

SUPPLEMENT ARTICLE

Technological Improvements in Three-Piece Inflatable Penile Prosthesis Design over the Past 40 Years

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ABSTRACT

Introduction. The advent of the penile prosthesis revolutionized the treatment of erectile dysfunction (ED), resulting in near-complete treatment efficacy and high patient satisfaction rates. While several types of penile prosthesis are available, the inflatable penile prosthesis (IPP) is the most commonly used device in the United States.

Aims. To describe the key modifications to IPPs from the two major manufacturers—American Medical Systems (AMS) and Coloplast—since the invention of the IPP, and to relate these changes to improvements in prosthesis function and patient outcomes based on available literature.

Methods. Review and evaluation of the literature between 1973 and present describing modifications in IPP design and the influence of these modifications on IPP durability and patient-related factors.

Main Outcome Measures. Data describing the impact of iterative improvements in three-piece IPP design on device function, durability, and patient outcomes.

Results. There were progressive improvements in IPP technology from both major manufacturers not only on the durability of the prosthesis but also on patient outcomes, with fewer device failures and lower infection rates. Notable improvements include incorporation of kink-resistant tubing, changes in the weave or addition of shear- and infection-resistant coatings to cylinder layers, pump and tubing connection modifications, the addition of rear tip extenders, and the incorporation of lockout valves to prevent autoinflation.

Conclusions. Numerous incremental modifications to the IPP from both major manufacturers since its invention have increased its durability and improved patient outcomes. **Pastuszak AW, Lentz AC, Farooq A, Jones L, and Bella AJ. Technological improvements in three-piece inflatable penile prosthesis design over the past 40 years. J Sex Med 2015;12(suppl 7):415–421.**

Key Words. Inflatable Penile Prosthesis; Kink-Resistant Tubing; Parylene Coating; Antibiotic Coating; Rear Tip Extender; Lockout Valve

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Introduction

Over 18 million men in the United States alone are affected by Erectile dysfunction (ED) [1,2]. A multitude of treatments for ED has emerged over the past several centuries, dating back to the eighth century BC, at which time

prayer, herbs, aphrodisiacs, and spirituality were the de facto treatment approaches [3]. During the 1930s, the first attempts at physical correction of ED were described, with Bogoras reconstructing an amputated penis using an abdominal tube pedicle graft with a section of rib cartilage to provide rigidity [4]. This approach ultimately failed due to reabsorption of the cartilage, and other attempts at autologous implantation were complicated by high rates of extrusion, erosion, or curvature. Similarly, implantation of foreign materials peri- or intercavernosally also resulted in high rates of device extrusion or erosion, and this persisted until materials were placed intracavernosally, an approach pioneered by Beheri in 1966 resulting in a more natural appearance [5,6]. Initial devices that were placed intracavernosally continued to have concealment issues and high rates of mechanical failure, and it was not until the inflatable penile prosthesis (IPP) was introduced in 1973 by F. Brantley Scott that complication and failure rates began to drop [7]. In 1975, the Small-Carrion semi-rigid malleable penile prosthesis was introduced, a version of which is produced by several manufacturers, and which continues to be the most popular penile prosthesis placed outside of the United States [8]. The current review, however, will focus on the iterative improvements specifically in the IPP.

Today, IPPs are produced and marketed by only two major manufacturers—American Medical Systems (AMS) (Minnetonka, MN, USA) and Coloplast (formerly Mentor) (Minneapolis, MN, USA)—with competition between the companies likely driving at least some of the modifications to confer an advantage in the market. Semirigid prostheses are available from several other manufacturers in addition to AMS and Coloplast, but since 1990, the majority of penile prostheses placed in the United States has been IPPs, with patient satisfaction rates in excess of 90% [5,9]. Despite high satisfaction rates for most patients with IPPs, a minority reports dissatisfaction with outcomes due to mechanical failure. Early IPP models had leakage rates as high as 70% [10–12]. Fortunately for patients and surgeons, the last four decades have ushered in advances in technology that have made the IPP one of the most reliable devices in prosthetic surgery. Here, we describe the iterative modifications in IPPs from both AMS and Coloplast, focusing on three-piece inflatable models and describing the impact of these modifications on mechanical failure rates and patient outcomes.

Aims

The aims of this study are to describe the key modifications to IPPs from the two major manufacturers—AMS and Coloplast—since the invention of the IPP, and to relate these changes to improvements in prosthesis function and patient outcomes based on available literature.

Methods

Review of relevant publications between 1973 through the present day describing modifications in IPP design and the influence of these modifications on IPP durability and patient-related factors was performed. Thirty-seven peer-reviewed publications were identified, reviewed, and compared where appropriate.

Main Outcome Measures

Data describing the impact of iterative improvements in three-piece IPP design on device function, durability, and patient outcomes.

Results

The Original IPP and Its First Modifications

The first three-piece IPP consisted of two nondistensible single-layer Dacron-reinforced silicone cylinders with both a pump for inflation as well as another for deflation. Produced and marketed by AMS, this original implant was used only between 1973 and 1974 before being modified, as it was prone to cylinder aneurysms and leakage (Figure 1) [13,14]. The first set of modifications included a single inflation/deflation mechanism; a round, flat reservoir, albeit with seams prone to rupture; and expandable cylinders. Later, more minor modifications included a seamless, spherical reservoir and the addition of rear tip extenders (RTEs) to facilitate more accurate implant sizing intraoperatively, with these implants being utilized through 1983 [5]. These first IPPs were prone to failure, with revision or complication rates of approximately 60% 3–11 years after insertion [10].

Cylinders and Tubing: Essential, Iterative Improvement of the IPP

In 1983, AMS introduced its 700 model IPP with polytetrafluoroethylene (PTFE) sleeves intended to reduce wear between silicone parts. Also added were connectors that did not require suture ligation, thicker cylinders, and new front and rear tip

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