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Multicenter Analysis of Long-Term Outcomes of Artificial Urinary Sphincter Surgery After Urethroplasty

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Study Need and Importance: Inserting an artificial urinary sphincter (AUS) in patients who have had urethroplasty is a complex undertaking, and the literature on outcomes is limited, especially regarding whether and how urethroplasty technique affects the results. We evaluated complications of AUS insertion after urethroplasty in a multi-institutional cohort.

What We Found: We found that patients who had undergone nontransecting urethroplasty before AUS insertion had significantly higher explantation-free survival rate at 5 and 10 years: 69% (95% CI: 53-80) and 62% (95% CI: 42-77) compared with transecting urethroplasty rates of 38% (95% CI: 24.5-51) and 17% (95% CI: 5.4-33), respectively (log-rank, $P < .001$; Figure).

Limitations: Our study was limited by its retrospective nature and because follow-up in the nontransecting group was statistically shorter, although there was still better initial device survival in this group. There may also be some selection bias based on a higher proportion of posterior urethroplasties in the transecting group, and the possibility that patients felt to be particularly high risk were not offered AUS.

Interpretation for Patient Care: Patients who undergo transecting urethroplasty are more prone to experience AUS complications earlier and with higher likelihood vs those undergoing AUS insertion after nontransecting urethroplasty. Surgeons should take this into consideration and proceed with caution when undertaking urethroplasty in a patient who may experience incontinence afterward. Transecting urethroplasty in the incontinent prostate cancer survivor should be limited to those with obliterative strictures alone.

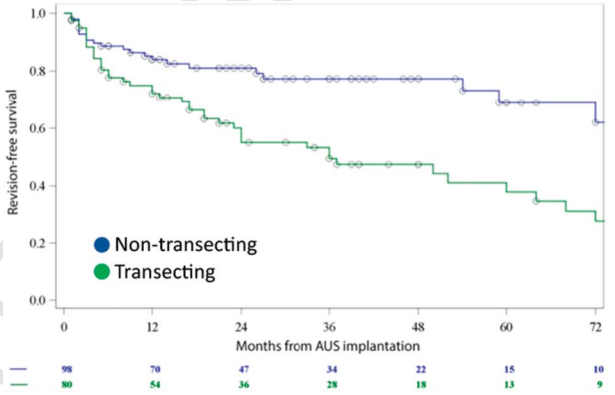

Figure. Kaplan-Meier curve demonstrating artificial urinary sphincter (AUS) device survival according to type of urethroplasty. Here, device survival equals surgical revision for any reason.

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Original Clinical Article

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Multicenter Analysis of Long-Term Outcomes of Artificial Urinary Sphincter Surgery After Urethroplasty

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Purpose: The artificial urinary sphincter (AUS) is the gold standard for male stress urinary incontinence. There is limited and conflicting evidence examining outcomes in AUS insertion after urethroplasty, particularly whether and how urethroplasty techniques affect them. We evaluated complications of AUS insertion after urethroplasty in a multi-institutional cohort. We hypothesize that complications occur at higher rates and vary between transecting and non-transecting urethroplasty.

Materials and Methods: We retrospectively reviewed patients who underwent AUS after urethroplasty at 15 institutions. Demographic and clinical variables were analyzed. Urethroplasties were categorized as transecting or non-transecting. Long-term complications included AUS infection, erosion, and mechanical failure.

Results: One hundred seventy-eight cases were identified performed by 17 surgeons (range 4-40) from 15 institutions with a median follow-up of 33.5 (IQR 46) months. AUS complications requiring explantation, including infection, erosion, and mechanical failure after transecting urethroplasty, occurred in 56.2%

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compared with 23.5% after nontransecting urethroplasty ($P < .001$). Transecting urethroplasty technique was correlated with increased risk of device explant both from erosion ($P = .004$) and atrophy ($P = .008$). Radiation (HR, 0.46, 95% CI: 0.28-0.76, $P = .002$), hypertension (HR, 0.44, 95% CI: 0.27-0.73, $P = .0008$), and patient age (>68; HR, 0.5, 95% CI: 0.3-0.81, $P = .004$) also correlated to risk of device explantation.

Conclusions: Risk of experiencing AUS complications is higher in patients with transecting urethroplasty compared with the nontransecting group. Nontransecting urethroplasty may be advisable if a subsequent need for AUS is anticipated.

Key Words: urethral stricture, artificial urinary sphincter, stress urinary incontinence, urethral sphincter

The artificial urinary sphincter (AUS) is the gold standard treatment option for male stress urinary incontinence (SUI).[1] Although there are several other treatment options for male SUI including male slings and adjustable balloons, the AUS has the highest long-term patient satisfaction rates[2] and is more effective.[3] Nevertheless, it carries with it a 14.8% to 44.8% risk of reoperation secondary to infection, erosion, mechanical failure, and recurrent incontinence.[1]

In contemporary management of prostate cancer (PCa), more patients undergo multimodal therapy and are surviving longer and, as a result, present with a combination of later adverse sequelae, including a combination of urethral obstruction and urinary incontinence, and a more fragile urethra.[4] While a relatively rare occurrence, previous studies have examined outcomes of AUS after urethroplasty. Although these studies demonstrate higher overall complication and explantation rates,[4-6] few studies compare outcomes of urethroplasty type (transecting vs nontransecting).[7] Transecting the corpus spongiosum can have lasting repercussions by disrupting antegrade spongiosal flow through the bulbar arteries.[8-10] The urethra is forced to rely on more distant and tenuous retrograde flow from the dorsal arteries ending in the glans.

We evaluated the outcomes of AUS placement after urethroplasty using a large, multi-institutional cohort stratified by urethroplasty type by comparing the rates of AUS explantation, complications, and longevity of AUS after implantation in patients undergoing transecting vs nontransecting urethral repair. We theorized that a history of urethral transection would adversely affect AUS longevity. This is important as it would inform approach to urethroplasty when subsequent SUI, and a likely need for AUS, is anticipated.

MATERIALS AND METHODS

The study protocol was Institutional Review Board approved.

Design and Participants

A retrospective multi-institutional cohort study including all patients who had undergone transperineal urethroplasty followed by AUS insertion were included between 2002 and 2021. Patient data were obtained from 17 surgeons across 15 international institutions. Data were tabulated retrospectively. Patients were excluded if the urethral reconstruction was performed through a transabdominal approach or if urethroplasty occurred at the time of AUS insertion. Approach for AUS insertion (transperineal vs penoscrotal) was left to the discretion of the surgeon. Similarly, cuff sizing and selection of a transcorporal approach was also left to surgeon discretion.

None of the authors in this group had a routine practice of instructing patients to deactivate their device nightly.

Outcome Variables

The primary outcome of interest was device removal due to either infection, erosion, mechanical failure, and urethral atrophy. Urethral atrophy proves difficult to define quantitatively and relies on the surgeon's intraoperative

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Author Contributions:

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Data analysis and interpretation: Stanisic, Flynn, Nikolavsky, Hays, Angulo, Simhan, Loh-Doyle, Sterling, Dorado, Venkatesan, Rusilko, Dahlem, Vereecken, Boyd, Martins.

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Data acquisition, organization, analysis, manuscript draft: Davis, Hays.

Data mining, chart review: Davis, Hays, Kolyvas, Higgins, Ludwig, Stanisic, Vereecken, Dahlem.

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qualitative assessment of the urethral segment located inside the AUS cuff, in comparison with caliber and tissue quality of adjacent urethra. The surgeon also would confirm at this time that there is no mechanical failure of the device that would explain recurrent incontinence. In patients requiring device removal, we also examined the time to removal.

Covariables

Preoperative characteristics included patient age at the time of urethroplasty, BMI, smoking status, history of radiation, history of prostatectomy, and comorbidities (including hypertension, PCa, and diabetes) and stricture characteristics including etiology, length, and location.

Operative details related to the urethroplasty included technique defined as transecting urethroplasty (excision and primary anastomosis [EPA] and augmented anastomotic urethroplasty) or nontransecting urethroplasty (which included vessel sparing EPA, nontransecting EPA, and augmentation urethroplasty including dorsal onlay, ventral onlay, and dorsal inlay). We also catalogued operative details related to the artificial sphincter including component selection, cuff location, and whether transcorporal urethral mobilization was performed.

Analysis

The statistical analysis was performed using Statistical Analysis System 9.4 (SAS Institute Inc.). For descriptive statistics, mean and SD or median and IQR were calculated for quantitative variables and qualitative ones were described using absolute and relative frequencies. The groups of patients compared are transecting vs nontransecting urethroplasty. The Wilcoxon rank sum test was used to compare continuous variables. The χ^2 contingency test or Fisher exact test were performed to compare categorical variables.

Explant-free interval was investigated using the Kaplan-Meier analysis method with significance evaluated by a 2-sided log-rank test. Device survival was calculated as the time from AUS implant to explantation, with follow-up starting at the time of AUS implantation. The end event is defined as the time of explantation. Censoring was the date of the last time the patient with an AUS implanted was free of end event due for any reason (surgical revision, AUS removal due to mechanical failure, urethral erosion, or infection). All the variables with statistical significance in univariable analysis were evaluated in a multivariable Cox regression model using the stepwise variables selection method.

The stepwise model was used to avoid the multicollinearity effect between factors. Variables included in the multivariable model were those statistically significant on univariable analyses. Owing to the limited sample size, the threshold level for variables entry was 0.15 and stay 0.1. For continuous variables (patient age, length of stricture, and BMI), median values were used as cutoffs.

RESULTS

We identified 178 cases of AUS after urethroplasty performed by 17 surgeons at 15 institutions with a median follow-up of 33.5 (IQR 46) months. All of the patients had undergone primary urethroplasty for urethral stricture, and once the urethra demonstrated durable patency, underwent primary AUS implantation. Of these, 80 patients underwent transecting urethroplasty (median follow-up 38 [IQR 57.5] months) and 98 patients had nontransecting reconstructions (median follow-up 26 [IQR 35] months; $P = .0094$).

Patient Characteristics

Age, smoking status, genitourinary trauma, and history of genitourinary radiation were similar between the 2 groups (Table 1). There was a difference in median stricture length between the 2 groups: 2 (IQR 1) cm in transecting urethroplasty vs 3 (IQR 2) cm in the nontransecting arm ($P < .001$; Table 1). There was a higher proportion of posterior stenosis in the transecting group 86.2% vs 66.3% ($P = .0022$; Table 1, Supplemental Table 1, https://www.jurology.com). We were unable to demonstrate a difference between groups in AUS approach; AUS cuff position and AUS cuff size were similar in the 2 cohorts (Table 1).

Urethroplasty Technique

We found a higher overall perioperative complication rate (requiring device explantation) after transecting urethroplasty compared with nontransecting urethroplasty, at 20% in the transecting group and 10.2% in the nontransecting group ($P = .066$; Table 1). The number of patients not requiring explantation at 60 months was 13 in the transecting urethroplasty group and 15 in the nontransecting group.

Among 80 patients who had transecting urethroplasty, 25 (31.2%) experienced AUS erosion, 11 (14%) experienced urethral atrophy, and 6 (7%) experienced mechanical failure (Table 2). Examining the 98 patients who underwent nontransecting urethroplasty, 13 (13.3%) experienced erosion, 3 (3.1%) experienced urethral atrophy, and 2 (2%) had mechanical failure. The comparison between the technique of urethroplasty and each reason of explant confirmed that both erosion ($P = .004$) and urethral atrophy ($P = .008$) were higher in the transecting urethroplasty cohort (Table 2).

In the devices that failed, the overall median time to removal was 12 (IQR 27) months. Patients who had undergone nontransecting urethroplasty before AUS insertion had significantly higher explantation-free survival rate at 5 and 10 years, 69% (95% CI: 53-80) and 62% (95% CI: 42-77) compared with transecting urethroplasty rates of 38% (95% CI: 24.5-51) and 17% (95% CI: 5.4-33), respectively (log-rank, $P < .001$; part A of Figure, Supplemental Table 2A, https://www.jurology.com). Median survival, indicating the time point where 50% of AUS devices have been explanted, was 36 months in the transecting urethroplasty group and 143 months in the nontransecting group (95% CI: 21-64 months in transecting group, 95% CI: 72 – no upper limit; $P = <.001$).

Table 1. *Patient Demographics and Characteristics*

Characteristic	Total (n = 178)	Transecting (n = 80)	Nontransecting (n = 98)	*P* value
Age, median (IQR)	66 (10)	70 (10)	67 (9)	.22[a]
BMI, median (IQR)	27.3 (5.5)	27 (5.2)	27.5 (6.4)	.83[a]
Stricture location, No. (%)				
Posterior	134 (75)	69 (86)	65 (66)	.002[b]
Anterior	44 (25)	11 (14)	33 (34)	
Stricture length, median (IQR)	2.5 (1.5)	2 (1)	3 (2)	< .001[a]
Patient history, No. (%)				
Radiation	72 (40)	34 (42)	38 (39)	.61[b]
Radical prostatectomy	98 (55)	47 (59)	51 (52)	.37[b]
Radical prostatectomy + radiation	48 (27)	23 (29)	25 (26)	
Complications, No. (%)	26 (15)	16 (20)	10 (10)	.07[b]
Clavien grade, No. (%)				
I	6 (30)	4 (29)	2 (33)	.57[c]
II	10 (50)	8 (57)	2 (33)	
III	4 (20)	2 (14)	2 (33)	
Comorbidities, No. (%)				
Prostate cancer	142 (80)	61 (76)	81 (83)	.29[b]
Diabetes mellitus	46 (26)	24 (30)	22 (22)	.25[b]
Hypertension	80 (45)	41 (51)	39 (40)	.13[b]
Follow-up, median (IQR), mo	33 (44)	38 (58)	26 (35)	.009[a]
AUS cuff size, No. (%)				
3.5 cm	4 (2.3)	0 (0)	4 (2.1)	.19[b]
4.0 cm	45 (25)	18 (22)	27 (28)	
4.5 cm	86 (49)	46 (57)	40 (41)	
5.0 cm	23 (13)	8 (10)	15 (15)	
5.5 cm	16 (9)	7 (9)	9 (9)	
6.0 cm	3 (1.7)	1 (1.2)	2 (2.1)	
AUS cuff position, No. (%)				
Bulbar	104 (55)	41 (51)	63 (64)	.19[b]
Transcorporal	81 (43)	37 (46)	34 (35)	
Other	3 (1.6)	2 (2.5)	1 (1)	
AUS approach, No. (%)				
Perineal	170 (96)	78 (97)	92 (94)	.25[b]
Penoscrotal	7 (4)	2 (2.5)	5 (5.2)	
Other	1 (0.5)	0 (0)	1 (1)	

Abbreviations: AUS, artificial urinary sphincter.
Comparison between urethroplasty groups.
[a]Mann-Whitney *U* test.
[b] χ^2 test.
[c] Fisher exact test.

The group of nontransecting urethroplasty patients also fared better when examining AUS erosions specifically, with higher explantation-free survival rates at 5 and 10 years at 80.8% (95% CI: 66.1-89.6) and 80.8% (95% CI: 66.1-89.6) vs transecting group, 64.9% (95% CI: 51.3-75.6) and 40.4% (95% CI: 16.9-63), respectively (log-rank, $P = .013$; part B of Figure, Supplemental Table 2B, https://www.jurology.com).

Overall device survival was lower in the transecting urethroplasty group, HR 0.42 (95% CI: 0.26-0.71). On examination of device survival for erosion and atrophy separately, transecting urethroplasty was also associated with lower device survival for erosion (HR, 0.44, 95% CI: 0.22-0.86) and for atrophy, HR 0.28 (95% CI: 0.08-0.99; part B and C of Figure, Supplemental Table 2B-C, https://www.jurology.com).

Table 2. *Association Between Artificial Urinary Sphincter Explant (and Reasons) and Type of Urethroplasty*

	Type of urethroplasty		
Outcomes	Transecting, No. (%)	Nontransecting, No. (%)	*P* value
AUS in place	35 (44)	75 (76)	< .001[a]
AUS explanted	45 (56)	23 (23)	
Atrophy	11 (14)	3 (3.1)	.008[a]
Erosion	25 (31)	13 (13)	.004[a]
Infection	2 (2.5)	5 (5.1)	.46[b]
Mechanical failure	6 (7.5)	2 (2)	.14[b]
Other reasons	1 (1.2)	0 (0)	.44[b]

Abbreviations: AUS, artificial urinary sphincter.
[a] Cox test.
[b] Fisher exact test.

Other Factors

Aside from urethroplasty technique, device survival was associated with the absence of hypertension (HR, 0.44, 95% CI: 0.27-0.73), no history of radiation (HR, 0.46, 95% CI: 0.28-0.76), no history of PCa (HR, 0.37, 95% CI: 0.18-0.75), and age younger than 68 years (HR, 0.5, 95% CI: 0.3-0.81; Table 3). Other factors, including age, length or location of stenosis, BMI, smoking status, or history of diabetes, were not associated with device survival on univariable analysis (Table 3).

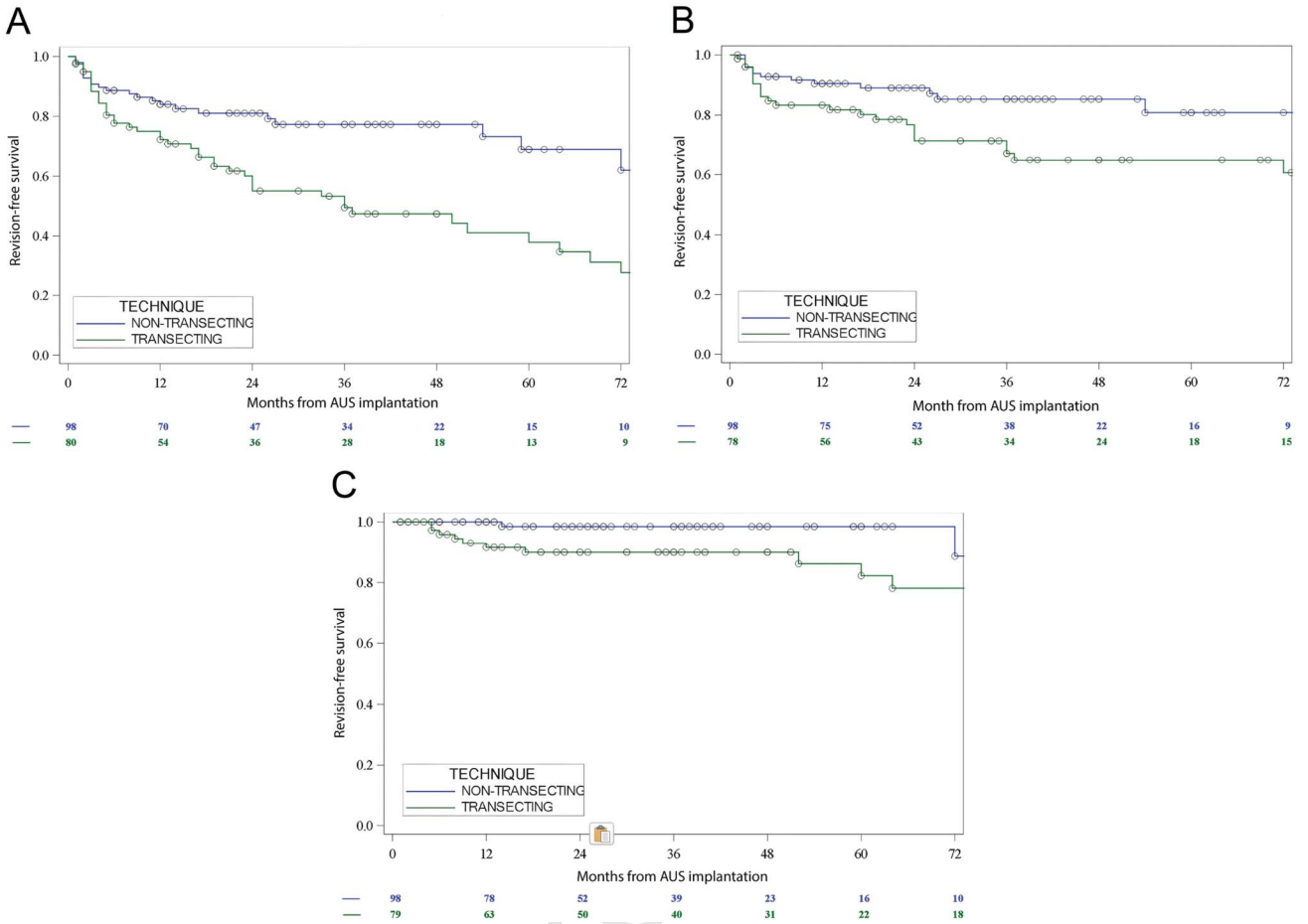

Figure. Artificial urinary sphincter (AUS) device survival according to type of urethroplasty. A, Surgical revision due to any reason (log-rank, $P = .0006$). B, Surgical revision due to urethral erosion (log-rank, $P = .01$). C, Surgical revision due to urethral atrophy (log-rank, $P = .03$).

Multivariable Analysis

In multivariable analysis, the technique of urethroplasty is associated with device explantation (HR, 0.46, 95% CI: 0.27-0.78), as do radiotherapy (HR, 0.51, 95% CI: 0.3-0.88), hypertension (HR, 0.51, 95% CI: 0.31-0.86), and patient age (HR, 0.56, 95% CI: 0.33-0.94; Table 3).

Multivariable analysis did check for interactions of various, potentially confounding, factors such as technique, radiation, and age. These interactions were not statistically significant.

Urethral stricture recurrence was not monitored systematically or specifically after AUS insertion, and accordingly, this was not tabulated.

DISCUSSION

In this multi-institutional longitudinal assessment of AUS survival in patients with a history of urethral reconstruction, our findings tell a compelling story: AUS survival maybe multifactorial, but transecting the urethra appears to significantly

Table 3. *Cox Regression Model to Predict Artificial Urinary Sphincter Explant*

Univariate analysis	HR	95% CI	*P* value
Nontransecting vs transecting urethroplasty	0.43	0.26-0.71	< .001
Patient age ≤68 vs >68 y[a]	0.5	0.3-0.81	.004
Stenosis location anterior vs posterior	1.3	0.74-2.2	.38
Length of stricture ≤2.5 vs >2.5 cm[a]	0.87	0.53-1.4	.58
Urethroplasty without vs with complications	0.67	0.36-1.3	.21
BMI <28 vs ≥28[a]	0.96	0.57-1.6	.88
No PCa vs PCa	0.37	0.18-0.75	.004
No radiation vs radiation	0.46	0.28-0.76	.002
No diabetes vs diabetes	0.99	0.58-1.7	.97
No hypertension vs hypertension	0.44	0.27-0.73	< .001
Nonsmoker vs smoker	1.0	0.6-1.7	.99
No recurrence vs recurrence of stricture	0.96	0.41-2.2	.92
Continent vs incontinent before urethroplasty	0.63	0.34-1.2	.27
Multivariate analysis	**HR**	**95% CI**	***P* value**
Nontransecting vs transecting urethroplasty	0.46	0.27-0.78	.003
No radiation vs radiation	0.51	0.3-0.88	.01
No hypertension vs hypertension	0.51	0.31-0.86	.01
Patient age ≤68 vs >68 y[a]	0.56	0.33-0.94	.03
No PCa vs PCa	0.49	0.23-1.0	.06

Abbreviations: PCa, prostate cancer.
[a] Cutoffs based on median values.

affect its resilience, particularly when surrounded by an AUS. In comparing overall outcomes, the transecting urethroplasty group that underwent subsequent AUS placement had a higher risk of AUS complications. Furthermore, the complications also occurred earlier, resulting in faster time to AUS removal. In subgroup analysis of erosion and atrophy separately, the story repeats itself. In short, transecting urethroplasty leads to earlier and more frequent AUS device removal.

In a general population of artificial sphincter recipients, approximately 26% of patients required reoperation,[11] although there is a reported range from 14% to 44%.[1] In our review, 56% of patients with a history of transecting urethroplasty had device failure or complication requiring removal. Likely, not all these patients went on to reinsertion of AUS, effectively compounding the failure rate. By contrast, the device removal rate in the nontransecting group was closer to the general 26% rate, at 23%.

The focus on maximizing AUS survival is prompted by the steady increase in PCa survivors and refinements in treatment over the past few decades. Understanding and minimizing the AUS complication profile while maximizing device longevity becomes imperative.[11-13] Our assertion was that a lack of adequate spongiosal perfusion after transection would be exacerbated by constriction from an artificial sphincter and that this would be evident when comparing AUS outcomes in transecting and nontransecting urethroplasty.

Robotic prostatectomy recipients treated with adjuvant or salvage pelvic radiotherapy tend to be those at most risk for scarring and incontinence.[14] Many studies have established radiation as a risk factor for AUS erosion and explantation.[2,15] In this analysis, the proportion of patients who were radiated in both transecting vs nontransecting groups was equivalent ($P = .61$). In all cases, radiation occurred before urethroplasty and was the etiology of the development of urethral stricture. Multivariable analysis confirmed that radiation independently predicted AUS failure in this series.

Other risk factors such as hypertension and older age (>68) also independently placed patients at risk for subsequent AUS explantation. In the present cohort, patients older than 68 years experienced device failure or removal earlier than those younger than 68 years (the median age of the entire cohort), HR 0.5 (95% CI: 0.3-0.81). Our data imply that older patients may have less robust vasculature, perhaps due to hypertension, or are more likely to have competing medical problems which predispose to an AUS complication.

Outcomes of AUS placement after urethroplasty have been examined previously in several smaller studies; however, unlike this series, none has offered a definitive conclusion. In a prior investigation by Maurer et al,[5] 17 patients with AUS placement after prior buccal mucosa graft urethroplasty (BMGU) were compared with those who had not undergone prior BMGU, and no significant differences were identified in rates of erosions. These investigators identified an increased risk of device infection in those with prior BMGU, but no significant differences in explantation. Breyer et al[4] examined 11 patients with AUS after urethroplasty and reported that EPA posterior urethroplasty was associated with an 8-fold increased risk of explantation compared with AUS placement in noncompromised urethras. All prior investigations were limited by small sample sizes and single institutional cohorts.

Fuller et al[16] reported that the median time to explantation of initial AUS was significantly shorter in patients with radiation when compared with patients without (26 vs 36 months, $P = .04$). Similarly, Mann reported that prior radiation was associated with earlier time to AUS erosion.[9] These reports are all generally confounded by heterogeneity between types of urethroplasty and history of radiation and most notably limited by small sample size. Within this context of limited scrutiny of AUS outcomes after urethroplasty, there has been no specific examination of how specific urethroplasty techniques affect AUS outcomes differently. It is not possible to ascribe radiation as the cause of stricture disease with complete certainty. However, the impact of radiation on the urethra cannot be discounted regardless of when it occurred before AUS insertion.

Our study is not without limitations, the first of which is the retrospective nature of our review. The median follow-up was statistically shorter in the nontransecting urethroplasty group (26 [IQR 35] months) compared with the transecting group (38 [IQR 57] months). It is possible that long-term complication rates or device survival converge, although the better initial survival of the device in the nontransecting group is still evident and encouraging. Other limitations include the possibility of selection bias (patients felt to be higher risk for complication may not have been offered AUS at all), as well as the inherent heterogeneity in surgeon technique even with the same approach to urethroplasty and AUS insertion, which may all affect outcomes.

Another limitation may be the higher number of posterior urethroplasties in the transection group ($P = .02$). Both pathophysiology and repair may result in more extensive vascular compromise that predispose to AUS complication. Finally, the study was not designed to include a control group of patients with AUS implantation without history of urethroplasty.

Despite these limitations, the present report adds valuable insights to the approach for AUS after urethroplasty. Based on our results, one should proceed with caution when undertaking urethroplasty in a patient who may experience incontinence afterward. Given similar success rates in nontransecting urethroplasty,[17] the number of scenarios calling for transecting urethroplasty in the incontinent PCa survivor should be limited to those with obliterative strictures alone. Alternately, if transection cannot be avoided, conservative component selection (i.e., 51-60 cm H_2O balloon, looser cuffs), delayed activation, or alternate means of treating subsequent incontinence may warrant heavier consideration.[14,18-20]

CONCLUSIONS

Patients who undergo transecting urethroplasty are more likely to experience AUS complications earlier and with greater likelihood compared with those undergoing nontransecting urethroplasty. Nontransecting urethroplasty may be advisable if a subsequent need for AUS is anticipated.

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