Title

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Outcomes of Urethroplasty to Treat Urethral Strictures Arising From Artificial Urinary Sphincter Erosions and Rates of Subsequent Device Replacement

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OBJECTIVE To evaluate the success of urethroplasty for urethral strictures arising after erosion of an artificial urinary sphincter (AUS) and rates of subsequent AUS replacement.

PATIENTS AND METHODS From 2009-2016, we identified patients from the Trauma and Urologic Reconstruction Network of Surgeons and several other centers. We included patients with urethral strictures arising from AUS erosion undergoing urethroplasty with or without subsequent AUS replacement. We retrospectively reviewed patient demographics, history, stricture characteristics, and outcomes. Variables in patients with and without complications after AUS replacement were compared using chi-square test, independent samples *t* test, and Mann-Whitney U test when appropriate.

RESULTS Thirty-one men were identified with the inclusion criteria. Radical prostatectomy was the etiology of incontinence in 87% of the patients, and 29% had radiation therapy. Anastomotic (28) and buccal graft substitution (3) urethroplasty were performed. Follow-up cystoscopy was done in 28 patients (median 4.5 months, interquartile range [IQR]: 3-8) showing no urethral stricture recurrences. Median overall follow-up was 22.0 months (IQR: 15-38). In 27 men (87%), AUS was replaced at median of 6.0 months (IQR: 4-7) after urethroplasty. In 25 patients with >3 months of follow-up after AUS replacement, urethral complications requiring AUS revision or removal occurred in 9 patients (36%) and included subcuff atrophy (3) and erosion (6). Mean length of stricture was higher in patients who developed a complication after urethroplasty and AUS replacement (2.2 vs. 1.5 cm, $P = .04$).

CONCLUSION In patients with urethral stricture after AUS erosion, urethroplasty is successful. However, AUS replacement after urethroplasty has a high erosion rate even in the short-term. UROLOGY 107: 239–245, 2017.

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Since its introduction in 1972, the artificial urinary sphincter (AUS) has become the standard of care for male stress urinary incontinence. Patients have high satisfaction and improved quality of life after AUS placement.[1,2] In 2012, it was estimated that over 150,000 patients worldwide had an AUS implant.[1]

Despite its effectiveness, the AUS device has a high complication rate. Revision surgery or explantation rates are 21%-53% at 5 years.[3-5] Complications of AUS placement include mechanical failure, urethral atrophy, infection, and erosion. Previous studies report AUS erosion rates over a wide range (2%-28%).[1,4-8] AUS erosion can lead to dense urethral stricture by disruption of the urethra and the corpus spongiosum allowing urinary extravasation, which creates an intense inflammatory response. Some studies have evaluated urethral stricture rates after AUS erosion and have promoted "in situ" repair or immediate urethroplasty, at the time of erosion, to avoid these strictures.[9,10] However, there are no data about management of urethral strictures, when they do occur after AUS erosion, and the subsequent possibility of AUS replacement. This question has immediate relevance to affected patients and surgeons who perform regular AUS implantation.

We hypothesized that urethroplasty and AUS replacement were feasible in most men after urethral stricture after AUS erosion. Given the rarity of these patients, we aimed to use data from a multicenter group to assess the outcomes of urethroplasty and rate of subsequent AUS replacement in a larger group of patients to inform surgical decision making.

PATIENTS AND METHODS

We identified patients with our inclusion criteria in 8 of 12 sites in the Trauma and Urologic Reconstruction Network of Surgeons (http://www.turnsresearch.org), as well as the Cleveland Clinic, Duke University, and the University of Alberta.

We included patients with a history of urethral stricture arising from AUS erosion who underwent delayed urethroplasty (after the erosion event) with or without subsequent AUS replacement. Information reviewed included patient demographics, etiology of incontinence, history of pelvic or prostate radiotherapy, history of urethral or penile surgeries (excluding circumcision), stricture characteristics, AUS specifics, management, and complications. We included men in outcome analysis if they had >3 months of follow-up. Clavien-Dindo classification was used to describe postoperative complications.[11] Charlson comorbidity index was used to assess preoperative comorbidities.[12] Stricture location within the bulbar urethra was categorized as proximal (from the junction of the membranous urethra to the distal portion of the central tendon in the perineum), mid (from the distal central tendon to the junction of the inferior scrotum), and distal (within the scrotum, ending distally at the penoscrotal junction).

Urethroplasties were performed using standard techniques based on surgeons' preference and were classified as excision and primary anastomosis or buccal mucosa graft substitution urethroplasty. Postoperatively patients were managed with an indwelling catheter, which was removed generally after a follow-up urethrogram revealed no signs of extravasation. The decision to replace the AUS was at the discretion of the surgeon and desire of the patient. The technique was classified as either transcorporal or standard placement. Replacement AUS follow-up was calculated based on the last visit that the patients had an active AUS. Patients were censored when the replacement AUS was removed due to recurrent erosion.

A descriptive approach was used to present the data using mean, standard deviation (SD), median, and 25th-75th interquartile range (IQR) when appropriate. Categorical variables were compared using chi-square test (or Fisher exact test). Continuous variables were compared using independent samples *t* test or Mann-Whitney U test when appropriate. Statistical significance was assessed at the .05 level.

RESULTS

Demographics

From 2009-2016, we identified 31 men who underwent delayed urethroplasty for urethral strictures arising from AUS erosion. Mean age and body mass index were 73.2 (SD: 7.0) years and 28.1 (SD: 3.7) kg/m^2, respectively. Radical prostatectomy was the etiology of incontinence in 27 patients (87%). Nine patients (29%) had external beam radiation therapy (either as adjuvant or salvage treatment). Before urethroplasty, the patients had a median of 3 (IQR: 2-4) urethral or penile operations (Table 1). These operations included AUS implantation and explantation, placement of inflatable penile prosthesis, male urethral sling, urethral dilations, and direct visual internal urethrotomy (DVIU). Three patients had a history of 2 previous AUS implantations and explantations; 3 other patients had a history of a urethroplasty, prior AUS erosion, and referral.

Table 1. Patient demographics and urologic history

Number of patients	31
Age, mean (SD), y	73.2 (7.0)
BMI, mean (SD), kg/m^2	28.1 (3.7)
Charlson comorbidity index, median (IQR)	6 (4-7)
Incontinence etiology, N (%)	
RRP	19 (61%)
RRP + EBRT	8 (26%)
TURP	3 (10%)
TURP + EBRT	1 (3%)
Previous urethral or penile procedures, median (IQR)	3 (2-4)
Duration of initial AUS, median (IQR), mo	31 (12-79)

AUS, artificial urinary sphincter; BMI, body mass index; EBRT, external beam radiation therapy; IQR, 25th-75th interquartile range; RRP, radical retropubic prostatectomy; SD, standard deviation; TURP, transurethral resection of the prostate.

Stricture Characteristics and Urethroplasty Specifics

Median duration of initial AUS was 31.0 months (IQR: 12-79 months) before removal for erosion. Mean stricture length was 1.7 cm (SD: 0.8) and was in the bulbar urethra in all cases. In all cases, the stricture was at the site of the AUS erosion. Urethroplasties were performed using excision and primary anastomosis (n = 28, 90%) or buccal mucosa graft (n = 3, 10%) techniques. Patients with no anastomotic leakage had their urethral catheter removed at a median of 22.0 days (IQR: 19-27 days) after their surgery (Table 2). Of the 28 patients (90%) who had a documented posturethroplasty urethrogram, 3 patients (11%) were found to have extravasation, which resolved in all cases with observation and continued catheterization. Postoperative complications included wound infection in 3 patients (Clavien-Dindo grade II) and myocardial infarction in 1 patient (Clavien-Dindo grade IV). Follow-up cystoscopy was performed in 28 patients (90%) at a median of 4.5 months (IQR: 3-8 months) and showed patent urethra in all cases with no recurrence. Twenty-nine patients had a follow-up of >3 months with a median of 22.0 months (IQR: 15-38) (Table 2).

AUS Replacement

In 27 of 29 men (93%) with >3 months of follow-up, the AUS was replaced at median of 6 months (IQR: 4-7 months) after urethroplasty. The replacement technique was either transcorporal (n = 18) or standard placement (n = 9). A summary of AUS replacement data is presented in Table 3.

Twenty-five men with AUS replacement after urethroplasty had >3 months of follow-up after their AUS replacement (median: 22 months, IQR: 9.5-33.0). In these 25 men, cuff-related urethral complications occurred in 9 patients (36%) and included subcuff atrophy in 3 patients (managed with cuff downsizing) and urethral erosion in 6 patients (managed with AUS explantation). Two additional patients had pump migration (managed with surgical relocation of the pump in the scrotum). The initial reasons for incontinence in the 9 patients with urethral complications were radical retropubic prostatectomy (±external beam radiation therapy) in 8 patients and transurethral resection of the prostate in 1 patient. Summary characteristics of patients with and without urethral complications are presented in Table 4. The only significant difference between the two groups was a shorter stricture length in men without urethral complications (1.5 vs 2.2 cm, $P = .04$). All of the 19 men with AUS remaining in place with >3 months of follow-up (including 3 patients that had cuff downsizing) reported 1 pad per day urinary leakage or less.

Table 2. Urethral stricture and urethroplasty summary in the study population

Stricture length, cm	
Mean (SD)	1.7 (0.8)
Stricture location within bulbar urethra	
Proximal	9 (29%)
Mid-portion	16 (52%)
Distal	6 (19%)
Urethroplasty technique, N (%)	
EPA	28 (90%)
BMG	3 (10%)
Time to catheter removal, d	
Median (IQR)	22.0 (19-27)
Time to cystoscopy follow-up, mo	
Median (IQR)	4.5 (3-8)
Total follow-up after urethroplasty, mo	
Median (IQR)	22.0 (15-38)

BMG, buccal mucosa graft; EPA, excision and primary anastomosis.

Table 3. Summary of patients with AUS replacement after urethroplasty

N	27
Time from urethroplasty to AUS replacement, mo	
Median (IQR)	6.0 (4-7)
AUS replacement technique, n (%)	
Standard	9 (33%)
Transcorporal	18 (67%)
Incontinence etiology, N (%)	
RRP	16 (59%)
RRP + EBRT	7 (26%)
TURP	3 (11%)
TURP + EBRT	1 (4%)
AUS cuff size, cm	
3.5	1
4.0	9
4.5	8
5.0	5
5.5	3
6.0	1
Follow-up after AUS replacement, mo	
Median (IQR)	22.0 (9.5-33.0)

COMMENT

This study establishes urethroplasty outcomes in urethral strictures induced by AUS erosion and subsequent AUS replacement rates. We found that urethroplasty was a successful treatment for AUS erosion–induced urethral strictures, with a high anatomic success rate (established by posturethroplasty cystoscopic examination). Additionally, AUS replacement after urethroplasty was common in our study population (93%), although it had a high urethral complication rate even in the short-term follow-up of our study.

Urethral erosion is a serious complication of AUS placement, occurring in up to 27% of high-risk patients.[1,13] It necessitates AUS explantation and secondary replacement at a later stage if feasible. Most urethral erosions occur during the first 2 years after device implantation.[1,3,5] Well-established risk factors for AUS erosion include comorbidities, such as cardiac disease, metabolic syndrome, and diabetes, as well as a history of radiotherapy.[5,7] Also, preventable factors such as urethral catheterization

Table 4. Comparison of patients with and without complications after (N = 25)

	No Urethral Complication	Urethral Complication	*P*-value*
N	16	9	
Age, y	74.7 (7.5)	70.8 (5.2)	0.17
BMI, kg/m^2	28.7 (3.1)	28.7 (3.5)	0.99
Charlson comorbidity index			0.36
Median (IQR)	6.0 (3-7)	6.0 (4-8)	
No. of previous urethral procedures			0.89
Median (IQR)	3.0 (2-4)	3.0 (2-7)	
Stricture length, cm			0.04
Mean (SD)	1.5 (0.6)	2.2 (1.0)	
AUS replacement technique, N (%)			0.59
Standard	6 (37.5%)	3 (33%)	
Transcorporal	10 (62.5%)	6 (67%)	
AUS cuff size, cm			0.30
3.5	0	1	
4.0	5	3	
4.5	6	2	
5.0	2	2	
5.5	3	0	
6.0	0	1	
Radiation history, N (%)	5 (31%)	2 (22%)	0.99
Time from urethroplasty to AUS replacement, mo			0.48
Median (IQR)	6.0 (4.0-7.0)	6.0 (4.5-8.7)	
Follow-up after AUS replacement, mo			0.66
Median (IQR)	23.5 (8-33)	16.0 (12-37)	

BMI, body mass index.

* Tested using chi-square (Fisher exact test) for categorical variables, Student *t* test for continuous variables; for Charlson comorbidity index and number of previous urethral procedures, Mann-Whitney U test was used.

(with or without proper AUS deactivation) can increase risk of erosion.[14] Recent studies have concentrated on the acute management of urethral erosion and subsequent urethral stricture risk.[9,10] These studies divide management into urethral repair versus catheter placement and reliance on healing of the urethral erosion by secondary intention. However, data are scarce on the true rates of stricture formation after AUS erosion. Rozanski et al reported that patients who underwent urethral repair at the time of erosion had a stricture rate of 38% compared with 85% for patients with only urethral catheter placement.[10] Of the overall cohort, 62% developed urethral strictures, but only approximately one-third of these patients underwent urethroplasty. The outcomes of these urethroplasties were not included in the study, and the rate of overall AUS replacement, in the patients who experienced erosion, was only 34% versus 93% within our study population. Among the 34% of men having AUS replacement, the authors did not differentiate the rates of AUS replacement after urethroplasty versus those patients whose erosion healed without stricture formation and had an AUS replaced. However, in a recent multi-institutional study, Gross et al suggested that urethral stricture occurs in about 32% of men after AUS cuff erosion, and there is no statistically significant difference in stricture rates based on type of repair at the time of AUS explantation (40% after urethrorrhaphy, 29% after catheter only, and 14% after urethroplasty).[15]

The options for management of urethral strictures are endoscopic (DVIU or urethral dilation) versus urethroplasty. The success rate of DVIU is poor[16,17] and controversial even for routine urethral stricture management.[18-20] Urethral strictures after AUS erosion are often associated with a segmental gap in the urethra and intense fibrosis in the area of the urethral injury. In this respect, the findings are very similar to severe straddle trauma with transection of the urethra. Intuitively, DVIU in this setting is even more unlikely to be successful. In our study, only 11 patients (35%) had a history of dilation or DVIU before urethroplasty, which is lower than that of studies reporting urethroplasty outcomes in a broader population of patients.[21,22] The lower rate of endoscopic management may indicate a prejudice within the group of surgeons to treat these strictures by urethroplasty, possibly due to the dense nature of the fibrosis. In the study from the University of Texas Southwestern, only one-third of patients with resultant strictures after AUS erosion were treated with urethroplasty; however, the authors did not comment on how many patients were treated successfully by endoscopic means versus managed with indwelling catheters or watchful waiting.[10] Another apt point of comparison between strictures from AUS erosion with those arising from straddle injury is the success of urethroplasty. We found urethroplasty after AUS erosion to have a surprisingly high success rate (100%), with 93% of men having this established by cystoscopy. Urethroplasty after straddle injury also has a very high success rate (>90%), established in multiple studies, despite a similar degree of intense fibrosis.[23] Perhaps the very high success rate has to do with the fact that these "strictures" are really injuries with normal urethra on either end of the fibrotic gap.

Rates of AUS replacement after erosion-induced strictures are not established in previous studies; however, the authors from the University of Texas Southwestern concluded that ". . .most men who develop strictures following AUS cuff removal never have the device replaced, thus continuing to suffer from severe urinary incontinence."[24] This observation is contrary to the findings in our study where 93% of men with >3 months of follow-up (27 of 29 men) underwent AUS replacement. The urethral complication rate was very high in our study, after AUS replacement, but those who were successfully managed by cuff downsizing or avoided a repeat erosion (78%) were almost all socially dry (ie, ≤1 pad per day).

In our study, after nearly 2 years of follow-up, 9 men (36%) had a urethral complication. Three patients were successfully managed with cuff downsizing; however, 6 patients needed AUS explantation due to erosion (24%), which is similar to the rates reported in the literature for complex redo AUS operations.[4,25-27] There are some limited data, which serve as a comparison to our series, on AUS implantation after urethroplasty for other reasons than AUS erosion, such as vesicourethral anastomotic stricture after prostatectomy. In a small series from Italy, the authors reported 6 patients who underwent successful anastomotic urethroplasty. All of the patients had an AUS placement after 7 months of urethroplasty and 1 patient (17%) had an erosion after 6 months of AUS implantation needing device explantation.[28] Similarly, McGeady et al reported that a previous history of urethroplasty was associated with an 8-fold risk of AUS surgery failure.[29] Pelvic radiotherapy is another risk factor for AUS erosion.[7,29] We did not find significant associations between radiation exposure and repeat AUS erosion, which is likely due the small sample size. However, we did find that the length of the urethral stricture after AUS erosion was significantly higher in patients having a urethral complication after AUS replacement. This could be attributed to the more extensive urethral mobilization during the urethroplasty needed for longer strictures, further compromising blood supply and increasing the risk of repeat AUS erosion.[29]

The AUS replacement technique (transcorporal vs standard) was at the discretion of the individual surgeon, and the majority of patients (67%) had transcorporal replacement of the device. Transcorporal placement was originally described for patients with a small diameter urethra in which placement of a 4-cm cuff would not produce urethral coaptation, or the urethra was at a very high risk of subsequent erosion. The procedure creates a tunnel through both corporal bodies, incorporating the ventral portions of the corporal tunica albuginea into the tissue surrounded by the cuff to serve as a protective and bulking layer to the urethra. This approach has been successfully described in patients with urethral atrophy, AUS erosion or infection, or previously nonfunctioning AUS cuffs.[13,30,31] An argument for AUS replacement in a transcorporal fashion after urethroplasty is that the need to mobilize the urethra from the corporal bodies is obviated. The urethra is typically densely adhered to the corporal bodies from previous mobilization for urethroplasty, and the risk of urethral injury is high. In addition, unless something can be done to mitigate the risk of repeat AUS erosion, such as transcorporal placement, then proceeding with urethroplasty and AUS replacement does not make much sense, as one would expect the same outcome.

This study has a number of limitations. First, the small sample size limited our analysis of factors associated with poor outcomes after AUS replacement, such as radiation exposure and number of previous urethral surgeries. This small sample size was because of the infrequency of urethral strictures caused by AUS erosion (only 31 patients in 11 centers, over 7 years). We also lacked the details about the initial AUS placement and the exact nature of prior procedures in some patients as the majority were referred after AUS erosion and explantation. For this reason, we cannot comment on how the acute management of erosion would impact urethral stricture risk. Additionally, the follow-up period after AUS replacement was short, and the complication rate in our study will, no doubt, rise over time, although most erosions tend to occur during the first 2 years. We did not attempt to describe additional details about management once AUS erosion occurred after replacement of the AUS (6 patients), as this population of patients becomes increasingly complex and unique. We also did not describe management of patients who developed a urethral diverticulum after AUS erosion, which is another urethral complication mostly needing surgical correction prior to AUS replacement. In addition, due to the rarity of these patients, we were unable to analyze differences in outcomes between surgeons and management strategies.

CONCLUSION

In patients with urethral stricture after AUS erosion, urethroplasty is successful and AUS replacement rates are high. However, AUS replacement after urethroplasty has a high erosion rate even in the short-term. Men undergoing AUS replacement after urethroplasty should be counseled about the risks of subsequent erosion, as this may inform their decision making about alternative treatments, such as urinary diversion or conservative management.

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EDITORIAL COMMENT

This is a well presented and researched manuscript describing a multi-institutional retrospective review of 31 men with bulbar urethral strictures that occurred after artificial urinary sphincter (AUS) erosion who underwent delayed urethroplasty (after the erosion episode) with or without subsequent AUS replacement during 2009-2016. These patients represent a rather uncommon but extremely clinically challenging group even for experienced reconstructive urologists and AUS implant surgeons. Theirs is a very complex situation involving prior prostate surgery and/or radiation therapy, potential hormonal therapy, prior bladder neck and/or penile surgeries, multiple urethral surgeries, as well as other medical comorbidities such as metabolic syndrome, etc. The findings reported by the authors are certainly limited by the short clinical follow-up of the small number of patients who underwent a variety of pre- and post-AUS surgical procedures and/or other treatments. Taking these limitations into consideration, this collaborative group's report advances our understanding of this complex heterogeneous population of men and adds value to the existing reconstructive urology/implant literature and cancer survivorship literature. The authors' conclusion that urethroplasty appears to be very effective for these typically short densely spongiofibrotic urethral strictures is a welcome addition to the literature supporting this concept. Urologists familiar with effectively treating physiologically similar urethral strictures (such as perineal straddle injuries) with urethroplasty may find this conclusion fairly evident. In this small series, despite urethroplasty for AUS erosion related stricture being successful, the subsequent AUS replacement was found to have a high erosion rate in the short-term, perhaps greater than other series involving high risk patients. It is not possible in this small series to determine to what degree any prior prostate surgery and/or radiation play a main role; to what degree the urethroplasty and/or prior bladder neck/urethral/penile surgery play a part; to what degree their urethral vascularity is compromised or not; to what degree metabolic and hormonal factors are involved; etc. We recognize that all of this is multifactorial. Longer term follow-up with larger patient numbers will be helpful in terms of determining which patient characteristics and populations are at even higher risk for erosion than those men we already consider "high risk" going forward. This manuscript provides tangible value for surgeons when we are counseling our patients in the midst of them dealing withwhat is typically a devastating AUS erosion that may be followed by a consequent urethral stricture requiring additional surgical management in the hope of being able to potentially replace the AUS at a later date. This informed and shared decision making process requires a significant collaborative effort between us as urologic surgeons and our patients in an effort to provide them with best possible durable outcomes even in these most challenging clinical situations.

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