High Submuscular Placement of Urologic Prosthetic Balloons and Reservoirs via Transscrotal Approach

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ABSTRACT

Introduction. Traditional placement of inflatable penile prosthesis (IPP) reservoirs and/or artificial urinary sphincter (AUS) balloons into the space of Retzius may be challenging following major pelvic surgery.

Aim. The aim of this study is to report our 1-year experience using a novel technique for high balloon/reservoir placement beneath the rectus abdominus muscle, thus completely obviating deep pelvic dissection during prosthetic urologic surgery.

Methods. A retrospective review of all patients who underwent IPP and/or AUS placement between June 2011 and June 2012 was performed. All had AUS balloons and/or IPP reservoirs placed in a submuscular location by bluntly tunneling through the external inguinal ring into a potential space between the transversalis fascia and the rectus abdominus muscle using a long, angled, lung grasping clamp.

Main Outcome Measures. Patient demographics, perioperative outcomes, and initial follow-up patient-reported outcomes were reviewed.

Results. During the study period, 120 submuscular balloons/reservoirs were inserted in 107 consecutive patients who underwent placement of an IPP (61 patients), AUS (33 patients), or both (13 patients). Among our 48 most recent patients, 41 (85%) reported they were totally unable to feel their balloon/reservoir, and all but two patients reported no bother from the submuscular balloon/reservoir placement. Of the 120 total submuscular balloons and reservoirs, surgical time and outcomes of the prosthetic procedures appeared similar to those placed using traditional methods; two reservoirs required revision surgery for repositioning.

Conclusions. High submuscular placement of genitourinary prosthetic balloons and reservoirs via a transscrotal approach is both safely and effective, while avoiding deep retropubic dissection. **Morey AF, Cefalu CA, and Hudak SJ. High submuscular placement of urologic prosthetic balloons and reservoirs via transscrotal approach. J Sex Med 2013;10:603–610.**

Key Words. Urinary Incontinence; Artificial Urinary Sphincter; Erectile Dysfunction; Penile Prosthesis

Introduction

Traditional insertion of the artificial urinary sphincter (AUS) and multicomponent inflatable penile prosthesis (IPP) involves placement of a saline filled balloon or reservoir into a deep retropubic location. Many surgeons place urologic prosthetic balloons and reservoirs (UPBR) into the space of Retzius by blind puncture through the transversalis fascia, a technique that has been widely employed for decades but has a recognized risk of troublesome complications [1–15]. To avoid the retropubic space in high-risk patients with prior extensive pelvic surgery, various maneuvers have been described for placing UPBR in an "ectopic" location superficial to the transversalis fascia, including the infrapubic approach [16–19].

We developed a novel technique for reliable transscrotal placement of UPBR high beneath the rectus abdominus muscle, and we present our initial 1-year experience using patient-reported outcomes.

Methods

A consecutive series of patients were evaluated who underwent IPP and/or AUS placement from

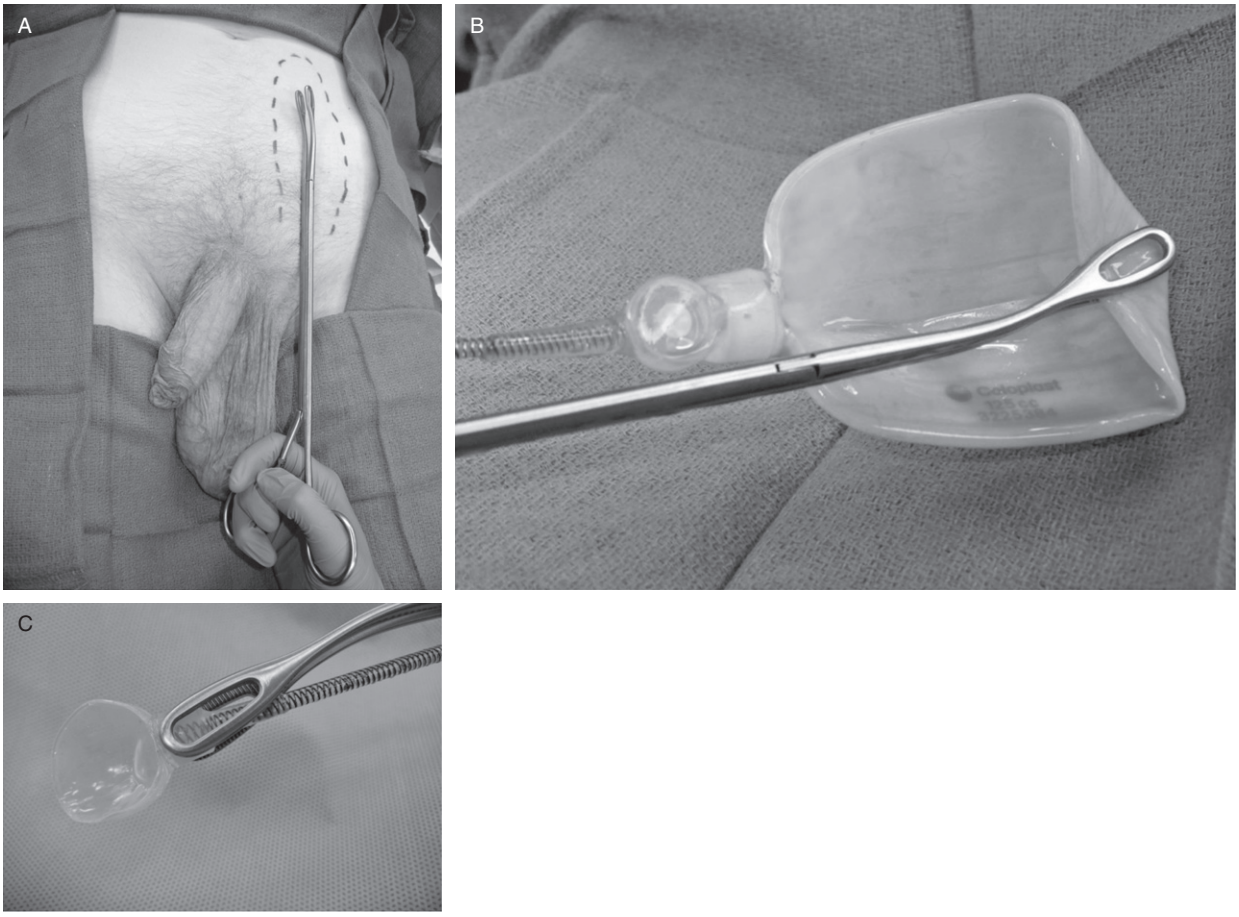

Figure 1 (A) The Foerster lung grasping clamp is passed via the scrotal incision into the external inguinal ring; there the paddles are spread to elevate the rectus abdominus muscle. For combined AUS/IPP implants, the AUS balloon may be placed superior to the IPP reservoir within the same submuscular tunnel. (B) The blunt paddles of the Foerster clamp atraumatically grasp the IPP reservoir opposite the tubing exit site to deliver it high in the submuscular tunnel. (C) The more delicate AUS balloon is delivered by grasping the thick silicone hub. AUS = artificial urinary sphincter; IPP = inflatable penile prosthesis

June 2011 and June 2012, the time frame coinciding with our decision to perform standardized UPBR placement in a submuscular location for all urologic prosthesis patients, regardless of prior surgical history. Patients were counseled about the submuscular reservoir/balloon location and that the device may be palpable depending on the patient's body habitus. For all AUS cases, 61–70 cm H2O balloons were routinely filled with 24-cc injectable saline. Among penile implants, either the AMS 700 CX/LGX device with the Conceal (American Medical Systems, Minneapolis, MN, USA) reservoir or the Coloplast Titan implant with the 125 cc Titan CL (Coloplast, Minneapolis, MN, USA) reservoir were used at the discretion of the patient and surgeon. Reservoirs were filled with injectable saline solution to a volume appropriate for the maximal ex vivo capacity of the cylinder length used for each respective patient.

Surgical Technique—Creation of Submuscular Tunnel

All IPP components were placed via a transverse upper scrotal incision. For AUS cases, the pressure-regulating balloon (PRB) was placed via a 2-cm upper scrotal counterincision after cuff placement through a perineal incision. To facilitate submuscular dissection, a pediatric Deaver retractor was placed into the external inguinal ring. A potential space between the rectus abdominus muscle and the transversalis fascia was initiated bluntly with the surgeon's finger. A Foerster lung grasping clamp (Scanlan International, St. Paul, MN, USA; Figure 1A) was then introduced into the upper portion of the external inguinal ring to elevate the rectus abdominus muscle away from

the transversalis fascia by spreading the paddles firmly in an anterior–posterior plane. The Foerster clamp was then advanced to further develop the submuscular space cephalad toward the ipsilateral nipple by using a "four spread technique" in alternating anterior–posterior and horizontal planes. The Foerster clamp was then used to grasp (Figure 1B, C) and deliver the UPBR high into the submuscular tunnel. For combined AUS/IPP double implant cases, a "staggered ipsilateral" placement technique was employed in which the PRB was first placed as cephalad as possible, with the IPP reservoir then deployed just caudally within the same submuscular tunnel. The UPBRs were filled, tubing connections were made, and pump(s) were then each placed into separate subdartos pouches via the scrotal incision.

Patient-Reported Outcomes

Beginning in February 2012, all patients who underwent AUS and/or IPP placement were given a standardized questionnaire (Figure 2A) at their 6-week postoperative visit and then at the 3-month subsequent visit. Reponses were scaled to allow easy interpretation and comparison. The surgeon also indicated on the postoperative questionnaire if he could palpate the balloon/reservoir.

Data Analysis

Patient demographics, perioperative data, and postoperative questionnaire responses were tabulated and analyzed in Excel (Microsoft, Redmond, WA, USA). Patients were grouped by implant type, body mass index (BMI), and reservoir volume to identify potential risk factors for device palpability and decreased overall satisfaction. Univariate analysis of categorical and continuous variables was performed using Fisher's exact test and independent sample *t*-test, respectively. Statistical significance was set at $P < 0.05$, and reported P values were two sided.

Results

A total of 120 submuscular balloons/reservoirs were inserted in 107 consecutive patients during the 12-month study period. Average patient age was 67 years (range 42–83) with an average BMI of 29.7 (19.4–50.7). Sixty-one patients received an IPP, 33 patients received an AUS, and 13 patients received dual AUS/IPP implantation. Stress urinary incontinence (SUI) was a complication of prostate cancer treatment for all AUS patients, including prostatectomy in 33 patients, radiation in six patients, and both radiation and prostatectomy in six patients. Erectile dysfunction was due to prostate cancer treatment in 37 patients and other organic causes in 34 patients. Thirteen IPP patients had coexistent Peyronie's disease. Seven IPP cases were revisions, and 10 AUS cases were replacement procedures, all of whom underwent placement of a new UPBR with our submuscular technique.

Submuscular UPBR placement was possible in all patients in this consecutive series—no prosthetic devices required an abdomimal counterincision or perforation into the space of Retzius in this consecutive series of cases. In 13 men, synchronous AUS/IPP was performed with both UPBRs placed on the same side in a staggered manner. AUS balloon volume was 24 mL in all cases and averaged 59 mL (30–100) for IPP reservoirs. Mean surgery duration was 80 minutes (range 58–122) for AUS placement, 61 minutes (37–85) for IPP placement, and 108 minutes (64–148) for IPP/AUS placement. Early postoperative complications included one scrotal hematoma managed expectantly and one case of urinary retention that resolved after 4 days of catheter decompression.

Two patients early in our series presented with palpable UPBR at 8 and 24 weeks following surgery: one had reservoir herniation due to inadequate cephalad location of his submuscular space and one had reservoir that was placed into a subcutaneous location. Both reservoirs have been successfully replaced into a high ipsilateral submuscular location at a subsequent operation using the same Foerster clamp dissection technique with no additional complications. Among the 46 AUS patients, one sustained an erosion of a 3.5-cm cuff; the rest have had good AUS functionality, and no other revisions or removals have been required.

Questionnaires were completed by 48 men at a mean 2.3 months (1.1–11.2) after initial surgery (Figure 2B). The overwhelming majority of patients (41 of 48, 85%) were unable to palpate their UPBR. AUS patients (24%) were more likely to report being able to palpate their UPRB than were IPP patients, but this difference was not statistically significant (AMS Conceal palpable in 9%, Coloplast Titan CL palpable in 17%, $P > 0.05$). IPP reservoir volume and BMI were not associated with UPBR palpability (mean volume 38 cc when palpable vs. 45 cc when not palpable, $P = 0.38$; BMI mean 28.7 kg/m^2 when palpable vs. 29.8 kg/m^2 when not palpable, $P = 0.62$). Only two patients were mildly bothered by feeling the balloon; none were significantly bothered. Overall

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

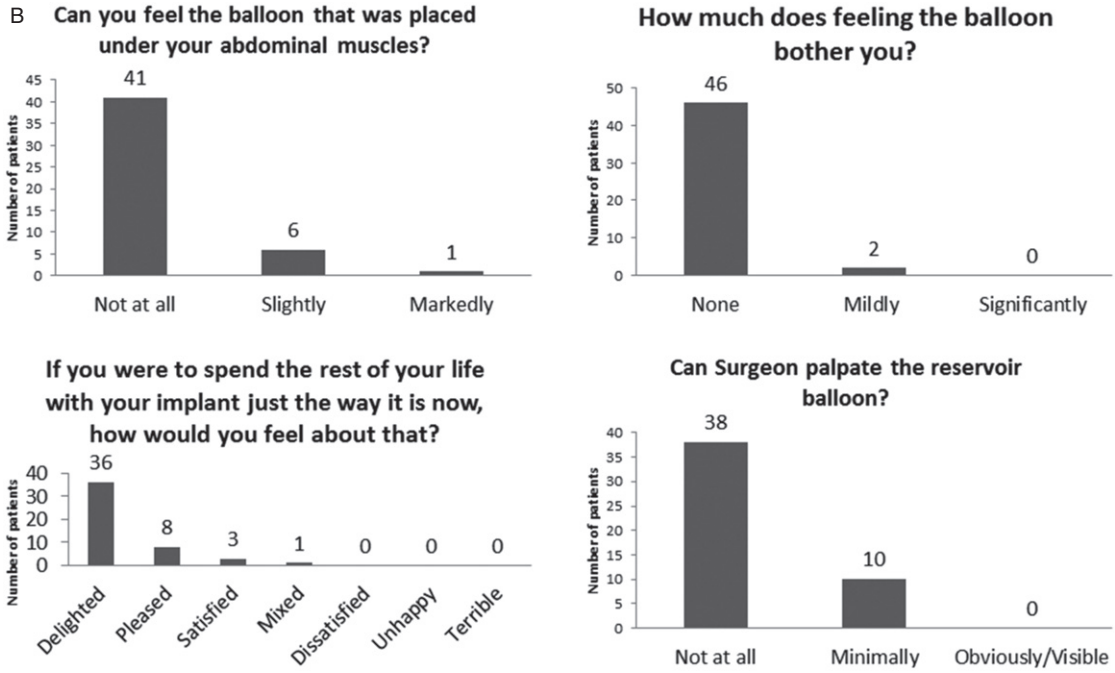

Figure 2 At their postoperative follow-up visit, patients were asked to fill out a questionnaire (A) to determine if they could palpate their UPBR, how much being able to palpate it bothers them, and how satisfied overall they are with their implant. The surgeon also made a note of how palpable the UPBR was on physical exam. (B) Responses from patients and surgeon on the follow-up questionaire: the majority of patients were unable to palpate their UPBR (41 of 48, 85%), were not bothered by their UPBR (46 of 48, 96%), and were overall delighted with their implant (36 of 48, 75%). The UPBR was not palpable by the surgeon in 38 of 48 cases (79%) and only minimally palpable in the rest.

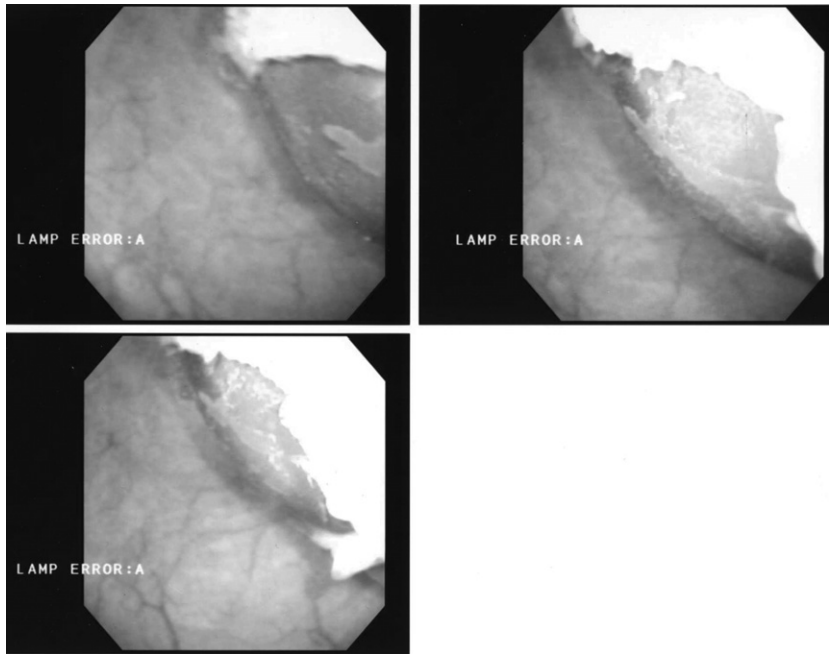

Figure 3 Cystoscopic examination 1 year after an uneventful IPP procedure (with traditional reservoir placement technique in space of Retzius) in this robotic prostatectomy patient reveals an IPP reservoir that eroded into the bladder dome.

self-reported patient satisfaction was high at initial follow-up. No vascular, bowel, bladder, or ureteral complications were noted among any patients in this series.

Discussion

Rationale for Alternative Balloon/Reservoir Placement

Although placement of UPBR into the space of Retzius via blind puncture of the inguinal floor has been routinely performed for tens of thousands of men over the past four decades, this traditional retropubic approach may be treacherous in select patients with previous pelvic surgery, such as those with a history of renal transplant, mesh hernia repair, colostomy, or neobladder. Additionally, we now increasingly encounter men who have had transperitoneal robotic-assisted laparoscopic prostatectomy (RALP) during which the lower peritoneum is incised and reflected away from the retropubic space thus "intraperitonealizing" the space of Retzius. In RALP patients, blind puncture through the inguinal floor during traditional UPBR placement may promote intraperitoneal placement with its attendant risks [20].

Even in low-risk patients, we have occasionally encountered reservoir placement complications using the traditional approach (Figure 3). The potential complications of retropubic UPBR placement have been well documented, including bladder perforation or erosion [2,4–6,10], ureteral obstruction [8,9], bowel erosion or obstruction [11–13,15], hernia [14], and vascular obstruction or injury [1,3,7]. Despite their rarity, such complications have serious clinical and medicolegal implications, requiring implant revision or removal at a minimum and additional surgical exploration when vascular or bowel injuries occur.

Alternative Balloon/Reservoir Placement Options

Historically, upper abdominal counterincisions were described to expose and incise the abdominal wall fascia for submuscular UPBR placement under direct vision in high-risk patients [21]. Although safe and effective, enthusiasm for this approach remains limited by the time and morbidity of a second incision. In 2002, Wilson et al. reported a novel method for transscrotal ectopic IPP reservoir placement using blunt manual submuscular dissection to avoid the retropubic space in high-risk patients without the need for a counterincision [19]. Wilson's technique popularized creation of an "ectopic" space cephalad to the external inguinal ring between the anterior abdominal musculature and the transversalis fascia. In 2005, Wilson's group reported a similar small series in which a similar approach was employed for transscrotal placement of AUS balloons—importantly, without demonstrable adverse device functionality [18]. For infrapubic IPP procedures, Perito popularized the use of a

nasal speculum for infrapubic submuscular reservoir placement [16,17].

We have found that the blunt manual dissection required for Wilson's low submuscular technique is often difficult and painful for the surgeon's finger when attempting to perforate into the potential space; moreover, the reservoir or balloon then rests just inside the inguinal ring where it is prone to herniation. Similarly, we have observed that the nasal speculum is not long enough to enable creation of an adequate submuscular pocket when used through the scrotal approach. The flat paddles of the hinged Foerster clamp used in this series impart a significant mechanical advantage for prying the muscular sheath away from the fascia. The submuscular tunnel created is ample and allows safe, reliable delivery of the UPBR approximately 6–8 inches cephalad to the external inguinal ring, a position that obviates the risk of herniation and the need to suture the external inguinal ring closed as required with other techniques [18].

A major advantage of our submuscular tunnel technique is that it consistently enables access from the scrotal incision to a "virgin" plane of dissection slightly higher on the abdominal wall, thus allowing reliable UPBR placement in virtually all patients regardless of the complexity of their anatomy or surgical history (including mesh hernia repairs, neobladders, or prior ipsilateral UPBR placement). Furthermore, for combined AUS/IPP cases, the length of the clamp allows staggered ipsilateral placement of both UPBRs on the same side, thus simplifying the procedure by limiting dissection within a single unilateral submuscular tunnel. Short-term outcomes have revealed similar short operative times, lack of perioperative complications, predictable device functionality, and a high level of patient satisfaction.

IPP Innovations That Facilitate Submuscular Placement

Prior to 2000, submuscular placement was avoided due to concerns about auto-inflation in approximately 10% of IPP patients due to direct pressure on the balloon from the abdominal wall musculature [19]. The advent of "lock-out valves" in 2002 by Mentor (now Coloplast) and in 2006 by American Medical Systems, virtually eliminated auto-inflation [19,22]. Another remaining problem was the potential for palpability of submuscular UPBR, especially in thin patients [19]. Our series is the first to assess the newly redesigned flat reservoirs (Conceal and Titan CL). Our initial experience with these flat reservoirs placed submuscularly is favorable, reflecting a negligible rate of palpability and high degree of patient satisfaction regardless of UPBR type, volume, or patient BMI. Current AMS pricing shows no difference between the Conceal and conventional reservoir. Coloplast no longer offers their conventional reservoir but have switched to the 75-mL cloverleaf and the 125-mL cloverleaf that are equal in price.

Although statistically similar, there was a trend toward increased palpability of AUS balloons (24%) compared with Conceal (9%) and Titan CL (17%) reservoirs. We feel that this trend may be due to either the pressurized state of the filled AUS balloon and/or its spherical shape compared with the nonpressurized, flat profile of the two IPP reservoirs. We have therefore attempted to place AUS balloons slightly more medially, where the device is shielded by the increased bulk of the rectus abdominus muscle, which seems to minimize AUS balloon palpability.

Strengths and Limitations

We believe our technique represents a distinct improvement over other submuscular placement techniques and a significant advance in prosthetic urology. This unique report constitutes a large, mixed, consecutive series of alternative UPBR prosthetic cases; it is the first to incorporate a uniform high submuscular UPBR placement technique using a single incision transscrotal approach, and it is also the first to describe synchronous ipsilateral placement of AUS balloons and IPP reservoirs.

We have found this technique of submuscular UPBR placement to be simple and easy to teach and learn, which is critical as our institution is a tertiary training center for residents and fellows. We feel it is important to teach our residents this technique so that they may safely perform alternative UPBR placement when faced with a hostile abdomen or challenging dissection. Other advantages include those associated with the traditional transscrotal prosthetic approach including avoidance of an abdominal incision, direct scrotal access for subdartos pump placement, and direct access to the corpora for additional corporal reconstruction as needed.

One potential concern of high submuscular UPBR placement is the issue of UPBR management in the event of reoperation should surgical revision be necessary during the life of the implant.

Due to the lack of mechanical failure and/or infection observed in this our first year of routine submuscular experience, we have yet to encounter this problem. If an implant infection were to occur after high submuscular UPBR placement, 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 is not palpable. For noninfected revisions, the UPBR is emptied and the tubing cut proximally allowing it to retract out of the surgical field in anticipation of contralateral replacement [23]. We have not found that the high submuscular placement technique places the inferior epigastric artery at risk of injury. We have not encountered this complication, and it appears improbable as the course of the inferior epigastric artery is shielded beneath the transversalis fascia [24].

Limitations of our study include short overall follow-up and use of a nonvalidated questionnaire. Although this study examines an expanded series of patients treated with a modification of a previously published technique, it does not address long-term outcomes. Although the possible delayed effects of sustained abdominal musculature forces on the PRB in a submuscular location are unknown, our initial experience (like Wilson's series) did not demonstrate adverse device functionality with ectopic PRB placement [18]. Long-term AUS outcomes after PRB placement are a study of larger scope that is currently underway. Nevertheless, this report represents a noteworthy initial experience consisting of one year of consecutive cases performed at a high-volume prosthetic center using new flat reservoirs for which published outcomes are otherwise lacking. Although traditional methods of UPBR placement are widely utilized and have been safely employed for tens of thousands of patients over the last four decades, this preliminary experience provides important clinical evidence that strongly supports the safety and continued expansion of the high submuscular alternative placement strategy, especially in high-risk patients.

Conclusions

High submuscular placement of genitourinary prosthetic balloons and reservoirs via a single incision, transscrotal approach is a safe and reliable technique that avoids deep retropubic dissection.

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Statement of Authorship

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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;4:1185–7.
2 Brusky J, Dikranin A, Aboseif S. Retrieval of inflatable penile prosthesis reservoir from the bladder. Int J Impot Res 2005; 17:302–3.
3 Deho' F, Henry GD, Marone EM, Sacca' A, Chiesa R, Rigatti P, Montorsi F. Severe vascular complication after implantation of a three-piece inflatable penile prosthesis. J Sex Med 2008;5: 2956–9.
4 Dupont MC, Hochman HI. Erosion of an inflatable penile prosthesis reservoir into the bladder, presenting as bladder calculi. J Urol 1988;139:367–8.
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;146:847–8.
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;18:316–7.
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;6:2064–7.
11 Leach GE, Shapiro CE, Hadley R, Raz S. Erosion of inflatable penile prosthesis reservoir into bladder and bowel. J Urol 1984;131:1177–8.
12 Luks FI, Huntley HN, Tula JC, Pizzi WF. Small-bowel obstruction by an inflatable penile prosthesis reservoir. Surgery 1989;106:101–4.
13 Nelson RP Jr. Small bowel obstruction secondary to migration of an inflatable penile prosthesis reservoir: Recognition and prevention. J Urol 1988;139:1053–4.
14 Sadeghi-Nejad H, Sharma A, Irwin RJ, Wilson SK, Delk JR. Reservoir herniation as a complication of three-piece penile prosthesis insertion. Urology 2001;57:142–5.
15 Singh I, Godec CJ. Asynchronous erosion of inflatable penile prosthesis into small and large bowel. J Urol 1992;147: 709–10.
16 Perito PE. Ectopic reservoir placement—No longer in the space of Retzius. J Sex Med 2011;8:2395–8.
17 Perito PE, Wilson SK. Traditional (retroperitoneal) and abdominal wall (ectopic) reservoir placement. J Sex Med 2011;8:656–9.
18 Wilson SK, Delk JR 2nd. Ectopic placement of AMS 800 urinary control system pressure-regulating balloon. Urology 2005;65:167–70.
19 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: 1475–8.
20 Sadeghi-Nejad H, Munarriz R, Shah N. Intra-abdominal reservoir placement during penile prosthesis surgery in post-robotically assisted laparoscopic radical prostatectomy patients: A case report and practical considerations. J Sex Med 2011;8:1547–50.
21 Riemenschneider HW. Epigastric placement of reservior for inflatable penile prosthesis. Urology 1981;17:79–81.
22 Knoll LD, Henry G, Culkin D, Ohl DA, Otheguy J, Shabsigh R, Wilson SK, Delk II J. Physician and patient satisfaction with the new AMS 700 momentary squeeze inflatable penile prosthesis. J Sex Med 2009;6:1773–8.
23 Rajpurkar A, Bianco FF Jr, Al-Omar O, Terlecki R, Dhabuwala C. Fate of the retained reservoir after replacement of 3-piece penile prosthesis. J Urol 2004;172:664–6.
24 Chung BI, Sommer G, Brooks JD. Chapter 2—Anatomy of the lower urinary tract and male genitalia. In: Wein AJ, ed. Campbell-walsh urology. 10th edition. Philadelphia, PA: Elsevier; 2011:33–70.