, including 271/1554 patients (17%) who underwent primary artificial urinary sphincter placement over the study period. Around 2.3% of patients experienced device infection after artificial urinary sphincter procedures. In the “minimal-touch” era, 3/526 patients (0.7%) experienced device infection, including 1/271 (0.4%) of those with primary artificial urinary sphincter placement. In comparison, 46/2075 patients (2.7%) experienced device infection using the historical approach, with 29/1283 (2.3%) of primary artificial urinary sphincter placements resulting in removal for infection. Notably, 90% of device infections occurred within the first 6 months after primary placement. The difference in cumulative incidence of device infections at 12 months did not meet our threshold for statistical significance for either the total cohort of all AUS procedures (primary and revision) or the sub-group of only those patients undergoing primary artificial urinary sphincter placement (Gray K-sample test; $P=.13$ and $.21$, respectively).

Conclusion: The “minimal-touch” approach for artificial urinary sphincter placement represents an easy-to-implement modification with potential implications on device outcomes. While early results appear promising, longer-term follow-up with greater statistical power is needed to determine whether this approach will lower the infection risk.

Keywords: Prostatectomy, artificial urinary sphincter, urine

Introduction

Male stress urinary incontinence (SUI) can be devastating, and treatment has a significant positive impact on patient well-being and quality of life.¹ Treatment options depend on incontinence severity as determined by measures such as pads per day (PPD), pad weight, and patient-reported bother.² For the man with mild SUI, options include observation, pelvic floor strengthening, urethral bulking agent injections, and male urethral sling.³ In contrast, men with more severe incontinence (>2-3 PPD), radiation, and absence of sphincter coaptation on preoperative urethroscopy are better served with the placement of an AMS 800® Artificial Urinary Sphincter (AUS; Boston Scientific, Marlborough, Mass, USA).⁴

Treatment success varies based on the definition used, but a recent study found that nearly 90% of patients reported feeling “much better” after their AUS procedure.^{5,6} Several factors compromise outcomes including mechanical malfunction, urethral atrophy, and most importantly, device erosion or infection which may occur in 3%-8%.⁶⁻⁸ Infection, which tends

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to occur early in the postoperative period, is a devastating complication that requires device removal.⁶ Immediate device replacement, or "salvage," after a local washout may be considered, but the data regarding this practice in the setting of infected AUS are limited.⁹

The "no-touch" technique for inflatable penile prosthesis (IPP) placement was championed by Dr. Francois Eid, although the concept is well-established in other areas such as orthopedic surgery, neurosurgery, and plastic surgery.¹⁰ The no-touch approach is based on the presumption that prosthesis infections result from direct inoculation with local bacteria on the surrounding skin. Normal skin flora are commonly implicated in bacterial colonization and infection.^{11,12} After the initial skin incision and retractor placement, a new drape is applied to cover all exposed skin, thereby eliminating contact between the skin and the prosthesis. With their "no-touch" technique, Eid and colleagues found an IPP infection rate of <0.5%.^{10,13} However, to our knowledge, there is a paucity of data regarding operative techniques to minimize skin-device interaction during AUS placement. Starting in 2014, we implemented a "minimal-touch" protocol for AUS placement wherein the perineal and abdominal skin exposure is limited to minimize the risk of device seeding with skin flora. Herein, we describe our "minimal-touch" approach for AUS placement and evaluate the infection rate compared to a historical cohort of patients who underwent placement through a standard approach with full skin exposure.

Materials and Methods

After institutional review board approval from the Mayo Clinic (IRB #18-000464), a retrospective review of our institutional database was performed to identify patient demographics and postoperative outcomes for all patients who underwent AUS surgery at our institution from 1983 to 2018. As of 2013, all subsequent data have been entered and maintained prospectively with written patient consent. For the current study, we sought to focus on those patients who underwent primary AUS placement. Three consecutive high-volume prosthetic surgeons performed the procedures over the timeframe of the study, with a single surgeon performing all AUS procedures as of 2000. All implanted AUS devices were AMS 800 which were placed in a transcorporal approach. Perioperative antibiotic dosing was consistent across all 3 surgeons and included vancomycin and gentamicin at time of surgery followed by a short course of Keflex or trimethoprim/sulfamethoxazole. Patients less than 18 years old, those who had a

history of prior AUS, those who underwent AUS placement secondary to neurogenic bladder, and those who declined research consent were excluded.

Description of "Minimal-Touch" Approach for Artificial Urinary Sphincter Placement

The skin is prepped with a chlorhexidine-based solution from the supra-umbilical abdomen to the anterolateral thighs including the perineum and superior buttocks. Surgical drapes are placed such that only the lower abdomen, genitals, and perineum are exposed. At this time, an loban-Incise drape (3M corporation, Maplewood, Minn, USA) is placed over the anterior abdominal wall to cover the exposed skin down to the level of the penopubic junction (Figure 1). Additional loban is then placed along the posteromedial thighs and across the perineum, just under the junction of the posterior scrotum and perineum (Figure 2). The penis and scrotum are left exposed to facilitate passage of a sterile 12-French urethral catheter. The scrotum is covered with a surgical lap pad and retracted away from the perineal incision by the assistant.

A 6-cm midline perineal incision is made along the median raphe overlying the bulbar urethra. Dissection is carried out to expose the bulbar urethra with care taken to maintain the bulbocavernosus muscle intact. We found that a Gelpi-retractor provides adequate exposure and minimizes the time associated with retractor placement. A plane is developed between the dorsal aspect of the bulbar urethra and the corpus cavernosum. The bladder neck is occluded by placing gentle tension on the catheter balloon, and an antibiotic solution is gently instilled along the catheter with an angiocatheter to rule out the presence of urethral injury. The urethra is measured with a measuring tape to determine the appropriate cuff size and the device is prepared on the back table in standard fashion. During this time, the wound is copiously irrigated with an antibiotic solution of

MAIN POINTS

- Artificial urinary sphincter (AUS) implantation is associated with a low risk of device infection.
- The "minimal-touch" approach is a safe, easy-to-implement method to reduce AUS infections beyond previously published infection rates.
- Among AUS devices which were infected, 93% occurred within the first year.
- The overall risk of post-operative AUS infection in this series was low at 2.3%.
- Implementation of our "minimal-touch" technique to AUS surgery reduced post-operative infection risk to 0.4%.
- The "minimal-touch" technique is an easy surgical modification that may reduce the risk of device infection.



Figure 1. loban drape placed over the exposed abdomen skin to the level of the penopubic junction.



Figure 2. Additional loban drape is placed over the medial thighs and perineum. The penis and scrotum are retracted superiorly with a laparotomy pad.

gentamicin, neomycin, and polymyxin. The surgeon and assistants change outer gloves at this point.

The AUS cuff is brought to the field and placed in standard fashion. Invariably, during urethral exposure and antibiotic irrigation, a small amount of skin just lateral to the perineal incision will be exposed. Care is taken to avoid any contact between the skin and AUS cuff/tubing. An antibiotic-soaked lap pad is then placed in the perineal wound to cover the exposed AUS device and the tubing. This is placed in a sterile plastic bag which is subsequently secured to the drape (Figure 3). The surgeon and assistant once again change outer gloves. Attention is then turned to the lower anterior abdominal wall for pressure-regulating balloon (PRB) and scrotal pump placement.

A 4–6 cm midline abdominal incision is made just above the pubic symphysis through the previously marked-out incision through the loban drape. This is carried down to the rectus fascia. A space is developed deep into the rectus muscle for PRB placement and the fascia is subsequently closed. The PRB is filled to the appropriate volume. Copious antibiotic irrigation is applied throughout this process. Next, the scrotal pump is placed. A plane is developed between the abdominal wall incision and the ipsilateral hemiscrotum (anterior to the testicle and just lateral to the media raphe) with a Hegar dilator. The pump is passed into this location through the abdominal incision. The cuff tubing is removed from the protective bag and delivered from the perineum to the abdominal incision with care to avoid any contact with the exposed skin. Finally, the tubing is cut to length and all components are attached via Quick Connects (Boston Scientific, Marlborough, Mass, USA). After ensuring appropriate device cycling, the device is left inactivated. All incisions are closed in multiple layers. Patients return at 6 weeks for device activation and teaching.



Figure 3. After the sphincter cuff is placed, the tubing and cuff are wrapped in a sterile laparotomy pad which is then placed within a plastic bag to prevent prolonged exposure to the air or surrounding perineal skin.

Statistical Analysis

Our primary outcome was a comparison of device infection rates between those who underwent the “minimal-touch” approach for AUS placement and our standard technique. Continuous features were summarized with means and standard deviations, while categorical features were summarized with frequency counts and percentages. Univariate analysis was performed to evaluate differences among those in the “minimal-touch” and standard cohorts. Cumulative incidence was estimated as time from AUS implantation to subsequent repeat surgery for device infection. Gray’s test was used to determine whether the “minimal-touch” technique affected the cumulative incidence of device infection. All statistical tests were 2-sided, with a P -value $< .05$ considered statistically significant. Statistical analysis was performed using the Statistical Analysis Software (SAS) software package (SAS Institute, Inc.; Cary, NC, USA).

Results

A total of 2601 AUS procedures were performed at our institution, including 1554 patients who underwent primary AUS placement and met inclusion criteria for the current study. In total, 526/2601 procedures (20%) were performed using our “minimal-touch” approach, including 271/1554 patients (17%) who underwent primary AUS placement. Patient demographics for the cohort of patients who underwent primary AUS placement are shown in (Table 1). Patients who underwent the “minimal-touch” AUS placement had a higher body mass index (mean 31 vs. 29; $P < .0001$) and were more likely to have a history of radiation therapy (55% vs. 30%; $P < .0001$), prior to urethral sling (7% vs. 3%; $P = .0016$), androgen deprivation therapy (25% vs. 15%; $P < .0001$), and hypertension (70% vs. 61%,

Table 1. Baseline Characteristics of Men Undergoing AUS Surgery at Our Institution for the First Time. Continuous Variables Reported with Median and Mean Values. Categorical Variables Reported as Frequency Counts with Percentages in Parenthesis.

	Min Touch Technique (N = 271)	Previous Method (N = 1283)	Total (N = 1554)	P
BMI				
N	267	867	1134	<.0001
Mean (SD)	30.8 (4.3)	28.8 (4.2)	29.3 (4.3)	
Median	30.6	28.3	28.8	
Q1, Q3	27.7, 33.6	26.0, 31.3	26.4, 31.9	
Range	(21.3–46.0)	(16.9–45.5)	(16.9–46.0)	
Sling				
No	252 (93.0%)	1225 (97.0%)	1477 (96.3%)	.0016
Yes	19 (7.0%)	38 (3.0%)	57 (3.7%)	
XRT				
No	122 (45.4%)	894 (70.5%)	1016 (66.1%)	<.0001
Yes	147 (54.6%)	374 (29.5%)	521 (33.9%)	
CAD				
No	205 (77.1%)	578 (73.1%)	783 (74.1%)	.1983
Yes	61 (22.9%)	213 (26.9%)	274 (25.9%)	
HTN				
No	91 (34.2%)	304 (38.7%)	395 (37.5%)	.1935
Yes	175 (65.8%)	482 (61.3%)	657 (62.5%)	
Peripheral vascular disease				
No	257 (96.6%)	743 (94.6%)	1000 (95.1%)	.1970
Yes	9 (3.4%)	42 (5.4%)	51 (4.9%)	
Cerebrovascular disease				
No	263 (98.5%)	753 (95.6%)	1016 (96.3%)	.0276
Yes	4 (1.5%)	35 (4.4%)	39 (3.7%)	
Chronic pulmonary disease				
No	249 (93.3%)	731 (93.1%)	980 (93.2%)	.9388
Yes	18 (6.7%)	54 (6.9%)	72 (6.8%)	
Diabetes				
No	231 (86.5%)	658 (83.6%)	889 (84.3%)	.2585
Yes	36 (13.5%)	129 (16.4%)	165 (15.7%)	
Moderate or severe renal disease				
No	260 (97.4%)	760 (97.2%)	1020 (97.2%)	.8691
Yes	7 (2.6%)	22 (2.8%)	29 (2.8%)	
Obesity (BMI > 35)				
No	237 (88.8%)	728 (92.9%)	965 (91.8%)	.0351
Yes	30 (11.2%)	56 (7.1%)	86 (8.2%)	
Coumadin				
No	53 (81.5%)	186 (79.5%)	239 (79.9%)	.7149
Yes	12 (18.5%)	48 (20.5%)	60 (20.1%)	
Aspirin				
No	20 (31.3%)	35 (11.6%)	55 (15.0%)	.0001
Yes	44 (68.8%)	267 (88.4%)	311 (85.0%)	
Other anticoagulation				
Missing	248	1204	1452	.1962
No	14 (60.9%)	59 (74.7%)	73 (71.6%)	
Yes	9 (39.1%)	20 (25.3%)	29 (28.4%)	
Robotic RRP				
No	134 (50.0%)	703 (91.2%)	837 (80.6%)	<0.0001
Yes	134 (50.0%)	68 (8.8%)	202 (19.4%)	
TURP				
No	254 (95.5%)	626 (76.3%)	880 (81.0%)	<.0001
Yes	12 (4.5%)	194 (23.7%)	206 (19.0%)	

(Continued)

Table 1. Baseline Characteristics of Men Undergoing AUS Surgery at Our Institution for the First Time. Continuous Variables Reported with Median and Mean Values. Categorical Variables Reported as Frequency Counts with Percentages in Parenthesis. (*Continued*)

	Min Touch Technique (N = 271)	Previous Method (N = 1283)	Total (N = 1554)	P
Laser TURP				
No	256 (96.2%)	734 (96.5%)	990 (96.4%)	.8734
Yes	10 (3.8%)	27 (3.5%)	37 (3.6%)	
Does the patient currently smoke?				
No	257 (94.8%)	722 (93.8%)	979 (94.0%)	.5230
Yes	14 (5.2%)	48 (6.2%)	62 (6.0%)	
XRT				
No	127 (47.4%)	703 (69.6%)	830 (64.9%)	<.0001
Yes	141 (52.6%)	307 (30.4%)	448 (35.1%)	
Lupron				
No	199 (75.1%)	656 (85.3%)	855 (82.7%)	.0002
Yes	66 (24.9%)	113 (14.7%)	179 (17.3%)	

AUS, artificial urinary sphincter; BMI, body mass index; SD, standard deviation; XRT, Radiation therapy; TURP, transurethral resection prostate; RRP, Radical Prostatectomy; CAD, Coronary artery disease; HTN, Hypertension.

$P = .036$). They were less likely to be using aspirin concurrently (69% vs. 88%, respectively; $P = .0001$). Given that patients undergoing the “minimal-touch” approach were representative of a more modern cohort, it is not surprising that these patients were more likely to have undergone robotic prostatectomy (50% vs. 9%; $P < .0001$) and less likely to have undergone transurethral resection of the prostate for outlet obstruction (24% vs. 5%; $P < .0001$). The mean (standard deviation; range) length of follow-up available for the minimal-touch group was 0.7 years (1.0; 0.1–5.8) compared to 7.8 (6.4; 0.1–34.1) in the historical cohort ($P < .0001$).

In total, 49/2601 patients (2.3%) who underwent AUS surgery at our institution experienced device infection, including 30/1554 (2%) of those who underwent primary AUS placement. In the “minimal-touch” era, 3/526 patients (0.7%) experienced device infection, including 1/271 (0.4%) of those with primary AUS placement. In comparison, 46/2075 patients (2.7%) experienced device infection using the historical approach, with 29/1283 (2.3%) of primary AUS placements resulting in removal for infection. Notably, 90% of device infections occurred within the first 6 months after primary placement (Table 2). The difference in cumulative incidence of device infections at 12 months did not meet our threshold for statistical significance for either the total cohort of all AUS procedures (primary and revision) or the sub-group of only those patients undergoing primary AUS placement (Gray K-sample test; $P = .13$ and $.21$, respectively). (Figures 4 and 5)

Table 2. Proportion of Infections by Time Interval (Years) for Patients Undergoing Primary AUS Placement Using the Traditional Technique.

Years	% Infections
0–0.5	90.0
0.5–1.0	3.3
1.0–1.5	0
1.5–2.0	0
2.0–2.5	0
2.5–3.0	0
3.0+	6.7

AUS, artificial urinary sphincter.

Discussion

Artificial urinary sphincter infectious complications can be devastating for both the surgeon and the patient, compromising the improvements in quality of life.¹ Here, we described our “minimal-touch” approach for AUS placement, wherein the majority of surrounding abdominal and genitourinary skin is covered by loban surgical drapes to minimize interaction between the prosthetic and the surrounding skin (and thereby limit the risk for device seeding by organisms contained within the skin flora). We hypothesized that our simple, easy-to-implement approach would decrease the risk of post-operative device infections. While longer-term outcome assessment is needed, our early results are excellent with <1% infection risk in the first 271 primary AUS devices placed via this simple modification.

Defining AUS infections can be challenging, and there is significant heterogeneity in the literature. For instance, many studies lump together device infection and urethral erosion as a single outcome.^{6,8} Infection in the absence of erosion is clear-cut. In contrast, in many instances, it is not readily apparent whether erosion results in bacterial-seeding or device infection precedes urethral erosion. Here, we defined AUS infection based on history/exam and intraoperative findings suggestive of infection (incisional redness, warmth, swelling, or discharge, pump fixation, fever, leukocytosis, increasing pain, etc.) in the absence of urethral erosion. Historically, AUS infections were thought to occur early after device placement due to device seeding with virulent organisms at the time of implantation.⁶ Our findings support this notion. Specifically, in our historical cohort of men who undergo primary AUS placement over a 30-plus year time period, we found that 90% of device infections occurred within the first 6 months.

Urologic-prosthetic infections presumably result from bacterial seeding at the time of device placement in the majority of cases.¹⁴ However, previous work has shown that bacterial colonization does not lead to clinical infection in all instances.^{11,12} Biofilm refers to the complex network of bacteria and extracellular matrix that allows organisms to survive on the implant.¹⁵ Positive bacterial cultures and/or biofilm are found nearly in 40% of AUS devices and up to 80% of IPPs when removed for non-infected etiologies.^{11,12,16} Not surprisingly,

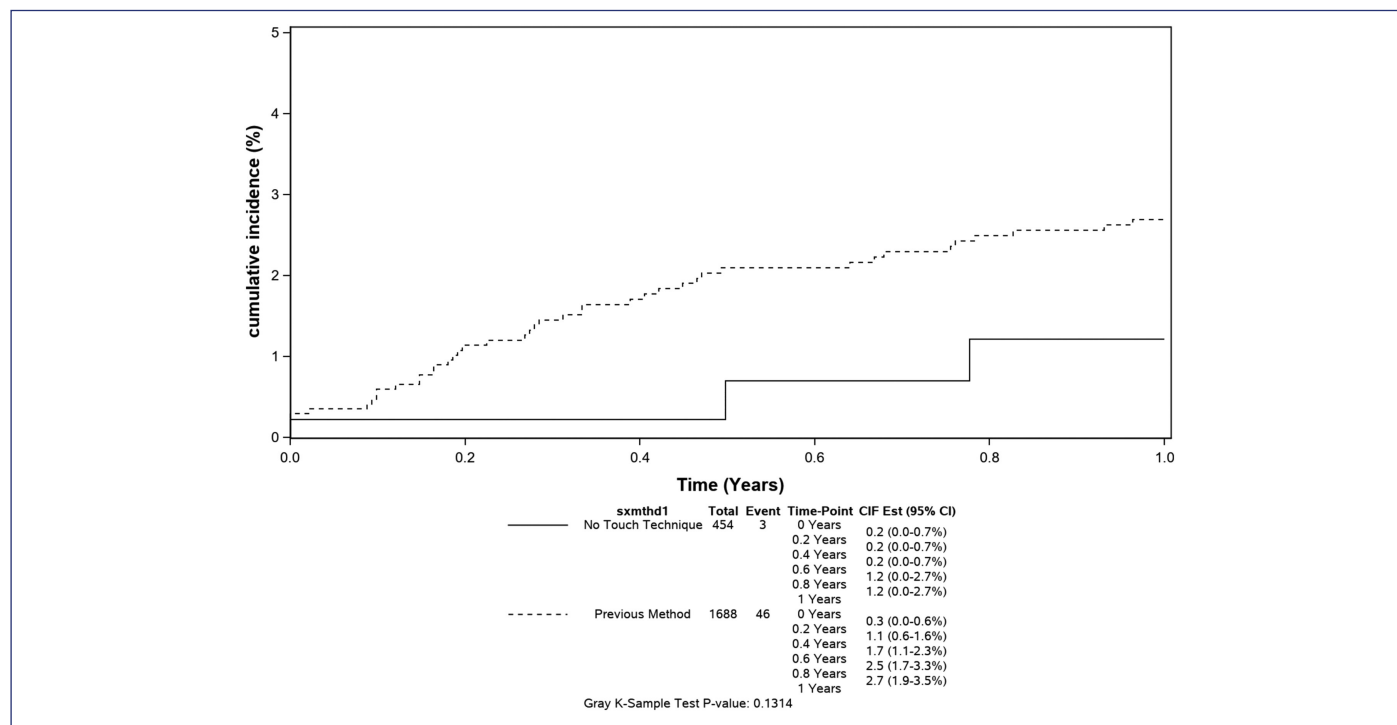


Figure 4. Cumulative incidence of infection for all device placements (primary and revision surgery).

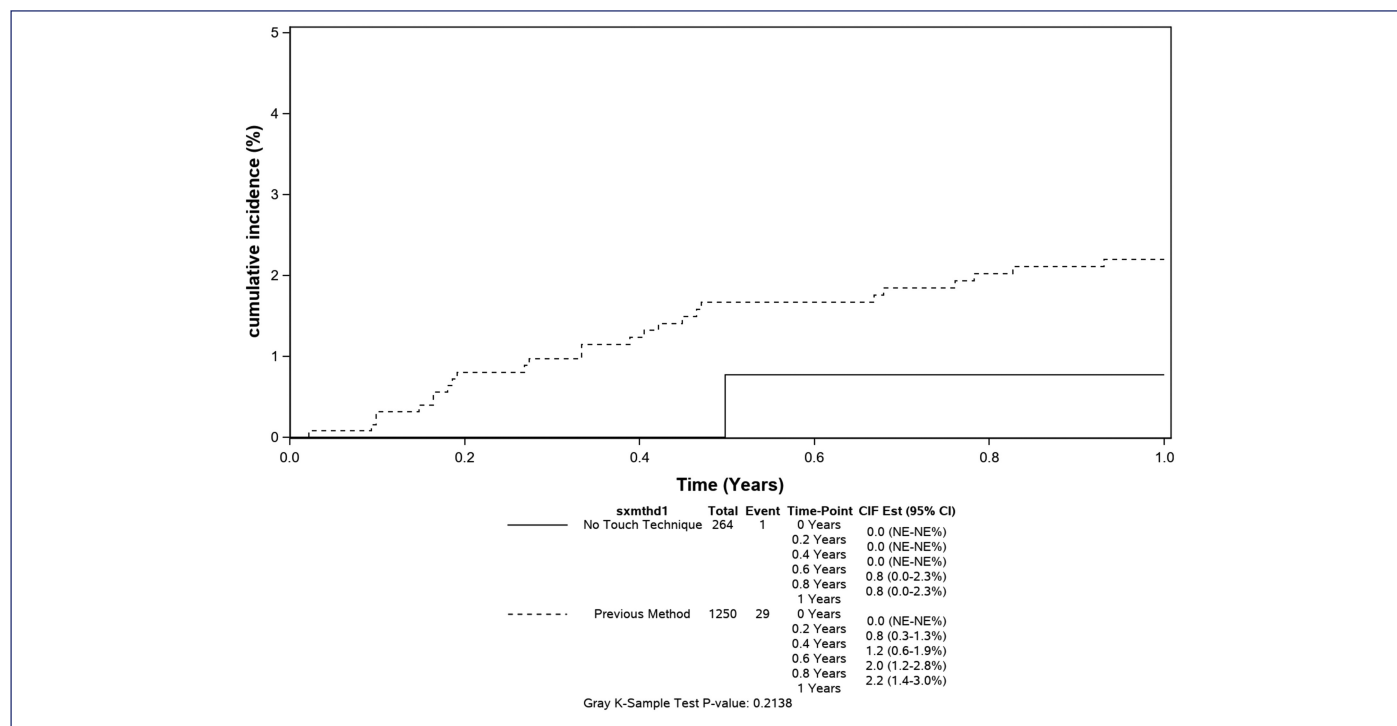


Figure 5. Cumulative incidence of Infection by patient (primary AUS placement). AUS, artificial urinary sphincter.

gram-positive organisms such as *Staphylococcus aureus* and *epidermidis* are frequently implicated in device infections and colonization, although gram-negative bacilli and even yeast can be seen as well.^{17,18} Thus, it seems logical to presume that preventing exposure of the prosthetic device to the skin, such as with our “minimal-touch” technique, would result in a lower risk of infection.

Antibiotic-impregnated prosthetic devices (Inhibizone; Boston Scientific) and hydrophilic polymer coatings that allow absorption of antibiotic solutions (Bioflex; Coloplast; Humlebaek, Germany) were developed to limit the risk of device seeding during placement.¹⁹ These innovations have clearly resulted in a lower risk for device infection with IPPs. In contrast, the data surrounding antibiotic-impr

egnated AUS devices are less clear, with several studies revealing similar infection rates with and without Inhibizone.^{20,21} This may be due in part to the innate differences in the size/shape of the devices (i.e., greater surface area with the IPP) and the anatomic location into which the devices are placed. Others have proposed alternative techniques as a means of minimizing the risk of device infection. Eid and colleagues championed the “no-touch” technique for penoscrotal IPP placement.^{10,13,22} They found that utilizing antibiotic-coated IPPs resulted in drop in their infection rate from 5% to 2%, and subsequent implementation of their no-touch approach further dropped the infection rate to an impressive level of up to 0.46%.¹³ Recently, Weinberg and colleagues showed that a “modified no-touch” technique for the subcoronal IPP placement was feasible as well, although long-term device outcomes including infection were not reported in the initial manuscript.²³

To our knowledge, this represents the first report to describe patient outcomes using a “no-touch,” or as we describe, a “minimal-touch,” approach to AUS placement. To date, since implementing these simple steps, we have yet to experience a single-device infection in 164 patients. This appears favorable when compared to the historical rate of 2% that we identified in 1254 patients who underwent AUS placement without or “minimal-touch” modifications, although this difference did not reach the *P*-value threshold of $<.05$. This was true for both primary AUS placement and when we assessed all primary and revision cases at our institution. The lack of statistical significance likely stems in part from the small number of infection events in our cohort and the overall low rate of device infection. Despite our large number of AUS placements, it is likely that a much larger cohort would be necessary to power such an analysis. We must also emphasize that the follow-up was significantly shorter for the “minimal-touch” cohort (0.7 years vs. 7.8 years; $P < .0001$). This is not surprising given that our current technique was implemented only 4 years ago, whereas our historical cohort includes patients who underwent AUS placement as far back as 1983. However, we also found that the vast majority of infections occur within the first 6–12 months of AUS placement, suggesting that a spike in late infectious complications is unlikely. Also, while our analysis of preoperative demographics between the “minimal-touch” and standard-technique cohorts revealed differences in several variables, previous work has not shown significant differences in device survival based on these and other factors.^{24–29} Artificial urinary sphincter placement is a challenging procedure with a substantial learning curve prior to achieving optimal outcomes.³⁰ Given the minimal added time or complexity, we feel that even a slight decrease in device infections supports our “minimal-touch” approach as an opportunity to optimize outcomes, particularly for those less-experienced surgeons who may have an increased complication rate during their early experiences with AUS placement.

Our report has important limitations. The outcomes, particularly in the modern era, represent those from a high-volume tertiary referral practice and may not accurately reflect results from other lower-volume surgeons. This is retrospective review without a true control group, and as such, this study design carries inherent bias which must be considered. Due to the small number of infection events and the lack of infections in the “minimal-touch” cohort, we were unable to perform a multivariable analysis controlling for other important variables that may impact infection. Moreover, we did not perform a

power analysis for the current study, and as was previously emphasized, given the low incidence of infection, a larger cohort may be necessary to provide more definitive data regarding the utility of the minimal-touch technique. The influence of perioperative antibiotics is also unclear from the current analysis. Finally, although as we have shown the majority of infections occurred within the first 6–12 months, the follow-up is substantially shorter with the “minimal-touch” cohort, and more balanced longer-term outcome assessment is needed.

In our analysis of patients undergoing primary AUS placement, we found a relatively low infection rate of 2.3%, with more than 90% of infections occurring within the first year after implantation. After implementing our “minimal-touch” approach for primary AUS placement in 2014, we have seen only a single device infection over the first 271 devices placed with this simple modification, which adds minimal time to the operation. While further comparative studies are necessary, the “minimal-touch” approach may be considered to optimize outcomes with primary AUS placement.

Ethics Committee Approval: Ethical committee approval was received from the Ethics Committee of Mayo Clinic (Approval no: 18-000464).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

Peer-review: Externally peer-reviewed.

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Video: <https://youtu.be/KMB8GwVei5Q>

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