



Dual Prosthetic Implantation After Radical Cystoprostatectomy and Neobladder: Outcomes of the Inflatable Penile Prosthesis and Artificial Urinary Sphincter in Bladder Cancer Survivors

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OBJECTIVES	To determine the impact of radical cystectomy and orthotopic neobladder (NB) diversion on device-related outcomes in patients who undergo subsequent placement of both, an artificial urinary sphincter (AUS) and 3-piece inflatable penile prosthesis.
MATERIALS AND METHODS	Using an institutional prosthetic database, we identified 39 patients who underwent radical cystectomy and NB and subsequent implantation of both prosthetic devices from 2003 to 2017. Patient demographics, perioperative data, and postoperative outcomes including prosthetic infection, mechanical failure, revision surgery, and functional outcomes were examined and compared to an appropriate matched group of patients (n = 48, non-neobladder group).
RESULTS	No intraoperative complications were observed. After median follow-up of 94 months (12-177 months), 1 patient developed an infection of their penile prosthesis and 4 patients developed an erosion of their AUS. In each case, the infection did not involve the other device. Two patients required revision surgery of their penile prosthesis due to mechanical failure (reservoir leak, n = 1; cylinder aneurysm, n = 1). Twenty-one patients underwent elective revision surgery to improve continence (cuff downsizing, n = 18; pressure-regulating balloon exchange, n = 3). There were 6 cases of AUS mechanical failure. No reservoir-related complications such as herniation or erosion were observed. Compared to the control group of non-neobladder patients, there were no significant differences in prosthetic infection, mechanical failure, and revision surgery.
CONCLUSION	The AUS and 3-piece inflatable penile prosthesis can coexist safely in patients with NB without an increased risk of device-related complications. UROLOGY 127: 127–132, 2019. © 2019 Elsevier Inc.

After radical cystoprostatectomy (RC), patients must adapt to anatomical and functional changes to the urinary system.^{1,2} Surgical techniques have evolved to lessen the impact of these consequences and to maintain “normalcy.” No technique better represents this goal than the orthotopic neobladder (NB) which allows for the preservation of anatomical voiding

without the need for a visible stoma.³ Despite its advantages, many patients with NB are bothered by coexistent erectile dysfunction (ED) and bothersome stress and nocturnal urinary incontinence (UI) and may ultimately require combined prosthetic reconstruction.⁴⁻⁷

The inflatable penile prosthesis (IPP) and artificial urinary sphincter (AUS) have long been considered the gold standard options for ED and UI, respectively. While several studies have shown that dual device implantation is safe and effective in patients after radical prostatectomy, there are no series describing the outcomes of dual device implantation in patients following RC with NB.⁸⁻¹⁰ To address this deficiency, we present our long-term outcomes of 3-piece IPP and AUS placement in this anatomically complex and unique subset of patients.

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MATERIALS AND METHODS

Using our Institutional Review Board-approved databases, we identified 39 patients who underwent RC and NB and subsequent implantation of an AUS and IPP (AMS 800, AMS 700 Boston Scientific, Marlborough, MA) from 2003 to 2017. Patients were included if they had devices placed synchronously or metachronously. All patients were treated at single center with surgeries performed by 2 fellowship-trained surgeons. This cohort of patients was then compared to a group of patients who underwent dual device implantation during the same study period without a history of RC and NB to determine the impact of cystectomy and NB and other patient-specific characteristics on device outcomes.

Patient Selection, Timing of Surgery, and Preoperative Preparation

The first step in successful treatment of ED and stress urinary incontinence (SUI) is timely diagnosis. Once these conditions are identified, patients are counseled on the available treatment options, including definitive prosthetic repair.

Patients undergoing implantation either did not respond to conservative management strategies or elected for upfront prosthetic reconstruction. Before 2011, the decision to perform synchronous or metachronous dual implantation was based on a shared decision-making framework between the patient and the surgeon. Since 2011, all prosthetic devices have been placed in a staged fashion with AUS typically preceding IPP placement.

Prior to both procedures, atraumatic hair removal, drainage of the urinary bladder, and alcohol-based skin preparation and scrub are performed before incision. Broad spectrum intravenous antibiotics are administered for infection prophylaxis.

Device Implantation

AUS implantation is performed through a midline perineal incision to access the proximal bulbar urethra. After mobilization of the proximal bulbar urethra, the urethra is measured and the cuff size is chosen at the discretion of the surgeon. The pump is placed toward the midline in the scrotum in an easily accessible subdartos pouch. IPP implantation occurs through an infrapubic incision. In patients with an AUS, the proximal dilation of the corpora cavernosa must be performed conscientiously due to the presence of the urethral cuff. Both prosthetic balloons are placed in the lateral retroperitoneal space accessed by a counter incision as detailed in a separate study from our institution.¹¹ To avoid iatrogenic interruption to the other prosthetic device and its tubing, the second device's components are placed in the contralateral scrotal and retroperitoneal space, respectively.

The lateral retroperitoneum is our preferred location for alternative reservoir placement due to its low pressure, relative absence of adhesions, and the ease of interrogating the reservoir if revision or removal is required. To access this space, a 2-cm oblique incision is made, 2-cm medial to the anterior superior iliac spine. Dissection is then carried through the subcutaneous layers until the aponeurosis of the external abdominal oblique muscle is identified. The aponeurosis is then incised in the direction of its fibers and the external oblique, internal oblique, and transversalis abdominis muscles are split atraumatically. Transversalis fascia is divided and an extraperitoneal pocket is then created using blunt dissection to accommodate the prosthetic reservoir.

Postoperative Care and Follow-up

The following day, patients are discharged after removal of urinary catheters and suction drains. Routine postoperative follow-up consists of evaluation at 4 weeks after IPP placement with timing of subsequent visits determined by mastery of the device and patient satisfaction. In patients without history of pelvic radiation or urethral surgery, device training and activation of the AUS occurs 6 weeks after implantation. Patients are subsequently seen in follow-up in 4-6-month intervals. Patients are also followed according to cancer-specific surveillance protocols by their respective urologic oncologists.

Outcomes

Patient demographics, perioperative data, and postoperative outcomes were collated. Device outcomes of interest were reservoir complications, prosthetic infection, mechanical failure, AUS erosion, and the need for revision surgery. Mechanical failure was defined as any defect or malfunction in any component of the IPP or AUS that resulted in a structural or functional failure preventing use of the device. Revision of the AUS to improve continence when a malfunction or leak was not identified was not classified as mechanical failure. Functional outcomes were also examined. Patients were asked to quantify their daily pad usage and current sexual function using the International Index for Erectile Function-5 which was administered to all patients by a single clinician-investigator using a protocol approved by the Institutional Review Board.

Statistical Analysis

Baseline cohort characteristics, perioperative data, and postoperative outcomes were compared between the neobladder and non-neobladder groups. Categorical and continuous variables were summarized using frequency percentages and mean and standard deviation, respectively. The chi-squared, Fisher's exact, and paired *t* tests were used to compare continuous and categorical variables as appropriate. Univariate and multivariable logistic regression analysis were used to identify the impact of specific clinically relevant patient factors on device outcomes. A *P* value of $<.05$ on a 2-tailed test was considered statistically significant. Statistical analysis was performed using Stata Statistical Software (StataCorp LP, College Station, TX).

RESULTS

The study group consisted of 39 patients with a median age at time of RC of 63.6 (range: 37-73.5). Median age was 65.2 years and 64.1 years at IPP and AUS implantation, respectively. The median follow-up was 94 months and 40 months for the neobladder and non-neobladder groups, respectively.

Baseline Cohort Characteristics

During the same study time period, there were 48 patients in the comparison group. Patient demographics and operative details are summarized in [Table 1](#). There were no differences in age, BMI, and rates of hypertension, diabetes, and coronary artery disease between the neobladder and non-neobladder groups. The ONB group were more likely to have a history of smoking (56% vs 25%, $P = .003$) and treatment with cisplatin-based chemotherapy and less likely to have history of previous pelvic radiotherapy (10% vs 48%, $P < .001$) or a concurrent diagnosis of prostate cancer (26% vs 98%, $P < .001$). [Table 2](#) summarizes device outcomes in both cohorts.

Table 1. Baseline cohort characteristics and operative details in patients with dual artificial urinary sphincter and inflatable penile prosthesis implantation

Variable	Neobladder Mean (± SD) or n (%)	No Neobladder Mean (± SD) or n (%)	P Value
n	39	48	
Age at time of AUS	65.2 ± 1.5	67.5 ± 1.2	.219
Age at time of IPP	64.1 ± 1.4	66.8 ± 1.5	.201
BMI	28.5 ± 0.7	27.5 ± 0.8	.352
Smoking history	22 (56.4)	12 (25.0)	.003
Diabetes	7 (18.0)	16 (33.0)	.106
Hypertension	19 (48.7)	25 (52.1)	.755
Coronary artery disease	3 (7.7)	11 (22.9)	.078
Previous radiotherapy	4 (10.3)	23 (47.9)	<.001
Cisplatin-based chemotherapy treatment	12 (30.7)	0 (0)	<.001
Prostate cancer diagnosis	10 (25.6)	47 (97.9)	<.001
Bladder cancer diagnosis	39 (100)	4 (7.7)	<.001
Timing of dual implantation			<.001
Synchronous	13 (33.3)	0 (0)	
AUS first	10 (25.6)	37 (78.7)	
IPP first	16 (41.0)	10 (21.3)	
AUS cuff size*			.007
4	4 (10.3)	19 (39.6)	
4.5	29 (70.4)	25 (52.1)	
5	5 (12.8)	4 (8.3)	
AUS reservoir volume*			.004
51-60	0 (0)	9 (18.8)	
61-70	38 (97.4)	39 (81.3)	

AUS, artificial urinary sphincter; BMI, body mass index, IPP, inflatable penile prosthesis.

* One patient in the neobladder group had missing data (n = 1).

Reservoir Complications

No cases of adjacent organ injury or NB perforation occurred in the study population during AUS or IPP placement. After long-term follow-up, no complications such as reservoir herniation or erosion into adjacent structures such as bowel or urinary diversion were observed.

IPP and AUS Infectious Complications

One patient (2.6%) experienced unremitting pain with inflation for 1 year after device implantation. A salvage removal and replacement was performed due to presumed low-grade infection. Afterwards, the pain resolved and the prosthesis became useable. The patient underwent successful AUS placement 2 years afterwards. No patients with AUS had an infection of the device in the NB group.

IPP and AUS Mechanical Failure

Two patients (5.1%) developed mechanical failure of their IPP requiring revision surgery (reservoir replacement due to leak, n = 1, cylinder replacement, n = 1). There were 6 (15.3%) cases of AUS mechanical failure (cuff leak, n = 3; reservoir leak, n = 2; unspecified leak, n = 1). In each case, the defective part was identified and replaced.

AUS Erosive Complications

A total of 4 patients (10.2%) developed an erosion of their AUS cuff which required explantation, urethral reconstruction, and urethral catheter placement. As per our standard practice, the urethral catheter was kept in place for 4 weeks. After 4 weeks, the catheter was removed if the defect was healed. Three patients underwent successful reimplantation subsequently. No

Table 2. Device outcomes in patients with dual artificial urinary sphincter and inflatable penile prosthesis implantation

Variable	Neobladder Mean (± SD) or n (%)	No Neobladder Mean (± SD) or n (%)	P Value
AUS outcomes			
AUS erosion	4 (10.3)	5 (10.4)	1.000
AUS infection	0 (0)	2 (4.16)	.497
AUS failure	6 (15.4)	6 (12.5)	.698
AUS revision	21 (69.2)	36 (75.0)	.549
IPP outcomes			
IPP infection	1 (2.6)	1 (2.1)	1.000
IPP failure	2 (5.1)	5 (10.4)	.367

patients had urinary fistulae form after urethral erosion. In each instance, the IPP remained free of infection. Two patients performed clean-intermittent catheterization with a 16-french catheter on a daily basis to empty their NB. No erosive complications were observed in those 2 patients.

AUS Revision Surgery to Treat Persistent Incontinence

Twenty-one patients (53.8%) in the NB study cohort underwent elective revision surgery of their AUS to improve continence (cuff downsizing, n = 18; pressure regulating balloon (PRB) exchange, n = 3).

Multivariable Logistic Regression Analysis for Device Outcomes

Multivariable logistic regression analysis was performed on the entire cohort of dual implants (n = 87) to determine if NB urinary diversion and other clinical factors were independent predictors of relevant AUS and IPP outcomes (Table 3). NB was not an independent risk factor for poor device outcomes including: AUS revision, AUS erosion, AUS failure, IPP infection, and IPP failure. In patients with dual implants, increasing age (odds ratio, OR 1.32, P = .041) and presence of diabetes (OR 71.3, P = .035) were independent predictors of AUS infection, while smoking history (OR 6.27, P = .020) and previous pelvic radiotherapy (OR 6.14, P = .038) increased the odds of AUS failure. Interestingly, radiation was not found to be a significant risk factor for AUS erosion. There were no significant predictors of AUS revision surgery, AUS revision, or IPP outcomes.

Synchronous versus Metachronous Placement

Patients in the NB group were more likely to undergo synchronous device placement (33% vs 0%, P < .001). Thirteen patients underwent synchronous AUS and IPP placement in the NB group, compared to none in the non-neobladder group. Synchronous placement of AUS and IPP was not associated with poorer device outcomes compared to patients who had metachronous placement in the NB group.

Functional Outcomes

20 patients in the NB cohort were successfully contacted for telephone interview. Nineteen patients were not successfully contacted due to incorrect contact information or patient demise. Eleven patients were still sexually active and reported a mean Sexual Health Inventory for Men (SHIM) score of 22.8 (19-25). Patients reported using a median of 1 pad per day (range: 0-3).

DISCUSSION

While there has been increased focus on survivorship and quality-of-life following radical cystectomy, many patients with NB continue to be effected by both ED and UI despite the availability of excellent treatment options such as the AUS and IPP.^{7,12,13,14} With several studies demonstrating successful outcomes of these devices individually in patients with history of RC, our study now confirms that dual device implantation can be performed safely in this complex patient population without a negative impact on long-term device outcomes, including infection and reservoir-related complications.^{11,15}

Table 3. Multivariable logistic regression analysis of the impact of patient characteristics on device outcomes in patients with dual artificial urinary sphincter and inflatable penile prosthesis implantation

Outcomes	Predictors	Odds Ratio	95% CI	P Value
AUS revision	Neobladder	0.95	0.31-2.90	.926
	Age	0.97	0.92-1.03	.359
	Smoking	0.47	0.17-1.33	.155
	XRT	1.27	0.38-4.21	.697
AUS erosion	Neobladder	1.00	0.15-6.82	.997
	Age	1.16	1.02-1.32	.022
	Smoking	0.93	0.17-4.94	.928
	XRT	1.01	0.15-6.83	.991
AUS infection	Diabetes	71.30	1.36-3749.1	.035
	Age	1.32	1.01-1.71	.041
	Smoking	12.80	0.56-291.61	.109
	XRT	7.19	0.24-217.04	.257
AUS failure	Neobladder	1.56	0.30-8.09	.594
	Age	0.97	0.90-1.05	.480
	Smoking	6.27	1.33-29.46	.020
	XRT	6.14	1.11-33.99	.038
IPP infection	Neobladder	1.31	0.06-26.86	.863
	Age	1.07	0.88-1.29	.503
	Smoking	1.39	0.07-27.79	.831
IPP failure	Neobladder	0.55	0.08-3.75	.548
	Age	0.99	0.90-1.08	.792
	Smoking	0.77	0.12-4.69	.772
	XRT	1.31	0.24-7.15	.755

CI, confidence interval; XRT, previous pelvic radiotherapy.

Based on univariate and multivariate analysis, NB was not found to be an independent risk factor for device complications. Continence and sexual function outcomes were found to be excellent and similar to patients without NB. Although our study population is unique, our results parallel published studies describing dual device implantation in patients with history of radical prostatectomy. In addition to functional outcomes, our anecdotal experience is in concurrence with the study of Mancini et al that demonstrated that when patients have both devices it does not complicate the use of the other device.¹⁶

Our study differs in several ways including our preferred timing of surgery and surgical technique compared to studies of patients with history of prostatectomy. The order of device placement is dependent on what is most bothersome to the patient. In our overall experience, patients presenting with both ED and UI are typically bothered most by UI and will seek to correct this first. An AUS-first approach may help to avoid climacturia and decrease their dependence on protective garments and pads prior to restoring their sexual function. While our series suggests that patients undergoing synchronous AUS and IPP placement do not have compromised outcomes for both devices, our preference is to implant these devices in a staged fashion and to allow at least 3 months to pass before implanting the second device. Because of the potential for urethral cuff erosion when prosthetic cylinders are in place, we recommend a thorough risk assessment be performed before implantation of the second device that considers patient comorbidities and factors that impact urethral vascularity.¹⁷

While many of the studies of dual device implantation describe device placement through a single scrotal incision, it is our practice to proceed with AUS placement through a perineal incision and IPP placement through an infraumbilical approach.^{9,10,18,19}

While IPP implantation can be done through an incision based on surgeon preference, AUS placement should proceed through a perineal approach as it allows for more proximal placement of the urethral cuff and results in superior continence outcomes when compared to a penoscrotal approach.^{8,20-22}

One of the other differentiating features of our study is our preference for reservoir placement. As previously described, prosthetic reservoir balloons are placed in the lateral retroperitoneal space in patients with hostile anatomy through a counter-incision made medial to the iliac crest.¹¹ With over 30 years of experience placing reservoirs in this space, we have found that it is an ideal location that is typically free of significant adhesions and scarring after major urologic surgery, can be done expeditiously, and does not result in a palpable bulge. Although others have described reservoir-related complications related in patients with urinary diversion, we experienced no reservoir-related complications from either device after long-term follow-up.^{23,24} We also support the use of other alternative locations described by other high volume implanters who have described dual prosthetic balloon

placement placed in a high submuscular fashion.²⁵⁻²⁷ Irrespective of location, reservoir implantation should proceed in a way that is safe and familiar to the operating surgeon and the space itself should be of sufficient capacity and low intrinsic pressure.

Although we found no increased risk of mechanical failure in patients with NB when compared to non-NB patients with both devices, as is the case when any urologic prosthetic is implanted, patients are susceptible to the inherent risks of device failure in both the IPP and AUS.²⁸⁻²⁹ In addition, as has been reported extensively, many patients choose to undergo AUS revision surgery to further improve urinary continence. Our AUS revision rate of 53.8%, in which most patients underwent cuff downsizing may be attributed to a cuff selection strategy that sought to minimize the risk urinary retention in patients with NB by choosing a size that was not overly snug or tight during initial placement. Subsequent revisions were undertaken only after sufficient NB emptying was demonstrated in follow-up.

While we found no increased risk of penile prosthesis failure or removal in our study, it is important to acknowledge that a recent study of a large statewide database showed dual device implantation was associated with increased risk of reoperation of the IPP, including explant, compared to patients with IPP alone.³⁰

Importantly, our study also confirms that dual device implantation results in favorable patient-reported outcomes in patients with history of NB which are consistent with those reported in patients with the AUS, IPP, and both devices.

While our experience is encouraging, we acknowledge that these patients are complex and have comorbid conditions including prior treatment with chemotherapy that may impact outcomes. While we saw no increased risk of complications in patients who received cisplatin-based chemotherapy, further study is needed to elucidate the long-term influence of chemotherapy treatment on prosthetic device survival.

This study is strengthened by the sample size of this unique patient population, long-term follow-up, and objective patient-reported outcome data. Prerevision pad usage data was not consistently available in the medical record. Though we sought to reduce attrition bias, we are undoubtedly impacted by the bias inherent to retrospective studies which may underestimate rates of mechanical failure and infection. Due to our institution's reputation as a regional center of excellence for prosthetic implantation and revision, most patients that experience mechanical failure represent for evaluation even if they have not been seen in clinic for many years prior.

CONCLUSION

Dual implantation of AUS and IPP can be performed safely in patients after RC and orthotopic NB without an increased risk of infectious complications, mechanical failure, cuff erosion, or revision surgery when compared to

non-neobladder patients with both devices. NB patients with dual implants should be counseled on the risk of mechanical failure, requiring corrective surgery and the potential to undergo revision surgery to further improve continence, though this risk is not increased compared to patients without a history of NB urinary diversion.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.urology.2019.01.010>.

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