# Natural History of Artificial Urinary Sphincter Erosion: Long-term Lower Urinary Tract Outcomes and Incontinence Management

**Bridget L. Findlay, Anthony Fadel, Sierra T. Pence, Cameron J. Britton, Brian J. Linder, and Daniel S. Elliott**

**OBJECTIVE** To describe long-term lower urinary tract outcomes and incontinence management after AUS erosion, including risk factors associated with each outcome.

**METHODS** We retrospectively reviewed our prospectively maintained AUS database for men undergoing device explantation for urethral erosion from January 1, 1986 to October 10, 2023. Outcomes included development of urethral stricture and management of post-explant incontinence (eg, pads/clamp, catheter, salvage AUS, supravesical diversion). Risk factors were tested for association with stricture formation and repeat AUS erosion using logistic regression.

**RESULTS** Around 1943 unique patients underwent AUS implantation during the study period, and 217 (11%) had a device explantation for urethral erosion. Of these, 194 had complete records available and were included for analysis. Median follow-up from implantation was 7.5 years (IQR 2.7-13.7) and median time to erosion was 2 yrs (IQR 0-6). Ninety-six patients (49%) underwent salvage AUS placement. Of those, 38/96 (40%) were explanted for subsequent erosion. On multivariable analysis, no factors were significantly associated with risk of salvage AUS erosion. On multivariable model, pelvic radiation (OR 2.7; 95% CI 1.0-7.4) and urethral reapproximation during explant for erosion (OR 4.2; 95% CI 1.5-11.2) were significantly associated with increased risk of urethral stricture ($P < .05$). At the time of last follow-up, 69/194 (36%) patients had a functioning salvage AUS, including both initial and subsequent salvage implants.

**CONCLUSION** Following AUS erosion, radiation history and urethral reapproximation at explantation were risk factors for development of urethral stricture. Salvage AUS replacement can be performed, but has a higher rate of repeat urethral erosion. UROLOGY 193: 204–210, 2024. 

The artificial urinary sphincter (AUS) is the preferred treatment for severe stress urinary incontinence (SUI) following prostate cancer treatment, with more than 150,000 implantations worldwide.[1,2] Implants have an acceptable longevity, with an estimated revision-free survival of 50%-60% at 10 years, and a sustained positive effect on quality of life.[3,4] However, the associated risks include need for revision in the setting of atrophy or mechanical failure, and more rarely explantation for device infection or erosion. Estimated erosion rates are reported between 5%-18% with an increased risk seen in those with coronary artery disease, hypertension, pelvic radiation, prior urethroplasty, and following traumatic attempts at catheter placement.[4-9]

Device explantation for erosion is a severe complication with significant quality-of-life implications. Of those who undergo salvage reimplantation, rates of subsequent explantation for erosion/infection range between 9%-35%.[10-13] An additional potential complication after an AUS erosion is urethral damage and resultant fibrosis leading to stricture formation. Urethral stricture prevalence following AUS erosion ranges between 10%-40%.[5,14-16] While surgical management of these strictures is an option, patients should be counseled on the increased risk of erosion following AUS reimplantation.[9,17]

Long-term management of urinary incontinence or lower urinary tract complications following AUS erosion is not well defined. In a study of 40 patients with AUS

*The authors declare that they have no relevant financial interests*

*From the Department of Urology, Mayo Clinic, Rochester, MN*

*Address correspondence to: Daniel S. Elliott, M.D., Department of Urology, Mayo Clinic, 200 1st St SW, Rochester, MN 55905. E-mail: Elliott.daniel@mayo.edu*

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explantation with in situ urethroplasty for cuff erosion, 35% of patients had a permanent urinary diversion (eg, chronic catheter or cystectomy) and another 38% had persistent SUI managed conservatively with pads at a median follow-up of 30 months.[16] However, larger cohort studies are needed to better evaluate these outcomes and facilitate patient counseling post-AUS explantation for erosion. Herein, we aim to describe long-term lower urinary tract outcomes and incontinence management after AUS erosion, including risk factors associated with each outcome.

## MATERIALS AND METHODS

After obtaining institutional review board approval, we retrospectively reviewed our prospectively maintained AUS database for men undergoing device explantation in the setting of urethral erosion from January 1, 1986 to October 10, 2023. Baseline characteristics, including age, history of prostatectomy, pelvic radiation, androgen-deprivation therapy (ADT), as well as presence of urethral stricture/stenosis prior to primary AUS implantation were collected. Patients with incomplete charts were excluded. Specific outcomes of interest included time to erosion, development of urethral stricture, and management of post-explant incontinence (pads/clamp, catheter, supravesical urinary diversion). Time to erosion was determined based on date of last revision surgery or original implant if no revisions took place. Urethral erosion was confirmed via cystoscopy either during clinic evaluation or at the time of device explantation. Urethral stricture/stenosis was diagnosed post-operatively by cystoscopy.

At our institution, urethral reapproximation is not routinely performed at the time of explantation. Instead, a urethral catheter is placed following cuff explantation for approximately 6 weeks and a peri-catheter retrograde urethrogram (RUG) is performed prior to catheter removal. All 3 device components (urethral cuff, pressure regulating balloon, and scrotal pump) were removed at the time of device explanation. Risk factors were tested for association with stricture formation, urinary diversion, and salvage AUS erosion by univariable logistic regression.

The design for our multivariable logistic regression model adhered to the 10 events per variable guideline to ensure reliability, particularly given our sample size of 194 participants. For outcome occurrences, we distinguished between anterior urethral stricture (n = 57) and erosion of a salvage implant (n = 39), where multivariable analyses were feasible and conducted based on the guideline. However, for the diversion outcome (n = 12), the limited number of events precluded a multivariable analysis, ensuring our approach remained statistically robust and minimized the risk of overfitting.

As a secondary analysis, we aimed to assess the impact of stricture formation on incontinence management strategies post-erosion. To evaluate the association between stricture formation and the selection of these methods, we applied the Chi-squared test for statistical significance across all categories, utilizing Fisher's exact test for urinary diversion due to its expected small sample sizes. Additionally, we calculated the standardized difference in proportions to quantify the effect size. Absolute values in standardized difference > 0.2, 0.5, and 0.8 were considered as small, moderate, and large effect sizes, respectively.[18,19] SPSS 28.0 was used to conduct all statistical analyses.

## RESULTS

### Demographics

A total of 1943 unique patients underwent AUS implantation during the study period, and 217 (11%) had a device explantation for urethral erosion. Of these, 194 had complete records available and were included in the analysis. Among these, 124 patients (64%) underwent primary implantation at our institution, while 70 patients (36%) had AUS placement elsewhere. The median patient age was 76 (IQR 71-80) years old at the time of explant. One hundred and sixty-two patients (84%) had a previous prostatectomy and 111 (57%) had history of radiation, with 24 (12%) diagnosed with radiation cystitis. A total of 43 (22%) patients had surgical treatment of urethral stricture/stenosis prior to primary AUS implantation. Of the 194 explants, 61 (31%) had previously undergone at least 1 revision/replacement of the original AUS (Table 1). The median time of follow-up from original implant date was 7.5 years (IQR 2.7-13.8) and the median follow-up duration from the first erosion was 2.0 years (IQR 0.5-5.6).

### Operative Data

The median time to erosion following implantation was 1.6 years (IQR 0.4-5.8). Cuff size was documented for 127/194 (65%) patients. The most common cuff size explanted was 4.5 (100/127, 78%). Only 3/127 (2%) were tandem cuffs. Intraoperatively, 21/194 (11%) patients underwent urethral reapproximation at the time of explant. The median time to catheter removal post-operatively was 44 days (IQR 40-57) with 15 patients requiring prolonged catheterization secondary to contrast extravasation on retrograde urethrogram. In those requiring prolonged catheterization, the median time to catheter removal was 74 days (IQR 51.5-95.5), with a range of 35-190 days. Of these, 3/15 (20%) developed a urethrocutaneous fistula managed with suprapubic catheter. A total of 11/15 (73%) had a prior history of radiation, 6/15 (40%) had history of endoscopic management of urethral stricture/stenosis prior to AUS placement, and 5/15 (33%) underwent urethral reapproximation at the time of explant.

### Outcomes

A total of 73/194 (38%) developed a urethral stricture/stenosis following device explantation. Of note, 24/73

**Table 1.** Clinical and demographic features of patients with AUS explantation for urethral erosion.

| Demographic and Clinical Factors | |
|---|---|
| Age at first implant (years) | 71 (66-76) |
| Age at time of explant (for first explant only) | 76 (71-80) |
| Follow-up duration after 1st implant (years) | 7.5 (2.7-13.7) |
| Follow-up duration from erosion (years) | 2.0 (0.5-5.6) |
| Radiation (yes) | 111 (57%) |
| Radiation cystitis (yes) | 24 (12%) |
| Diabetes Mellitus type II | 40 (21%) |
| *Smoking* | |
| Current | 9 (5%) |
| Former | 79 (40%) |
| Never | 62 (32%) |
| Unknown | 44 (23%) |
| ADT | 93 (48%) |
| *Surgical factors* | |
| Urethral reapproximation at erosion | 21 (11%) |
| Previous Prostatectomy (yes) | 162 (84%) |
| Stricture treatment pre-sphincter placement | 50 (26%) |
| Stricture treatment within 6 months of erosion | 16 (8%) |
| *Outcomes* | |
| Time to erosion (days) | 565 (127-2133) |
| Time to 1st salvage implant (days) | 243 (168-360) |
| Time to 2nd salvage (days) | 215 (204-268) |
| Number of salvage implants | - |
| 0 | 98 (50%) |
| 1 | 79 (41%) |
| ≥ 2 | 17 (9%) |
| Urethral stricture/stenosis after erosion | 73 (38%) |
| *Urinary incontinence management* | - |
| Pads/clamp | 63 (33%) |
| Catheter (urethral + suprapubic) | 48 (25%) |
| Supravesical urinary diversion | 12 (6%) |
| Salvage AUS | 69 (36%) |

*Results are presented as N (%) for categorical variables and median (IQR) for continuous variables.

(33%) of these patients had a stricture prior to primary AUS placement. Stricture location included site of cuff erosion in the anterior urethra (44/73; 60%), at the vesicourethral anastomosis or bladder neck within the posterior urethra (16/73, 22%), and both anterior and posterior urethra (13/73, 18%). Of those who developed a stricture/stenosis 60/73 (82%) required treatment in the form of dilation (N = 20), transurethral resection (N = 4), laser/cold knife incision (N = 7), intermittent self-dilation (N = 24), or urethral reconstruction (N = 5). The remaining strictures were observed given their “wide bore” nature and ability to accommodate a 17 Fr flexible cystoscope. Prior pelvic radiation (OR 2.73; 95% CI 1.001-7.43; $P$ = .049) and urethral reapproximation during explant for erosion (OR 4.16; 95% CI 1.54-11.22; $P$ = .005) were associated with increased risk of urethral stricture on multivariable analysis (Table 2).

Distribution of incontinence management after AUS erosion is reflected in Figure 1. Following initial explantation for erosion, 96 patients (49%) elected to proceed with salvage AUS reimplantation. Median time to reimplantation was 8.0 months (IQR 5.5-11.8). Repeat explantation for erosion and/or infection was performed in 38 (40%) of these salvage AUS implants. Of these, 17/38 (44%) elected for an additional salvage implant. History of pelvic radiation (OR 2.36; 95% CI 1.02-5.44; $P$ = .04), ADT (OR 3.12; 95% CI 1.34-7.29; $P$ = .009), and any stricture/stenosis prior to or after AUS erosion (OR 2.55; 95% CI 1.03-6.29; $P$ = .04) were both significantly associated with higher odds of erosion on univariable regression. However, they were no longer significant on multivariable analysis ($P$ > .05; Table 3).

At the time of last follow-up, 69 (36%) of patients had a functioning salvage AUS (including both initial salvage and subsequent salvage), while 63 (33%) managed their SUI with pads and/or penile clamp, 27 (14%) with a urethral catheter, 21 (11%) via suprapubic tube placement, and 12 (6%) by urinary diversion. On univariable analysis, pelvic radiation was associated with a higher odds of undergoing diversion (OR 8.0; CI 1.1-

**Table 2.** Univariable and multivariable analysis of factors associated with urethral stricture formation.

| | Univariable | | Multivariable | |
|---|---|---|---|---|
| | OR (CI) | *P*-value | OR (CI) | *P*-value |
| Age at first implant in years (increasing) | 0.97 (0.93-1.01) | .15 | 0.95 (0.91-0.99) | .046 |
| Number of revision surgeries (increasing) | 1.32 (0.82-2.13) | .26 | 1.003 (0.63-1.60) | .99 |
| Radiation (yes) | 1.62 (0.85-3.09) | .15 | 2.73 (1.001-7.430) | .049 |
| ADT (yes) | 1.31 (0.70-2.44) | .40 | 0.63 (0.25-1.60) | .33 |
| Stricture treatment pre-AUS implantation (yes) | 1.27 (0.63-2.55) | .51 | 1.56 (0.74-3.29) | .90 |
| Urethral reapproximation at erosion (yes) | 4.00 (1.58-10.16) | .004 | 4.16 (1.54-11.22) | .005 |
| Prior Sling (yes) | 0.27 (0.03-2.19) | .22 | - | - |
| Age at time of explant in years (increasing) | 0.99 (0.95-1.03) | .53 | - | - |
| IPP (yes) | 1.60 (0.65-3.91) | .30 | - | - |
| Prior bulking agent (yes) | 0.75 (0.24-2,42) | .64 | - | - |

*Factors tested for association with stricture occurrence post sphincter placement on multivariable logistic regression were selected a priori and limited to 6 due to an outcome occurrence of 57.

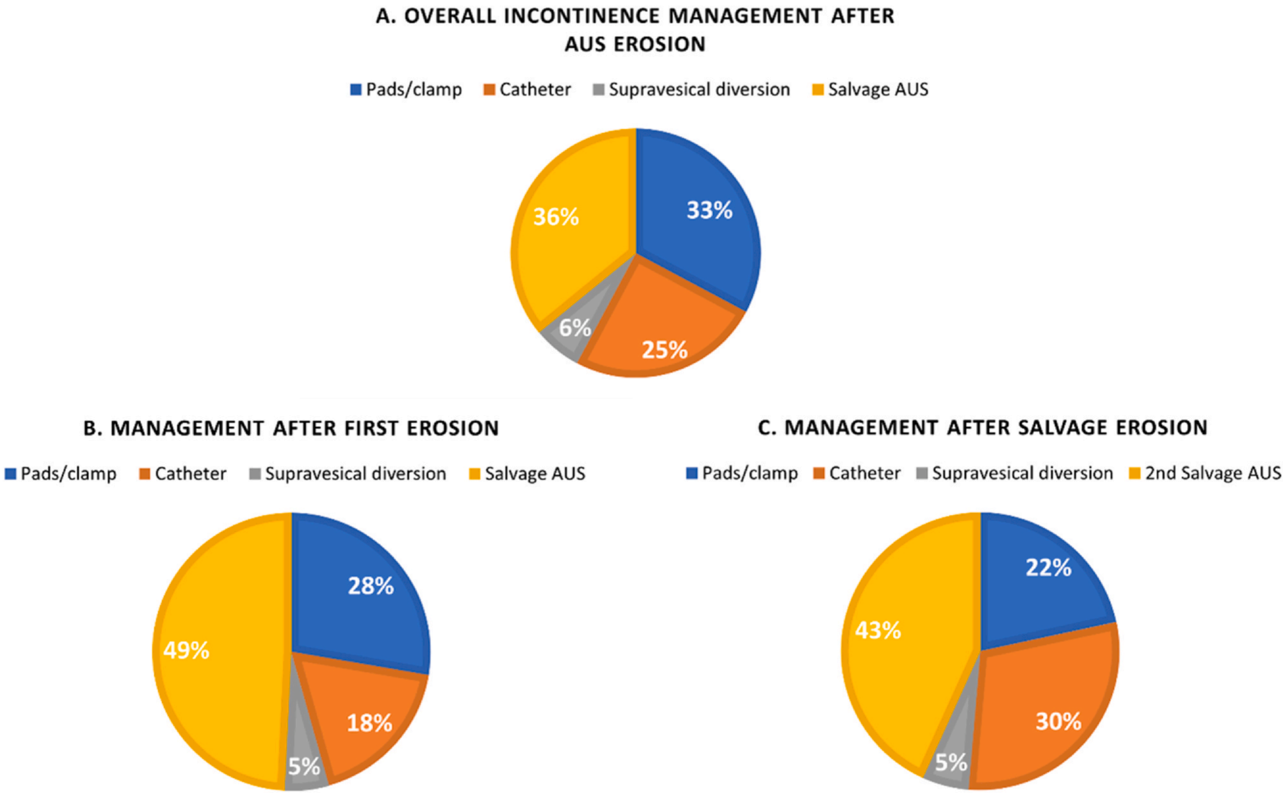


**Figure 1.** Distribution of incontinence management after AUS erosion at the time of last follow-up **(A)**, following first erosion event **(B)**, and after salvage AUS erosion **(C)**. Of note, 36/96 (37.5%) of salvage AUS implants had an explantation for erosion, and therefore, this is the sample represented in **(C)**.

69.7; *P* = .04) while a higher age at time of explant was associated with a lower odds (OR 0.9; CI 0.86-0.99; *P* = .04).

Pads/clamps were less frequently utilized in patients with strictures compared to those without (19% vs 41%, *P* = .002), with a standardized difference in proportions of 0.48. Instead, they were more likely to be managed by a catheter (43% vs 14%, *P* < .001, standardized difference of 0.67). Urinary diversion rates did not significantly differ among stricture (10%) and non-stricture (4%) groups (*P* = .14, standardized difference of 0.22) The same is true for AUS salvage rates (28% in stricture group, 41% in non-stricture group, *P* = .07, standardized difference of .28).

## COMMENT

Management of patients after device removal for AUS erosion can be challenging. Understanding long-term lower urinary tract complications and bladder management strategies can aide in patient counseling. Here, we

**Table 3.** Univariable and multivariable analyses of factors association with repeat urethral erosion following salvage device implantation.

| | Univariable | | Multivariable | |
|---|---|---|---|---|
| | OR (CI) | p-value | OR (CI) | *P*-value |
| Radiation (yes) | 2.36 (1.02-5.44) | .04 | 1.18 (0.38-3.65) | .78 |
| ADT (yes) | 3.12 (1.34-7.29) | .009 | 2.36 (0.77-7.24) | .13 |
| Any stricture pre- and post- AUS (yes) | 2.55 (1.03-6.29) | .04 | 2.30 (0.83-6.41) | .11 |
| Urethral reapproximation at erosion (yes) | 0.23 (0.03-2.01) | .18 | 0.17 (0.02-1.68) | .13 |
| Age at first implant in years (increasing) | 0.95 (0.89-1.00) | .07 | - | - |
| Age at time of explant in years (increasing) | 0.96 (0.91-1.02) | .16 | - | - |
| number of revision surgeries (increasing) | 0.84 (0.44-1.60) | .59 | - | - |
| IPP (yes) | 1.40 (0.46-4.26) | .55 | - | - |
| Prior sling (yes) | 2.25 (0.36-14.14) | .39 | - | - |
| Prior bulking (yes) | 0.70 (0.20-2.51) | .58 | - | - |

***** Factors tested for association with erosion of salvage implant on multivariable logistic regression were selected a priori and limited to 4 due to an outcome occurrence of 39.

present a large series describing the long-term complications associated with AUS erosion, as well as strategies for incontinence management post-erosion. Additionally, we identify risk factors for these complications, including erosion of salvage AUS implants, and how they impact future incontinence management strategies.

### Urethral Stricture

Urethral stricture formation is a known sequelae of AUS erosion, with an incidence ranging between 10%-40% following device explantation.[5,14-16] There are a variety of risk factors associated with erosion, including radiation, extent of erosion defect, and urethral repair.[14,15,20,21]

Following cuff explantation, data regarding management of the urethral defect is conflicting. Options include conservative management with a catheter versus reconstructive options. In situ urethroplasty can be performed as a means of definitive repair at the time of device explantation for erosion.[21,22] When compared to management of cuff erosion with urethral or suprapubic catheter diversion alone, in situ urethroplasty was associated with decreased risk of urethral stricture formation and higher rate of AUS reimplantation.[21] Chertack et al. advocated for urethral defect management based on individual patient characteristics as well as degree of erosion.[20] When comparing outcomes of Foley catheter placement, abbreviated urethroplasty, and mobilization with primary urethral anastomosis, primary anastomosis was performed more frequently in the setting of severe erosions, and Foley catheter management alone for severe erosions was more likely to result in urethral stricture formation.[20]

We do not routinely perform urethral reapproximation or reconstruction at the time of explantation, and instead leave a urethral catheter in place for 6 weeks postoperatively with pericatheter RUG prior to catheter removal. Within our series, urethral reapproximation was associated with a 4× higher risk of development of urethral stricture on multivariable regression model. Other risk factors for stricture formation were radiation exposure and increasing number of revision surgeries. Krughoff et al found stricture formation was more prevalent in the radiation group and was independent of extent of urethral erosion.[14] Their group routinely performs capsular reapproximation without formal urethral reconstruction.

Overall, 2/71 (3%) patients who developed a urethral stricture following erosion underwent formal urethroplasty in anticipation of future salvage AUS implant. Alternatively, 33/71 (46%) patients underwent endoscopic management, with 14/33 (42%) patients proceeding to salvage AUS placement following stricture management. Ultimately, there was no increased risk of erosion of salvage AUS in the setting of prior urethral stricture. These results highlight the frequency of less invasive endoscopic options for urethral stricture treatment.

Our findings indicate that urethral stricture formation following AUS erosion significantly influences incontinence management strategies, with a notable shift from the use of pads/clamps to catheterization among affected patients. This shift highlights the clinical relevance of stricture formation in determining post-erosion patient care. While urinary diversion and AUS salvage rates did not show significant differences, the observed small effect sizes suggest that even non-significant trends might have clinical implications worth exploring further.

### Salvage AUS Implantation

With appropriate counseling and patient selection, salvage AUS implantation can be considered following prior erosion. In our practice, we typically wait at least 6 months before considering a salvage AUS implantation, although we describe a median time to reimplantation of 9 months (IQR 6-13) in a prior series.[10] However, factors that may delay salvage implantation include management of urethral stricture or ongoing urine leak from the site of erosion. Within our series, 96/194 (49%) patients underwent at least 1 salvage implant following erosion, with a subsequent erosion rate of 40% (38/96). However, 17/38 (45%) patients with salvage erosion underwent a second salvage implant with a similar erosion rate of 41% (7/17). Only 2 patients underwent a third salvage AUS implant. Of note, 69/194 (36%) were still functionally using a salvage implant at a median follow-up of 2 years from first erosion. Taking into consideration the potential need for multiple salvage implant surgeries and the risks associated with those, cumulative success of all salvage AUS in this study was 72% (69/96).

Our standard approach includes transcorporal cuff placement for all primary implants, however, others favor reserving this option for salvage settings. Despite efforts to avoid dorsal urethral dissection and provide increased bulk around the urethra for larger cuff placement, there was no difference in subsequent erosion rates using the transcorporal approach.[16]

The risk of subsequent erosion following salvage AUS implantation is estimated between 19%-46%.[9,16,23] Our salvage explant rate (40%) is consistent with these prior studies. Interestingly, 16/38 (42%) patients who had an erosion of their salvage AUS underwent another implantation thereafter, with an expectedly high repeat erosion rate of 50%. Ongoing management of urinary incontinence in these patients is challenging and associated with increased morbidity. Van Dyke et al described urethral ligation and permanent suprapubic catheter placement as a reasonable option for maintaining continence in comorbid patients with particularly devastated urethras.[24] Although the complications associated with this approach were roughly 50%, these risks are overall acceptable when compared to an alternative approach such as diversion.

### Alternative Incontinence Management Strategies

Post-erosion incontinence management is variable, likely related to a combination of individual quality of life priorities and patient-specific factors such as competing comorbid risks. In our study population, 33% of patients continued conservative management with pads/penile clamps while 25% had a chronic indwelling catheter (suprapubic or urethral). A total of 12 (6%) patients ultimately underwent cystectomy with urinary diversion for a variety of reasons including radiation cystitis, fistula, or persistently bothersome urinary incontinence. The only risk factor associated with cystectomy with urinary diversion was prior pelvic radiation. These results are supported by Chertak et al, where 35% of patients had a form of permanent urinary diversion, whether in the form of chronic catheterization or supravesical diversion, and 38% continued with conservative management.[16]

While strategies including chronic catheterization or pad/clamp use are less invasive and lower risk for complications compared to salvage AUS placement or diversion, they still have associated morbidity. Chronic incontinence can lead to skin irritation, breakdown, and infection. Alternatively, chronic catheters are shown to have complications related to infection, urethral erosion, and stone formation. The psychosocial implications of these conservative strategies, including restricted social activities and activities of daily living, are also worth mentioning.[25]

### Limitations

There are several limitations to consider. First, this was a retrospective review of a prospectively collected database, and therefore certain variables were not able to be consistently ascertained, such as percent involvement of urethral erosion, location of erosion, descriptions of systemic signs of infection or frank purulence at the time of explant, or stricture classification. Therefore, we are unable to draw any relationships between cases undergoing urethral reapproximation and extent of urethral erosion at the time of explant. The outcomes also represent surgical management by subspecialist physicians with high surgical volumes at an academic center, thus results may not be generalizable. Additionally, as a destination tertiary care center, follow-up in some instances was limited as patients may have continued their care locally. Finally, while this study sheds light on various management strategies of incontinence or complications following AUS erosion, we lack the ability to achieve more subjective data on patient-reported quality-of-life measures that may have influenced counseling discussions on treatment options and their ultimate treatment decisions.

## CONCLUSION

AUS erosion is associated with long-term consequences with significant quality-of-life implications. Following AUS erosion, radiation history and urethral reapproximation at the time of device explant were found to be risk factors for development of urethral stricture. While reimplantation of an AUS after erosion was feasible, patients should be counseled on the higher rate of repeat urethral erosion. Future studies should be aimed at identifying patient-reported quality-of-life measures that guide counseling discussions for incontinence management following AUS erosion.

## Declaration of Competing Interest

The authors declare that they have no conflict of interest.

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