

## Efficacy of Pressure Regulating Balloon Exchange in Men With Post Artificial Urinary Sphincter Persistent or Recurrent Stress Urinary Incontinence



Rachel A. Moses, Sorena Keihani, James R. Craig, Jacob Basilius, James M. Hotaling, Sara M. Lenherr, William O. Brant, and Jeremy B. Myers

<b>OBJECTIVE</b>	To assess the efficacy of exchanging the pressure regulating balloon (PRB) to 71-80 cm H <sub>2</sub> O in patients with persistent or recurrent stress urinary incontinence (SUI) following artificial urinary sphincter (AUS) placement.
<b>METHODS</b>	Patients with SUI following AUS placement who underwent PRB replacement between 2011 and 2017 in the absence of urethral cuff malfunction, atrophy, stricture, or erosion were reviewed. Primary outcomes included changes in pad per day (PPD), Incontinence Symptom Index score, and Incontinence Quality of Life (I-QOL). Secondary outcomes included rates of device erosion and all-cause explant or revision. Differences were compared between patients with and without erosion, explant, or revision. Kaplan Meier device survival analysis was performed.
<b>RESULTS</b>	Twenty two patients ( $67 \pm 9$ years, body mass index of $30 \pm 5$ kg/m <sup>2</sup> ) with a median follow up of 22.4 months (IQR 9.3, 47.3) were included. Incontinence etiology included radical prostatectomy in 60% of patients. After PRB exchange, the average number of PPD decreased from $4.0 \pm 3.0$ to $1.0 \pm 1.6$ PPD ( $P = .01$ ), as did Incontinence Symptom Index scores ( $21.6 \pm 8.5$ vs $16.3 \pm 8.1$ , $P < .001$ ) and Incontinence Quality of Life ( $15.2 \pm 6.8$ vs $7.2 \pm 3.4$ , $P = .01$ ). Three patients with prior radiation (14%) experienced cuff erosion. The explantation/revision rate was 45%(10/22) at 33.5(IQR 8.9,48) months. Kaplan-Meier analysis demonstrated 68%(15/22) and 41%(9/22) retained their device for 12 and 24 months, respectively.
<b>CONCLUSION</b>	PRB exchange can transiently alleviate persistent or recurrent post-AUS SUI in the absence of mechanical failure or urethral pathology. Caution is warranted in patients with prior radiation as this was a risk factor for urethral erosion. Although many patients may require device revision within 2 years, it can be a temporizing solution that avoids urethral manipulation and peri-procedural device deactivation. UROLOGY 123: 252–257, 2019. © 2018 Elsevier Inc.

The artificial urinary sphincter (AUS) remains the most effective treatment for moderate to severe male stress urinary incontinence (SUI).<sup>1,2</sup> The system is far from perfect though with studies showing up to 50% of patients require reoperation for 5 years.<sup>3,4</sup> Established protocols exist for post-AUS incontinence when there is mechanical failure, system leak, urethral erosion, or concomitant overactive bladder.<sup>5-7</sup> These

protocols have utilized techniques for AUS cuff component revision including urethral cuff repositioning,<sup>8</sup> downsizing, and tandem cuff placement.<sup>4,9,10</sup> In addition to these complications, insufficient pressure generated by the pressure regulating balloon (PRB) is a known cause of persistent incontinence in the absence of a leak or urethral pathology.<sup>6,11,12</sup> Although a 61-70 cm H<sub>2</sub>O PRB is the most common PRB size used for index bulbar urethral AUS placement,<sup>1,12</sup> isolated PRB exchange with a 71-80 cm H<sub>2</sub>O balloon may help improve continence rates without potentially detrimental urethral manipulation<sup>4</sup> and with the benefit of immediate device activation. Few authors have investigated improvement in post-AUS incontinence using a higher pressure PRB as a revision maneuver.<sup>4,13,14</sup>

Funding: No funding was utilized to carry out this study/develop this manuscript.

Conflict of interest: The author declares no conflict of interest.

From the Center for Reconstructive Urology, University of Utah, Salt Lake City, UT; and the Veterans Affairs Medical Center, Salt Lake City, UT

Address correspondence to: Rachel A. Moses, M.D., M.P.H., Center for Reconstructive Urology, University of Utah, 30 North 1900 East, Salt Lake City, UT 84132  
E-mails: rachel.moses@hsc.utah.edu; mores.rachel.a@gmail.com

Submitted: June 1, 2018, accepted (with revisions): July 13, 2018

In this series, we sought to determine the outcomes of PRB exchange in patients suffering from persistent or recurrent SUI after AUS placement in the absence of mechanical failure or urethral atrophy. We hypothesized that patients would have improved incontinence and could postpone additional cuff-related surgeries with increased the PRB pressure.

## METHODS

A retrospective chart review was conducted on patients who underwent AUS PRB exchange for persistent or recurrent SUI following AUS placement at a single academic medical center between 2011 and 2017. Patient characteristics (including age, body mass index [BMI], Charlson comorbidity index), etiology of incontinence, prior history of AUS placement with explantation, and prior history of pelvic radiotherapy were collected. Index AUS placement for this study was defined as the AUS placement that was done prior to PRB exchange. Operative reports were reviewed to extract index AUS placement characteristics including: PRB pressure, PRB fluid amount (at the time of PRB exchange), urethral cuff size, method of cuff placement (standard vs transcorporeal), presence of an inflatable penile prosthesis, and time elapsed between index AUS placement and PRB exchange. All patients underwent a thorough history and physical to determine the etiology of persistent or recurrent incontinence symptoms (stress vs urgency). Select patients with mixed incontinence refractory to pharmacotherapy underwent urodynamic evaluation and were excluded if no SUI was present. Mixed incontinence was defined as patients that used Over Active Bladder (OAB) treatments (anticholinergics, botulinum toxin, etc.) or had diagnosis based upon Urodynamics (UDS). All patients underwent cystourethroscopy evaluation prior to consideration of PRB exchange. Patients were excluded if there were clinical findings to suggest mechanical failure (inability to cycle the device), poor endoscopic cuff coaptation (with retrograde flow), urethral stricture, urethral erosion, or urethral atrophy. Urethral atrophy was determined by endoscopic visual inspection with retrograde flow. This was defined as urethral thinning at the level of the cuff as determined by surgeon judgment.

### PRB Exchange Procedure

Patients underwent general anesthesia in the operating room and were then prepped and draped in sterile fashion. An incision was made over the prior AUS PRB insertion site and dissection was performed until the PRB was identified. The blue PRB tubing was then clamped and transected. The previously placed PRB fluid was evacuated, measured, and compared to prior operative report to confirm there was no fluid loss to indicate an occult leak. If the fluid amount was equal to the index fluid amount, the PRB was exchanged. The site with irrigated aggressively with antibiotic-containing solutions including bacitracin and a modified Mulcahy washout.<sup>15</sup> The new 71-80 cm H<sub>2</sub>O device was then implanted and filled with 25 mL of sterile saline. The PRB tubing was reconnected to the tubing from the pump with the quick connect system. The fascia and skin were then closed with absorbable sutures. The device was then checked for appropriate cycling and left activated; patients used their device immediately following the procedure.

## Outcomes

Primary SUI outcome measures included number of pads per day (PPD) used, as well as validated patient-reported outcome measures (PROMs) including the Incontinence Symptom Index (ISI)<sup>16</sup> and the incontinence quality of life measure (I-QOL).<sup>17</sup> Incontinence measures were administered prior to index AUS placement (if the index placement was performed at our institution), pre PRB exchange, and within 6 months post-PRB exchange. Secondary outcome measures of interest included rates of urethral erosion and all cause failure (defined as device explantation or revision), each qualifying as a Clavien-Dindo complication grade 3b (requiring an operative procedure under general anesthesia).<sup>18</sup> Patients were included if they had at least 4 months of follow up after PRB upsizing.

## Statistical Analysis

Pre and post-PPD and questionnaire scores were compared using paired *t* test. Clinical characteristics were compared between patients experiencing post-PRB exchange erosion or all cause failure vs those with retained devices during the study period using chi-square for categorical and *t* test for continuous variables. PRB exchange survival curves were created using follow up time from exchange procedure and last follow up using Kaplan-Meier analysis. All tests were two-sided with statistical significance defined as *P* < .05.

## RESULTS

### Demographics

We identified 22 men who underwent exchange of a 61-70 cm H<sub>2</sub>O PRB to a 71-80 cm H<sub>2</sub>O PRB for persistent or recurrent SUI following index AUS placement. All included patients had otherwise normally functioning AUS devices without urethral atrophy or additional pathology. The PRB exchanges were performed at a median time of 7.5 months (IQR 4.2, 14.3) months after index AUS implantation. The average age of the cohort was 67 ± 9 years, with a BMI of 30 ± 5 kg/m<sup>2</sup>, and Charlson Comorbidity Index Score of 5 ± 2. The etiology for urinary incontinence was treatment of prostate cancer with prostatectomy, radiation, or the combination of both in 81% (18/22). Thirty six percent (8/22) of the cohort had a prior history of primary or secondary radiation. Four patients had benign incontinence etiologies including transurethral resection of the prostate (1), transurethral microwave prostatic ablation (1), spina bifida (1), pelvic fracture urethral injury (1). Sixty four percent (14/22) had a prior history of AUS placement and explantation prior to the index AUS for this study and 32% (7/22) had stress-predominant mixed urinary incontinence. These results are summarized in [Table 1](#).

### Initial AUS Placement Characteristics

The summary of AUS placement characteristics prior to PRB exchange are presented in [Table 1](#). Transcorporeal placement was done in, 32% (7/22), and the average cuff size was 4.5 ± 1. Twenty seven percent (6/22) had a concomitant inflatable penile prosthesis already in place. No patients had a 3.5 cm cuff. At the time of PRB exchange, the amount of fluid evacuated was equal to the index PRB fluid amount and ranged from 23-25 mL depending on the amount placed in the index reservoir.

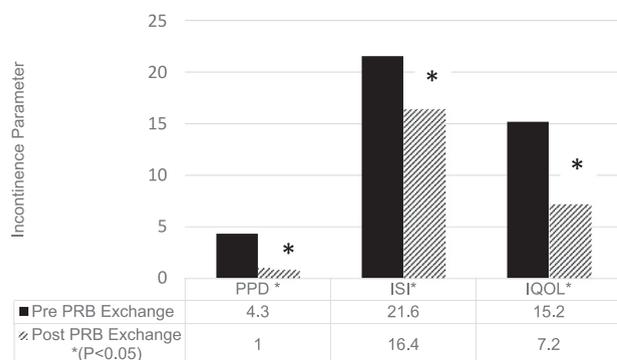
**Table 1.** Demographic and index AUS characteristics (N = 22)

Demographics	
Average age (SD), y	67 (9)
Average BMI (SD), kg/m <sup>2</sup>	30 (5)
Average Charlson comorbidity index (SD)	5 (2)
Any smoking history, N, (%)	5 (23%)
Diabetes, N, (%)	5 (23%)
Incontinence etiology, N, (%)	
Prostatectomy	10 (45%)
Prostatectomy + Radiation	3 (14%)
Radiation	5 (23%)
Benign*	4 (18%)
Mixed urinary incontinence, N, (%)	7 (32%)
Any previous radiation exposure, N, (%)	8 (36%)
Prior AUS placement/explant	14 (64%)
AUS placement technique	
Transcorporal	7 (32%)
Standard	15 (68%)
Presence of inflatable penile prosthesis	6 (27%)
Average AUS cuff size, mean (SD)	
3.5	0 (0%)
4	6 (27%)
4.5	7 (32%)
5	2 (9%)
5.5	5 (23%)
6	1 (4%)
6.5	1 (4%)
Average time to PRB exchange, M, (IQR)	7.5 (4.2,14)
Average follow-up time, M, (IQR)	22.4 (9.3, 47.3)

\* Transurethral resection of the prostate (1), transurethral microwave prostatic ablation (1), spina bifida (1), pelvic fracture urethral injury (1).

### PRB Exchange Outcomes

**Primary Outcomes.** The median follow-up time for the entire cohort was 22.4 months (IQR 9.3, 47.3). Complete PPD data prior to PRB exchange and initial post PRB exchange evaluation were available on the entire cohort. The average PPD rate significantly decreased from  $4 \pm 3$  PPD to  $1 \pm 1.6$  PPD,  $P = .01$ . Additionally, ISI, and I-QOL scores pre- and post-PRB exchange were available for approximately 50% (11/22) of the cohort. ISI and I-QOL scores also improved following PRB exchange: ISI  $21.6 \pm 8.5$  vs  $16.3 \pm 8.1$ ,  $P = .001$ , and I-QOL  $15.2 \pm 6.8$  vs  $7.2 \pm 3.4$ ,  $P = .01$  (Fig. 1).



**Figure 1.** Displays graphical differences in incontinence parameters pre and post-PRB Exchange.

**Secondary Outcomes.** Three patients (14%) developed urethral cuff erosions at 1 month, 2 months, and 15 months respectively. All these patients had history of prior radiation therapy. Characteristics of the patients who experienced erosion (n = 3) and those who did not (n = 18) are compared in Table 2. History of radiation exposure, 100% vs 26% ( $P = .04$ ) was the only significant difference between these groups.

Ten patients (45%) underwent all cause device explantation or revision during the study period at an average time of  $21 \pm 20$  months (Supplementary Table 1). The devices were explanted due to erosion in 3 of the 10 patients as outlined in the above paragraph.

The other 7 patients underwent complete device revision because of persistent or recurrent leakage at an average of  $40 \pm 15$  months. The etiologies for these included poor cuff coaptation (n = 4) at 41, 43, 48, and 53 months, worsening urinary urge incontinence (n = 2) at 12 and 27 months, and urethral atrophy (n = 1) at 58 months. The only factor that was significantly different in the post PRB exchange explant/revision group was higher rates of mixed incontinence (70% in the explant group vs 17% in the no explant group,  $P = .02$ ). Of the 12 patients who had their devices in place with a mean follow up time of  $20 \pm 21$  months, PPD use, ISI, and IQOL scores remained stable at an average of  $1.6 \pm 0.56$  PPD,  $16 \pm 8$ , and  $4.75 \pm 4.3$ , respectively. Kaplan-Meier survival analysis (Fig. 2) showed that for 12 months, the majority of patients retained their 71-80 cm H<sub>2</sub>O PRB at 68% (15/22), however this dropped to 41% (9/22) by 24 months.

## DISCUSSION

This study presents outcomes of PRB exchange to 71-80 cm H<sub>2</sub>O for the management of persistent or recurrent SUI following AUS placement in the absence of device failure or urethral pathology. For primary outcomes, we found most patients in our series demonstrated significantly improved PPD, ISI, and IQOL scores after PRB exchange to 71-80 cm H<sub>2</sub>O. In addition, almost 70% and 41% of patients were free from revision with stable urinary incontinence parameters for 1 and 2 years after PRB exchange. Perhaps the most morbid AUS complication (urethral erosion) only occurred in patients with a history of pelvic radiation. Unique to our study, success of PRB exchange was also measured with changes in PROMs and not just PPD use or revision/removal rates.

Previous studies have outlined the work up and management of persistent or recurrent SUI,<sup>6,7,19</sup> however, few have focused on management of continued incontinence in the absence of AUS system fluid loss, cuff erosion, urethral atrophy, or uncontrolled urgency incontinence.

Insufficient pressure generated by the PRB is a known cause of persistent incontinence in some patients.<sup>6</sup> The PRB is the continence generator of the AUS system. A 61-70 cm H<sub>2</sub>O is the most common PRB used for index bulbar urethral AUS placement.<sup>1,12</sup> Failure of the PRB may occur when there is a system leak, however, it can also happen in the absence of a leak.<sup>6,11,12</sup> Prior reports have demonstrated decreased PRB pressures without identified leak at the time of AUS explant,<sup>11,12</sup> suggesting that the PRB may lose the ability to apply adequate

**Table 2.** Univariate comparison of patients with and without AUS erosion following PRB exchange

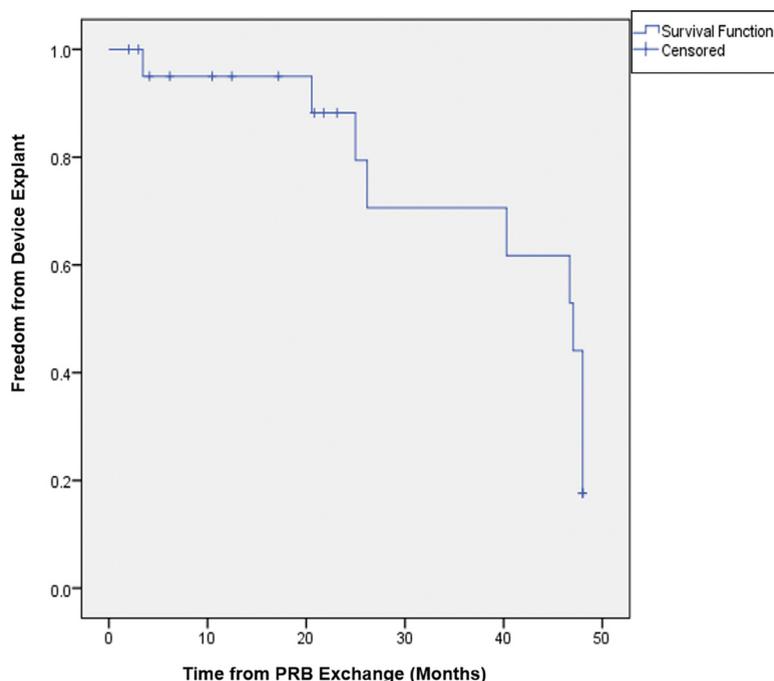
Characteristic	Erosion (n = 3)	No Erosion (n = 19)	P Value
Age, y (SD)	66 (4)	67 (9)	.89
BMI, kg/m <sup>2</sup> (SD)	27 (5)	31 (5)	.28
Average Charlson comorbidity index (SD)	8 (6)	5 (2)	.13
Average AUS cuff size (SD)	5 (1)	5(1)	.61
Transcortical AUS replacement technique, n (%)	0 (0%)	7 (35%)	.32
Prior history of AUS explant, n (%)	1 (33%)	13 (68%)	.53
Radiation history, n, (%)	3 (100%)	5 (26%)	.04

urethral pressure over time. While typically the 71-80 cm H<sub>2</sub>O is reserved for bladder neck placement,<sup>12</sup> it has been suggested as a salvage operation for persistent incontinence due to insufficient PRB pressure following AUS placement.<sup>4,6,13,14</sup>

A few prior studies have evaluated PRB exchange as compared to alternate revision maneuvers for persistent incontinence. Wang et al<sup>14</sup> evaluated a cohort of patients requiring an AUS revision procedure for persistent incontinence. PRB exchange (27%) was compared to cuff revision alone (14%)(15/106). The authors found improved incontinence rates (measured by PPD) in the PRB exchange group. More recently Eswara et al,<sup>13</sup> compared AUS revisions for urinary leakage, which included PRB exchange. They found improved continence rates with decreased PPD use, in the PRB exchange group, compared to alternate

maneuvers. Further, they found that AUS cuff downsizing was associated with an increased rate of mechanical failure as compared to PRB exchange. Maximilien et al<sup>20</sup> also reviewed 31 patients who either had their PRB exchanged for 71-80 cm H<sub>2</sub>O (21 patients) or “re-pressurized” (ie, filled with an additional 2-7mL of fluid, 10 patients). At an average follow up time of 23 months they found superior continence rates (1PPD vs 2PPD, *P* = .03) and lower erosion rates (33% vs 80%, *P* = .02) in patients having their PRB exchanged. While we did not compare between revision modalities, our study demonstrates a similar improvement in continence as compared to the other studies.

Notably in our series, despite initial, significantly improved PROMs, 68% and 41% required explant or revision for 1 and 2 years including 3 patients who developed cuff erosion. Although, these rates may



Percent Survival (Number at Risk) Following PRB Exchange			
0 Months	12 Months	24 Months	48 Months
100% (22)	68%(15)	41% (9)	18% (4)

**Figure 2.** Displays a Kaplan-Meier survival analysis exploring AUS PRB exchange device survival.

seem high, they are similar to other types of revision maneuvers demonstrated by Linder et al (pooled revision rate 50% for 2 years, urethral erosion rate approximately 17%).<sup>19</sup> It should be mentioned that when excluding patients with a history of radiation that developed cuff erosion, the average time to device failure was around 40 months. This may suggest that in the nonirradiated patient, PRB exchange may further prolong AUS revision. In contrast to alternate revision maneuvers, PRB exchange is arguably less invasive, avoids urethral manipulation, and allows for immediate device activation.

As stated previously, the 3 patients who developed urethral cuff erosion in our study had prior pelvic radiation. Radiation has been shown to be a risk factor for AUS erosion in numerous studies.<sup>21-24</sup> Our series suggests that this population is at higher risk for urethral erosion with PRB exchange. This should be factored into decision making when considering single component AUS revisions in these patients. In addition to radiation exposure related complications, we found that urinary urgency was associated with all cause device explant or revision with 70% (7/10) having urinary urgency in the explant/revision group vs 17% (2/12) in the no explant group ( $P = .02$ ). In contrast to our findings, prior studies have demonstrated similar incontinence outcomes with AUS on patients with mixed urinary urgency incontinence as compared to pure SUI.<sup>25</sup>

Interestingly, the majority of the patients in this cohort were overweight or obese with an average BMI of 30 kg/m<sup>2</sup>. Prior studies have demonstrated an increased rate of mechanical failure in obese patients.<sup>14</sup> One theoretical explanation for this may be that increased BMI can increase the force on the AUS system, causing the PRB to fail. No studies to our knowledge have evaluated this phenomenon, however, this may be a patient population that would benefit from consideration of a 71-80 cm H<sub>2</sub>O PRB.

This study was limited by the inherent flaws of a small series and retrospective design. Follow up time frames were not often uniform and 4 patients in this series had less than 1 year follow up, likely impacting our survival analysis. Further, this was a small series of patients at a single academic medical center, thus the study lacks the statistical power for a multivariable regression analysis. Previously utilized measurements, such as urethral manometry, were not performed on most the cohort, thus were not utilized in our analysis. Further, due to the limitations of our review, we lacked data to differentiate persistent vs recurrent incontinence on a large portion of the cohort. Therefore, a sub analysis was not carried out. Despite these shortcomings, this series is one of the largest evaluating single component AUS revision and only one of a few studies that use pre and postoperative PROMs to evaluate improvement.

## CONCLUSION

This study demonstrates that PRB exchange to 71-80 cm H<sub>2</sub>O can transiently alleviate post-AUS persistent or recurrent SUI in a select group of patients lacking clinical signs of mechanical failure or urethral pathology. Prior pelvic radiation was a risk for urethral erosion therefore, caution is warranted in the irradiated patient. Like any isolated AUS revision maneuver many patients ultimately needed complete device revision after 2 years, however this technique avoids urethral manipulation and allows for continued periprocedural device activation. These findings suggest PRB exchange may be an efficacious, short-term solution for post-AUS SUI in the appropriately selected patient.

## SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.urol.2018.07.052](https://doi.org/10.1016/j.urol.2018.07.052).

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had been able to identify those patients who had prior AUS with reasons for previous explant, but the retrospective nature of this series did not allow this. In addition, there is a clear distinction between patients with persistent vs recurrent incontinence which was not evaluated in this series. Persistent incontinence indicates a possible cuff sizing issue, while recurrent incontinence is more consistent with a device malfunction, eg, like a PRB losing pressure. In general, all surgeons in this arena could benefit from a better systematic way to trouble-shoot the AUS and especially assess for urethral atrophy. Cystoscopic inspection can be fraught with uncertainty in some cases and the premise of this manuscript is upregulating the PRB is effective when urethral atrophy has not occurred. Finally, some continued sobering reminders that irradiated patients have a higher risk of erosion and in fact constituted the 3 erosions seen in this cohort.

While AUS implanters all experience the considerable satisfaction of allowing patients to regain their quality of life when these devices work well, there is nothing more frustrating than a patient who redevelops leakage and is unable to be salvaged satisfactorily. These authors should be congratulated for adding to our understanding of possible interventions to assist men whose incontinence returns after AUS placement. Ultimately, perhaps the most honest advice we should disseminate to men is that while AUS remains the best modality in our surgical armamentarium, future revisions remain a high likelihood. Therefore, like so many purchases, caveat emptor.

**Gregory T. Bales**, Section of Urology, University of Chicago Hospitals, Chicago, IL

<https://doi.org/10.1016/j.urology.2018.07.053>  
UROLOGY 123: 257, 2019. © 2018 Elsevier Inc.

## EDITORIAL COMMENT



The paper above adds to the growing body of evidence that the pressure regulating balloon (PRB) of the artificial urinary sphincter (AUS) system plays a critical role in controlling and effecting continence rates. Many urologists who perform AUS insertion feel that the pressure generated from the PRB can be inconsistent and there is a real need for future investigations to evaluate PRBs with a manometer to better analyze pressures. Perhaps these authors will prospectively assess this in future patients to better pinpoint revision approach. Also, there are many instances when performing an AUS revision that there is fluid loss in the PRB without any discernible evidence of leak from any of the components. This presents a conundrum to clinicians and frequently necessities compete revision with an entire new AUS system. Regardless, the results of this small series suggest that improved continence rates can be obtained by switching the 61-70 cm H<sub>2</sub>O pressure PRB to a 71-80 cm H<sub>2</sub>O pressure in select situations. The obvious advantage to this revision technique is it greatly simplifies the procedure by avoiding urethral dissection and allows patients to immediately reactivate the device, because there will be no scrotal swelling associated with the new placement of a pump. It would have been helpful if the authors

## AUTHOR REPLY



Thank you for the insightful feedback on our study evaluating exchange of the artificial urinary sphincter (AUS) pressure regulating balloon. We agree it would be beneficial to know more of the details regarding the nature of incontinence (recurrent vs persistent) and the etiologies of the prior AUS explants, which was not obtained in 64% of the cohort. Of note, however, there was no significant difference in erosion rates, perhaps the most morbid outcome, between those with a prior AUS implant/explant and those who underwent pressure regulating balloon exchange with a virgin AUS. Further, it is important to emphasize that this procedure is beneficial in a very select cohort, ideally the nonirradiated patient with pure stress incontinence lacking urethral atrophy. Despite the efficacy demonstrated by our study, there is certainly a need for multi-institutional, prospective studies evaluating this management option for post AUS incontinence.

**Rachel A. Moses, Sorena Keihani, James R. Craig, Jacob Basilius, James M. Hotaling, Sara M. Lenherr, William O. Brant, Jeremy B. Myers**, University of Utah, Salt Lake City, UT; Veterans Affairs Medical Center, Salt Lake City, UT

<https://doi.org/10.1016/j.urology.2018.07.054>  
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