



Is there still a place for malleable penile implants in the United States? Wilson's Workshop #18

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Abstract

The use of semirigid rod penile prosthesis for the management of erectile dysfunction was first described over 85 years ago. Since then, there have been numerous design advancements leading to improved overall durability, concealability, rigidity, and natural feel. However, the inflatable penile prosthesis (IPP) still has a higher patient satisfaction rate and is currently the most commonly inserted prostheses in the United States. There are still certain situations and conditions where the simplicity of a rod may be preferred over an IPP. A pair of semirigid rods has been shown to have less risk of malfunction and need for revision surgery. In addition, patients with poor manual dexterity, those undergoing a salvage for infection prosthesis and those with a prolonged (> 48 h) priapic episode may be better served with a rod than an IPP. Finally, in patients compromised by infection or priapism, the rods can later successfully be exchanged for an IPP with potentially longer, wider cylinders with resultant greater patient satisfaction.

Introduction

Erectile dysfunction (ED) affects 40% of men over the age of 40, with the prevalence of ED increasing with age [1]. Unlike many countries in the world, in the United States (US) government insurance (Medicare) and many private insurers cover the cost of both the inflatable and rod penile prostheses for the treatment of refractory ED. When compared side to side, the IPP boasts higher patient and partner satisfaction rates [2]. Not surprisingly, 90% of penile prosthesis implanted in the US today are of the IPP variety. This observation calls into question whether or not the rod penile prosthesis have a place in modern clinical practice. In the following work, we will review the history of the semirigid rod and highlight the special situations where it outshines its inflatable counterpart

Historical aspects of semirigid penile implants

In 1936, Bogoras first described the use of rib cartilage for penile reconstruction in war victims whose penises had been amputated during battle [3]. This was described as an “Os Penis” and the rib was placed outside the corpora cavernosum. This technique went through several modifications and was later abandoned due to increased complications including infection, erosion and penile deformity.

Over the course of the next several decades, many other types of material were used to develop the rods. An early prototype made out of acrylic was described by Goodwin and Scott in 1952 [4]. In 1966, Beheri utilized polyethylene and was the first published report to place the device in an intra-corporal location [5]. With the invention of the Small-Carrion silicone prosthesis, semirigid prostheses for erectile dysfunction became a mainstream therapy. The maturation of the devices took three different pathways: soft silicone rods, mechanical semirigid rods and malleable penile prostheses (MPP). Fifty years later, the rods with malleable wire insert (MPP) seems to have become dominant in the marketplace. The history of how this happened is fascinating.

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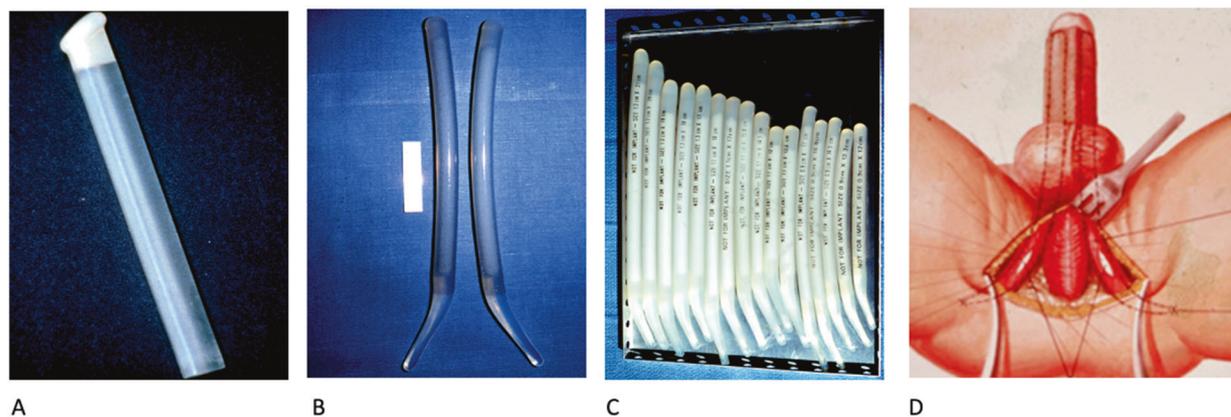


Fig. 1 Silicone semirigid penile prostheses. **a** Pearlman prosthesis. **b** Small-Carrion prosthesis. **c** Sizers for Small-Carrion. **d** Perineal placement of rods.



Fig. 2 Vintage silicone rod prostheses. **a** Finney Flexirod prosthesis. **b** Gerow penile prosthesis removed surgically. **c** Old photo from journal showing (a) Pearlman, (b) Small-Carrion, (c) Subrini.

Soft semirigid rod penile implants

Pearman in 1967 was the first to use medical grade silicone in the penis as an erectile device [6]. He initially placed the single cylinder outside the corpora cavernosa, but later realized that the results were better when the device was placed intracorporeally (Fig. 1a). In the early 1970's Drs. Michael Small and Hernan Carrion introduced the Small-Carrion prosthesis composed of a silicone exterior filled with a viscous silicone gel for malleability [7] (Fig. 1b). The prosthesis came with a sizer set containing all the available sizes and the surgeon placed the sizers to see which fit best before the definitive cylinders were implanted. The components of the kit were washed, sterilized in an autoclave and used on the next case (Fig. 1c). The Small-Carrion was placed through a perineal incision (Fig. 1d).

Dr. Roy Finney pioneered the Flexirod® in the late 1970s. This prosthesis consisted of paired silicone cylinders with the distal part firm, the middle part relatively soft for bending and the proximal part a series of segments which could be trimmed to fit appropriately into the erectile bodies (Fig. 2a) [8]. In the early 1980's Dr. Frank Gerow, a plastic

surgeon practicing in Houston Texas, became interested in restoring erections. He was a patient of Dr. Brantley Scott, the originator of the 3-piece inflatable penile implant. Gerow was one of the pioneers of the silicone breast implant in the 1960's. He convinced the leading breast implant manufacturer at the time, Dow Corning, to fabricate horseshoe-shaped silicone prototypes on his behalf. He then inserted these strangely shaped devices into both corporal bodies through a lateral corporal incision, obliterating the intercavernosal septum resulting in the ventral surface of the implant straddling that structure. There were no publications of outcomes of the Gerow implant and it is unknown how many were actually implanted. Nevertheless, JJM has photos of two of the devices (Fig. 2b) removed in Houston 30 years later.

The soft silicone semirigid implant provided an erection which tended to buckle and penises containing them were difficult to conceal in public. As mechanical and malleable semirigid rod implants became more popular in the US, the soft silicone devices virtually disappeared from the American market-place by the early 1990's. In Italy and France, however, urologists have continued to implant soft silicone rods consisting of a pair of inexpensive, thin, silicone rods

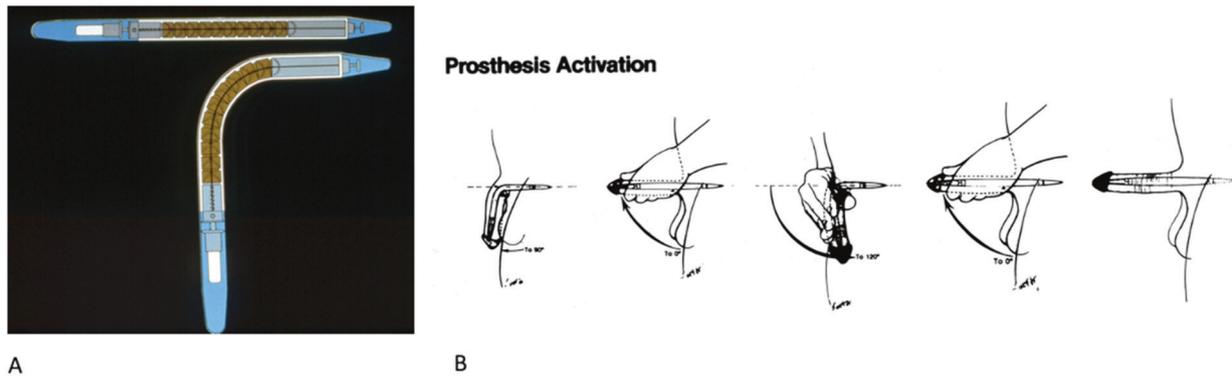
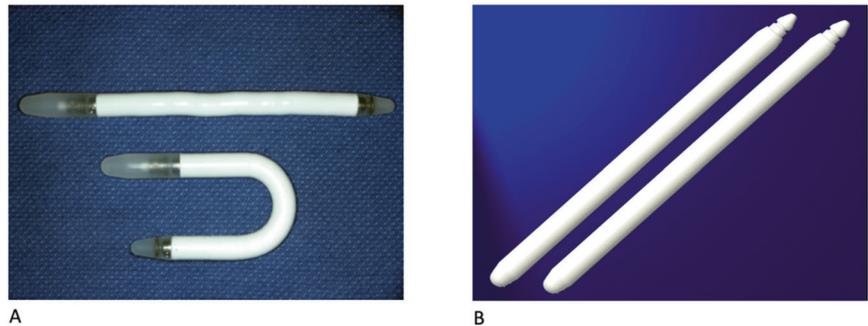


Fig. 3 Semirigid mechanical prosthesis. a Omniphase/Duraphase. **b** Switching erection on and off of Omniphase prosthesis.

Fig. 4 AMS purchase of Dacomed produces spectra. a Dacomed Dura II®. **b** AMS Spectra®.



known as the Subrini Virilis® prosthesis (Fig. 2c) in younger patients with mild to moderate impotence and venous leakage [9]. These devices are not hard but flexible and capable of being elongated without traction. Their flexibility allows the penis to hang when the patient is standing, particularly if enhanced by suspensory ligament release. These men can develop some tumescence but not enough rigidity for dependable penetration. The soft implant gives them the stiffness necessary for sexual intercourse.

Mechanical semirigid rod penile implants

In the early 1980's Dr. Gerald Timm, the engineer behind the original 3-piece inflatable implant, founded Dacomed Corporation and introduced the Omniphase® penile implant [10]. This novel device consisted of 2 cylinders containing a series of polysulfone segments which articulated in a ball and socket fashion held together by a central cable attached to a switch (Fig. 3a). Switching once, ventrally toward the scrotum from a horizontal position (Fig. 3b), caused the cable to shorten, bringing the segments together giving rigidity. Switching again in a similar fashion allowed the cable to relax, rendering the device flail. Proximal and distal tips were added to the body of segments to adjust size within the corporal bodies, so that the articulating segments were positioned at the penoscrotal junction for maximal

bendability. When the consignment inventory arrived at one's Operating Room, over 100 boxes were necessary to contain all the variables.

Ultimately, it was not the complexity of parts or overwhelming number of trays that caused the Omniphase® to fall out of favor but rather the difficulty with positioning the switch and one cylinder becoming out of phase with the other cylinder. It was soon succeeded by the Duraphase® implant which had the same polysulfone segments and distal and proximal tips, but no switch mechanism for alternating between rigid and flail. This implant became popular due to giving equal or better support to the erection compared to other available semirigid rod devices but also very easy bendability. Dr. Douglas Trapp, a private practice implanter became Dacomed's medical director and traveled the country teaching subcoronal insertion. This was necessary because the device required an extensive corporotomy when implanted via the traditional penoscrotal incision for implantation of semirigid rods.

Unfortunately, over time the polysulfone segments tended to wear, rendering the device flaccid and the cable holding the segments together fractured on occasion. Dacomed enhanced the device by replacing the segments with ones composed of high molecular weight polyethylene and the cable with smaller and more numerous strands. This new device was introduced as the Dura II® (Fig. 4a) and proved to be more mechanically reliable than the Duraphase

Fig. 5 Jonas malleable prosthesis. a Jonas prosthesis with measuring rod. **b** Wire fracture in Jonas Implant.

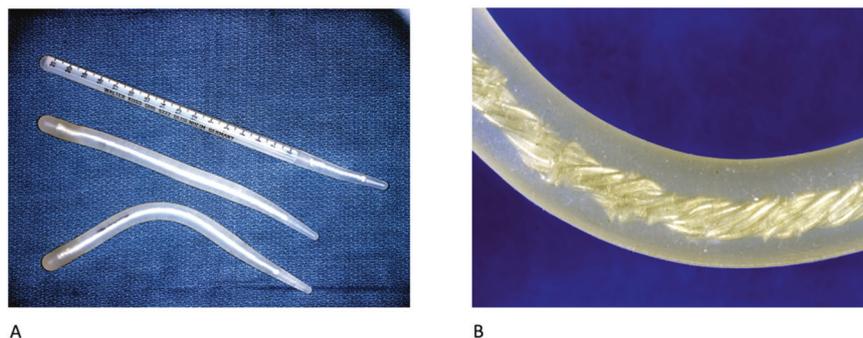


Fig. 6 Previous generation of malleables in US. a AMS 600/650. **b** Mentor Accuform®.

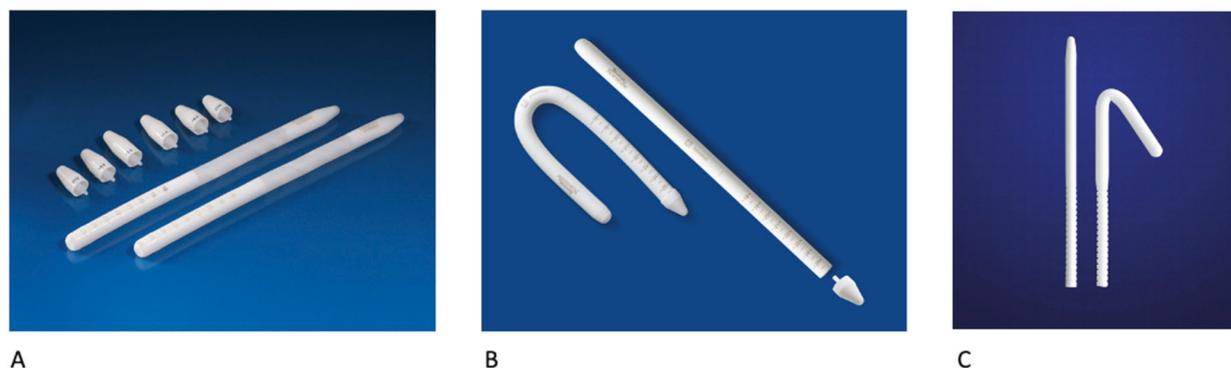
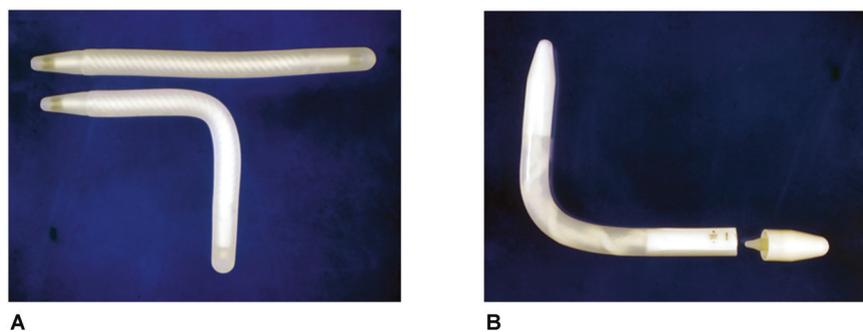


Fig. 7 Semirigid rod implants available in US today. a Coloplast Genesis®. **b** Boston Scientific Tactra®. **c** Rigicon Rigi10®.

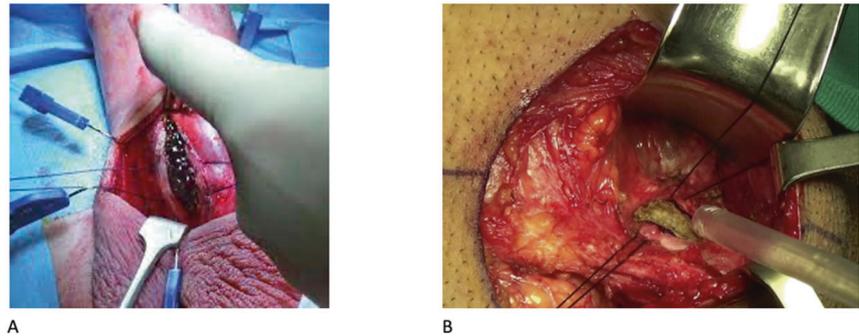
[11]. American Medical Systems (AMS) eventually purchased this device around 2000, enhanced the implant and decreased the number of boxes. It was marketed as the Spectra® (Fig. 4b). Wilson filmed the first video featuring subcoronal implantation of Spectra in 2001. After purchasing this mechanical technology, AMS discontinued manufacture of the malleable AMS 650 implant (see below).

Malleable semirigid rod implants (MPP)

The first non-hydraulic silicone penile implant with a metal malleable core was pioneered by Dr. Udo Jonas, a German

Urologist, manufactured by Walter Koss, and introduced to the American marketplace in 1980 [12]. The metal component of the Jonas implant was braided silver strands, and it could be bent into position with minimal spring back (Fig. 5a). The strands however tended to fracture, rendering the device flail (Fig. 5b). In the US, the Jonas prosthesis was soon replaced in popularity by the AMS 600: paired silicone cylinders with a braided stainless-steel core (Fig. 6a). An outer jacket could be stripped from the 13 mm girth cylinder leaving it with 11 mm diameter. Rear tip extenders could be added to adjust the cylinder length. The AMS 650 which was more easily bendable than the AMS 600, soon replaced it.

Fig. 8 Corpora cavernosa after priapism. **a** Acute implantation: corpora filled with old blood. **b** Elayed implant: corporal fibrosis.



Mentor Corporation (now Coloplast) followed the AMS malleables with the introduction of the Accuform implant: paired silicone cylinders with individually wrapped silver strands as the core (Fig. 6b). The proximal end could be trimmed, and end caps added for the appropriate length. In 2003 Mentor added a hydrophilic coating to its malleable rods and renamed the implant the Genesis® (Fig. 7a).

For most of the first two decades of the 21st century, the Spectra® (Fig. 4b) and the Genesis® (Fig. 7a) were the only two semirigid rods available in the US. The Spectra® was considerably more expensive to manufacture and Boston Scientific Corporation, the successor to AMS, replaced it in 2019 with the Tactra® (Fig. 7b). These silicone cylinders have a core of Nitinol, a nickel titanium alloy, with properties of considerable rigidity and bendability. Boston Scientific did not coat the new prosthesis with InhibiZone®, the antibiotic coating of its 3-piece inflatable implant, despite strong support from the prosthetic urology literature demonstrating the effectiveness of this coating in reducing penile implant infections >50% [13]. The Genesis® and Tactra® implants both have trimmable proximal segments to which end caps can be added, and both are supplied in identical length and girth sizes. Another MPP just newly introduced in the US market by Rigicon is the Rigi10® (Fig. 7c). This MPP comes in 5 diameters (9mm–13mm) and two different and trimmable lengths (23 cm and 25 cm). This MPP does not have a hydrophilic or antibiotic coating.

MPP in the setting of priapism

The incidence of priapism in the US is 1.5 per 100,000 person-years [12]. There has been growing numbers of penile prosthesis placement for the treatment of ED due to refractory ischemic priapism (RIP). One of the main advantages of placing a penile prosthesis in patients with RIP is cost savings. The estimated cost of treating priapism in the US is \$41,909 per admission with an overall annual cost of almost \$124 million [14]. Tausch et al. reported their 6-year experience with the acute insertion of a MPP in patients with RIP [15]. The average preoperative duration of

RIP was 82 h and the average estimated cost of RIP was \$83,818, which included 4 ER visits [range 1–27], 2 hospital admissions [range 1–5], 1.5 shunt procedures [range 1–3], 5 irrigation and drainage procedures using phenylephrine injection [range 2–20], and 5 hospital admission days [range 2–14]. In this study, their cost of the acutely placed MPP only added \$3850 and if it had been done sooner in the patient's clinical course cost savings would have been significant as the patient became pain free and was discharged in 24 h.

There has been debate not only on the timing of surgery (acute vs delayed) but also on the type of prosthesis used (MPP vs IPP) in patients presenting with RIP. Insertion of MPP acutely is easier surgery than delayed when the corpora have become fibrotic and the lumen is obliterated (Fig. 8a, b). Ralph et al. identified 43 patients undergoing the implantation of a MMP and 7 patients undergoing the implantation of an IPP for RIP [16]. At 15.7 months follow-up, 6% of patients had an infection, 12% of patients required revision surgery and 84% had resumed intercourse with an overall satisfaction rate of 96%. The argument for using a MPP shortly after a RIP event is the potential decreased risk of infection, preservation of penile length without placing responsibility for the patient to cycle the device, and the ability to easily exchange the MPP for an IPP at a later time [17]. The argument for placing an IPP at the time of RIP is that there is greater patient satisfaction with an IPP and the ability to avoid the risks and costs associated with additional implant procedures [18].

Zacharakis et al. in 2015 assessed whether a delayed exchange to an inflatable implant allows upsizing of the cylinders in patients who had undergone early MMP insertion for RIP [19]. Over a 30-month period, 10 patients with ischemic priapism underwent an early insertion of a MPP. After a median of 130.5 days, all of these patients underwent exchange of the MPP to an IPP. At the time of penile implant exchange, there was a median upsize in the length of the cylinders of 1 cm in either one or both corporal bodies (range 0–3 cm). These authors concluded that insertion of a MPP is an acceptable option for patients with RIP. In addition, even though some patients deliberately

had a shorter implant inserted initially for reasons of a previous distal shunt procedure, the cylinders were successfully upsized following a period of resolution.

MPP in the setting of salvage procedure

In 1996, our author, JJ Mulcahy, first introduced the immediate salvage procedure for a penile prosthesis infection. He removed the infected prosthesis, extensively washed out the implant spaces and inserted a new, sterile IPP. This resulted in reducing corporal fibrosis and resultant penile shrinkage [20]. Dr. Mulcahy's seminal paper described the removal of all of the prosthesis components followed by a 7 step irrigation with antiseptic solutions. His initial study reported 91% of men (10 out of 11 patients) remained infection-free over 21 months. His follow-up study found that 82% of men (45 out of 55 patients) remained infection-free at 35 months follow-up [21].

More recently there has been interest in using a MPP at the time of salvage procedure to diminish the risk of recurrent infection and other potential complications while still preserving penile length. Several surgeons at tertiary referral centers today have now begun using MPP during salvage procedures. These surgeons believe that this could be a safer transition to eventually receiving an IPP. One of the benefits of using a MPP during a salvage procedure is a shorter operative time and less components inserted and therefore possibly a decrease the reinfection rate [22]. Regardless of whether the reinfection rate is reduced, a strong advantage is the MPP nicely maintains the corporal space and decreases the risk of subsequent corporal fibrosis and penile loss of length.

Several studies have assessed the use of a MPP in the setting of a salvage procedure. Placement of an MPP during a salvage procedure is especially useful in the setting of scrotal fixation or suspected scrotal infection. Placement of a MPP avoids placing a pump in the previously infected scrotal space and potentially decreases the risk of extrusion in the setting of an already attenuated scrotal skin. Kohler et al. retrospectively reviewed 6 men who underwent IPP removal for pump erosion or infection and salvage placement of a MPP [23]. After a 2 year follow-up, all patients remained infection free. One patient developed an impending erosion of a malleable rod and underwent an elective removal of the MPP. The authors concluded that placement of a MPP in the setting of scrotal infection or erosion is a favorable surgical option.

A study by Gross et al. assessed the removal of an infected IPP and placement of a MPP in 58 men [24]. All men underwent the Mulcahy irrigation protocol and the mean follow-up was 8.4 months after the salvage procedure. These authors found that 93% of patients remained infection-free at follow-up. The authors concluded that a salvage procedure

with a MPP was safe and offered a lower infection rate than replacement of an IPP (7% vs 18%, respectively). While the MPP initially served as a bridge for patients until they eventually went on to receive an IPP, there were patients in this series who elected to keep their MPP. Gross et al. reported that 69% of infection-free patients still had their MPP at their most recent follow-up at 8.4 months [24]. This study suggests that some patients may not elect to exchange their MPP for an IPP possibly due to fear of a recurrent infection, concern for future prosthetic malfunction, need for revision surgery or satisfaction with their MPP.

It should be noted that all of the studies quoted this section on MPP in the setting of salvage surgery for infection prefer the Coloplast Genesis® MPP over competitive malleables because of its infection retardant overlay. The hydrophilic coating gives the treating physician the ability to tailor the antibiotics in the saline solution used to activate the coating to cultures obtained from the infected patient's implant spaces.

The use of a MPP in select population of patients

Peyronie's disease

MPP have been successfully used in men with a history of Peyronie's disease (PD). Habous et al. from Saudi Arabia evaluated patient satisfaction and effectiveness of the MPP vs. IPP in patients with PD [25]. In this study, 166 men with ED and PD were evaluated for 24 months after the insertion of a MPP or IPP. These authors found that 94% and 83.3% of patients had total resolution of their curvature at the end of the operation with a MPP or IPP, respectively. In addition, there was no difference in mean satisfaction scores between the two groups. In another study by Ghanem et al. from the US, the authors assessed patient satisfaction and efficacy of a MPP placement in men with PD [26]. Twenty men with PD underwent placement of a MPP, and 65% of the patients reported complete straightening of the penile shaft. They also reported that 87% of the patients were satisfied with the MPP.

Although many studies have reported increased patient satisfaction with a MPP for PD, there have also been reports of partner dissatisfaction with a MPP for PD. Montorsi et al. assessed outcomes of 50 men with PD and ED who were treated with a MPP [27]. Forty-eight patients and 29 partners were reassessed at a follow-up for at least 60 months. These authors found that only 48% of patients and 40% of partners were totally satisfied with the long-term functional results of the MPP. The most common reasons for dissatisfaction with the MPP were decreased penile sensitivity, poor concealability, and loss of natural tumescence.

Spinal cord injury

Many spinal cord injured (SCI) patients, particularly with impaired manual dexterity, prefer a MMP over an IPP. SCI patients find it easier to perform clean intermittent catheterization or wear a condom catheter with a MMP in place. However, there is concern of the possible increased risk of erosion with a MMP in SCI patients. SCI patients with absent penile sensation are less likely to identify early signs of cylinder erosion. A study by Kim et al. assessed 48 SCI men with malleable prostheses over 11.7 years [28]. The overall complication rate was 16.7% which included 8.3% device infection and 4.2% erosion. The overall satisfaction rate of the MMP in this study was 79%.

In another study by Zermann et al. from a German Rehabilitation hospital, 245 patients with brain injury or SCI were assessed over a 16-year period [29]. There were 147 patients that had a MMP and 33 that had an IPP. At a mean follow-up of 7.2 years, 83% of men were able to resume sexual intercourse. Cylinder perforations occurred in 18% of MMP versus 0% of IPP patients. After the findings from this Spinal Cord Injury Center, physicians treating SCI tended to use IPPs more often, instructing their patients to inflate to create just enough tumescence to fill the condom and only inflate fully for sexual purposes.

Other considerations: malfunction, erosion and need for revision surgery

Some of the benefits of a MMP is the decreased risk of malfunction, erosion and need for subsequent revision surgery. Lacy et al. conducted a retrospective review from 2000 to 2013 of 6586 patients who underwent penile prosthesis placement within the Veterans Affairs (VA) system [30]. All patient had at least one-year follow-up. Over the course of 13 years, there were 5703 (86.6%) IPP and 883 (13.4%) MMP placed. The MMP had higher 1-, 5-, and 10-year rates of freedom from revision compared with IPP ($P < 0.001$). The reoperation rate for a MMP was 13 and 17% at 5 and 10 years, respectively. Over the same period of time, the reoperation rate for an IPP was 16 and 26% at 5 and 10 years, respectively. In another study by Minervini et al., out of 393 MMP cases, there was a 0.5% malfunction rate [31]. An additional series reported a 100% malfunction free survival over 5.7 to 11.7 years in 133 patients. Thus, patients who are concerned about decreasing their risk for revision surgery may be better candidates for a MMP [11, 28].

The rate of erosion with IPP and MMP has also been studied. The AUA ED Guidelines reviewed the rate of erosion for MMP and IPP in 7 and 20 studies, respectively [2]. The rate of erosion for IPP was on average 2.5% (range 0–6.5%) and for a MMP was on average 4.1% (range

0–17.5%). With chronic compression on the corpora cavernosum and the urethra, it is not surprising that the MMP is more likely to have an erosion. Slightly downsizing the malleable cylinders during implantation can help mitigate the risk of erosion.

In the US, third party coverage rarely distinguishes between reimbursing malleables preferentially over the more expensive IPP despite a difference in cost of 3 times (\$4000 vs \$12000). That is certainly an explanation for the disproportionate selection of the more complex and more often revised IPP over malleable semirigid rods. In other countries malleables are fully reimbursed while IPP's require additional out of pocket expense from the patient. In these countries, malleables are more often inserted into a cost-conscious population.

Satisfaction with MMP

Although patient satisfaction rates are higher with the IPP, the satisfaction rates with the MMP can be considered quite good. A review of IPP and MMP satisfaction rates found that the mean satisfaction rates with an IPP and a MMP were 86.2% (range 85.8–88.3%) and 75.1% (range 66.1–88.7%), respectively [31]. Is one model of MMP more satisfying? Casabe et al. compared satisfaction rates in men following placement of a Spectra ($n = 36$) and a Genesis® ($n = 24$) using the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaire adapted for penile implants [32]. Mean EDITS scores did not indicate superiority of one MMP over the other. Mean overall satisfaction scores for the Genesis® and the Spectra® were 77.1% and 75.6%, respectively. The Tactra® and Rigi10® prostheses are too new to have satisfaction assessments.

Conclusion

With the high satisfaction rate and prompt reimbursement from medical insurance coverage, it is not surprising that the more expensive IPP is overwhelmingly the most commonly inserted prostheses in the US. However, MMP has been shown to have less risk of malfunction and reduced need for revision surgery. We believe a certain population of patients are better served with the simplicity of a MMP as opposed to an IPP. These patients include those with poor manual dexterity, those undergoing a salvage penile prosthesis procedure, and those with a prolonged (> 48 h) priapic episode. In patients compromised by infection or priapism, the MMP can later successfully be exchanged for an IPP with potentially longer, wider cylinders and greater patient satisfaction. As long there exists clinical rationale for improved patient outcome and continued patient

interest, the semirigid prosthesis will remain a staple in the prosthetic urologist's arsenal.

Compliance with ethical standards

Conflict of interest MK: Consultant Boston Scientific. JM: Consultant Boston Scientific, Coloplast. LW: none. SW: Consultant Coloplast, International Medical Devices. Lecturer Boston Scientific Stockholder NeoTract

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