SUPPLEMENT ARTICLE

The Evolution of the Inflatable Penile Prosthesis Reservoir and Surgical Placement

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ABSTRACT

The traditional inflatable penile prosthesis (IPP) reservoir placement is below the transversalis fascia in the space of Retzius. In 2002, Dr. Steve Wilson described ectopic reservoir placement, thereby providing a safe and effective alternative for implant surgeons. This new approach obviated the need for a second incision and decreased operative times during surgery. In the manuscript, he also described the introduction of a reservoir lock-out valve, which prevents autoinflation of the penile implant. The development of lockout valves and flat reservoirs has contributed to the early success and feasibility of submuscular placement techniques. Thirteen years after Dr. Wilson's pivotal study, this technique should be in the armamentarium of all urologic prosthetic surgeons. Accordingly, in certain subsets of patients, ectopic/ submuscular reservoir site placement should be considered a safe, effective alternative to standard reservoir placement in the space of Retzius. **Hakky T, Lentz A, Sadeghi-Nejad H, Khera M. The evolution of the inflatable penile prosthesis reservoir and surgical placement. J Sex Med 2015;12(suppl 7):464–467.**

Key Words. Penile Prosthesis; Erectile Dysfunction; Penis; Impotence; Reservoir; Lock-Out Valve; Ectopic Placement

Introduction

In the 1970s, Scott et al. developed the first inflatable penile prosthesis (IPP) that ushered in a new era in the management of erectile dysfunction [1]. Since their inception, multiple innovations have been made to reduce device infection rates and to improve the function, reliability, and cosmesis of penile implants. Early IPP reservoir modifications that improved longevity included the developments of a seamless, spherical reservoir, kink resistant tubing, and elimination of the internal reinforcing rod or stem [2].

To date, there are two reservoirs available on the market. American Medical Systems (AMS, Minnetonka, MN, USA) has developed the Conceal™ (AMS) reservoir, which is used with the AMS inflatable implants. The Conceal has the capacity to hold up to 65–100 mL, depending upon surgeon preference. Coloplast utilizes a Cloverleaf™ (Coloplast, Minneapolis, MN, USA) reservoir system that comes in two sizes: 75 cc and 125 cc. Both Titan Cloverleaf reservoirs also employ a specially engineered lock-out valve at the neck of the reservoir designed to prevent auto-inflation [2,3].

Auto-Inflation

Despite high satisfaction rates for the majority of patients with IPPs, a small subset report dissatisfaction with outcomes due to mechanical malfunction. A variety of mechanical failures can occur, including auto-inflation of the IPP, which can be annoying, embarrassing, and uncomfortable. Currently, most experts in the field attribute auto-inflation to formation of a constrictive capsule surrounding the prosthesis reservoir balloon [4].

This issue commonly occurs in the early postoperative period, and it is caused by abdominal pressure forcing fluid from the reservoir into the cylinders [4]. While auto-inflation is generally a benign problem, it has been documented to cause

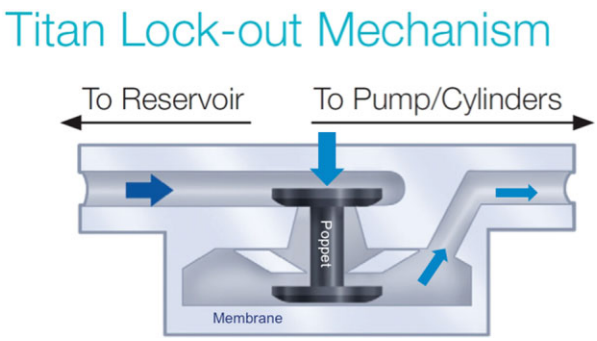

Figure 1 Lockout valve figure.
Pressure generated in the reservoir pushes the poppet down; thereby, "locking out" leakage that causes auto-inflation. During implant inflation a vacuum is created by the bulb squeeze, which pushes the membrane inward so that it pushes the poppet open, allowing fluid to flow from the reservoir to the cylinders. At rest, the membrane relaxes and the poppet returns to the closed state. The pump/cylinder set generates back-pressure that pushes the membrane away from the poppet protecting against accidental contact [7].

severe consequences such as cylinder erosion described by Kobayashi et al. where the right cylinder eroded through the corpora caused by chronic auto-inflation [5]. Wilson et al. recommend that a capsulotomy be performed in order to reposition the reservoir. Additionally, laparoscopic ablation of the capsule has also been described, albeit this is difficult in the more obese patient [4,6]. Current auto-inflation rates in the literature are 2–3% of patients receiving the AMS 700CX implant and to date the only reported Coloplast rate of auto-inflation is that by Wilson et al. at 1.3% [4,6]. The rate of autoinflation may increase with increasing placement of ectopic reservoirs in the subfascial space hence the creation of a lock-out valve has been quintessential in the surgeon's transition from the space of Retzius (SOR) to ectopic reservoir placement.

Lockout Valve

In 2000, Mentor Corporation (Santa Barbara, CA, USA), now Coloplast Corporation (Minneapolis, MN, USA) added an enhanced reservoir with a lock-out valve to their line of IPPs. The lock-out mechanism contains a "poppet" valve that does not allow fluid to exit when pressure is applied to the reservoir [4]. Specifically, the lock-out valve works by responding to fluid pressure changes in the tubing to the prosthesis and not to pressure from the reservoir. During cylinder deflation, the valve opens to positive pressure in the tubing. During cylinder inflation, when the collapsed bulb recovers, negative pressure opens the valve (Figure 1). Therefore, negative pressure must be created from the pump side to allow fluid to flow from the reservoir, and furthermore elevated reservoir pressure does not result in fluid flow into the cylinders. In contrast to Coloplast, AMS introduced the MS pump with a lock out valve in the pump itself in 2006.

Dr. Wilson et al. published their experience with the Mentor Alpha-1 penile prosthesis with reservoir lock-out valve in 2002 [4]. From January 1, 1998 until April 1, 2001, 499 patients received an Alpha-1 penile prosthesis. All implants were placed via a high scrotal incision by a single surgical team. The standard nonlock-out reservoir was used in 284 virgin implants and 55 revision replacement implants. The newer lock-out valve reservoir was used in 114 virgin implants and 46 revisions. Of note, eight patients underwent ectopic reservoir placement between the anterior abdominal wall musculature and the transversalis fascia due to the obliterated retropubic space. In the immediate postoperative period, each patient in the lock-out valve group was specifically asked about experience with auto-inflation and additionally the penis was examined for evidence of auto-inflation.

In the group with standard reservoir placement, early auto-inflation was recorded as a complaint in 37 patients (11%). In 20 cases the problem resolved and in 11 patients the problem persisted but was not considered bothersome enough to indicate additional surgery. Six patients (2%) elected capsulotomy to correct the problem. Of the eight lock-out valve implants placed ectopically, none of these patients reported auto-inflation despite the theoretical higher pressure exerted in the submuscular space. No revision surgeries were performed for mechanical failure, infection, or patient dissatisfaction [4].

Although the Mentor Alpha-1 lock-out valve is certainly an example of keen mechanical engineering, the most noteworthy contribution of this article is the utilization of an ectopically placed lock-out valve reservoir in a subset of patients with an obliterated retropubic space. This landmark article could not have been timelier as it was published on the precipice of the robotic surgery revolution in which the standard retropubic approach to radical prostatectomy has been nearly abandoned for the intraperitoneal robot-assisted laparoscopic prostatectomy.

Reservoir Placement Locations

Several different approaches for placement of the IPP have been reported, including penoscrotal,