

## ORIGINAL ARTICLE

# A retrospective analysis of risk factors for IPP reservoir entry into the peritoneum after abdominal wall placement

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Placement of an inflatable penile prosthesis (IPP) is the most effective treatment modality for men with ED refractory to medical management. We have previously demonstrated a protocol for IPP reservoir placement within the abdominal wall musculature, which was shown to be a safer location than traditional placement in the retropubic space of Retzius. The aim of this study was to review our complications with IPP reservoir entry into the peritoneum after abdominal wall placement of the reservoir. We retrospectively reviewed our two patients with peritoneal entry of the reservoir after posterior to transversalis fascia and anterior to transversalis fascia placement during virgin and compromised IPP cases, respectively. Our goal was to assess common inherent patient and surgical factors that resulted in this complication in order to develop a management algorithm to prevent future occurrence during alternative reservoir placement. Peritoneal reservoir entry was identified in two patients. These patients were both noted to be thin (mean body mass index (BMI) 18.5 kg/m<sup>2</sup>), current or former smokers. Peritoneal entry was identified early after reservoir placement. Neither of the patients suffered bowel injury and both subsequently underwent successful reservoir removal and IPP replacement. Both are currently doing well with functional IPPs on follow-up. Peritoneal entry of the reservoir occurs very rarely and, in our series, occurred in a cohort of patients with low BMI and tobacco use history. We recommend early identification of similar patients and subsequent reservoir placement anterior to transversalis fascia with caution to prevent peritoneal entry.

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## INTRODUCTION

ED is a devastating disorder with vascular, neurogenic, pharmacological and psychogenic etiologies.<sup>1,2</sup> Inflatable penile prostheses are widely recognized as the definitive surgical treatment for ED unresponsive to conservative therapies,<sup>3,4</sup> and the past 40 years have brought significant innovation and refinement to these devices and to surgical technique.<sup>5</sup> Among these advances is the use of alternative reservoir placement sites<sup>6–8</sup> to minimize risk of vascular<sup>9–13</sup> and viscus<sup>14–26</sup> injury caused by inflatable penile prosthesis (IPP) reservoir placement in the retropubic space of Retzius. Alternative reservoir placement has been shown to be safe, simple and effective in reducing risk of injury while allowing for proper IPP functionality after placement from either the infrapubic<sup>27</sup> or penoscrotal approaches.<sup>28</sup>

We previously published the largest series in the literature of 2687 patients who underwent alternative reservoir placement.<sup>27</sup> In our single-surgeon study, posterior to transversalis fascia (PTF) IPP reservoir placement took place the vast majority of the time (83%), with anterior to transversalis fascia (ATF) placement used as an alternative in patients with anatomical issues due to significant previous pelvic surgery (17%). Complication rates in the 2239 PTF patients in that study were very low and included bladder perforation (2, 0.09%), reservoir herniation (2, 0.09%) and device infection (21, 0.94%). Complications in the 447 ATF patients were similar, with higher likelihood of a palpable reservoir and/or reservoir herniation. Both cohorts have since had extensive follow-up, and peritoneal reservoir entry was identified in two of the patients in our earlier series.

## Aims

PTF and ATF IPP reservoir placements remain safe, simple and effective in properly identified patients. The aim of this retrospective study was to identify anatomical and health history issues in the patients who had peritoneal entry of the IPP reservoir to better predict this potential complication and properly prepare for cautious ATF placement intraoperatively.

## MATERIALS AND METHODS

The study population consisted of a consecutive series of 2687 men who underwent first-time IPP via an infrapubic incision with PTF reservoir placement between January 2002 and December 2012. These men were deemed safe for PTF reservoir placement as they did not have a past surgical history of radical retropubic prostatectomy, colon surgery, cystectomy, herniorrhaphy or aortofemoral bypass. The Coloplast Titan (Coloplast, Minneapolis, MN, USA) was used in all patients, as it has a low-profile Cloverleaf reservoir with a bellows-like configuration that allows it to be flat when underfilled but cylindrical when fully expanded. In general, we used the 125 cc reservoir filled with 70–85 cc of saline, with occasional use of the 60 cc reservoir filled with 40–50 cc.

PTF and ATF reservoir insertion were previously described in detail. The two techniques begin identically, with divergence after insertion of the 80 mm closed nasal speculum into the inguinal ring. In PTF placement, the speculum handle tip is used to perforate the transversalis fascia in a downward manner. The handle is then rotated so that the orientation of the speculum tip is changed from posterior to cephalad. The instrument is then advanced to the handle in a cephalad manner. The nasal speculum paddles are spread to dilate the potential space. Air is evacuated from the reservoir, and it is fashioned into a 'cup' shape by spreading the Cloverleaf

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**Figure 1.** Follow-up imaging demonstrating reservoir in the correct ATF position.

reservoir sides laterally. A small pediatric Yankauer tip is placed into the depression of the cup and used to pass the reservoir as far cephalad as possible between the maximally spread speculum, with care taken to keep the lockout mechanism anterior.

In ATF reservoir insertion, the tip of the nasal speculum is passed through the external ring and forcibly advanced cephalad. The back wall of the inguinal canal is thus perforated without perforation of the transversalis fascia. The speculum is advanced the length of the paddles, placing it ATF but posterior to the overlying rectus abdominis muscles. The reservoir is then passed in a similar manner as above.

Informed consent was obtained from patients for photo use.

#### Main outcome measures

To date, two patients were postoperatively identified as having peritoneal entry of the reservoir. We reviewed preoperative patient health characteristics, history of prior pelvic surgery, intraoperative documentation, postoperative follow-up, complication presentation and imaging for this group. Follow-up visit data were available for up to 48 months after surgery, at intervals of 6 months. We were further able to assess long-term outcomes from this complication, including resolution of peritoneal reservoir entry and eventual IPP replacement.

#### RESULTS

Peritoneal reservoir entry was identified in two patients. These patients were both noted to be thin (mean body mass index (BMI)  $18.5 \text{ kg m}^{-2}$ ), current or former smokers. BMI in that range in combination with smoking history was not seen in any of the other patients in the series. Peritoneal entry was identified early after reservoir placement. Neither patient suffered bowel injury and both subsequently underwent successful reservoir removal and replacement. Both are currently doing well with functional IPPs on follow-up.

The first patient was a 71-year-old male at IPP implantation. Past medical history was notable for noninsulin-dependent diabetes mellitus and prostate cancer. He had previously undergone a robotic radical prostatectomy 3 years prior to initial presentation for ED. He complained of ED refractory to PDE5 inhibitor therapy and was not responsive to intracavernosal injections or interested in a vacuum erection device. He was a former smoker with a 15 pack-year history. Height was 188 cm and weight was 76 kg, with BMI calculated at  $21.5 \text{ kg m}^{-2}$ . No abnormal findings aside from previous surgical scars were noted on physical exam. The patient

underwent an uneventful infrapubic insertion of an IPP with reservoir placement ATF.

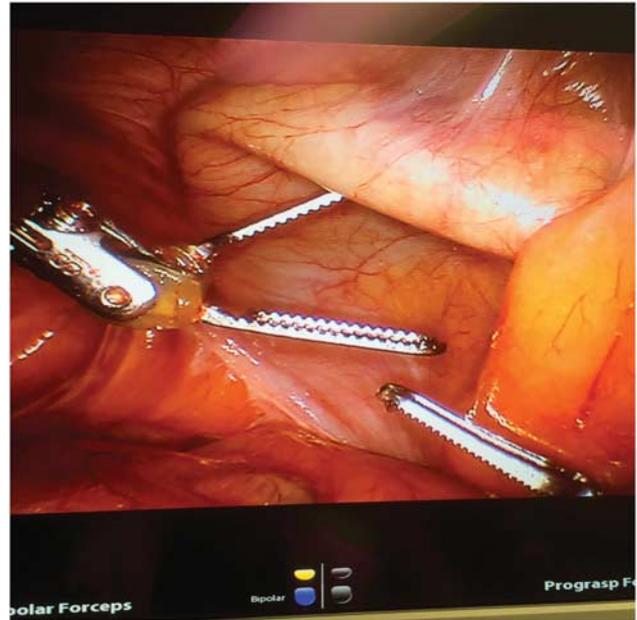
Eleven months later, the patient was brought to the hospital with symptoms consistent with a small bowel obstruction. Imaging revealed a small bowel obstruction secondary to an intraperitoneal hernia caused by a loop of tubing with the attached reservoir. He was admitted for supportive care and brought to the operating room for definitive management. A small peritoneal window was created and the reservoir removed leaving the tubing leading to the IPP capped. Six weeks later, an infrapubic incision was utilized to place the reservoir ATF, in the standard manner, after localizing the previously placed tubing. Follow-up imaging (Figure 1) demonstrated the reservoir in proper position. The patient tolerated both procedures without incident. Sixteen-month follow-up reveals no other complications.

The second patient was a 68-year-old male at IPP implantation. Past medical history was notable for hypertension, benign prostatic hyperplasia and peptic ulcer disease. He had previously undergone an exploratory laparotomy for his peptic ulcer disease, as well as a laparoscopic cholecystectomy. He complained of ED refractory to PDE5 inhibitor therapy and was not responsive to intracavernosal injections or interested in a vacuum erection device. He was a current smoker with a 30 pack-year history. Height was 161 cm and weight was 40 kg, with BMI calculated at  $15.4 \text{ kg m}^{-2}$ . No abnormal findings aside from previous surgical scars were noted on physical exam. The patient underwent an uneventful infrapubic insertion of an IPP with reservoir placement PTF.

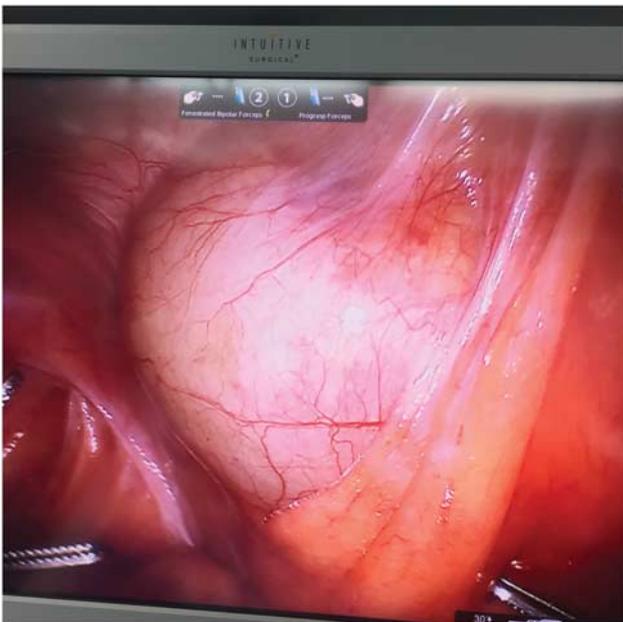
Eighteen months after IPP placement, the patient developed a right inguinal hernia for which he underwent a robotic herniorrhaphy (see Figure 2). During this surgery, the implant reservoir was encountered in the hernia sac by the general surgeon (see Figures 3 and 4). The implanting surgeon was called to the operating room and incision was made on the patient's left side after removing the herniated reservoir in order to place the reservoir ATF on the contralateral side. The patient tolerated both procedures without incident. Twenty-month postoperative follow-up reveals no other complications.



**Figure 2.** Preoperative view of reservoir in hernia sac.



**Figure 4.** Intraoperative robotic view of deflated reservoir in hernia sac.



**Figure 3.** Intraoperative robotic view of inflated reservoir in hernia sac.

## DISCUSSION

The goal of alternative reservoir placement during IPP implantation is to avoid the catastrophic complications that can turn a successful elective surgical correction into a disaster. In our previous study, we established the utility of PTF and ATF in avoiding bladder, bowel and vascular injury. There were no

instances of erosion into bladder or bowel or vascular compromise in that series.<sup>27</sup> Since publication, the Food and Drug Administration has approved labeling changes for the Coloplast Titan to incorporate alternative reservoir placement. Other surgeons have also noted variability in reservoir placement in cadaver models via other techniques described in the literature, which raises questions about consistency in alternative placement.<sup>29</sup> In general, however, we note that experienced implanters are concerned regarding pelvic anatomy following robotic prostatectomy procedures and finding a safety advantage in alternative reservoir placement.<sup>30</sup> As a result, we believe that it is vital to analyze any potential failings of alternative reservoir placement in order to maximize the success of this technique.

In our previous series, we determined that patients with previous pelvic surgery were best suited for ATF placement. In this retrospective analysis, we did find one patient with a virgin pelvis and one patient with a compromised pelvis suffering from the same complication: an intraperitoneal reservoir. This correlates with the work of other authors with similar findings.<sup>21</sup> After analyzing the inherent factors common to these patients, we have determined that the relative risk of not negotiating the proper plane between transversalis fascia and peritoneum during dissection for penile implant reservoir placement utilizing abdominal wall placement may be higher in patients with a low BMI and history of tobacco use. These clinical findings in implant patients should alert any urologist to having abdominal wall placement of the reservoir in their skill set to prevent the potential complication.

Limitations to the ATF technique include palpable or visible reservoir and inguinal reservoir herniation. Limitations to our study include the biases and errors inherent to any retrospective review. And we note that our sample size of peritoneal reservoir migration patients is very small, which limits the amount of information that can be extrapolated from their experiences. In addition, we were unable to capture data on patients who may have followed up elsewhere with other complications. The distinct possibility remains that there may be more cases of intraperitoneal placement that we are simply not aware of from our overall cohort.

That being said, we continue to recommend alternative reservoir placement with great enthusiasm. We hope that this series helps prevent future peritoneal complications and refines surgical technique for determining PTF vs ATF reservoir placement. We welcome further research into alternative reservoir placement that adds to the growing body of work surrounding this surgical advancement.

## CONCLUSIONS

Peritoneal entry of the reservoir occurs very rarely and, in our series, occurred in a cohort of patients with low BMI and tobacco use history. We recommend early identification of similar patients with ATF reservoir placement to prevent peritoneal entry.

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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