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SURGERY

Explantation of High Submuscular Reservoirs: Safety and Practical Considerations

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ABSTRACT

Background: Over the past decade, high submuscular (HSM) placement of inflatable penile prosthesis (IPP) reservoirs has emerged as a viable alternative to space of Retzius (SOR) placement; however, data comparing the feasibility and complications of HSM vs SOR reservoir removal do not presently exist.

Aim: To present a comparison of the safety, feasibility, and ease of removal of HSM vs SOR reservoirs in a tertiary care, university-based, high-volume prosthetic urology practice.

Methods: Data were retrospectively collected on patients who underwent IPP reservoir removal between January 2011 and June 2020. Cases were separated into 2 cohorts based on reservoir location. Statistical analysis was performed using Fisher's exact and Chi-squared tests for categorical variables and Student's *t*-test for continuous variables. Timing from IPP insertion to explant was compared between the HSM and SOR groups using the Mann-Whitney U test.

Outcomes: Time from IPP insertion to explant, operative time, intraoperative and postoperative complications, and need for a counter incision were compared between the HSM and SOR groups.

Results: Between January 2011 and June 2020, 106 (73 HSM, 33 SOR) patients underwent IPP removal or replacement by a single surgeon at our institution. Average time from IPP insertion to removal was 43.6 months (24.2 HSM, 52.7 SOR, $P = .07$)—reservoir removal occurred at the time of device explant in 70 of 106 (66%) cases. More HSM reservoirs were explanted at the time of IPP removal compared with the SOR cohort (54 of 73, 74% HSM vs 16 of 33, 48.5% SOR, $P = .01$). Similar rates of complications were noted between the HSM and SOR groups (1.9% vs 6.3%, $P = .35$). There was no significant difference in need for counter incision between the 2 groups (24 [42%] HSM vs 4 [25%] SOR, $P = .16$) or in average operative times (76.5 ± 38.3 minutes HSM vs 68.1 ± 34.3 minutes SOR, $P = .52$).

Clinical Implications: Our experience with explanting HSM reservoirs supports the safety and ease of their removal.

Strengths and Limitations: Although the absolute cohort size is relatively low, this study reflects one of the largest single-institution experiences examining penile implant reservoir removal. In addition, reservoir location was not randomized but was instead determined by which patients presented with complications necessitating reservoir removal during the study period.

Conclusions: HSM reservoir removal has comparable perioperative complication rates and operative times when compared with SOR reservoir removal. **Kavoussi M, Bhanvadia RR, VanDyke ME, et al. Explantation of High Submuscular Reservoirs: Safety and Practical Considerations. J Sex Med 2020;17:2488−2494.**

Key Words: Erectile Dysfunction; High Submuscular; Inflatable Penile Prosthesis; Reservoir

INTRODUCTION

Inflatable penile prosthesis (IPP) remains the gold standard treatment of refractory erectile dysfunction.[1] Although conventional reservoir placement has been in the space of Retzius (SOR), alternative reservoir placement strategies have gained popularity within the urologic prosthetic community.[2−4] Recent modifications in technique have focused on reducing palpability and increasing the anatomic reproducibility of reservoir

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placement. Reservoirs are now commonly placed between the transversalis fascia and the belly of the rectus abdominis muscle, in what has been termed a high submuscular (HSM) location.[5]

HSM placement has gained increasing popularity over the past decade given its safety profile. One 2013 survey reported that a majority of members of the Sexual Medicine Society of North America saw HSM placement as a safe and beneficial method that should be taught in physician training courses.[6] A more recent multi-institution survey found that many high-volume implanters prefer HSM placement over SOR, given a lower perceived risk of visceral or vascular injury and ease of learning.[3] In 2015, the Food and Drug Administration granted approval for HSM IPP reservoir placement to Coloplast (Minneapolis, Minnesota), thus affirming the role of alternative reservoir placement in the mainstream of prosthetic urology.[7]

HSM placement has been shown to be a well-tolerated and safe alternative that avoids the rare—but potentially catastrophic—deep pelvic complications that may be associated with reservoir placement in the SOR.[8–15] By avoiding the deep pelvis altogether, HSM virtually eliminates the risks of major bladder, bowel, and vascular injuries.[4] While critics have questioned the palpability and bother of HSM reservoirs, multiple studies have shown that most reservoirs are not palpable by the patient and that even when palpable, are rarely bothersome.[16] Rates of revision for palpability have been reported at 2–3.4%, and satisfaction rates as high as 96% have been reported.[16,17] Given its safety, efficacy, and high levels of patient satisfaction, some high-volume implanters have argued HSM placement may represent a new standard of care.[2,4,18,19]

While numerous studies have evaluated the safety and outcomes of HSM reservoir placement, no studies have evaluated the safety and feasibility of reservoir removal. Given an overall revision rate of 7–11%, this is an important factor to consider when deciding approach for reservoir placement. As such, we present a retrospective analysis of our experience with removal of HSM reservoirs in our high-volume practice and compare this with SOR reservoir removal.

MATERIALS AND METHODS

Data Collection

Data were retrospectively collected on all patients who underwent IPP explantation between January 2011 and June 2020. Cases were excluded from final analysis if the reservoir was left in situ via the "drain and retain" method.[20] The decision on whether to remove the reservoir or whether to "drain and retain" was made by the senior surgeon based on intraoperative findings. Cases were stratified into 2 cohorts based on reservoir location (HSM vs SOR).

Patient demographics, time from IPP placement to explant, operative time (time from incision to close), intraoperative complications, postoperative complications, and the need for a counter incision were compared between the SOR and HSM groups. Statistical analysis was performed using Fisher's exact test and Chi-squared testing for categorical variables and Student's *t*-test for continuous variables. Timing from IPP placement and explant was compared between HSM and SOR groups using the Mann-Whitney U test. Significance was set at $P < .05$.

Surgical Technique

The IPP components are accessed via a transverse penoscrotal incision. Intraoperative cultures are obtained if there is any clinical concern for infection; regardless, the field is copiously irrigated with gentamicin solution throughout the procedure. Attention is first turned to the scrotal pump, which is identified and dissected out. The tubing is then traced back to the lateral aspect of the corpora, and bilateral corporotomies are made via electrocautery to access and remove the cylinders.

To locate the reservoir, the remaining tubing is traced into the groin until the reservoir connection is reached. The tubing is divided, which allows complete deflation of the reservoir. Firm traction is placed on the residual reservoir tubing to deliver the reservoir into the operative field. In the event that the reservoir does not readily descend, the senior surgeon determines the fate of the reservoir. In the absence of infection, the tubing is cut as high as possible under traction (allowing proximal migration once tension is released), and the drained reservoir is retained in situ. If the "drain and retain" protocol is contraindicated (ie, in the case of infection), an abdominal counter incision is made to access the reservoir directly. The location of the counter incision is guided by palpation; in cases where the reservoir is not readily palpable, intraoperative ultrasonography is used for identification.

RESULTS

During the study period, 106 (73 HSM, 33 SOR) patients underwent IPP explantation (Table 1), 87 of whom (64 HSM, 23 SOR) were initially implanted at our institution. Average time from IPP insertion to removal was 43.6 ± 51.4 months. Patients undergoing HSM and SOR reservoir removal were similar in terms of age, body mass index, and comorbidities (Table 2). In both groups, infection was the most common indication for explant, followed by mechanical failure, implant erosion, and reservoir related complications such as leak, herniation, and bother (Table 2).

Of the 106 IPP device removal cases, 70 cases (66%) underwent complete device explantation including removal of the reservoir; the remaining 36 had reservoirs left in situ via the "drain and retain" method. Indications for reservoir removal were similar between the 2 groups, with infection being the most common cause for explantation (Table 2). There was no significant difference in the rate of reservoir removal between devices implanted at our institution and those that were not (88.9% HSM placed at our institution vs 81.3% SOR reservoirs, $P = .42$). HSM reservoirs were significantly more likely to be

Table 1. Patient characteristics

Characteristic	HSM (n = 73)		SOR (n = 33)		*P* Value
Explanted reservoirs					
	54	74.0%	16	48.5%	.01
Demographics					
CAD	15	20.5%	11	33.3%	.16
DM	18	24.7%	12	36.4%	.21
HTN	45	61.6%	24	72.7%	.27
COPD	3	4.1%	3	9.1%	.30
Tobacco Hx	35	47.9%	19	57.6%	.36
CKD	2	2.7%	4	12.1%	.05
CHF	1	1.4%	3	9.1%	.05
BMI	28.0	19.6–38.4	30.2	20.6–51.0	.06
Follow-up (mos.)	5.6	0–77	12.5	0–100	.08
Age	63.9	43–84	68.0	51–84	.07

BMI = body mass index; CAD = coronary artery disease; CHF = congestive heart failure; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus; HSM = high submuscular; HTN = hypertension; SOR = space of Retzius; Tobacco Hx = Tobacco history.

explanted compared with SOR reservoirs (74% HSM vs 48.5% SOR, $P = .01$, Table 1). Total operative times were similar between the 2 groups (76.5 ± 38.3 minutes HSM vs 68.1 ± 34.3 minutes SOR, $P = .52$ Table 3). Counter incisions were more common in the HSM group than those in the SOR group (42.0% HSM vs 25% SOR) although this did not reach statistical significance ($P = .16$, Table 3).

There was no significant difference in mean time from initial IPP placement to device explant between HSM and SOR groups, although it favored longer duration in the SOR group (24.2 ± 24.1 months vs 52.7 ± 41.8 months, $P = .07$). Patients who underwent "drain and retain" had a significantly greater mean time from IPP placement to intervention by 50.4 months compared with patients who underwent removal (28.2 ± 28.1 months vs 78.6 ± 72.3 months, $P < .001$). There was no difference in time to explant between patients who underwent a counter incision and those who did not (25.1 ± 26.0 months vs 30.8 ± 29.5 months, $P = .31$).

Similar overall complication rates were noted between the HSM and SOR groups (1.9% vs 6.3%, $P = .35$, Table 3). Among patients undergoing HSM reservoir removal, 1 (1.9%) patient who was on therapeutic anticoagulation for an artificial aortic valve developed a spontaneous retroperitoneal hematoma after restarting his anticoagulation. The patient was taken for exploratory laparotomy, where the hematoma was evacuated, and the source of venous bleeding was identified—far from any

Table 2. Comparison of reservoir removal patients (HSM vs SOR)

Characteristic	HSM (n = 54)		SOR (n = 16)		*P* value
Demographics					
CAD	13	24.1%	5	31.3%	.56
DM	13	24.1%	5	31.3%	.56
HTN	30	55.6%	12	75.0%	.16
COPD	3	5.6%	3	18.8%	.1
Tobacco Hx	27	50.0%	12	75.0%	.08
CKD	2	3.7%	2	12.5%	.18
CHF	1	1.9%	2	12.5%	.05
BMI	29.3	30.1–51.7	28.4	20.3–37.1	.6
Follow-up (mos.)	6.3	0-75	11.6	0-61	.55
Age	63.4	43–77	70.1	51–84	.55
Indication for revision:					
Infection	18	34.0%	9	56.3%	.14
Mechanical failure	16	30.2%	4	25.0%	1.00
Tissue erosion	12	22.6%	2	12.5%	.50
Reservoir complication	8	15.1%	1	6.3%	.67

BMI = body mass index; CAD = coronary artery disease; CHF = congestive heart failure; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus; HSM = high submuscular; HTN = hypertension; SOR = space of Retzius; Tobacco Hx = Tobacco history.

Table 3. Comparison of reservoir removal outcomes between HSM and SOR groups

Outcomes	HSM (n = 54)	SOR (n = 16)	*P* Value
Complications	1 (1.9%)	1 (6.3%)	.35
Counterincision	24 (44%)	4 (25%)	.16
OR Time	76.5 (26-201)	68.1 (35–155)	.52

HSM = high submuscular; OR = operating room; SOR = space of Retzius.

dissection that occurred during the initial operation. Given the location, we believe that this complication was secondary to the patient's anticoagulation and could have happened after either HSM or SOR removal. Among the 15 SOR cases, 1 (6.3%) patient required laparoscopic removal of a reservoir. This patient had a history of 5 prior IPPs with multiple retained SOR reservoirs and required total device removal secondary to an infected IPP that was extruding through the urethral meatus. Preoperative imaging revealed 2 reservoirs in an intraperitoneal position. These reservoirs were subsequently laparoscopically removed from the retroperitoneum and the intersigmoid fossa, respectively. The postoperative course was further complicated by chronic inflammatory changes in the suprapubic area secondary to what was found on imaging to be retained tubing within the SOR. No further intervention was deemed necessary and this resolved in the remote postoperative period. It is unclear whether these reservoirs had migrated after SOR placement or were inadvertently placed into an intraperitoneal position.

DISCUSSION

The modern-day IPP is impressively durable, with a 10-year survival rate as high as 78%.[21,22] Reported all-cause reoperation rates range from 7 to 11%, most commonly due to mechanical failure and infection.[23,24] In cases of mechanical failure, use of the "drain and retain" method provides a safe option to obviate the need for reservoir removal.[25] To date, multiple large studies have demonstrated the risks of reservoir retention to be quite low, regardless of reservoir location.[20,25–30] Implant infections, however, require complete removal of all device components.[20,25]

Numerous studies have been performed on the safety and efficacy of both HSM and SOR reservoir placement techniques for IPPs. What has not been performed, however, is an objective look at reservoir removal in these 2 groups. Given our high-volume, tertiary care practice, we herein present our experience with removal of HSM reservoirs and compare this with our experience with SOR reservoir removal.

The UT Southwestern Reservoir Removal Experience

This robust experience demonstrates that removal of HSM reservoirs offers comparable perioperative outcomes compared with SOR reservoir removal. Indications for removal were similar between the 2 groups, with infection being the most common cause for explantation regardless of reservoir location. Interestingly, we found that 3 quarters of patients with HSM reservoirs were explanted, vs only half of SOR cases, which were more likely to be managed with the "drain and retain" method. This is despite similar infection rates between the 2 groups. As explantation was initially attempted in all reservoirs, this likely reflects 2 things: first, the relative ease of HSM reservoir delivery compared with SOR and second, the additional confidence in removing the superficially located HSM reservoir, which is well away from the critical structures of the deep pelvis (SOR).

No significant difference was observed in average operative time between the 2 groups. While other studies have described shorter operative times with ectopic reservoir removal, our data found the time required for HSM and SOR reservoir removal to be similar.[31] The complication rate was also similarly low between the 2 groups. Only a single patient experienced a significant (Clavien Grade III or higher) complication requiring reoperation, and we believe that this was a reflection of patient disease rather than a breakdown in surgical technique.

The use of a counter incision for reservoir removal was more common in the HSM cohort, though this did not reach significance. Notably, there was no difference in time from IPP placement to explant in patients who required a counterincision for reservoir removal, suggesting neither that fibrosis from long standing device placement nor increased distance from the scrotum affected surgical outcomes. As adoption of HSM reservoir placement continues to increase in prosthetic urology, our results suggest that when device explant is undertaken, HSM reservoir removal appears to be as safe and feasible as SOR.

Anatomic Considerations of Reservoir Removal

Proponents of the SOR reservoir note that reservoir removal is more likely to be achieved through a single incision, obviating the need for—and morbidity of—a second incision. But, while counter incisions in our study were less common in the SOR group, this did not reach significance. Moreover, SOR reservoir placement involves close proximity to multiple critical structures including the bowel, bladder, and iliac vessels.[32] Reflecting this proximity, rare but potentially disastrous complications during IPP revision have been reported in the literature, including bladder laceration and injury to the nearby vessels causing intraoperative hemorrhage.[11,13,14,26] In an effort to avoid such complications, it is our practice to leave reservoirs in situ via the drain and retain method (in the absence of infection) if they are not delivered easily with gentle traction on the tubing.

By contrast, reservoirs placed in the HSM space are well away from critical pelvic structures. Some have proposed that the longer distance between the penoscrotal incision and reservoir afforded by the high submuscular location may present a challenge in removing the reservoir via a single incision.[33] Our experience, however, suggests that most HSM reservoirs can be delivered into the penoscrotal incision simply by placing firm

traction on the tubing during dissection. Furthermore, the potential space between the transversalis fascia and rectus muscle provides a continuous plane through which the reservoir can be delivered. This plane is devoid of both visceral structures and major vessels which nearly eliminates the risk for major complications. Recently, there has been increasing concern that so-called "high submuscular" reservoirs may not in fact be implanted in the intended plane.[34] Some authors have recommended the use of postoperative ultrasound to verify location postoperatively.[33] In our own practice, we have found that the risk of "misplaced" reservoirs can largely be mitigated by the use of a "five-step technique" that is designed to maintain the integrity of the transversalis fascia and ensure appropriate anatomic placement of the reservoir.[4]

When the HSM reservoir cannot be readily mobilized through the penoscrotal incision, an alternative approach can be employed. Direct visualization may be achieved using a lighted retractor or laparoscopic instruments via the inguinal ring.[31,35] We prefer use of a well-placed counterincision that can be guided by palpation, intraoperative ultrasonography, or preoperative computed tomography when available.[33,36] In our experience, most counterincisions were guided by palpation alone; in the event that palpation alone could not identify the reservoir, instillation of saline into the reservoir via the existing cut tubing facilitated palpation. In 4 cases, the reservoir was not readily palpable even after filling; in these cases, intraoperative ultrasound readily identified the reservoir without issue.

Implications for the HSM Reservoir

While SOR reservoir placement remains a valid option in many patients, the risk of rare but potentially catastrophic complications is increased in patients with history of pelvic radiation or radical pelvic surgery.[37] The past decade has seen robust data from multiple centers validating HSM reservoir placement as a viable alternative for IPP implantation that obviates these risks by avoiding the deep pelvis entirely.[3,4,16–18,38,39] Some high-volume implanters have even suggested that HSM reservoir placement may represent a new standard of care.[2,4,18,19] While studies have thoroughly investigated a wide range of outcomes for both SOR and HSM reservoirs including implantation, perioperative outcomes, long-term complications, and even patient satisfaction, reservoir removal outcomes remain largely unexplored. And, although the modern-day IPP is impressively durable, the need for reservoir removal does arise, making such outcomes pertinent to the overall characterization of both HSM and SOR reservoirs.

To our knowledge, this series is the largest of its kind and helps fill the void in the current IPP literature. Our data support the safety and feasibility of HSM reservoir removal and shows similar outcomes to SOR reservoir removal. These findings augment the existing data supporting HSM placement as a safe alternative method of reservoir placement in IPP implantation.

Limitations

This study's design presents standard limitations associated with retrospective cohort studies. This includes selection bias for patients undergoing reservoir removal vs retention. In addition, reservoir location was not randomized but was instead determined by which patients presented with complications necessitating reservoir removal during the study period. The imbalance in the size of study groups, as well as the lack of matching between the groups, clearly limits the statistic strength of these data. As most SOR IPPs were placed early in the study period, we were not able to control for advancements in implant design between the 2 groups. As mentioned previously, reservoir location itself may have influenced the surgeon's decision on whether to "drain and retain" the reservoir or to remove it completely. If a SOR reservoir is not removed easily, we are much more likely to follow "drain and retain" to avoid the risk of pelvic complications; this clearly represents a confounding factor. Conversely, in cases of device infection, the reservoir must be removed and cannot be left in situ. Removal of these reservoirs can be complex and may contribute to longer operative times.

Finally, our experience represents the practice of a single, high-volume implanter at a single institution. As such, our data may not accurately reflect the practice of the average urologist. Although the absolute cohort size is relatively low, this study still reflects the largest single-institution study investigating IPP reservoir removal. Prospective multi-institutional studies will be helpful address these limitations and further validate these results.

CONCLUSION

HSM reservoir removal can be achieved with similar operative times and comparable complication rates with SOR reservoir removal. Our experience further validates the safety of the HSM approach in the modern era of prosthetic urology.

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STATEMENT OF AUTHORSHIP

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