Penile prosthetic surgery and its role in the treatment of end-stage erectile dysfunction – an update

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ABSTRACT

The treatment of erectile dysfunction has been revolutionised with the introduction of orally active phosphodiesterase inhibitors which are successful in 70–80% of men. However, there remain a group of men in whom conservative treatment fails and surgical insertion of a penile prosthesis is required. This type of surgery has in the past been associated with technical difficulties and a high complication rate. This has spurred numerous developments in prosthesis design and surgical technique with the field changing at a rapid pace. Perhaps the most significant is the use of antimicrobial coatings on prostheses that have been shown to reduce the infection rate significantly. This review highlights those developments reported in the last 5 years.

KEYWORDS

Penile prosthesis – Erectile dysfunction – Antimicrobial coatings

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Penile implants have been used for the treatment of erectile dysfunction for over 30 years. Initial results were far from excellent due to both mechanical problems and the dreaded complication of infection. Improved outcomes have been achieved in recent times due both to improved surgical care and also developments in device manufacture. The role of penile prostheses has been discussed previously.¹ This review will concentrate on describing the most recent advances in this field.

Literature search

A Medline search was carried out using the search terms 'penile prosthesis' and 'penile implants'. The reference lists of key articles were also reviewed. Articles published since 2000 that reported a modification of prosthesis design or surgical technique were chosen in order to ensure that the review reflected current practice.

Implant types and improvements in implant mechanics

The main categorisation of penile implants is between inflatable and non-inflatable devices.

The non-inflatable devices are semi-rigid and may be silicone malleable rods (Fig. 1) or a series of articulating polyethylene discs with a central metal cable support. Non-inflatable implants are relatively cheap and easy to insert

Figure 1 Malleable penile prostheses, the Mentor Genesis.

with few mechanical complications. However, they provide a less than ideal result both in terms of cosmesis/concealment and quality of erection.

Inflatable implants aim to reproduce normal function as much as possible in both allowing penile flaccidity when not in use and subsequent girth/length expansion during

Figure 2 Inflatable penile prostheses: (A) the AMS 700 CX; (B) Mentor alpha-1. Both prostheses consist of three components, reservoir (R), cylinders (C) and pump (P). Lock out valve (LOV) can be seen on Mentor prosthesis.

erection. Although two-piece devices exist, these are not commonly used and three-piece devices comprising, penile cylinders, pump and fluid reservoir dominate the market (Fig. 2). There are two manufacturers, American Medical Systems (AMS) and Mentor Medical Ltd, both of which market devices with standard (AMS 700 CX and Mentor alpha-1) and narrow (AMS 700CXR and Mentor alpha-1 narrow based) cylinders. The narrow designs have been designed for use in smaller penises or those in which corporal diameter is reduced by fibrosis, for example due to Peyronie's disease, priapism or previous implant surgery. The improvements in

Figure 3 Bi-directional weave allows girth expansion in the AMS Ultrex prosthesis.

implant design that have been made in recent years include:

1. AMS introduced the Ultrex prosthesis which as well as allowing girth expansion as do all inflatable prostheses, allowed increase in length by up to 15%.² This was achieved using a bi-directional middle woven layer between the two layers of silicone (Fig. 3).
2. Auto-inflation of penile implants occurs because the prosthesis reservoir is within the abdominal cavity and hence pressure increases lead to fluid egress into the cylinders. Mentor solved this problem by introducing a lockout valve on its prostheses (Fig. 2B).³
3. Implant materials have improved in order to prevent wear of both the cylinders and connecting tubing. For example, Bioflex (Mentor inflatable cylinders) is a new polymer that has both increased tensile strength and abrasion resistance compared to standard silicone.
4. Many men found manipulation of the scrotal pump difficult and indeed this limited the use of inflatable implants to those with the necessary manual dexterity. This problem has been overcome with the introduction of the new AMS tactile pump (Fig. 4) that has been designed to improve patient satisfaction.⁴
5. Novel prosthesis coatings to reduce the incidence of infection (see below).

Advances in infection prevention

Infection is the most feared complication of penile prosthesis insertion and bacterial adherence to the material of the penile prosthesis is the crucial first step in its

Figure 4 The tactile pump designed by AMS which aids manipulation by patients. Inflation is achieved by squeezing the bulb (B) whose ridged surface aids grip. Deflation involves squeezing the deflation block (DB) which has ergonomic finger pads.

establishment. Standard penile prostheses have been made of hydrophobic material (polyurethane in Mentor alpha-1 and silicone in AMS 700-CX) and this would potentially favour bacterial attachment and thus formation of a biofilm. Both companies have responded to this problem by making changes to the implant materials.

Mentor introduced the new TITAN inflatable penile prosthesis, which is based on the Mentor alpha-1 but is coated with the hydrophilic material polyvinylpyrrolidone (PVP). This will absorb up to 23 times its weight in water. *In vitro* experiments have shown that PVP coated prosthesis material is subject to 41% less bacterial attachment than uncoated material when incubated with *Staphylococcus epidermidis*, a major pathogen in implant infection.⁵ Another advantage of the hydrophilic coating is that it facilitates absorption of water soluble antibiotics. Hellstrom *et al.*⁶ performed *in vitro* experiments comparing discs made of penile prosthesis base material that were either uncoated or coated with PVP. These were soaked in antibiotics (gentamicin and bacitracin) and then implanted subcutaneously into rabbits. The discs were removed after 1–5 days and antimicrobial efficacy tested by placing the discs in a bacterial culture. Uncoated discs had lost their antibiotic activity by 24 h whereas the hydrophilic coated discs maintained activity for at least 3 days. Similar findings have been demonstrated in PVP-coated shunts used in the treatment of hydrocephalus.⁷ A preliminary uncontrolled study has suggested reduced rates of infection using the new PVP-coated

prostheses.⁸ In a one-year period in the US, there were infections in 25/2357 PVP coated prostheses (1.06%) versus 10/482 standard Mentor alpha-1 (2.07%).

AMS have developed the InhibiZone implant which is coated with antibiotics (rifampicin and minocycline). These then elute into the surrounding tissues following implantation. The agents have been chosen because, in combination, they have been shown to reduce the development of bacterial antibiotic resistance. In a large retrospective comparison of 4205 patients, use of the InhibiZone coating reduced the infection rate at 180 days from 1.6% to 0.7% ($P < 0.005$).⁹

Clearly, prospective, controlled studies are required to confirm these encouraging findings.

Developments in surgical technique

There are several refinements in surgical technique that contribute to the improved success of penile implant surgery.

The penoscrotal approach first described 15 years ago¹⁰ is now most surgeons' standard approach and has replaced the infrapubic incision. It offers the advantages of excellent exposure, easy pump placement in the scrotum and a more cosmetic incision with less risk of dorsal penile nerve damage. A recent article has suggested that placing suction drains to reduce haematoma is not associated with an increased infection risk and, therefore, recommended.¹¹ Another report has demonstrated that performing implant surgery as a day-case procedure is feasible, associated with equivalent outcomes and at significantly reduced cost.¹²

Corporal fibrosis is a consequence of previous prosthesis surgery (especially if associated with infection), intracavernosal injections, prolonged priapism and Peyronie's disease. In the past, it was a very difficult situation in which to perform penile prosthetic surgery because of difficulties in creating sufficient room within the corpora cavernosa to accept the cylinders. The risk of corporal perforation was high and this was associated with less satisfactory outcome. Dilatation has been made less difficult with the introduction of specially designed Rosello dilators.¹³ Both prosthesis manufacturers also now provide implants with narrower cylinders that allow surgery in men who previously would have been inoperable.

In Peyronie's disease, corporal scarring not only leads to a bend in the penis but may also result in impaired erectile function. In this situation, insertion of a penile prosthesis has been used to correct both problems by forcibly straightening the penis with the implant inflated and using it as a splint so that the penis heals straight. Long-term results are encouraging.¹⁴ The use of multiple relaxing incisions in the tunica as an alternative to re-modelling also shows promise.¹⁵

Erectile dysfunction is expected in patients with uncorrected priapism after 24 h. In this situation, corporal fibrosis ensues

and pharmacological therapies are unlikely to be of benefit. Because a penile implant is likely to be the only method of restoring erections in this situation, it has been proposed that this should be performed immediately in order to avoid the difficulties associated with scarring.¹⁶

Management of complications

The traditional approach to managing infected implants was removing the prosthesis and then considering repeat surgery after a period of several months when all the infection had been eradicated. Unfortunately, the ensuing fibrosis made subsequent surgery difficult and, even if successful, the penis was usually shorter. In response to this problem, the so-called 'salvage' protocol was introduced for selected cases.¹⁷ Suitable patients are those with chronic infections due to organisms of relatively low virulence such as *S. epidermidis*; acute purulent infections or those due to resistant organisms such as MRSA are not appropriate for this technique. Salvage involves replacing the infected prosthesis immediately, after copious washout of the wound with a variety of antibiotic and antiseptic solutions (Table 1). Of implants, 82% are free of infection in the long term and there is also a reasonable success rate in terms of penile length preservation. Recently, it has been suggested that the salvage protocol should be used even when revision surgery is carried out for non-infective reasons as the infection rate is also reduced in these circumstances.¹⁸

Although mechanical failure of implants has been reduced, it still occurs at the rate of 10–20% within the first 5 years. If failure occurs within the first few months, replacement of the faulty part only can be considered. The problem is usually a leak and can be determined by either electrical detection of saline leak using an ohmmeter or instillation of contrast and seeing extravastation on X-ray. The advantage of replacing faulty tubing only is that a repeat corporal incision is avoided. Repeated corporal incisions are associated with penile fibrosis and shortening.¹⁹ Once the device has been in longer than 2 years, total replacement is advised.

One of the main reasons for patient dissatisfaction is unrealistic expectations of the nature of the erection produced using the implant. A typical complaint is the lack of glans engorgement, something that is expected given that only the corpora cavernosa are implanted. The use of sildenafil (Viagra) to enhance the prosthetic erection has been investigated and statistically significant improvements in sexual satisfaction reported.²⁰

In the salvage setting, it may be impossible to use a prosthetic device because of infection/fibrosis. There is promise that in the future it may be possible to use autologous tissues; for example, a recent case was described where vascularised fibula was implanted in a patient who had several failed implants.²¹

Table 1 Salvage protocol for immediate replacement of infected penile implants

- 1 Remove all prosthetic parts and foreign material
- 2 Irrigate wound with seven antiseptic solutions
 - Antibiotics (kanamycin, bacitracin)
 - Half-strength hydrogen peroxide
 - Half-strength providone iodine
 - Pressure irrigation with 1 g vancomycin and 80 g gentamicin in 5 l irrigating solution
 - Half-strength betadine
 - Half-strength hydrogen peroxide
 - Antibiotics (kanamycin, bacitracin)
- 3 Change gown, gloves, surgical drapes and instruments
- 4 Insert new prosthesis
- 5 Close wounds with no drains or catheters
- 6 Oral antibiotics for 1 month

Long-term results

The patient group that undergoes penile prosthesis surgery is one that has end-stage disease, unresponsive to less invasive forms of therapy. Numerous studies have demonstrated that satisfaction levels after implant surgery are very high. Two studies both looking at over 200 patients found that 79–92% of patients were still using the implant at least once a month, 5 years after surgery.^{22,23} Mechanical failure rates on long-term follow-up were 4–17% and infection rates 3–6%. The quality of erections was deemed excellent or satisfactory by 92% of patients and 83% of partners.²² One problem with these studies is that they have used subjective ratings of satisfaction to draw their conclusions. Validated questionnaires have now become available such as the International Index of Erectile Function (IIEF), which has been shown to be an excellent measure of treatment response in trials of oral therapy for erectile dysfunction.²⁴ This is available in both a full (15-question) and short (5-question) format (Table 2) and should be used in future studies on the outcome of penile prosthesis surgery.

A UK audit has suggested that long-term outcomes from implant surgery are better when surgeons/centres perform more than 20 procedures a year with a reduction in infection and revision rates.²⁵ With the significant cost of the device (about £5000), this makes a case for dedicated implant surgeons.

Table 2 IIEF-5 scoring system

Over the past 6 months	Score				
	1	2	3	4	5
How do you rate your confidence that you could get and keep an erection?	Very low	Low	Moderate	High	Very high
When you had erections with sexual stimulation, how often were your erections hard enough for penetration	Almost never or never	Much less than half the time	About half the time	Much more than half the time	Almost always or always
During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?	Almost never or never	Much less than half the time	About half the time	Much more than half the time	Almost always or always
During sexual intercourse, how difficult was it to maintain your erection to the completion of intercourse?	Extremely difficult	Very difficult	Difficult	Slightly difficult	Not difficult
When you attempted sexual intercourse, how often was it satisfactory for you?	Almost never or never	Much less than half the time	About half the time	Much more than half the time	Almost always or always

The IIEF-5 score is the sum of questions 1 to 5. The lowest score is 5 and the highest score 25.

Conclusions

Continuing evolution in the field of penile prosthetic surgery has led to improved outcomes and high levels of patient and partner satisfaction. It will continue to have an important role in those patients who do not respond to conservative therapy.

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Erratum

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Unfortunately in the May issue Mr Ashworth's name was omitted from the following Technical Tip. Please see correction below:

Ann R Coll Surg Engl 2006; **88**: 321.

Knee arthroscopy: 1-ml syringe as an outflow cannula

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