

Wilson's Workshop # 2

Should Occasional Implanters Learn Ectopic Placement of IPP Reservoirs?

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Running Title: Ectopic reservoir placement in IPP surgery

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Introduction

Reservoir placement is often the most anxiety-provoking aspect of inflatable penile prosthesis (IPP) surgery. Catastrophic injuries to vessel or visceral organs may occasionally occur, shattering the surgeon's confidence and tempting the individual to think, "I can make a living doing stones and prostates ... why do I need to do that tricky risky surgery?" In 45 years of practice SKW has seen numerous promising implanters abandon prosthetic urology after an unfortunate disastrous complication. When queried the reason, the surgeon will subterfuge, indicating that, "Viagra seems to be working better recently."

The traditional location for the reservoir is the prevesical space, which even in virgin patients without pelvic issues can result in bladder perforation or vascular injury. An excessively scarred prevesical space, following open or robotic pelvic surgery or the removal of a bladder or colon increases the risk of ruinous complication by adding the nightmare of bowel injury. Robotic pelvic surgery usually requires an intraperitoneal approach and robotic surgeons do not reestablish the peritoneal veil following prostatectomy, exposing intraperitoneal small intestine to what was previously the self-contained prevesical Space of Retzius. Placing a prosthetic reservoir into what could be considered a hostile, scarred pelvis then carries an even higher risk of calamity spawning new complications of small bowel injury, small bowel obstruction, or intestinal fistula.

Today, most high-volume implanters are using non-traditional reservoir location on a regular basis and some have switched to it exclusively (1, 2). In the US, where the highest volume of

IPP in the world are performed, 75% of the implants are done by occasional implanters ... individuals who do 4 or less per year (3). These abundant but infrequent implanters have been slower to embrace the newer locations for reservoir placement (2). Recently developed low profile reservoirs have been placed in non-traditional spaces, termed “ectopic” while others may prefer synonymous designations such as “alternative” or “submuscular” locations. This edition of Wilson’s Workshop will examine whether there should be more urgency for the adoption of ectopic reservoir placement by occasional implanters of IPP.

History of the Development of Ectopic Placement of IPP reservoirs

The first description of non-traditional reservoir placement was Remenschneider in 1980 (4). Mulcahy popularized this location which was extraperitoneal in the epigastric area via a separate high abdominal incision. **Figure 1A** Professor Schreiter, the highest volume implanter in Europe, promoted a pelvic intraperitoneal location for the reservoir in the 1990’s not requiring a second incision. Capsule formation did not occur, and this precluded auto inflation of the balloon (without lock-out valves) reservoirs of that time. The peritoneal cavity is the only area of the body where capsule formation around implant components does not occur. **Figure 1B** Absent a capsule, the large peritoneal space prevented the transmission of intrabdominal pressure to the reservoir. Schreiter never published his technique but was a frequent symposium presenter; prior to the turn of this century, intraperitoneal location was quite popular in Germany as a means of preventing auto inflation.

Historically, the traditional location of the IPP reservoir was determined by the original inventor of the IPP, F. Brantley Scott. Since the early reservoirs were essentially balloons that would be subjected to pressure from surrounding structures, a true space within the body was needed to prevent auto inflation. The space of Retzius was ideal because it was one of the only true spaces in the body and it was close in proximity to the penis.

Dr. Scott also understood the concept of capsule formation. When foreign bodies are placed anywhere in human tissues except the peritoneal cavity, capsule formation is stimulated. This capsule reaches maturity after 3-4 months and walls off the implant components with a thick fibrous sheath. **Figure 2A,B,C** Prior to the lock-out valve development, implanting surgeons learned that if the patient did not deflate his prosthesis in the early post-operative period, this capsule formed around constantly inflated cylinders and deflated reservoir. This patient would subsequently complain of inability to deflate or of spontaneous inflation without the owner's permission (1, 5). Prior to the development of lock-out valves, as many as 12% of patients complained of auto inflation. In 4% of the patients the problem was sufficiently noxious that reservoir revision was necessary (1, 5).

An interesting historical fact is that frontier surgeons knew about capsule formation. Unlike the frontier medicine portrayed by Hollywood, these surgeons rarely performed surgery to remove the bullets in extremities. There was no anesthesia except whiskey; there were no antibiotics and no sterile operating rooms. An open operation was usually followed by sepsis. If the gunshot patient was stable and not bleeding excessively, the patient was observed. The frontier physician

knew that within 3 months the bullet would be walled off by capsule and prevented from causing subsequent mischief. **Figure 2D**

Mentor/Coloplast was the first to market a lock-out valve in their reservoir in 2001. By 2003, AMS/Boston Scientific implants also enhanced their devices placing a lock-out valve in their pump. Since a true space was not needed for implants with lock-out valves, these much-awaited enhancements allowed the IPP reservoirs to be placed in non-traditional locations. Both implant companies rapidly responded to the “ectopic” marketplace with flat reservoirs. Boston Scientific now markets the low profile Conceal® reservoir designed and patented by SKW.

Figure 3A It resembles a pancake and is a complete departure from the original spherical design. Coloplast has a Cloverleaf® reservoir that can be half filled achieving a flat 1.5” configuration. Ectopic or non-traditional reservoir location is no longer “off label” as the Coloplast Cloverleaf is specifically FDA-approved for ectopic placement since 4/2015. **Figure 3B**

SKW first published intrabdominal wall placement of reservoirs and coined the term “ectopic” in 2002 (1). This novel location was stimulated by development of a bowel fistula following traditional placement of a reservoir in a cystectomy patient. Wilson described employing his finger to dissect the space and place the reservoir ectopically. The path is begun with the finger in the inguinal canal staying anterior to the transversalis fascia and finger dissecting underneath the abdominal wall muscles. The finger then forcibly passed cephalad piercing the back wall of the inguinal canal. A space anterior to the transversalis fascia and posterior to the muscle layers of the abdomen is created by moving the finger back and forth with the pad of the finger palpating the transversalis fascia underneath. **Figure 4B** This intraabdominal wall reservoir

location achieved with the finger never attained much popularity because the reservoir was usually visible and palpable in the patient's groin resembling a hernia. **Figure 5**

Experience has shown that if we place the reservoirs higher than the finger is long, there is less palpability. Perito pioneered using the long nasal speculum through an infrapubic incision and found much less visibility and palpability than with finger placement (6). **Figure 6A.** Morey got the reservoir even higher in the abdominal wall using the Forrester lung grasping forceps. Morey, in his publications, abandoned the word ectopic and substituted "high submuscular" placement of the reservoir. With this instrument or a long sponge stick forceps, the reservoir can be pushed into a position lateral to the umbilicus from either a scrotal or infrapubic incision⁷.

Figure 6B Wilson and associates designed an atraumatic grasping, double articulation clamp that is 14" long. The clamp is angled anteriorly to safely place the balloons high in the abdominal wall thus ensuring that all but the thinnest patient would not see or feel the reservoir.

Figure 6C

Unique Complications of Traditional Space of Retzius Reservoir Location

Injury to pelvic vessels: Because the iliac vein is so close to the site of transversalis fascia puncture, venous stasis caused by the filled to capacity reservoir or massive bleeding from vein laceration may accompany retroperitoneal reservoir insertion (7, 8). It is amazing how close the pelvic vessels are to the transversalis puncture site. **Figure 7** Utilizing cadaver dissection Henry and associates determined that the iliac vein was only 2-4 cm from the inguinal ring (8). A slight deviation laterally during the transversalis puncture can result in vessel compromise. This

“bleeding you can hear” can be a medical emergency as your IPP incision is inadequate to isolate and repair a hemorrhage caused by laceration of an iliac vessel. This catastrophic bleeding should be respected, finger pressure on the wound applied and an urgent call for a vascular surgeon’s assistance ought to be placed.

If the bleeding is from a pelvic vein rather than one of the major pelvic vessels, the hemorrhage may be controlled by Floseal® or another of the fibrinogen products. After digital pressure for 5 minutes, spread the hemostatic agent deep in the wound and gently apply pressure again. If the vessel is minor, we have had good success stopping the bleeding with this technique. Floseal® is always worth a try as it frequently takes 20-30 minutes before the consultant can arrive to address the situation with a larger abdominal incision. This life-threatening injury usually precipitates a malpractice action which is frequently successful.

Bladder Injury: This tricky situation usually occurs when blind placement of the reservoir is performed in a patient with a partially full bladder. Either the physician forgot to empty the bladder, or the case has progressed longer than usual, and the empty bladder has partially filled during the delay. It is rarely diagnosed by appearance of urine in the wound after puncture but usually is apparent only after the patient’s incision has been closed and blood is noted in the catheter bag. The conclusion of bladder perforation can be obtained by irrigating the catheter with saline or obtaining a CT or MRI. **Figure 8** Alternately, on the table or in the Recovery Room flexible cystoscopy can be utilized. Bladder injury during prosthesis implantation is another genesis for a litigation as it requires an immediate return to the surgical suite for

reservoir removal and repair. In fact, SKW's only successful malpractice suit came as a result of a reservoir placed inadvertently in a bladder.

Bowel injury: Intestinal damage may occur after traditional reservoir placement in patients with scarred or an obliterated retroperitoneal space e.g. after cystectomy. Bowel injury appears suddenly in the post-operative period heralded by fecal drainage out the incision or the closed suction drain. Typically, a knuckle of bowel migrated into the space the bladder had previously occupied and becomes trapped by adhesions from the previous surgery. Even if the physician carefully creates the space under direct vision, bowel can be compromised days later. The physician creates the reservoir space with careful finger dissection and the deflated reservoir is placed. The reservoir is then filled with fluid placing unsuspected pressure on the loop of bowel that has been rendered immobile by adhesions from previous surgery. Over 1-3 days the reservoir pinches the adjacent viscus creating necrosis of the bowel wall. **Figure 9A** The outcome horrifies patient and physician alike with odiferous drainage coming out the surgical incision. **Figure 9B.** Management of these bowel fistulae can be quite complex requiring exploration, implant removal, extended hospitalization and total parenteral nutrition (TPA). The senior author has experienced the complication 3 times in 45 years and over 11,000 IPP. Frankly he never wishes to see it again; he has memories of rounding for 30 days on a previously happy, elective implant patient that transformed into a depressed, angry and hungry patient requiring TPA.

Surgical Placement of Ectopic Reservoirs aka High Submuscular and Abdominal Wall

[Note: It is impossible to adequately describe surgical technique with simply words and photos. For complete expositions of non-traditional reservoir insertion, the reader is referred to www.vjpu-issm.info. These 6 videos tutor ectopic placement: Brennen M. VJPU 2018;2:143, Osmonov D. VJPU 2018;2:122, Haaky T VJPU 2017;2:106, Wilson SK. VJPU 2014;1:40, Kohler T. VJPU 2013;1:12, Cefalu C VJPU; 2013;1:1}

The pubic tubercle is cleaned of all overlying tissue with the finger or the Metzenbaum scissors.

Figure 10A It is stressed that the tubercle must be free of Scarpa's fascia. **Figure 10B**

Otherwise the reservoir will be placed in the abdominal wall superficial to some of the musculature resulting in a palpable and possibly visible component. The external inguinal ring is identified cephalad to the "squeaky clean" tubercle. An "S" retractor or baby Deaver is placed in the inguinal ring and used to retract the roof of the inguinal canal anteriorly. **Figure 10C** This maneuver is different from the retroperitoneal placement. In retroperitoneal placement the ring is pulled toward the head resulting in a "drum-head" of transversalis fascia outlined by the bony pelvis. In ectopic placement the ring is lifted to the sky to facilitate entry into the abdominal wall structures and avoid piercing the transversalis fascia. **Figure 10C**

Successful high submuscular reservoir placement positions the reservoir under all three abdominal muscle layers in a medial location where the muscles are heaviest. **Figure 11A,B** It is crucial to advance the reservoir quite cephalad with a long clamp staying medial beneath the Rectus and aiming the clamp "towards the ceiling" to prevent inadvertent intraperitoneal entry. If the long clamp is not kept anterior or parallel with the muscles, inadvertent intraperitoneal reservoir placement may occur. **Figure 12** If the reservoir is positioned close to the umbilicus,

beneath the heavy abdominal musculature and resting on the surface of the transversalis fascia, filling the reservoir with saline distorts the reservoir intraabdominally which results in the component not being visible or palpable on the abdomen. **Figure 13.**

Another critical component of ectopic reservoir placement is reservoir fill volume. Underfilling the reservoir leads to less chance of palpability and is recommended particularly with the Coloplast reservoir. The Cloverleaf reservoir is only 1.5” thick when half-filled **Figure 3B** but balloons up to almost 4” when filled to capacity. The maximum fill volume for each cylinder size varies according to manufacturer and the surgeon must coordinate cylinder selection with how much fluid to leave in the reservoir. Addition of Rear Tip Extenders in patients with long penises may be necessary to decrease cylinder capacity in these patients.

Discussion

The possibility of the previously mentioned life-threatening complications of traditional reservoir placement must be acknowledged by all implanters. While the life-threatening situations are admittedly rare, their risk of occurrence can be predicted by the patient’s history and comorbidities. Obviously, these difficulties are more likely to occur in patients with previous extensive pelvic surgery. Malpractice litigation in the US is a distinct possibility following the advent of vessel or viscus injury. Even if the lawsuit is not successful, the legal process is accompanied by physician anxiety and sleepless nights for at least 2 years. Why should any implanter take the risk when ectopic or high submuscular placement of the reservoir obviates its possibility?

What is the worst that can happen after abdominal wall placement of an IPP reservoir? *Blue leg or pulmonary embolus from iliac vein compression? Massive hemorrhage after iliac vein*

laceration? Urine or succus entericus draining out the implant incision? **No!** The worst that

can happen following ectopic reservoir placement is a visible or palpable reservoir. **Figure 14**

That particular reservoir was superficial and much too lateral where the abdominal muscles have no bulk. We believe the Pfannenstiel incision deflected the clamp laterally. Nevertheless, after 3 months capsule formation made it much less obvious; the shallow location did not affect the mechanical performance of the inflatable implant and the patient did not request repair.

Should the occasional implanter learn ectopic placement? We believe the answer is a strong yes particularly when a patient's history or comorbidity predict a scarred or obliterated Space of Retzius. Today's low-profile reservoirs are configured for ectopic placement. Multiple recent publications have demonstrated the safety and efficacy of the high submuscular technique, and a counter incision is not needed (9, 10). A current survey of SMSNA members showed 81% of high-volume IPP surgeons find placement of a reservoir in Space of Retzius challenging after pelvic surgery and an ectopic reservoir placement will avoid the potential complications.

Moreover, 90% felt residency programs should teach the ectopic or high submuscular placement (11). Non-traditional location for reservoirs is being practiced all over the world. A recent European study by Osmonov et al. confirmed ectopic reservoir placement had less complications and comparable satisfaction (12).

There is one caveat that addresses the possible visibility of the reservoir. It is mandatory for beginning ectopic implanters. Patients should be informed before the surgery that their reservoir might be palpable &/or visible. If it occurs and the patient was warned, patients are quite accepting as many medical devices require visibility – pacemakers, Interstim® regulator etc.

Finally, we believe the situation of low volume implanters failing to utilize this safer reservoir location is similar to their reluctance to use drainage following IPP to prevent scrotal hematoma. High volume surgeons see scrotal hematomas in 4% of their patients; a physician who does 100 IPP's/year would see a hematoma every 3 months and most drain to avoid it. An occasional surgeon who does 2 implants a year could go 12 years without the occurrence of excessive scrotal bleeding and typically do not utilize a post op drain. The Space of Retzius reservoir complications are very infrequent to all implanters and simply “out of sight, out of mind” to occasional surgeons.

Conclusion

Ectopic placement of reservoirs in the abdominal wall beneath the abdominal wall muscles has been around almost 20 years. During that time, many frequent implanters have embraced the ease of the procedure and the safety of its outcome. There have been no reports in the medical literature of any vessel laceration or other life-threatening complications (9, 10). Low-volume prosthetic surgeons have not been so adventuresome and ectopic placement is underutilized even when the pelvis is hostile. With the plethora of videos and cadaver workshops available, we hope occasional implanters will learn the technique and promote its safety to their patients.

Conflict of interest: Wilson is consultant to AMT, Coloplast, International Medical Devices and Lecturer for Boston Scientific. Simhan is Consultant for Boston Scientific and Coloplast. Osmonov is Consultant for Boston Scientific and Coloplast

Key words: ectopic, high submuscular, penile prosthesis reservoir

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Figure Legends

Figure 1: The Journey to Ectopic or High Submuscular Placement. A: 1980 epigastric reservoir³, B: 1990 intraperitoneal placement.

Figure 2: Everything Implanted (Even Bullets) in Humans Is Surrounded by Capsule. A: Reservoir capsule, B: Pump capsule, C: Cylinder capsule, D Frontier Surgery – surgery for bullet extraction was rare

Figure 3: Low Profile Reservoirs Developed for Ectopic Placement. A: Boston Scientific Conceal® Reservoir, B: Coloplast Cloverleaf® Reservoir

Figure 4: Anatomy of the Abdominal Wall or Ectopic Reservoir Placement. A: Abdominal wall, B: Finger placement of ectopic reservoir

Figure 5: Reservoir in Groin After Finger Placed Ectopic Reservoir

Figure 6: Latest Developments in Journey to Ectopic Placement. A: 2010 Perito nasal speculum, B: 2013 Morey lung clamp, C: 2015 Wilson clamp

Figure 7: Iliac Vein only 2-4 cm from Inguinal Ring

Figure 8: MRI Showing Reservoir in Bladder

Figure 9: Bowel Injury Following Traditional Reservoir Placement. A: Reservoir erosion into small intestine, B. Bowel contents draining through scrotal incision

Figure 10: Release of Scarpa's Fascia Is Key to Ectopic Placement of Reservoir. A: Red arrow points pubic tubercle, B: Lifting Scarpa's off tubercle, C: Deaver Lifted Reveals Transversalis Fascia

Figure 11: Cadaver Study Showing Proper Ectopic Location Medially Beneath Muscles and Lateral to Umbilicus. A: Cadaver dissection showing three layers of abdominal muscles and

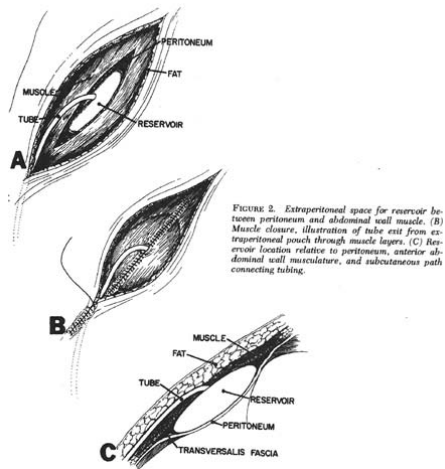
transversalis fascia, B. Clamp passed underneath muscles. Window incised on abdomen created to show clamp beneath muscles.

Figure 12: Inadvertent Piercing of Transversalis Fascia Results in Reservoir in Peritoneal Cavity: This patient underwent concomitant robotic prostatectomy and IPP. The error was discovered by the robot camera.

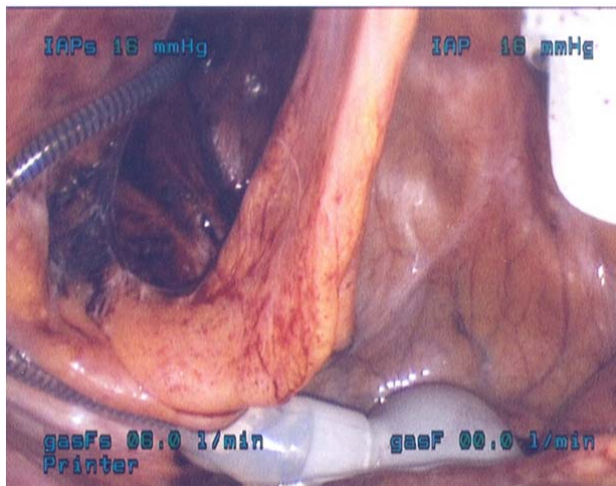
Figure 13: Reservoir Distorts Peritoneum Not Abdomen: Laparoscopic camera placed intraperitoneally

Figure 14: Visible and Palpable Ectopic Reservoir on Post Op Day 3. A: Improperly placed reservoir. B: Properly placed reservoir has no bulge

Figure 1: The Journey to Ectopic or High Submuscular Placement



A. 1980 epigastric reservoir³



B. 1990 intraperitoneal placement

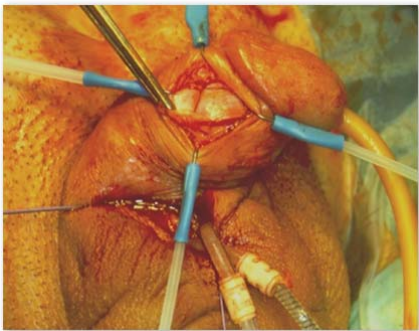
Figure 2: Everything Implanted (Even Bullets) in Humans Is Surrounded By Capsule



A. Reservoir capsule



B. Pump capsule

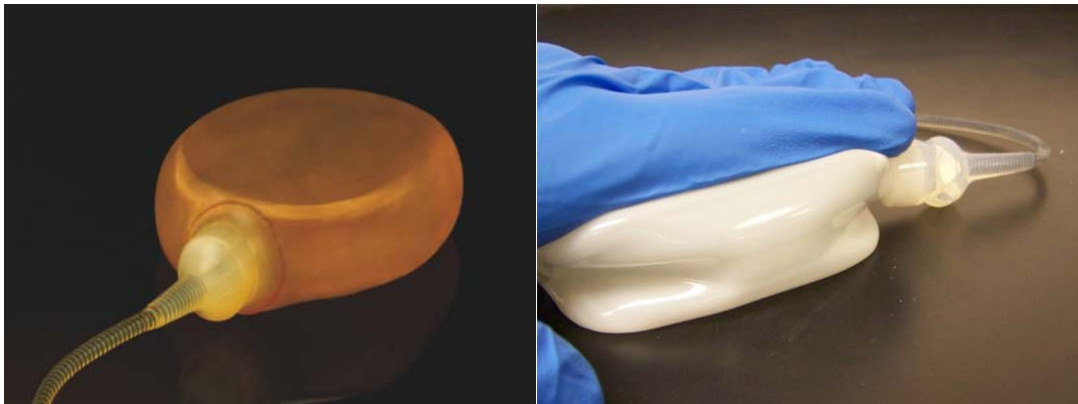


C. Cylinder capsule



D. Frontier surgery: surgery
For bullet extraction was rare

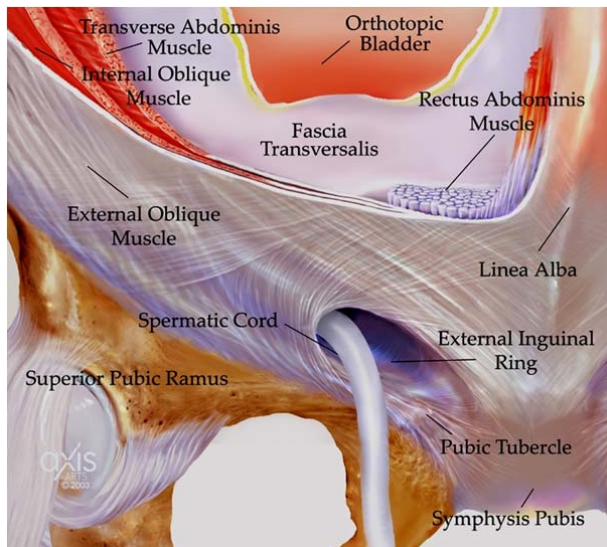
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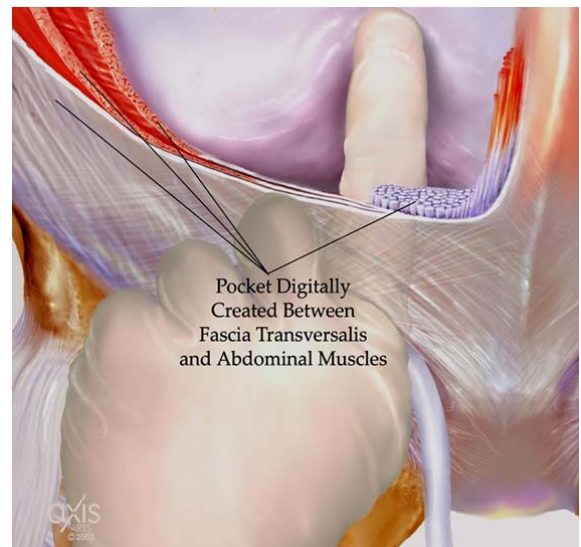
A. Boston Scientific Conceal® Reservoir.

B. Coloplast Cloverleaf® Reservoir

Figure 4: Anatomy of the Abdominal Wall or Ectopic Reservoir Placement



A. Anatomy of Abdominal Wall

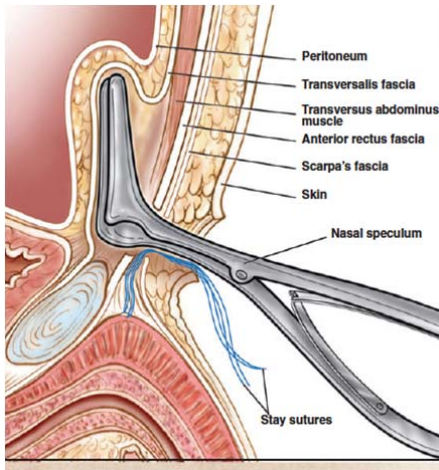


B. Finger placement of Ectopic Reservoir

Figure 5: Reservoir in Groin After Finger Placed Ectopic Reservoir



Figure 6: Latest Developments in Journey to Ectopic Placement



A. 2010 Perito nasal speculum



B. 2013 Morey lung clamp.



C. 2015 Wilson clamp

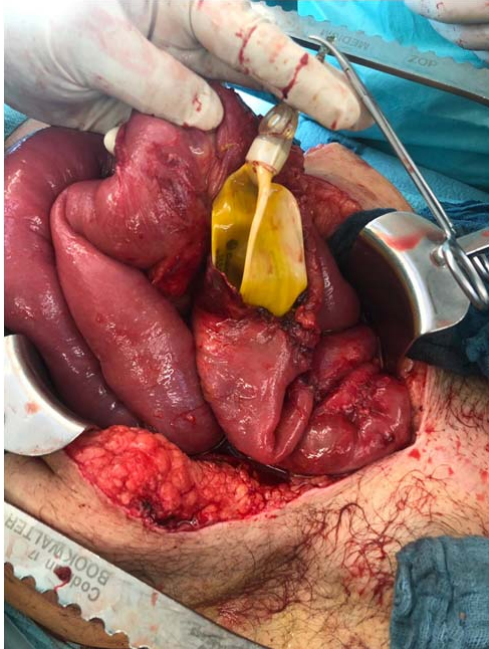
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Figure 9: Bowel Injury Following Traditional Reservoir Placement



A. Reservoir erosion into small intestine



B. Bowel contents draining through scrotal incision

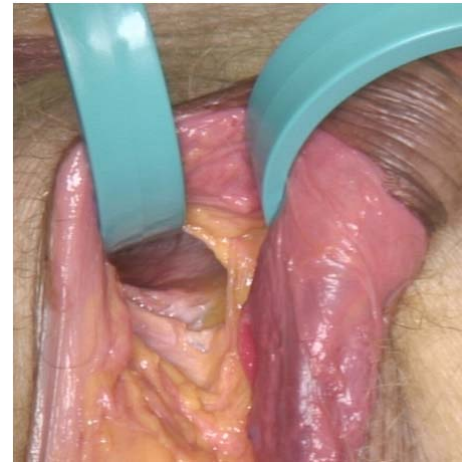
Figure 10: Release of Scarpa's Fascia Is Key to Ectopic Placement of Reservoir



A. Red arrow points pubic tubercle



B. Lifting Scarpa's off tubercle



C. Deaver Lifted Reveals
Transversalis Fascia

Figure 11: Cadaver Study Showing Proper Ectopic Location
Medially Beneath Muscles and Lateral to Umbilicus



A. Clamp passed underneath muscles. Window incised on abdomen created to show clamp beneath muscles.



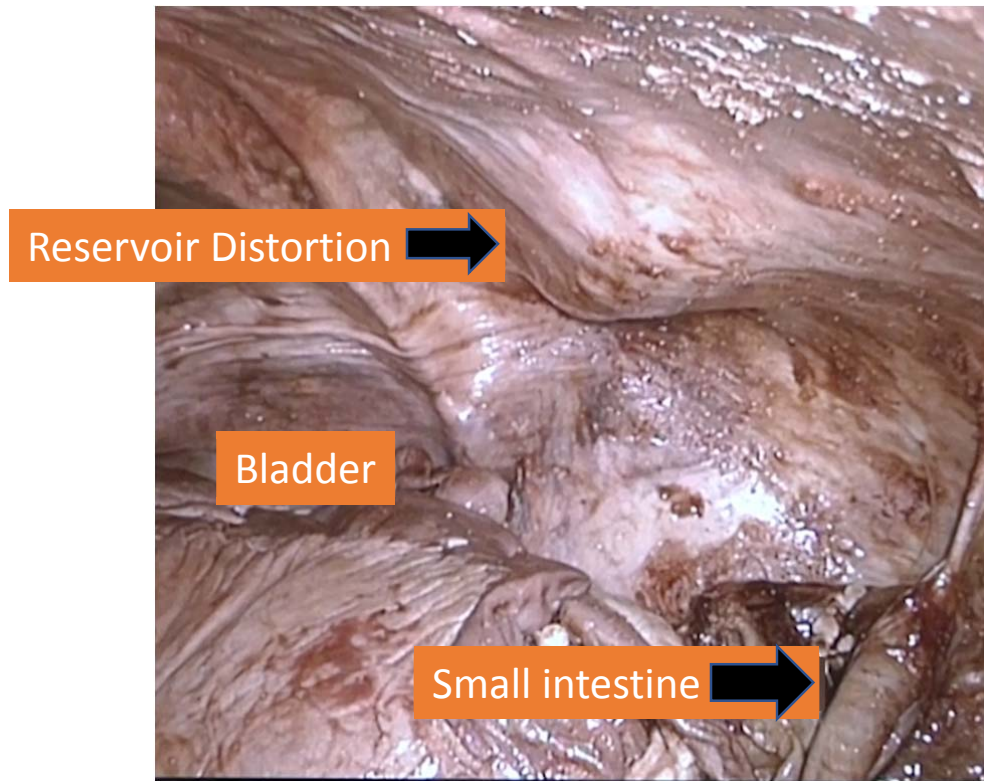
B. Cadaver dissection showing three layers of Abdominal muscles and transversalis fascia

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This patient underwent concomitant robotic prostatectomy and IPP. The error was discovered by the robot camera.

Figure 13: Reservoir Distorts Peritoneum Not Abdomen



Laparoscopic camera placed intraperitoneally

Figure 14: Visible and Palpable Ectopic Reservoir on Post Op Day 3



A. Improperly placed reservoir



B. Properly placed reservoir has no bulge