

SEXUAL MEDICINE REVIEWS

Ambicor Two-Piece Inflatable Penile Prosthesis: Background and Contemporary Outcomes

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ABSTRACT

Introduction: The two-piece inflatable penile prosthesis (IPP; Ambicor) might be a preferred option for men with erectile dysfunction (ED) who have significant retroperitoneal scarring, limited manual dexterity, or other issues. There are reported differences in outcomes and patient and partner satisfaction between three-piece and two-piece IPPs.

Aim: To report contemporary outcomes, patient and partner satisfaction, and mechanical durability data of the two-piece compared with the three-piece IPP.

Methods: A PubMed search was performed related to two-piece penile prostheses. Emphasis was placed on perioperative outcomes and patient and/or partner satisfaction scores. Non-English-language articles were excluded.

Main Outcome Measures: Use of the Ambicor two-piece penile prosthesis was assessed by outlining the contemporary literature. The etiology of ED in this population, mechanical attributes, penile morphologic changes, satisfaction, and its use in special populations were reviewed.

Results: The most common etiology of ED for placement of the device remains a vasculogenic cause (range = 11–62%). Overall complication rates were 2.1% to 11.2% for the general population. Mechanical failure was seen in 0.7% to 6.1%. Infection rates were 0.7% to 4.8%. Spontaneous deflation was seen in approximately 25%. Higher complication rates were found in transgender patients after neophallus creation and the two-piece IPP could offer better durability compared with the three-piece IPP. Longer operative times, greater use of advanced dilation techniques, and greater length loss also have been reported. Overall satisfaction rates are higher than 85%.

Conclusion: The predominant etiology of ED for two-piece penile prosthesis placement is vasculogenic. There is a trend toward IPP insertion in patients after radical prostatectomy or who have spinal cord injury. The two-piece device has similar complication rates and high patient satisfaction scores compared with three-piece IPPs. Further larger prospective studies are needed to validate our findings, resolve discrepancies in published outcomes, and contribute to the sparse data on this subject. **Ko OS, Bennett NE. Ambicor Two-Piece Inflatable Penile Prosthesis: Background and Contemporary Outcomes. Sex Med Rev 2017;X:XXX–XXX.**

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Key Words: Two-Piece Penile Prosthesis; Ambicor; Penile Prosthesis; American Medical Systems; Erectile Dysfunction; Sexual Dysfunction; Post Prostatectomy Erectile Dysfunction

INTRODUCTION

Since the introduction of the modern penile prosthesis by Scott et al¹ in 1973, it has become the gold standard treatment option for refractory erectile dysfunction (ED).² The penile prosthesis is currently available in two different iterations:

inflatable and semirigid (malleable). The inflatable penile prosthesis (IPP) is marketed in three-piece and two-piece varieties. The three-piece device has corporal cylinders, a flow regulator or pump, and a reservoir, whereas the two-piece device has an incorporated reservoir at the proximal aspect of the cylinders. The semirigid (or malleable) penile prosthesis consists of two moldable cylindrical chambers. By far, the three-piece IPP remains the most popular prosthesis option, constituting more than 75% of currently placed IPPs.^{3–6}

Currently, the only available two-piece IPP in the United States is manufactured by the Men's Health Division of Boston Scientific, Inc (Watertown, MA, USA), formerly of American

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Medical Systems (AMS; Minnetonka, MN, USA). The device is marketed as Ambicor. The impetus behind the two-piece design was to make the device easier to use in certain populations such as those with limited manual dexterity from neurologic or other disease states. This population benefits from the easier device activation and deactivation. For the implant, the device has been reported to be an attractive option because of the lack of blind reservoir placement in patients with retropubic scarring from previous surgery. Some surgeons believe that blind reservoir placement in a patient with previous retropubic surgery can increase the chances of bladder and vascular injury. This concern is being mitigated by the popularization of ectopic reservoir placement.

Although there is evidence to suggest that blind retroperitoneal reservoir placement for the three-piece IPP is safe, some providers remain appropriately concerned about post-radical pelvic surgery status for three-piece IPP placement.^{4,7–9} Tran et al¹⁰ reported a case of a three-piece IPP reservoir that eroded into a Studer neobladder in a patient after radical cystoprostatectomy (RP). Moreover, some investigators have suggested that two-piece IPPs are appropriate for low-volume penile prosthesis implanters and their patients given the low complication and high patient satisfaction rates.^{11,12} Despite the overwhelming predominance of the three-piece IPP, two-piece IPPs remain an implantable option but, to our knowledge, there are no published reviews on two-piece IPP outcomes and satisfaction. Our goal is to provide a general background and a comprehensive literature review emphasizing overall complications, mechanical reliability, and patient (and partner) satisfaction for the two-piece IPP.

BACKGROUND OF THE TWO-PIECE IPP

Previously, Mentor (Irvine, CA, USA) and AMS manufactured the two-piece prostheses available in the United States. The Mentor GFS and Mark II were two-piece prostheses that were discontinued, presumably because of statistically higher complication rates and poor reliability compared with three-piece devices.¹³ The Mentor GFS device was introduced in 1988 (Figure 1) and consisted of two pieces with a scrotal component containing the reservoir and the pump. The subsequent rendition of this device became the Mark II, with the major difference being the lack of tubing connectors.¹⁴ AMS introduced the Ambicor in 1994 as a successor to their one-piece self-contained IPP Dynaflex. The Dynaflex was an inflatable one-piece device designed in 1990 that incorporated an internalized fluid resistor mechanism, which allowed for device deflation with bending of the device¹⁵ (Figure 2). The AMS Corporation strategically decided to introduce the Ambicor to compete with the Uniplate (a two-piece prosthesis marketed by Surgitek [Racine, WI, USA] in 1984) and the Mark II.¹⁶

As mentioned earlier, the Ambicor is currently the only two-piece prosthesis available in the United States. Structurally, it contains two paired cylinders made of silicone elastomer with

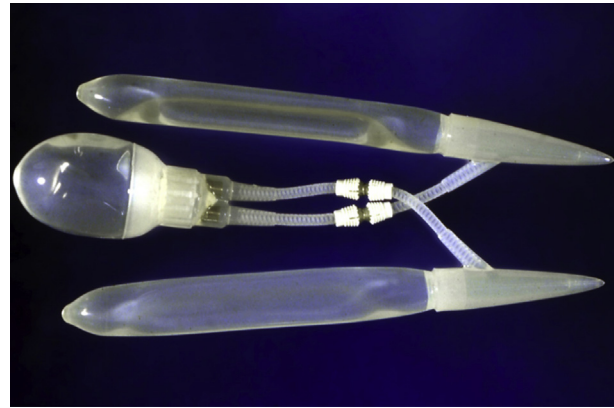


Figure 1. Mentor GFS penile prosthesis.

integrated proximal fluid reservoirs. There is a pre-connected, low-profile pump that is inserted in a scrotal Dartos pouch.¹⁷ The device is available in diameters of 12.5, 14, and 15.5 mm and lengths of 14 to 22 cm¹⁸ (Figures 3 and 4).

The proximal reservoirs and available rear-tip extenders (available from 0.5 to 3 cm), if needed, are placed in each proximal corpora and crus. Activation of the bulb results in fluid movement (3 mL) from the proximal reservoirs into each corporal cylinder.¹⁸ Deflation of the device involves deflecting the cylinders superiorly or inferiorly for several seconds, causing a pressure-time valve to open, resulting in return of fluid from the cylinders into the proximal reservoirs.¹⁶

The device underwent reconfiguration in 1998 because of early issues with mechanical failure as a result of the initial snap-on cone design of the rear-tip extenders. This design led to fracture of the proximal end of the prosthesis. There also was unassociated leaking of the tubing at the insertion site on the pump in the early implant.¹¹ The reconfigured implant contained modifications to the rear-tip extenders that consisted of stacking sleeves rather than the initial cone design and alterations to the tubing-bulb intersection to decrease fluid leak. Lux et al¹² reported on two-piece IPP outcomes after the 1998

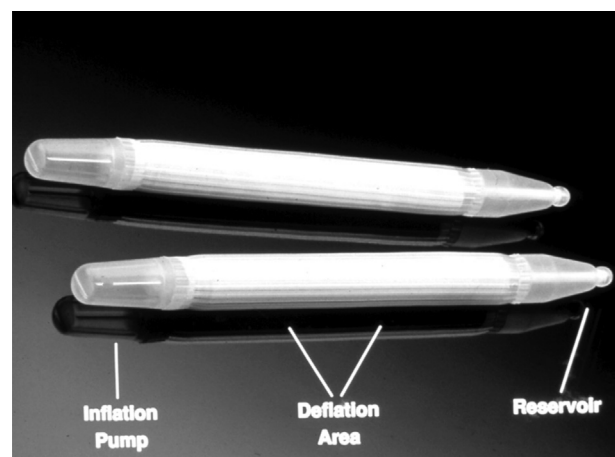


Figure 2. Dynaflex penile prosthesis.

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