High Submuscular Placement of Urologic Prosthetic Balloons and Reservoirs: 2-Year Experience and Patient-reported Outcomes

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OBJECTIVE To present our updated experience and patient-reported outcomes of high submuscular (HSM) placement of urologic prosthetic balloons and reservoirs (UPBRs).

METHODS A retrospective review was performed of patients who underwent inflatable penile prosthesis and/or artificial urinary sphincter placement between 2011 and 2013. UPBRs were placed in an HSM location between the transversalis fascia and the rectus abdominis muscle by blunt dissection through the external inguinal ring via a trans-scrotal approach. Patient demographics, perioperative outcomes, and patient-reported outcomes were reviewed.

RESULTS During the study period, 146 patients received 158 HSM implants: inflatable penile prosthesis reservoirs (n = 93) or artificial urinary sphincter balloons (n = 65). Patients completed a standardized survey at a mean of 3.2 months (range, 1.1-23.4 months) after surgery and were last followed up at a mean of 5.5 months (range, 1.1-28.7 months). Overall, 94% (n = 149) of UPBRs caused no bother, and patients were satisfied with 96% (n = 151) of implants. Patients were unable to palpate 80% (n = 126) of UPBRs and minimally palpate 16% (n = 26). The primary surgeon was unable to palpate 72% (n = 115) of UPBRs and minimally palpate 20% (n = 31). Type of UPBR, body mass index, reservoir volume, and reservoir manufacturer were not associated with patient or surgeon palpability. Of the 158 UPBRs placed, only 2 (1.3%) were revised due to bothersome patient palpability. No bowel, bladder, ureteral, or vascular injuries occurred.

CONCLUSION HSM placement of UPBR is safe and feasible, well tolerated, and avoids deep retropubic dissection. Patient-reported outcomes support low palpability, low bother, and high patient satisfaction. UROLOGY 84: 1540–1545, 2014. © 2014 Elsevier Inc.

Inflatable penile prosthesis (IPP) reservoirs and artificial urinary sphincter (AUS) balloons are traditionally placed in a retropubic location in the space of Retzius. Reported complications of retropubic placement include erosion and/or obstruction of urologic prosthetic balloons and reservoir (UPBR) into the bladder, neobladder, bowel, ureters, and vasculature.[1-16] Patients with prior pelvic surgery, especially radical prostatectomy and cystectomy, often have obliterated tissue planes and distorted anatomy within the pelvis, raising the risk for UPBR complications.

An early alternative approach to UPBR placement included the use a second upper abdominal counter-incision to expose and incise the abdominal wall fascia for submuscular UPBR placement under direct vision.[17] In an effort to avoid the time and morbidity of a second incision, Wilson et al[18,19] described an ectopic placement of IPP reservoirs in 2002 and AUS balloons in 2005. Blunt manual dissection into the external inguinal ring, superficial to the transversalis fascia, allowed for UPBR placement safely through a scrotal approach. Perito and Wilson[20] modified this technique for the infrapubic approach in 2011, incorporating a nasal speculum within the external ring to ease placement of IPP reservoirs.

We have experienced that the low ectopic placement technique by Wilson et al has been helpful for reoperative patients with challenging pelvic tissue planes; however, these patients are at times susceptible to visible and/or palpable herniation of the UPBR.[18-22] Furthermore, Perito's nasal speculum is not long enough to enable creation of an adequate submuscular pocket through a scrotal incision. We reported our initial experience with trans-scrotal high submuscular (HSM) placement of UPBR in 2013 and have since used this technique preferentially in the majority of prosthetic surgical cases.[23]

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We present our updated experience with a focus on palpability and bother after HSM placement of UPBR.

METHODS

With institutional review board approval, a retrospective study was conducted of all patients who underwent IPP reservoir and/or AUS balloon placement in an HSM position between March 2011 and August 2013. Since 2011, HSM placement has become our standard technique for UPBR placement, regardless of the patient's prior surgical history. All patients were counseled preoperatively regarding the risks and benefits of submuscular placement. All AUS balloons (AMS 800; American Medical Systems, Minneapolis, MN) were filled to 24 cc. Either the AMS 700 CX/LGX IPP with the Conceal reservoir (American Medical Systems, Minneapolis, MN) or the Coloplast Titan IPP with the 125 cc Titan Cloverleaf reservoir (Coloplast, Minneapolis, MN) were used at the discretion of the patient and surgeon. In general, smaller implants require less fluid, and we deliberately avoid overfilling submuscular reservoirs. After a test fill of the cylinders using a syringe to assess position, rigidity, and volume required, IPP reservoirs were initially overfilled to capacity to create a large flat reservoir and then deflated appropriately to a smaller adequate volume, depending on the cylinder length and volume (mean, 58 cc; range, 25-100 cc).

A total of 146 consecutive patients underwent 158 submuscular UPBR placements by a single surgeon: IPP reservoirs (n = 93) or AUS balloons (n = 65). Twelve of these patients underwent simultaneous IPP and AUS placement. Mean patient age at the time of surgery was 67 years (range, 41-90 years) with a mean body mass index (BMI) of 29.7 kg/m^2 (range, 18.2-50.7 kg/m^2). Erectile dysfunction was a complication of prostate or bladder cancer treatment in 46 patients (49%), prostatectomy or cystoprostatectomy in 41 patients (44%), radiation in 3 (3%) and both radiation and prostatectomy in 2 patients (2%). Forty-seven patients (51%) underwent IPP placement secondary to organic causes or pelvic trauma. Stress urinary incontinence was a complication of prostate cancer treatment for 63 patients (97%): prostatectomy in 43 patients (66%), radiation in 5 patients (8%), and both radiation and prostatectomy in 15 patients (23%). Two patients (3%) underwent AUS placement secondary to pelvic trauma. Thirteen (14%) IPP and 9 (14%) AUS cases were revision or replacement procedures and underwent placement of a new UPBR with the HSM technique.

Our HSM surgical technique has been previously described.[23] All UPBRs were placed through an upper scrotal incision. After initial blunt manual dissection into the external inguinal ring, a pediatric Deaver retractor was placed into the external inguinal ring to facilitate dissection along the transversalis fascia. A potential space between the rectus abdominis muscle and the transversalis fascia was initiated using the paddles of a Foerster lung-grasping clamp (Scanlan International, St. Paul, MN) to deliver the UPBR 6-8 inches into the HSM tunnel. Alternatively, a sponge stick can be used if a Foerster lung-grasping clamp is not available. UPBR were inflated and tested to assess for palpability and visibility before completion of the operation.

All patients underwent device teaching approximately 6 weeks after surgery and completed a standardized questionnaire at a mean of 3.2 months (range, 1.1-23.4 months). Mean total follow-up was 5.5 months (range, 1.1-28.7 months). The questionnaire assessed patient palpability, bother, and satisfaction of HSM placement. The survey also concomitantly assessed whether the primary surgeon could palpate the UPBR.

Patient demographics, perioperative data, and postoperative questionnaire responses were tabulated and analyzed in SPSS (IBM, Armonk, NY). Analyses of categorical and continuous variables were performed using the Pearson chi-square test and the independent sample t test, respectively. Univariate binary logistic regression was used to identify risk factors for UPBR palpability. Statistical significance was set at $P < .05$, and reported P values were 2 sided.

RESULTS

Mean duration of surgery was 95 minutes (range, 46-163 minutes) for surgeries involving AUS placement and 84 minutes (range, 37-170 minutes) for surgeries involving IPP placement. AUS balloons were filled to 24 cc in all cases. IPP reservoirs were filled to a mean of 58 cc (range, 25-100 cc). No patient required perforation into the space of Retzius; however, 1 patient required an abdominal counter incision due to significant postoperative scarring from a previous inguinal herniorrhaphy with mesh.

Questionnaires were completed by all patients at a mean of 3.2 months (range, 1.1-23.4 months) after surgery. The overwhelming majority of UPBR (n = 126, 80%) were not palpable (Fig. 1). AUS patients (n = 16, 25%) numerically reported higher rates of palpability of their UPBR than IPP patients (n = 16, 17%); however, the reported difference was not statistically significant ($P = .34$). The primary surgeon could not palpate 73% (n = 68) of IPP reservoirs and 72% (n = 47) of AUS balloons ($P = .79$). Type of UPBR, BMI, reservoir volume, and reservoir manufacturer were not risk factors for patient or surgeon palpability (Table 1). Only 5 AUS and 4 IPP patients were mildly or significantly bothered by UPBR placement ($P = .23$). The 2 AUS patients who reported significant bother did not require additional intervention after repositioning the reservoirs. One patient experienced herniation of an AUS regulating balloon into the right groin. The patient declined revision since he was asymptomatic and device function was not compromised. Overall, self-reported patient satisfaction was high: 97% (n = 52) of AUS and 96% (n = 89) of IPP patients were satisfied (delighted, pleased, or mostly satisfied; $P = .12$).

Mean total follow-up was 5.5 months (range, 1.1-28.7 months). Two (1.3%) UPBRs (1 reservoir and 1 balloon) required revision because of bothersome palpability and were successfully revised. Three (4.6%) AUS patients experienced cuff erosion and required removal. One patient who was diagnosed postoperatively with leukemia, developed infection of both the IPP and AUS and required removal. No bowel, bladder, ureteral, or vascular complications were noted among patients in this series.

COMMENTS

Traditional placement of UPBRs in the space of Retzius can result in complications, which include bladder

A

For Patient (Please circle the answer that best describes your feeling about each question):

1. Can you feel the balloon that was placed under your abdominal muscles?

1	2	3
Not at all	Slightly	Markedly

2. How much does feeling the balloon bother you?

1	2	3
None	Mildly	Significantly

3. If you were to spend the rest of your life with your implant just the way it is now, how would you feel about that?

1	2	3	4	5	6	7
Delighted	Pleased	Mostly satisfied	Mixed	Mostly dissatisfied	Unhappy	Terrible

For Surgeon:

Can you palpate the reservoir balloon?

1	2	3
Not at all	Minimally	Obviously/Visible

B

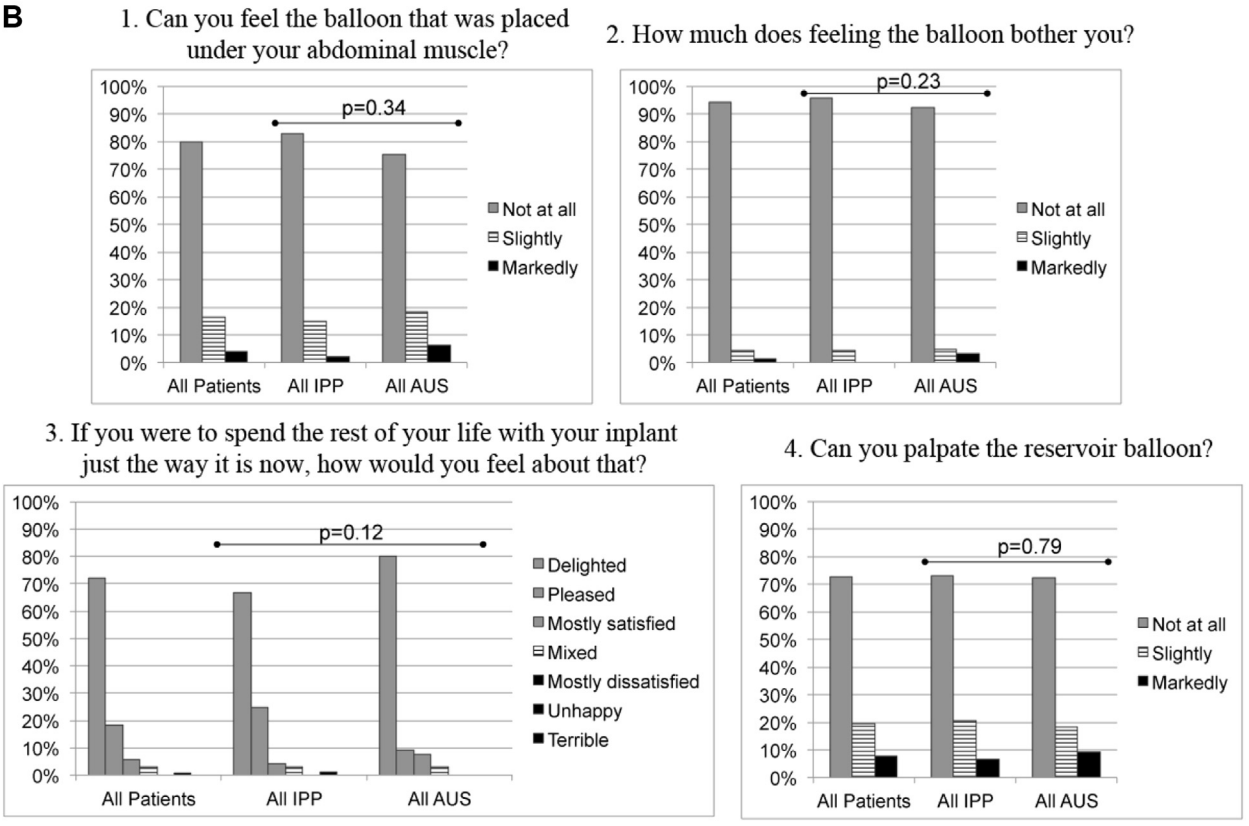

Figure 1. Patients completed postoperative questionnaires to determine if they could palpate the urologic prosthetic balloons and reservoir, how much being able to palpate it bothered them and how satisfied overall they are with their implant. The primary surgeon was also asked to assess urologic prosthetic balloons and reservoir palpability. Reponses between inflatable penile prosthesis and artificial urinary sphincter were compared using the Pearson chi-square test. AUS, artificial urinary sphincter; IPP, inflatable penile prosthesis.

perforation or erosion,[2,4-6,10] ureteral obstruction,[8,9] bowel erosion or obstruction,[11,13,15,16] vascular obstruction or injury,[1,3,7] and hernia.[12] Approximately 27% of implants are placed in men after radical prostatectomy, and approximately 70% of all radical prostatectomy surgeries are performed robotically.[24,25] Robotic-assisted

Table 1. Palpability of urologic prosthetic balloons and reservoirs in a high submuscular space

	Patient		Primary Surgeon	
Clinical Variables	OR (95% CI)	*P* Value	OR (95% CI)	*P* Value
AUS balloon vs IPP reservoir	1.03 (0.47-2.26)	.95	0.96 (0.47-1.95)	.91
AUS balloon				
BMI	1.01 (0.90-1.13)	.89	0.91 (0.81-1.03)	.12
IPP reservoir				
BMI	0.99 (0.88-1.11)	.80	1.02 (0.92-1.12)	.73
Reservoir volume	1.01 (0.98-1.05)	.39	1.00 (0.97-1.03)	1.00
AMS Conceal vs Coloplast Cloverleaf	0.88 (0.31-2.50)	.80	0.72 (0.28-1.85)	.49

AMS, American Medical Systems; AUS, artificial urinary sphincter; BMI, body mass index; CI, confidence interval; IPP, inflatable penile prosthesis; OR, odds ratio.

laparoscopic prostatectomy is predominantly conducted through a transpertioneal approach that obliterates the space of Retzius. In consequence, the abdominal organs become dependent in the pelvis and are at increased risk of injury during retropubic UPBR placement. Due to this scenario and the aforementioned complications, urologists are seeking alternative placements for UPBR.

Previous ectopic techniques introduced by Perito and Wilson[20] did not place the UPBR high enough to decrease palpability and hernia formation.[18,19] Our novel technique uses a Foerster lung-grasping clamp to create a submuscular tunnel cephalad to the external inguinal ring through a scrotal incision. The HSM position decreases the risk of UPBR herniation and palpability because the balloon can be placed almost to the level of the umbilicus.[26] Our submuscular tunnel technique also enables consistent access to a virgin plane. This allows for reliable UPBR placement, regardless of the complexity of their anatomy or surgical history. Furthermore, for combined IPP-AUS cases, the long length of the clamp allows for staggered ipsilateral placement of both UPBR on the same side, essentially simplifying the dissection to a single unilateral submuscular tunnel. The development of lockout valves and flat reservoirs has contributed to the early success and feasibility of submuscular techniques.

The importance of alternative placements was highlighted during the Sexual Medicine Society of North America annual meeting in 2011. More than 100 registered attendees participated in a poll querying opinions on alternative IPP reservoir placement.[27] Attendees reported that IPP reservoirs are either sometimes (46%) or frequently (36%) harder to place in the space of Retzius among robotic-assisted laparoscopic prostatectomy patients and that reservoir placement outside of the space of Retzius is sometimes (54%) or frequently (35%) advantageous for patients' safety. Respondents agreed (97%) that physician-training courses should specifically include content relating to alternative reservoir placement techniques. A nationwide survey of 25 surgeons who received training in HSM placement indicated that HSM placement is safe, easier to learn, and teach and additionally conveys lower risk to visceral and vascular structures compared with traditional space of Retzius placement.[28] A subset analysis of 9 high-volume implanters (>20 implants per year) identified the same sentiment as the entire group.

Physicians agree that more clinical and patient-reported outcomes of alternative reservoir placement techniques are needed. We previously described our initial patient-reported outcomes of 48 patients.[23] Patients and the primary surgeon could not palpate 85% (n = 41) and 79% (n = 38) of UPBRs, respectively. We continued our longitudinal study and report in this article the results from a much larger cohort (146 patients) who underwent 158 HSM implants. Similar palpability rates were observed in the larger cohort. Patients and the primary surgeon were unable to palpate 80% (n = 126) and 72% (n = 115) of UPBRs, respectively. Only 2 (1.3%) UPBRs required revision due to bothersome palpability.

The primary surgeon may have experienced observer bias due to knowledge of the location and shape of the balloons and/or reservoirs. Although it contains lower volume than the IPP reservoir, the AUS regulating balloon is pressurized and spherical, which may contribute to its palpability. Although the IPP reservoir is flat and not pressurized, its larger volume may contribute to its palpability. Surprisingly, BMI was not a risk factor for patient or physician palpability. The rectus abdominis and overlying abdominal tissue, although variable, seem to be sufficient to mask balloon and reservoir palpability in almost all ranges of BMI. UPBR manufacturer was not a risk factor for patient or physician palpability, likely because both AMS and Coloplast have developed flat reservoirs, which contribute to their low rate of palpability.

Stember et al[22] reported their outcomes of ectopic reservoir placement through an infrapubic approach for 2239 and 447 patients who underwent posterior (PTF) and anterior (ATF) to the transversalis fascia reservoir placement, respectively. Two patients who underwent PTF placement experienced reservoir herniation and required revision surgery. Two patients who underwent ATF placement reported palpable reservoirs and underwent surgical revision. Fifteen ATF placement patients felt the reservoir early in the postoperative period but became satisfied and did not seek correction. Six ATF patients developed postoperative reservoir herniation into the inguinal canal and underwent placement high in the abdominal wall. There were no injuries to the bowel

or major blood vessels in this series. Comparing rates of complication, only reservoir herniation reached statistical significance (1.34% for ATF vs 0.09% for PTF; $P < .001$). This is the second contemporary series to describe outcomes and complications rates of ectopic reservoir placements.

A potential concern of HSM UPBR placement is the management of UPBR in the event of reoperation should surgical revision be necessary. For noninfected revisions, we would empty the UPBR and cut the tubing proximally allowing it to retract out of the surgical field in anticipation of contralateral UPBR replacement.[29] If an implant infection were to occur, we would extract the pump, cuff, and/or cylinders via a penoscrotal incision, then make a counterincision over the affected UPBR guided by intraoperative ultrasound if the device cannot be removed from below. We have not encountered any issues or injuries of the inferior epigastric artery with HSM placement. This scenario appears unlikely because the course of the inferior epigastric artery is shielded beneath the transversalis fascia.[30]

HSM and other ectopic placement techniques have been suggested to expose balloons to sustained abdominal forces and therefore higher risk of failure. In actuality, the balloons develop a capsule, which protects the components from abdominal pressures. Similar to Wilson and Delk,[19] we have not noted adverse device functionality with ectopic AUS balloon placement.

Limitations of our study include the use of a nonvalidated questionnaire and an overall follow-up, which does not address long-term outcomes. This report represents a noteworthy experience consisting of a large cohort of 146 patients who underwent 158 UPBRs placements at a high-volume prosthetic center. This updated experience strongly supports the safety and continued expansion of the HSM alternative placement strategy, especially in high-risk patients.

CONCLUSION

HSM placement of UPBR is safe and feasible, well tolerated, and avoids deep retropubic dissection. Patient-reported outcomes demonstrate low palpability, low bother, and high patient satisfaction.

References

1. Brison D, Ilbeigi P, Sadeghi-Nejad H. Reservoir repositioning and successful thrombectomy for deep venous thrombosis secondary to compression of pelvic veins by an inflatable penile prosthesis reservoir. *J Sex Med.* 2007;4:1185-1187.
2. Brusky J, Dikranin A, Aboseif S. Retrieval of inflatable penile prosthesis reservoir from the bladder. *Int J Impot Res.* 2005;17:302-303.
3. Deho F, Henry GD, Marone EM, et al. Severe vascular complication after implantation of a three-piece inflatable penile prosthesis. *J Sex Med.* 2008;5:2956-2959.
4. Dupont MC, Hochman HI. Erosion of an inflatable penile prosthesis reservoir into the bladder, presenting as bladder calculi. *J Urol.* 1988;139:367-368.
5. Eldefrawy A, Kava BR. An unusual complication during inflatable penile prosthesis implantation. *Urology.* 2010;76:847.
6. Fitch WP 3rd, Roddy T. Erosion of inflatable penile prosthesis reservoir into bladder. *J Urol.* 1986;136:1080.
7. Flanagan MJ, Krisch EB, Gerber WL. Complication of a penile prosthesis reservoir: venous compression masquerading as a deep venous thrombosis. *J Urol.* 1991;146:847-848.
8. Hudak SJ, Mora RV. Unilateral ureteral obstruction due to a migrated inflatable penile prosthesis reservoir. *J Urol.* 2008;180:336.
9. Jiann BP, Ou CW, Lin JT, Huang JK. Compression of ureter caused by a retained reservoir of penile prosthesis. *Int J Impot Res.* 2006;18:316-317.
10. Kramer AC, Chason J, Kusakabe A. Report of two cases of bladder perforation caused by reservoir of inflatable penile prosthesis. *J Sex Med.* 2009;6:2064-2067.
11. Nelson RP Jr. Small bowel obstruction secondary to migration of an inflatable penile prosthesis reservoir: recognition and prevention. *J Urol.* 1988;139:1053-1054.
12. Sadeghi-Nejad H, Sharma A, Irwin RJ, et al. Reservoir herniation as a complication of three-piece penile prosthesis insertion. *Urology.* 2001;57:142-145.
13. Singh I, Godec CJ. Asynchronous erosion of inflatable penile prosthesis into small and large bowel. *J Urol.* 1992;147:709-710.
14. Tran CN, Boncher N, Montague DK, Angermeier KW. Erosion of inflatable penile prosthesis reservoir into neobladder. *J Sex Med.* 2013;10:2343-2346.
15. Leach GE, Shapiro CE, Hadley R, Raz S. Erosion of inflatable penile prosthesis reservoir into bladder and bowel. *J Urol.* 1984;131:1177-1178.
16. Luks FI, Huntley HN, Tula JC, Pizzi WF. Small-bowel obstruction by an inflatable penile prosthesis reservoir. *Surgery.* 1989;106:101-104.
17. Riemenschneider HW. Epigastric placement of reservior for inflatable penile prosthesis. *Urology.* 1981;17:79-81.
18. Wilson SK, Henry GD, Delk JR Jr, Cleves MA. The mentor Alpha 1 penile prosthesis with reservoir lock-out valve: effective prevention of auto-inflation with improved capability for ectopic reservoir placement. *J Urol.* 2002;168:1475-1478.
19. Wilson SK, Delk JR 2nd. Ectopic placement of AMS 800 urinary control system pressure-regulating balloon. *Urology.* 2005;65:167-170.
20. Perito PE, Wilson SK. Traditional (retroperitoneal) and abdominal wall (ectopic) reservoir placement. *J Sex Med.* 2011;8:656-659.
21. Perito PE. Ectopic reservoir placement—no longer in the space of Retzius. *J Sex Med.* 2011;8:2395-2398.
22. Stember DS, Garber BB, Perito PE. Outcomes of abdominal wall reservoir placement in inflatable penile prosthesis implantation: a safe and efficacious alternative to the space of Retzius. *J Sex Med.* 2014;11:605-612.
23. Morey AF, Cefalu CA, Hudak SJ. High submuscular placement of urologic prosthetic balloons and reservoirs via transscrotal approach. *J Sex Med.* 2013;10:603-610.
24. Carson CC 3rd, Mulcahy JJ, Harsch MR. Long-term infection outcomes after original antibiotic impregnated inflatable penile prosthesis implants: up to 7.7 years of followup. *J Urol.* 2011;185:614-618.
25. Lowrance WT, Eastham JA, Savage C, et al. Contemporary open and robotic radical prostatectomy practice patterns among urologists in the United States. *J Urol.* 2012;187:2087-2092.
26. Osmonov D, Kohler T, Wilson SK. Body donor study of ectopic and traditional reservoir placement. *Video J Prosthet Urol.* 2013;1:012.
27. Karpman E, Sadeghi-Nejad H, Henry G, et al. Current opinions on alternative reservoir placement for inflatable penile prosthesis among members of the Sexual Medicine Society of North America. *J Sex Med.* 2013;10:2115-2120.
28. Tausch TJ, Morey AF, Zhao L, et al. High submuscular versus space of Retzius placement of inflatable penile prosthesis reservoirs: results of a surgeon survey. *Can J Urol.* 2014;21:7465-7469.

29. Cefalu CA, Deng X, Zhao LC, et al. Safety of the "drain and retain" option for defunctionalized urologic prosthetic balloons and reservoirs during artificial urinary sphincter and inflatable penile prosthesis revision surgery: 5-year experience. *Urology*. 2013;82:1436-1439.
30. Chung BI, Sommer G, Brooks JD. Chapter 2 — Anatomy of the lower urinary tract and male genitalia. In: Wein AJ, ed. *Campbell-Walsh Urology*, Vol. 1. Elsevier; 2011:33-70.

EDITORIAL COMMENT

In my opinion, the authors present us with a paradigm-changing enhancement to 2 surgical techniques that have been around >40 years. The retroperitoneal space where artificial urinary sphincter (AUS) balloons and inflatable penile prosthesis (IPP) reservoirs have traditionally been placed can develop vessel or viscus injury during or after component placement. Placement of these components in the abdominal wall also known as "ectopic" or "high submuscular" eliminates the occasional life threatening injuries that can occur after traditional reservoir placement.

Widespread acceptance of the new location of these balloons could make these quality of life enhancing implants available to more patients. Despite 4 decades of availability, only a handful of urologists are truly comfortable with the surgical placement of these devices. The remainder of physicians do not mention to their afflicted patients the possibility of IPP or AUS or offers the surgery only to patients with no surgical barriers, that is, absence of obesity, hernia surgery, prostate cancer surgery, cystectomy, and so forth. Most of this physician reluctance and discomfort is spawned from the fear of reservoir complications—the dreaded blind component placement. As seen from this article, the only 2 complications that can occur are device palpability or herniation. Contrast this to bowel fistula, bladder laceration or erosion, and iliac vessel compression or hemorrhage, and we realize why occasional implanters might offer device implantation to more than the surgical "low lying fruit"—those patients without anatomic compromise.

Both American Medical Systems and Coloplast manufacture IPP reservoirs designed to be pancake shaped to facilitate less palpability in an ectopic location. These specially configured reservoirs can, at the present time, be considered "the elephant in the room." The manufacturers are not allowed to educate nontraditional device location because placement of the devices outside the space of Retzius represents an "off label" application of AUS and IPP. The last step in achieving widespread acceptance among the implanting community is to present investigations such as this fine study to the Food and Drug Administration for the purpose of achieving approval of this regulatory body.

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REPLY

We continue to observe that the high submuscular reservoir placement method is safe and well tolerated in the vast majority of patients. It allows safe implantation of the 3-piece device without (1) blind entrance into the retroperitoneum, and (2) the need for an abdominal incision. We have found that this technique works very well not only in men with a hostile abdomen but also in routine patients. Because it is a new technique, the submuscular dissection is virtually always performed in a virgin tissue plane, no matter how complex their surgical history, and we have easily used this technique in neobladder and transplant patients, among others. Hernia repairs with mesh are the most common obstacle we have faced.

As urologists continue to adopt this technique into their practice, a couple of tips should be mentioned. First, the passage of the clamp should be conducted parallel to the axis of the transversalis fascia, not perpendicular to it. Accordingly, we position the patient in the Trendelenberg position—this is especially helpful in patients with prominent intra-abdominal fat encroaching into the inguinal area. Once the dissection plane has been initiated above the inguinal canal, we flatten out the clamp so that its jaws are spread transversely, no longer in the A-P plane. Respect for tissue is warranted so that the clamp is spread in a controlled manner before advancing along the surface of the transversalis fascia. The dissection should be taken high enough for the reservoir to reside well above the inguinal ring, and reservoir position and palpability are always double-checked manually after filling with saline.

The submuscular reservoir placement technique has made the inflatable penile implant a safe and reasonable option for even the most challenging erectile dysfunction patients.

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