

The History of Nontraditional or Ectopic Placement of Reservoirs in Prosthetic Urology



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ABSTRACT

Introduction: Reservoir placement during implantation of prosthetic urology devices has been problematic throughout the history of the surgical treatment of erectile dysfunction and urinary incontinence. We thought it would be interesting to review the history of reservoir placement leading up to current surgical techniques.

Aim: To provide an overview of the past and present techniques for reservoir placement and discuss the evolutionary process leading to safe and effective placement of prosthetic reservoirs.

Methods: We reviewed data pertaining to inflatable penile prosthesis (IPP) reservoirs and pressure-regulating balloons (PRB) in a chronological fashion, spanning 25 years.

Main Outcome Measures: Main outcomes included a historical review of techniques for IPP reservoir and PRB placement leading to the subsequent incremental improvements in safety and efficacy when performing penile implants and artificial urinary sphincters.

Results: Prosthetic urologic reservoirs have traditionally been placed in the retropubic space. Over the years, urologists have attempted use of alternative spaces including peritoneal, epigastric, “ectopic,” posterior to transversalis, and high submuscular.

Conclusion: Current advances in prosthetic urologic reservoir placement allow safe and effective abdominal wall placement of reservoirs. These novel approaches appear to be so effective that urologists may now be able to cease using the traditional retropubic space for reservoir placement, even in the case of virgin pelves.

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Key Words: Penile Implant; Artificial Sphincter; Prosthetic Reservoir; Pressure Regulating Balloon

INTRODUCTION

Reservoir placement during implantation of prosthetic urology devices has always been problematic throughout the history of the surgical treatment of erectile dysfunction and urinary incontinence. In the United States, traditional insertion of the artificial urinary sphincter (AUS) and 3-piece inflatable penile prosthesis (IPP) has involved placement of a reservoir into the retropubic space. Unfortunately, this space has been shown to have close proximity to bowel, bladder, and vascular structures¹ and can be responsible for troublesome and rarely catastrophic complications.^{2–4} In April 2015, the United States Food and Drug Administration (FDA) approved placement of the Coloplast IPP reservoir (Coloplast, Humlebæk, Denmark) in a different location. We thought it would be interesting to review

the history of reservoir placement leading up to this surgical technique enhancement.

History

Throughout the 44 years of availability of these medical devices, physicians have experimented with placing the reservoir in locations other than the traditional space of Retzius. Twenty-five years ago, Professor Schreiter of Germany popularized placement of the IPP reservoir in the peritoneal cavity. The IPP in those years did not have a lockout valve and Schreiter's location avoided the annoying incidence of autoinflation that accompanied the placement of reservoirs in the traditional location. By placing the reservoir in this new location, he would avoid capsular formation around the reservoir. The peritoneal cavity was and still is the only location in the body where a foreign body does not stimulate capsule formation. Despite never publishing his data, Schreiter's technique was adopted by virtually all German implanters and used for years without significant autoinflation. Hundreds were implanted in what was history's first alternative location for reservoirs. Subsequently, Mulchahy, in the first effort to avoid surgically compromised pelvic anatomy

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common in candidates for IPP or AUS, described another extraperitoneal placement of the reservoir.⁵ In a severely scarred pelvis, the authors placed the reservoir in the epigastrium by making a separate subcostal incision and tunneling the tubing down to the pump through the abdominal wall. The alternative location successfully prevented possible vascular or viscus injury but never achieved widespread adoption, probably due to the complexity of another incision.

Device Enhancements

When Mentor Corporation introduced a reservoir in 1998 that had a valve in its neck that prevented abdominal pressure on the reservoir from causing cylinder inflation, the stage was set for placement of reservoirs in alternative locations. No longer was it necessary to have an actual space, such as the space of Retzius or intraperitoneal. The lockout valve demonstrated a significant reduction in autoinflation from 12% to negligible when the reservoir was placed in the traditional location in patients without compromised pelvic anatomy.⁶ The lockout valve allowed the reservoir to be placed in the abdominal wall even though it would be subjected to pressures from the musculature when the patient bent over or strained. In 2001, Wilson et al published the first description in patients with altered anatomy and coined the term “ectopic” to delineate the difference from the traditional location.⁷ Ectopic became a widely quoted industry term because of the fact that the FDA had, at that time, only approved placement of the reservoir in the retropubic space and considered ectopic placement “off label.”

Wilson’s description of the new ectopic method of reservoir placement introduced the reservoir by piercing the back wall of the inguinal canal with the finger and pushing the component into a space anterior to the transversalis fascia but underneath the muscles of the abdominal wall. The method never gained much traction with implanters because the resultant groin location of the reservoir tended to be palpable and occasionally herniated into the high scrotum.⁸ Wilson et al subsequently reported that the AUS pressure-regulating balloon could be placed in a similar “ectopic” position⁹ but was much less palpable due to its smaller size.¹⁰

To remedy the complaint from patients regarding palpable reservoirs after ectopic IPP placement, in 2010 AMS began to market a new flat reservoir shaped like a pancake. This reservoir was called Conceal and the patent for the component was filed by Wilson (Figure 1). The other manufacturer of IPPs, Coloplast (which had purchased the Mentor company in 2008), rapidly followed suit with a new reservoir that could mimic a flattened shape. The Cloverleaf reservoir has a bellows configuration that assumes a flat shape when only partially filled but assumes a cylindrical shape when filled to capacity (Figure 2).

Surgical Technique Enhancements

In 2011, in an attempt to preserve the advantages of ectopic placement while minimizing the palpability and hernia issues, the authors of this report introduced enhancements to the surgical

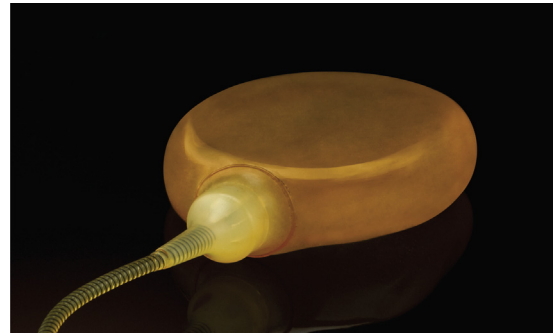


Figure 1. AMS Conceal Reservoir. Reprinted with permission from American Medical Systems, Inc (AMS). Figure 1 is available in color online at www.smr.jsexmed.org.

technique.¹¹ We believe these enhancements allow abdominal wall placement of reservoirs to be so effective that we now have largely ceased using the traditional retropubic space for reservoir placement even in patients with unspoiled pelvic anatomy. The surgical concepts are based on cephalad placement of the reservoir either posterior to transversalis fascia (PTF) or anterior to transversalis fascia (ATF) and can be used through either a penoscrotal or an infrapubic incision. With this approach, the initial steps of reservoir placement are identical for PTF and ATF. The bladder is emptied preoperatively by voiding or catheterization before implantation.

PTF Reservoir Insertion

For men with no prior history of significant pelvic surgery, a long (80-mm) nasal speculum is used to perforate the transversalis fascia in a downward fashion. The nasal speculum is immediately directed cephalad and advanced. The nasal speculum paddles are spread to dilate the space posterior to transversalis fascia but anterior to the peritoneum.

ATF Reservoir Insertion

In patients with a history of significant pelvic surgery, after the tip of the nasal speculum is passed to the external ring, it is forcibly advanced cephalad without perforating the transversalis fascia.

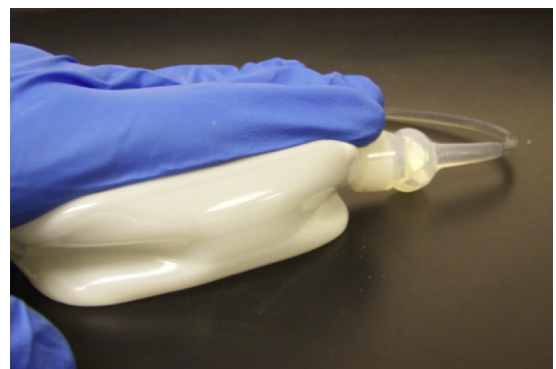


Figure 2. Coloplast Cloverleaf Reservoir with 50% fill. Reprinted with permission from Coloplast Corp. Figure 2 is available in color online at www.smr.jsexmed.org.

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