Published in final edited form as:

Urology. 2014 October ; 84(4): 934–938. doi:10.1016/j.urology.2014.05.043.

Risk Factors for Erosion of Artificial Urinary Sphincters: A Multicenter Prospective Study

William O. Brant, Bradley A. Erickson, Sean P. Elliott, Christopher Powell, Nejd Alsikafi, Christopher McClung, Jeremy B. Myers, Bryan B. Voelzke, Thomas G. Smith III, and Joshua A. Broghammer

Department of Surgery, Division of Urology, Center for Reconstructive Urology and Men's Health, University of Utah, Salt Lake City, UT; the Department of Urology, University of Iowa, Iowa City, IA; the Department of Urology, University of Minnesota, Minneapolis, MN; the Department of Urology, University of Kansas Medical Center, Kansas City, KS; the Department of Urology, Loyola University, Chicago, IL; the Ohio State University, Columbus, OH; the Department of Urology, University of Washington, Seattle, WA; and the Scott Department of Urology, Baylor College of Medicine, Houston, TX

Abstract

OBJECTIVE—To evaluate the short- to medium-term outcomes after artificial urinary sphincter (AUS) placement from a large, multi-institutional, prospective, follow-up study. We hypothesize that along with radiation, patients with any history of a direct surgery to the urethra will have higher rates of eventual AUS explantation for erosion and/or infection.

MATERIALS AND METHODS—A prospective outcome analysis was performed on 386 patients treated with AUS placement from April 2009 to December 2012 at 8 institutions with at least 3 months of follow-up. Charts were analyzed for preoperative risk factors and postoperative complications requiring explantation.

RESULTS—Approximately 50% of patients were considered high risk. High risk was defined as patients having undergone radiation therapy, urethroplasty, multiple treatments for bladder neck contracture or urethral stricture, urethral stent placement, or a history of erosion or infection in a previous AUS. A total of 31 explantations (8.03%) were performed during the follow-up period. Overall explantation rates were higher in those with prior radiation and prior UroLume. Men with prior AUS infection or erosion also had a trend for higher rates of subsequent explantation. Men receiving 3.5-cm cuffs had significantly higher explantation rates than those receiving larger cuffs.

© 2014 Elsevier Inc.

Reprint requests: William O. Brant, M.D., F.A.C.S., F.E.C.S.M., Center for Reconstructive Urology and Men's Health, University of Utah, 30 North 1900 East, Room 3B420, Salt Lake City, UT 84132. Dr.w.brant@gmail.com.

William O. Brant and Bradley A. Erickson contributed equally.

Financial Disclosure: William O. Brant is a consultant, proctor, meeting participant, and a grant recipient of American Medical Systems, a consultant and proctor in Coloplast, and a member of the Speaker's Bureau in Auxilium. Sean Elliott is a consultant in American Medical Systems and GT Urological, a grant recipient of Auxilium, and holds a leadership position in PercuVision. Nejd Alsikafi is a consultant in American Medical Systems. Jeremy Myers holds an unpaid leadership position in the International Volunteers in Urology. Joshua Broghammer is a consultant and proctor in American Medical Systems. The remaining authors declare that they have no relevant financial interests.

CONCLUSION—This outcomes study confirms that urethral risk factors, including radiation history, prior AUS erosion, and a history of urethral stent placement, increase the risk of AUS explantation in short-term follow-up.

Reported incontinence rates after radical prostatectomy range from 6% to 46%, and it has been estimated that 6%–10% of these men may eventually become candidates for surgical correction of their incontinence.^{1–3} The past decades have seen both a rise in the number of men receiving surgical treatment for prostate cancer (PCa) and their long-term survival. With this trend, a renewed focus is being placed on improving the quality of life in PCa survivors.

Since its introduction in 1972, the artificial urinary sphincter (AUS) has been the gold standard treatment for postprostatectomy incontinence. Although several alternatives exist for the treatment of postprostatectomy incontinence, the AUS results in the highest long-term patient satisfaction rates and remains a first-line treatment for cases of severe incontinence. However, the AUS is also an invasive procedure with associated risks, the most significant of which are infection and erosion, both of which require AUS explantation. Fortunately, the short-term rates of these complications are low, but recently reported, long-term, single-institution studies report the need for removal and/or revision to be as high as 50%.^{4,5}

There are well-established patient predictors for eventual AUS complications, most notably prior pelvic radiation⁴ and previous AUS erosion or infection.⁶ These may cause a variety of problems including obliterative endarteritis (eg, radiation) or significant scarring that leads to more difficult dissection (eg, previous explantation). In many cases, there is a decrease in urethral size, and ancillary maneuvers are often required to appropriately coapt the urethra, including urethral wrapping^{7,8} and transcorporal cuff (TC) placement. More recently, a 3.5-cm cuff was introduced to help the surgeons appropriately fit the cuff with smaller urethras, and short-term results with the use of this cuff have been encouraging.⁹

The purpose of this study was to evaluate the short- to medium-term explantation outcomes after AUS placement from a prospective follow-up study. The emphasis of the study is on understanding risk factors for cuff explantation in an era in which multiple options exist for managing high-risk patients. As men with PCa are living longer and more emphasis is being placed on their quality of life after treatment, it can be assumed that many men in whom we place AUS cuffs will eventually require revision, highlighting the importance of understanding how to best manage these difficult patients and improve the chances of a durable cure. We hypothesize that along with radiation, patients with any history of a surgery to the urethra will have higher rates of eventual AUS explantation for erosion and/or infection.

MATERIALS AND METHODS

Study Population

All consecutive patients between April 2009 and December 2012 undergoing AUS placement at 1 of the 8 institutions that make up the Trauma and Urologic Reconstruction

Network of Surgeons were included in this prospective outcomes study. All patients were required to have at least 3 months of follow-up for inclusion, but all other patients were included. Institutional review board approval was obtained for this study at each site.

Surgical Technique

Most patients underwent standard perineal placement. One surgeon placed all sphincters trans-scrotally. When determined to be appropriate by the individual surgery, the AUS placement was augmented by either TC placement¹⁰ or urethral xenograft wrapping.⁸ Although no standard protocol was used within the group to determine which patients were to receive TC placement or wrapping, these ancillary procedures were generally reserved when the surgeon felt the urethra to be compromised, in which case additional tissue from the tunica albuginea or xenograft was used in an effort to minimize erosion risk. No men in the series underwent double-cuff placement or concomitant procedures of the urethra, for example, direct visualization internal urethrotomy.

Primary Outcome

The primary outcome was the need for cuff explantation for either infection or erosion. Patients in the cohort who required explantation (with or without immediate new cuff placement) for other reasons (eg, mechanical failure) were, therefore, not considered failures. We did not specifically analyze postoperative continence outcomes in this study.

High Risk Definition

We hypothesized that direct insults to the urethra may lead to higher rates of urethral erosion and/or infection. We, therefore, evaluated the relationship between the primary outcome and the following patient characteristics: history of (1) pelvic radiation, (2) recalcitrant bladder neck contractures requiring multiple rounds of instrumentation, (3) urethroplasty, (4) UroLume (American Medical Systems, Minnetonka, MN) placement, and (5) AUS erosion and/or infections requiring explantation (at prior operation). Patients with any of the aforementioned risk factors were classified as “high risk.” We further analyzed the relationship between the aforementioned risk factors and ancillary surgical techniques including, (1) urethral xenograft wrapping, (2) TC placement, and (3) 3.5-cm cuff placement.

Statistical Analysis

We first described the overall outcomes of the entire cohort using simple statistics. Second, we analyzed the associations of the primary outcome by both risk factor and surgical technique using chi-square analyses, including an analysis of technique stratified by high and low risks. Finally, we performed a stepwise logistic regression analysis to determine which patient and surgical factors were independently associated with AUS explantation. All surgical and urethral variables were initially included in the model (significance of .3 to enter the model and .35 to stay in the model). All analyses were performed using SAS (version 9.3; Cary, NC), with a *P* value <.05 determining statistical significance.

RESULTS

Demographics

A total of 386 consecutive AUS patients were included in the analysis, with a mean age of 66.1 ± 10.8 years. The mean number $\pm$ standard deviation of AUS placements by surgeons was 48.3 ± 54.3 . The mean follow-up time was 2.3 ± 1.2 years.

Explantation Rates

A total of 31 explantations (8.03%) were performed during the follow-up period; 7 of which (1.91%) were specifically for infection. Further subanalyses of patients with infection were not performed because of the relatively low numbers. Explantation occurred at a mean follow-up of 15.1 ± 7.8 months, and the rates did not significantly differ between surgeons (range, 4.02%–14.86%; $P = .2$).

Risk Factors for Explantation

Patient characteristics by risk factor and surgical type are listed in Table 1. Overall explantation rates were higher in those with prior radiation (15.94% vs 3.63%; $P < .0001$) and prior UroLume (33.33% vs 7.43%; $P = .0047$). Men with prior AUS infection or erosion also had a trend for higher rates of subsequent explantation (13.33% vs 7.43%; $P = .06$). Men who underwent TC placement had similar rates of explantation (10.08% vs 7.12%; $P = .32$) than those not receiving TC. Men receiving 3.5-cm cuffs had significantly higher explantation rates (15.91% vs 7.02%; $P = .04$) than those receiving larger cuffs. Trans-scrotal placement ($n = 29$) of cuff did not affect erosion rates compared with transperineal placement (10.3% vs 7.8%; $P = .634$).

Table 2 stratifies by high ($n = 194$) and low ($n = 192$) risks. Explantation rates in the high-risk group were higher in men receiving a 3.5-cm cuff (27.27% vs 11.63%; $P = .0425$) but were lower in those receiving a TC. Explantation rates were higher as the number of urethral risk factors increased (Table 3).

Multivariate Logistic Regression

The results from the stepwise logistic regression procedure are shown in Table 4. Evaluation of individual risk factors reveals that prior radiation (odds ratio [OR], 4.872; 95% confidence interval [CI], 2.114–11.229), history of urethral stent placement (OR, 5.751; 95% CI, 1.231–28.860), and 3.5-cm cuff placement (OR, 3.308; 95% CI, 1.240–8.825) were the only independent significant predictors for cuff explantation.

COMMENT

The results from this prospective outcomes study confirm that patients with compromised urethras have an increased risk of eventual AUS explantation from erosion or infection. The overall explantation rate over the course of study was 8.03%, but the risk increased significantly as the number of urethral risk factors increased from 0 (3%) to 3 (25%). Importantly, when specifically analyzing surgical techniques in our high-risk population, we noted that men who had received a 3.5-cm cuff had significantly higher rates of

explantation, which was not the case for either TC or those augmented with urethral wrapping.

AUS Placement in the High-risk Patient

Although high-level evidence is lacking about how to best manage the high-risk AUS patient, multiple surgical techniques have been developed with the goal of protecting the damaged urethra. One approach has been to wrap the urethra with xenograft material to increase the urethral circumference. In our group, wrapping is done as a 360° wrap around the urethra. Rahman et al⁸ were the first to report the use of small intestinal submucosa (SIS) to augment the urethra during AUS placement. In each of the 5 patients in the study, the urethral size at the time of repair measured <4 cm in circumference, and the circumference was thus augmented with the SIS. The authors reported surgical and functional success in 4 patients (80%), with one requiring explantation for erosion. In contrast, Trost and Elliott¹¹ reviewed their 8 patients with a history of multiple cuff erosions who underwent repeat AUS placement augmented with SIS and noted that only 3 (38%) of these men were dry and had the sphincter still in place at a median follow-up time of a year.

A major concern about the standard AUS placement technique in compromised urethras is the need to elevate the urethra off the corporal bodies. In the compromised urethra, this maneuver not only has the potential to lead to direct urethral injury but also it may potentially lead to further urethral devascularization. Acknowledging these concerns, Nelson¹² first described an AUS placement that eliminated the need for urethral elevation by placing the cuff around the entirety of the corporal bodies. The TC technique, as it is now used, was described by Guralnick and Webster,¹⁰ and both functional (84%, reporting 0–1 pads/d) and durable (no explantations at 17 months) outcomes in 26 patients were excellent. Other TC studies have shown the technique to be especially effective and safe in the severely compromised urethra, including those with prior radiation, urethral reconstruction, and rectourethral fistula repairs.^{13,14} Concerns with the TC technique have been raised, however, including the potential for postoperative erectile dysfunction and higher rates of postoperative urinary retention.¹⁵

Another concern about AUS placement in the high-risk patient has been that the relatively small urethras often preclude placement of the appropriately sized cuff, potentially compromising the functional results. In 2010, American Medical Systems introduced a 3.5-cm cuff to the market to meet the surgeon's demand for a smaller cuff size. The first to report on outcomes using these cuffs were Hudak and Morey.⁹ In their series of 67 patients, 45 received a 3.5-cm cuff, and these men were more likely to have preoperative erectile dysfunction and prior radiation than those receiving larger cuffs. Importantly, short-term explantation rates in the 3.5-cm cuff population were similar to those receiving larger cuffs and TC, indicating that placement of a smaller cuff in compromised urethras was safe. This group also stated that the 3.5-cm cuff has decreased their institutional need for both TC placement and urethral wrapping maneuvers, potentially simplifying the surgery.⁹

Implications of Present Study Findings

Our study evaluated 386 consecutive AUS patients from 8 centers and had a very high percentage of high-risk patients, making it an excellent cohort to study outcomes in high-risk population. Our outcomes were similar to prior studies, with an overall explantation rate of 8%. As expected, our rates of explantation were significantly higher in men with known risk factors for erosion, most significantly pelvic radiation, with rates of erosion increasing significantly as the number of urethral risk factors increased. Prior UroLume and prior AUS explantations were highly predictive of explantation. Interestingly, a history of prior urethroplasty was not found to be a risk factor for explantation. A higher rate of erosion was expected in this group because of decreased local perfusion but it is possible that the resulting periurethral scar tissue after reconstruction may offer some protection.

Importantly, with our large numbers of patients, we were also able to study outcomes from various surgical maneuvers used in the high-risk population. Urethral wrapping was used in 13 patients, all of whom were high risk, and 2 patients ultimately required AUS explantation for erosion. With our small numbers, further analysis of this population was not possible, but this rate of erosion was similar to prior studies as described previously. A total of 119 men received TC placement, the majority of which were high-risk patients. Although the TC was not statistically protective from eventual erosion, the overall explantation rate of 11.24% in this high-risk population was lower than high-risk patients not receiving the TC and was similar to or lower than previously published studies of high-risk population.^{16–18} A total of 44 men received a 3.5-cm cuff, of which 50% were high-risk patients. In this group, the rates of eventual erosion were much higher than those in the group that received larger cuffs, and the higher risk of explantation remained even in multivariate models, suggesting that men receiving 3.5-cm cuffs in our cohort were subjected to a higher risk of eventual explantation even after accounting for risk factors including radiation and prior AUS removal. Although there are limited prior data regarding outcomes from the 3.5-cm cuff population, given the relatively short amount of time they have been available, we do not believe that these data suggest that something is inherently wrong with the cuff itself. Rather, we believe that these data show that a smaller urethra may indicate a compromised urethra that may not be always capable of supporting a functional AUS. Further studies comparing standard cuff placement vs TC placement in men with smaller compromised urethras will be required before we determine how to best surgically manage this subset of high-risk patients.

Study Limitations

Our study has several limitations. As a general limitation, although the study is prospective, techniques were not randomized, and to demonstrate the value of adjunctive techniques such as wrapping and TC approach, a randomized trial would need to be done in the high-risk population. For more specific limitations, one is that our mean follow-up time was only 2 years, and further follow-up will be required to determine the longevity of the AUS in our high-risk population. It is possible, for example, that although TC placement and urethral wrapping appeared to be superior to the 3.5-cm cuff in the high-risk population in preventing early explantation, longer follow-up may lessen the differences we observed. Second, we did not include functional outcomes in this study as our main concern was about

surgical safety, especially in the high-risk population. However, it is possible that smaller cuffs may provide superior urinary control, which may offset the higher risk of erosion when evaluating outcomes from the patient's perspective. Third, the surgical approach within and between network surgeons was not randomized, and we could therefore not make direct comparisons between surgical techniques to determine which was superior. Although we believe our multivariate models help to control this limitation, prospective studies will be required in this population before we definitively determine how to best manage their incontinence. Finally, nonurethral factors, such as body mass index and smoking history that are also known to affect the microvasculature⁴ and therefore erosion risk, were not included in the multivariate models.

CONCLUSION

This outcomes study confirms that urethral risk factors, including radiation history, prior AUS placement, and a history of urethral stent placement, increase the risk for AUS explantation in moderate-term follow-up. A novel finding in this study was that men receiving 3.5-cm cuffs experienced higher rates of explantation, especially in those with compromised urethras. The clinical implications of this finding are unknown, but it is likely the case that a smaller size urethra is a marker for potential tissue compromise and may suggest that TC placement and/or urethral wrapping maneuvers may be superior to placement of a 3.5-cm cuff in the compromised smaller urethra.

Acknowledgments

Funding Support: The funding source for this work is an unrestricted research grant to Dr. Brant from the Joe W. and Dorothy Dorsett Brown Foundation. There are no commercial sources of funding.

References

1. Kim PH, Pinheiro LC, Atoria CL, et al. Trends in the use of incontinence procedures after radical prostatectomy: a population based analysis. *J Urol*. 2013; 189:602–608. [PubMed: 23017528]
2. Comiter CV. Male incontinence surgery in the 21st century: past, present, and future. *Curr Opin Urol*. 2010; 20:302–308. [PubMed: 20531090]
3. Ficarra V, Novara G, Artibani W, et al. Retropubic, laparoscopic, and robot-assisted radical prostatectomy: a systematic review and cumulative analysis of comparative studies. *Eur Urol*. 2009; 55:1037–1063. [PubMed: 19185977]
4. Wang R, McGuire EJ, He C, et al. Long-term outcomes after primary failures of artificial urinary sphincter implantation. *Urology*. 2012; 79:922–928. [PubMed: 22305763]
5. Lai HH, Hsu EI, Teh BS, et al. 13 years of experience with artificial urinary sphincter implantation at Baylor College of Medicine. *J Urol*. 2007; 177:1021–1025. [PubMed: 17296403]
6. Lai HH, Boone TB. Complex artificial urinary sphincter revision and reimplantation cases—how do they fare compared to virgin cases? *J Urol*. 2012; 187:951–955. [PubMed: 22264456]
7. Margreiter M, Farr A, Sharma V, et al. Urethral buttressing in patients undergoing artificial urinary sphincter surgery. *J Urol*. 2013; 189:1777–1781. [PubMed: 23206425]
8. Rahman NU, Minor TX, Deng D, et al. Combined external urethral bulking and artificial urinary sphincter for urethral atrophy and stress urinary incontinence. *BJU Int*. 2005; 95:824–826. [PubMed: 15794791]
9. Hudak SJ, Morey AF. Impact of 3.5 cm artificial urinary sphincter cuff on primary and revision surgery for male stress urinary incontinence. *J Urol*. 2011; 186:1962–1966. [PubMed: 21944140]

10. Guralnick ML, Miller E, Toh KL, et al. Transcorporal artificial urinary sphincter cuff placement in cases requiring revision for erosion and urethral atrophy. *J Urol*. 2002; 167:2075–2078. discussion 2079. [PubMed: 11956443]
11. Trost L, Elliott D. Small intestinal submucosa urethral wrap at the time of artificial urinary sphincter placement as a salvage treatment option for patients with persistent/recurrent incontinence following multiple prior sphincter failures and erosions. *Urology*. 2012; 79:933–938. [PubMed: 22119252]
12. Nelson RP. Incorporation of corpora cavernosa in bulbous urethral artificial urinary sphincter. *J Urol*. 1986; 136:102–103. [PubMed: 3712591]
13. Aaronson DS, Elliott SP, McAninch JW. Transcorporal artificial urinary sphincter placement for incontinence in high-risk patients after treatment of prostate cancer. *Urology*. 2008; 72:825–827. [PubMed: 18752838]
14. Lee D, Zafirakis H, Shapiro A, et al. Intermediate outcomes after transcorporal placement of an artificial urinary sphincter. *Int J Urol*. 2012; 19:861–866. [PubMed: 22571275]
15. Smith PJ, Hudak SJ, Scott JF, et al. Transcorporal artificial urinary sphincter cuff placement is associated with a higher risk of postoperative urinary retention. *Can J Urol*. 2013; 20:6773–6777. [PubMed: 23783046]
16. Raj GV, Peterson AC, Toh KL, et al. Outcomes following revisions and secondary implantation of the artificial urinary sphincter. *J Urol*. 2005; 173:1242–1245. [PubMed: 15758761]
17. Raj GV, Peterson AC, Webster GD. Outcomes following erosions of the artificial urinary sphincter. *J Urol*. 2006; 175:2186–2190. discussion 2190. [PubMed: 16697836]
18. Walsh IK, Williams SG, Mahendra V, et al. Artificial urinary sphincter implantation in the irradiated patient: safety, efficacy and satisfaction. *BJU Int*. 2002; 89:364–368. [PubMed: 11872025]

Table 1

Univariate analysis of explantation rates by urethral and surgical variables

Predictor Variables	Explantation Rates, n (%)	P Value *
Urethral risk factors		
Radiation (n = 138)	22 (15.94)	<.0001
Recalcitrant bladder neck contracture (n = 61)	8 (13.11)	.1113
Urethroplasty (n = 28)	1 (3.57)	.367
Prior AUS explantation for erosion/infection (n = 75)	10 (13.33)	.0598
Prior urethral stent placement (n = 9)	3 (33.33)	.0047
Surgical risk factors		
Transcervical cuff placement (n = 119)	12 (10.08)	.3218
3.5-cm cuff placement (n = 44)	7 (15.91)	.0411
Urethral wrapping (n = 13)	2 (15.3)	.321

AUS, artificial urinary sphincter.

*
vs the explantation rate with the risk factor not present.

Table 2

Explantation rates by surgical variables of interest, stratified by risk*

Surgical Variable	Low Risk			High Risk		
	N	Erosion, n (%)	P Value†	N	Erosion, n (%)	P Value‡
Overall	192	5 (2.61)		194	26 (13.4)	
Transcorporal cuff placement	30	2 (6.67)	.1282	89	10 (11.24)	.4149
3.5-cm Cuff placement	22	1 (4.45)	.5434	22	6 (27.27)	.0425
Urethral wrapping	0	NA	NA	13	2 (15.3)	.828

NA, not applicable.

* High risk defined as having one of the following characteristics: history of (1) pelvic radiation, (2) recalcitrant bladder neck contracture, (3) urethral reconstruction, (4) prior artificial urinary sphincter explantation for infection or erosion, and/or (5) prior (or current) urethral stent.

† Chi-square comparison with men who did not undergo ancillary maneuver in low-risk population.

‡ Chi-square comparison with men who did not undergo ancillary maneuver in high-risk population.

Table 3

Explantation rates by the number of urethral risk factors present*

Number of Risk Factors	Patients (n)	Explantation Rate, n (%)	P Value (Trend)
0	192	5 (2.61)	.0019
1	106	14 (14.2)	
2	61	6 (9.84)	
3	24	6 (25)	
4	3	0 (0)	
Total	386	31 (8.03)	

* Urethral risk factors include history of (1) pelvic radiation, (2) recalcitrant bladder neck contracture, (3) urethral reconstruction, (4) prior artificial urinary sphincter explantation for infection or erosion, and/or (5) prior (or current) urethral stent.

Table 4
Multivariate logistic regression model of urethral and surgical factors predicting for AUS explanation

Variable	Point Estimate	Standard Error	Chi-square	P Value	OR	95% CI
Intercept	-3.662	0.3942	86.5032	<.0001		
Radiation	1.5836	0.4260	13.8184	.0002	4.872	2.114–11.229
Urethral stent	1.7494	0.7864	4.9487	.0261	5.751	1.231–28.860
3.5-cm Cuff	1.1963	0.5006	13.8184	.0169	3.308	1.240–8.825
Prior AUS	0.7796	0.4427	3.1014	.0782	2.181	0.916–5.192
Urethroplasty	-1.2591	1.0655	1.3964	.2373	0.284	0.035–2.292

CI, confidence interval; OR, odds ratio; other abbreviation as in Table 1.
Stepwise selection was used to create the model. All surgical and urethral risk factors were initial candidates for model inclusion. A significance of .3 was required to enter the model and a significance of .35 to stay in the model.