Current role of penile implants for erectile dysfunction

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Purpose of review

The purpose of this review is to appraise new developments and publications in the field of penile prosthetic surgery. Urologists dealing with erectile dysfunction need to recognize the value of penile prosthetic surgery as a very efficacious treatment for this common condition. This type of surgery is needed in a considerable proportion of patients with erectile dysfunction so this review is timely and relevant.

Recent findings

The main themes in the literature covered include risk factors for infection of penile prostheses, its prevention with the use of hydrophilic and antibiotic-coated prostheses, particularly in re-operations, and its management with the new rescue procedures. Surgical tips for prosthetic surgery are also reviewed as well as clinical outcomes and factors influencing them.

Summary

Of all the invasive treatments currently available, placement of a penile prosthesis is one of the most successful, giving high levels of satisfaction. With the aid of new technical advances, the risk of infection – the most feared complication – can be minimized so prosthetic surgery may play a major role in the treatment of erectile dysfunction.

Keywords

erectile dysfunction, penile prosthesis, infection of penile implants

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Introduction

Currently, penile implants play a secondary, but well defined, role in the treatment of organic irreversible erectile dysfunction. When pharmacological therapy, oral or locally administered, is ineffective or contraindicated, and when vacuum devices are unsatisfactory or unacceptable, implants have offered patients with erectile dysfunction a very predictable and reliable way of restoring sexual function [1]. At least 25–30% of patients with erectile dysfunction do not respond to oral pharmacotherapy, particularly to phosphodiesterase type 5 inhibitors; roughly 10–15% of patients not responding to oral drugs will be treated with intracavernosal pharmacotherapy, a modality with a high dropout rate. Thus, in the best scenario, around 15% of patients seeking treatment for erectile dysfunction have severe and irreversible damage of the erectile mechanism and are candidates for implantation surgery. This procedure is a very effective way of treating erectile dysfunction, conferring a high level of satisfaction to patients and their partners, even higher than that of oral therapy [2••]. There is a significant risk of complications, however, some of which may be disastrous [3]. Implantation surgery is not very complex compared with many other urological procedures, but sometimes it can be tricky, particularly when complications arise. The surgeon must have a clear idea of the most appropriate way to face any difficulties so as to prevent serious complications.

In this article we will review the latest scientific evidence published in the field of penile prosthetic surgery. Recent medical literature can be classified into three main areas of interest: infection of penile prosthesis, its prevention and management, surgical tips for prosthetic surgery and surgery clinical outcomes.

Infection of penile prosthesis: prevention and management

In general terms, infection associated with a penile prosthesis is considered a catastrophic event necessitating removal of the device. The usual source of contamination is the operative wound. The skin harbors numerous organisms and care in cleansing of the skin prior to surgery is of paramount importance. The most common organism associated with a penile implant infection is *Staphylococcus epidermidis*, a common skin inhabitant. Other organisms have been implicated and these are usually less aggressive pathogens. However, very aggressive organisms such as methicillin-resistant

Staphylococcus aureus or *Pseudomonas aeruginosa* have been associated with penile prosthesis infections. Fortunately, the incidence of implant-associated infection is relatively low, in the range of 1–10% of cases.

There has been much discussion in the past about the main risk factors for infection; it is now clear, however, that whenever the immune system is deficient the risk of infection is increased. Therefore, patients under treatment with corticosteroids or other immunosuppressive drugs, patients with poorly controlled diabetes mellitus and spinal cord injury patients are more prone to infection. In addition, when cavernosal tissue has a decreased vitality as occurs in fibrosis of any origin (diabetes, re-operation etc.), patients are at increased risk.

Cakan *et al.* [4•] assessed the risk factors associated with infection and found that, for a global incidence of 8.89% of infection, secondary implantation, uncontrolled diabetes, paraplegia and surgeon's inexperience were the most significant risk factors. Lotan *et al.* [5] confirmed these findings. In their series, the overall infection rate at final follow-up was 9.9% and 18.8% for primary and secondary prostheses, respectively, doubling the incidence of infection in re-operation cases.

To explain the higher risk of infection in revision surgery, a prospective study was conducted in which all clinically uninfected prostheses requiring revision were cultured [6••]. Culture-positive bacteria were found in 54 of 77 (70%) patients with clinically uninfected penile prostheses. In some patients more than one organism grew and, occasionally, the pump culture was negative but the biofilm was positive. Of 54 patients, 49 had positive (90%) culture for 10 different species of *Staphylococcus*. In conclusion, the authors reported that the majority of clinically uninfected penile prostheses have organisms growing in the implant spaces at re-operation. Most of these organisms are staphylococcal species; this finding would explain the higher incidence of infection during re-operation.

Recently, Darouiche [7••] published a review on current concepts in the treatment of infections associated with surgical implants in general. He recommends not using vancomycin in patients infected by methicillin-susceptible *Staphylococcus* spp. because this treatment is suboptimal. Rather, he suggests providing empirical coverage against methicillin-resistant *Staphylococcus* spp. for infections with an unidentified microbiologic cause; if the infected implant is retained or if the response to a single antimicrobial agent is inadequate, combination antibiotic therapy should be administered, which includes rifampin for staphylococcal infection. When performing the second stage of implant replacement, antibiotic coverage should be given against organisms isolated during the first surgery. Furthermore, long-term antibiotic therapy should be administered if a new implant is placed in a previously grossly infected area. The principles of surgical therapy are also quite simple: cure of infection is likely to require removal of implants infected by virulent organisms such as *S. aureus*, but removal may not be required in the case of infection by less pathogenic coagulase-negative staphylococci. Regardless of the microbiologic cause of infection, it is advisable to remove the infected implant if the patient has not had a response to seemingly appropriate antibiotic therapy. In such cases, all components of an infected implant should be removed to prevent a recurrence of infection and to ensure the absence of clinical and, if necessary, microbiologic evidence of infection before embarking on the second stage of surgical replacement.

An alternative to removal of all components and re-implantation later has been advocated by Mulcahy [8•] and is gaining popularity; it is termed the salvage or rescue procedure. This entails removal of all prosthetic parts and foreign material, cleansing the wound with a series of antiseptic solutions and replacing the prosthesis during the same procedure. This alternative is less successful when the tissue surrounding the prosthesis as well as the prosthesis cavity is infected. This occurs soon after the original surgery for placing the prosthesis when a considerable amount of cellulitis is evident in the wound with or without abscess formation. In these circumstances the use of systemic antibiotics for 48–72 h prior to the salvage has been shown to improve the chances of success. An obvious abscess or fluctuance should also be drained prior to the salvage procedure. If fluid is available for culture, the organisms involved can be determined and more appropriate antibiotics substituted systemically for 48–72 h prior to initiating a salvage procedure. Improvement or resolution of cellulitis suggests that the chance of the salvage procedure succeeding would be higher. The advantage of the salvage procedure is that most of the length of the penis will be maintained. In addition, it is easy to place cylinders while the cavities in the corpora cavernosa are open, rather than returning at a later date to create new cavities in the scar tissue. Mulcahy [8•] has recently published his results: over 11 years, 101 patients have undergone salvage using this technique, with 85 cases considered successful and 16 cases unsuccessful. Thus the overall success rate is 84%.

In a large retrospective study, Carson [9••] compared infection rates using the original inflatable penile prostheses, with some prostheses impregnated with InhibiZone (American Medical Systems, Minnetonka, Minnesota), a surface treatment combining rifampin and

minocycline hydrochlorideantibiotic, and other prostheses without antibiotic treatment. He compared the results in 4205 men, including 2261 with a mean age of 60.71 years who received prostheses with InhibiZone, and a control group of 1944 with a mean age of 61.04 years who received untreated prostheses. The treated group had an infection rate that was 82.4% lower than in the control group after 60 days and 57.8% lower after 180 days. The conclusion was that the use of antibiotic-impregnated components to target postoperative infections shows a statistically significant decrease in penile prosthesis infection rates in original implants.

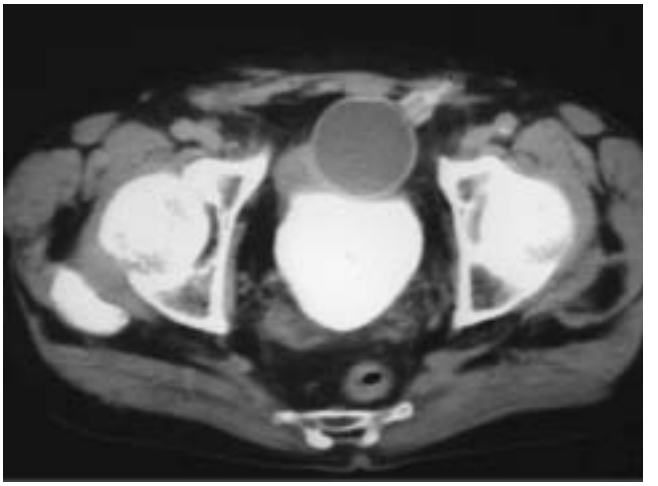
In another study, Hellstrom *et al.* [10•] investigated whether a hydrophilic coating (Resist), designed to inhibit bacterial adherence, applied to inflatable penile prostheses could prolong the effect of intraoperative antibiotics. Coated discs with gentamicin and bacitracin solution demonstrated a sustained inhibition against *S. epidermidis* for up to 3 days. This effect may prevent the colonization of *S. epidermidis* on penile implants and thereby reduce the chance of prosthetic infection. The etiology of this inhibition is based on the ability of the hydrophilic Resist coating to absorb water readily. Consequently, if the coated device is soaked in an antibiotic solution prior to implantation, it will contain some antibiotic at the time of implantation, which will then be eluted over a specified time period, for example, 3 days. This property also allows the implanting surgeon to select antibiotics at the time of implantation. If a hospital-acquired microorganism develops resistance to a specific antibiotic, an alternative antibiotic can be selected to address an emerging pattern of microbial resistance.

Hellstrom *et al.* [10•] point out that an important caveat in this regard is that the introduction of any new microbe-resisting coating should not result in the implanting surgeon reducing his vigilance, sterile technique, and use of antibiotics to prevent prosthetic infections. Despite the reported benefits from these innovations, a larger number of prosthesis implantations will need to be performed by a number of different centers and surgeons, followed over time, and analyzed in order to demonstrate a statistical benefit.

Surgical tips in prosthetic surgery

Penile prosthesis implantation surgery has traditionally been done under general or spinal anesthesia; however there is an evolving tendency to have this surgery done under local anesthesia, with nerve block, in an outpatient setting. Hsu *et al.* [11•] published a study on innovative penile crural block using local anesthesia in patients undergoing penile implantation as outpatient surgery. They substituted the traditional pudendal block by a combination of penile dorsal nerve block and bilateral crural block. They recommended using this procedure when implanting malleable or two-piece penile prostheses; however, the three-piece inflatable penile prosthesis is currently the device preferred by most implanting surgeons worldwide and the most popular approach is through a penoscrotal incision [12]. The penoscrotal approach avoids possible injury to the dorsal sensory nerves, provides easier and more complete corporeal exposure, and allows the pump to be anchored in the scrotal pouch. A variant of the penoscrotal approach, the transverse penoscrotal incision, has been suggested by Wilson *et al.* [13] as the preferred approach for dual implant in patients with incontinence and erectile dysfunction after a radical prostatectomy and for revision surgery. Most urologists are concerned about the 'blind' placement of the reservoir in the penoscrotal approach [14]. Only in special situations can the pre-vesical space be fibrotic and the transversalis fascia thickened. This is often caused by previous surgery, such as open prostatectomy, renal transplantation, or radiation therapy. The surgeon may opt for placement of a two-piece inflatable device, or making a separate incision for placement of the reservoir when there is no such pre-vesical space, for instance after radical cystectomy. One of the authors (I.M.) always uses a three-piece prosthesis and places the reservoir blindly through the penoscrotal incision in post-prostatectomy patients and through a second separate ilio-inguinal incision in the retroperitoneal space in radical cystectomy patients (Fig. 1). Complications from this placement are extremely rare, but a case of postoperative acute deep venous thrombosis due to compression of the external iliac vein by the prosthesis reservoir has been reported recently [15].

Figure 1. Pelvic computed tomography scan

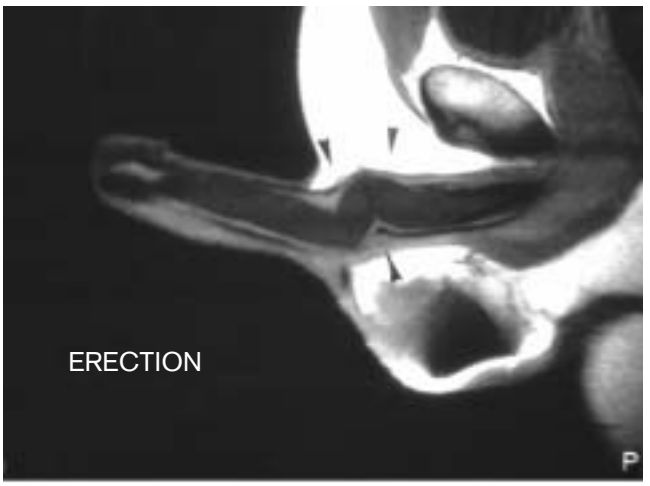


The reservoir can be perfectly distinguished in the pre-vesical space

When replacing the three-piece prosthesis for malfunction, there is still a debate on the best way to manage the reservoir of the original prosthesis. Removing a reservoir is far more difficult than its initial placement; we use a self-retaining rigid anuscope for removal of the reservoir and extended Bovie unit tip cutting down on the tubing, which is placed on gentle traction. Some surgeons leave the reservoir of the original three-piece device behind after removing the penile cylinders and scrotal pump of the malfunctioning device. Rajpurkar *et al.* [16•] evaluated whether the retained reservoir was at risk for complications. Of 85 patients who underwent 98 replacement procedures for a malfunctioning three-piece implant, none had erosion of the retained reservoir. In one patient infection of the replaced device developed, which was treated by removal of all components of the infected device, but the primary retained reservoir (from the original surgery) was left intact. The device was replaced at a later date. These findings suggest that the three-piece implant reservoir is not prone to erosion or infection under normal circumstances.

The re-implantation of an inflatable three-piece prosthesis in a patient with severe corporeal fibrosis represents a surgical challenge even for the experienced surgeon. Fibrosis of corpora cavernosa may occur from priapism, injection therapy, or from vascular insufficiency. The worst fibrosis development occurs as a result of removal of an infected penile implant. In these individuals, severe fibrosis results in penile shortening and reimplantation is the most difficult of all prosthetic urology cases. Dilatation of the scarred corporeal bodies is an arduous, time-consuming task. Wilson [17••] published an outstanding review describing newer tools and techniques to enhance placement of an inflatable device in patients with severe fibrosis. This includes the use of specially designed cavernotomes for dilating fibrotic corpora, the use of downsized prosthetic cylinders, alternative procedures to fix cylinders in the face of perforation as opposed to primary closure of the perforation, and replacing the original cylinders 1 year after the modified cylinders have served as tissue expanders. The cylinder sizing is of great importance. Montague and Angermeier [18] described a cylinder measurement technique that avoids the problem of oversizing that may occur, particularly in the case of the length-expanding Ultrex penile prosthesis, when cylinders that are too long can result in an S-shaped cylinder deformity. These types of deformities are sometimes difficult to diagnose. Thiel *et al.* [19] presented a series of cases to highlight the utility of magnetic resonance imaging, defining the normal and abnormal appearance of penile prostheses and so confirming our previously published work (Fig. 2) [20].

Figure 2. Penile magnetic resonance imaging scan



A buckled cylinder inside the corpora can be fully appreciated.

Clinical outcomes of penile prosthetic surgery

A recent study published by Salama [21] was designed to investigate satisfaction with the use of malleable penile prostheses among couples from the Middle East in treating erectile dysfunction. A total of 50 patients who underwent the insertion of malleable penile prostheses and their partners were evaluated with a retrospective clinical record review, as well as patient and partner questionnaires. Overall, 70% of the patients and 57% of the partners were satisfied with the prosthesis. These levels of satisfaction are lower than those reported in previous studies, which were 85% for patient and 70% for partner satisfaction with semi-rigid prostheses.

Rajpurkar and Dhabuwala [22••] compared erectile function status and satisfaction rates in patients who received treatment for erectile dysfunction with sildenafil, intracavernous prostaglandin E1 and penile implant surgery. They used the Erectile Dysfunction Inventory for Treatment Satisfaction questionnaire to determine treatment satisfaction and the Erectile Function Domain of the International Index of Erectile Function questionnaire to evaluate erectile status while on treatment.

The results of the study showed that at a mean follow-up of almost 2 years, patients who underwent penile implant surgery had significantly higher total scores than those maintained on sildenafil or intracavernous prostaglandin E1. Furthermore, a significantly greater number of patients who underwent surgery were moderately or completely satisfied compared with those on sildenafil and intracavernous prostaglandin E1.

Although long-term satisfaction is high, a general point to be considered is the destructive aspect of penile

prosthesis implantation. It is a common belief that erectile tissue is destroyed when the corpora cavernosa are dilated to make room for the cylinders of the implant. Surprisingly, subsequent to penile prosthesis implantation, some patients report regular spontaneous tumescence. Manning *et al.* [23] investigated whether the corpora cavernosa are capable of tumescence or even spontaneous erection after the implantation of inflatable three-piece prostheses. From a total of 32 individuals, 53% of the patients reported spontaneous tumescence without activation of the implant. Furthermore, one of these patients claimed full rigid spontaneous erections. General satisfaction with the prosthetic result was high at 91%.

A common complaint after penile implantation is the lack of glans engorgement after inflation, also called the cold-glans syndrome. Frequently this is a consequence of a lack of sexual stimulation, but sometimes in some patients the glans is soft and cold despite proper sexual stimulation. Mulhall *et al.* [24] published their experience with the use of sildenafil in 32 patients with this syndrome. Most patients responded to sildenafil with glans engorgement and reported significantly greater satisfaction scores than with an implant alone. Similar results were published recently by Lledo and Moncada [25] from our institution.

Conclusion

Penile implants have played a definite role in the management of erectile dysfunction since their introduction in the urological armamentarium over 30 years ago. This role has changed and evolved with the launching of phosphodiesterase type 5 inhibitors. Currently, this procedure is considered the last treatment option, but a very efficacious one. A substantial percentage of patients with erectile dysfunction will not respond to a conservative pharmacological treatment and will need a penile prosthesis. Urologists must be aware of the numerous advances made in this field in the last year. A great deal of scientific evidence has been published: advances in the design of penile prosthesis, advances in the strategies to prevent and manage infection and advances in the comprehension of the degree of satisfaction with this efficacious mode of therapy for erectile dysfunction.

References and recommended reading

Papers of particular interest, published within the annual period of review, have been highlighted as:
- • of special interest
- •• of outstanding interest

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