

## New techniques in medicine

# The role of penile prosthetic surgery in the modern management of erectile dysfunction

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### Summary

**The management of erectile dysfunction looks set to be revolutionised with the introduction of effective oral therapies. There will remain, however, some men who do not respond to conservative measures. This article reviews the important role of penile prosthetic surgery as a treatment option in these patients.**

**Keywords:** penile prosthesis; erectile dysfunction

Erectile dysfunction may be defined as the consistent inability to obtain or maintain a penile erection sufficient for satisfactory sexual relations.<sup>1</sup> It is difficult to assess how common the problem is as many sufferers do not seek help. Perhaps the best estimate of the prevalence of erectile dysfunction comes from the Massachusetts male ageing study.<sup>2</sup> This was a cross-sectional questionnaire based survey of ageing and health in 1290 men aged 40–70. Nine questions were related to erectile dysfunction and men were divided into not impotent (48%), minimally impotent (17%), moderately impotent (25%) and completely impotent (10%). These data highlight the implications of erectile dysfunction for healthcare provision, particularly as males are living longer and older men have raised expectations with regard to sexual health. It is estimated that only 2.6 to 5.2% of patients with erectile dysfunction seek treatment annually,<sup>3</sup> but this is likely to increase significantly as the problem is marketed as a curable condition. Sufferers may present to a wide range of medical specialties, and it is therefore important for all doctors to be aware of the options available to the man with erectile dysfunction.

### Therapeutic options in erectile dysfunction

There are a wide range of treatment modalities for erectile dysfunction (box 1). Currently, most men with organic impotence are treated with vacuum constriction devices or intracavernosal injection therapy. Vacuum devices are cheap and relatively safe, and in carefully selected patients the satisfaction rate has been reported as up to 84%,<sup>4</sup> but not all men find them suitable. The most commonly used substance for injection therapy is alprostadil (prostaglandin E<sub>1</sub>), and this is effective in producing an erection in over 80% of patients with erectile dysfunction.<sup>5</sup> However, in the long-term, up to 60% of men drop out for reasons including loss of effectiveness, penile pain or simply loss of interest. Recently intra-urethral alprostadil (MUSE) has been developed in an effort to improve tolerability.<sup>6</sup> The introduction of Viagra (sildenafil, a phosphodiesterase type 5 inhibitor) looks set to revolutionise treatment of erectile dysfunction.<sup>7</sup> This is an orally active agent with 85% initial success rate and is well tolerated, therefore it is likely that there will be far fewer dropouts than with injection therapy. Penile prosthetic surgery has usually been reserved for those patients, approximately 5% of those treated for impotence, that do not respond to or fail to tolerate conservative modalities. It is possible that Viagra usage may prevent penile prosthetic surgery in some cases. However, there will still be men who fail to respond to all conservative therapies and penile prosthetic surgery will continue to have an important role in this patient cohort. Indeed it seems likely that with the increased profile of erectile dysfunction since the launch of Viagra, more men will seek help and there may even be an increase in the number of patients requiring penile implants. It is therefore salient to review the current issues in penile prosthetic surgery.

### Penile prostheses

Currently available prostheses fall into two main groups, semi-rigid rods and inflatable devices. Both types have undergone many developments to combat problems that have arisen over time. Surgeon and patient preference together with cost considerations will determine which type of device is likely to be most suitable.

#### SEMI-RIGID RODS

Modern semi-rigid prostheses consist of a silicone jacket surrounding a core of metal wires or coils (figure 1). They are easier to bend and have less springback

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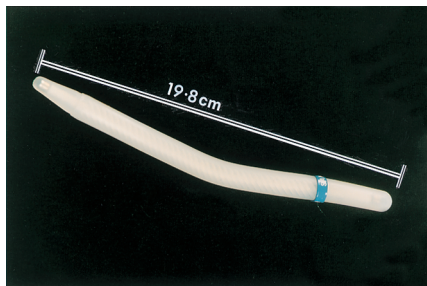
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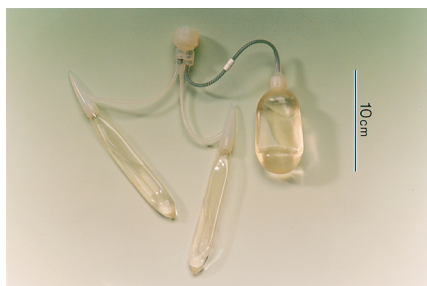
**Major treatment options for erectile dysfunction**

- psychotherapy
- oral therapy (Viagra)
- vacuum erection device
- intracavernosal injection / intra-urethral therapy
- penile prosthesis

**Box 1**



**Figure 1** A typical semi-rigid prosthesis



**Figure 2** A typical three-piece inflatable prosthesis

**Indications for insertion of penile prosthesis**

- organic or psychogenic impotence where less invasive therapies are ineffective or not tolerated
- Peyronie's disease associated with erectile dysfunction
- penile fibrosis after priapism or intracavernosal injection therapy

**Box 2**

than older devices. The penis is always 'full' with this type of implant in place, and it should be worn in the upward position against the abdomen when not in use. The device is quick and easy to implant and this may even be done under local anaesthesia. It is an ideal prosthesis for patients with reduced manual dexterity and is also suitable for older patients, especially those with concurrent medical illness. The high mechanical reliability means that re-operation is rare. Semi-rigid devices are the most commonly used types of prosthesis in the UK due to cost considerations. In the USA inflatable devices are implanted preferentially.

**INFLATABLE DEVICES**

The basic components of an inflatable device are two inflatable cylinders, a reservoir and a pump mechanism to transfer fluid from reservoir to cylinders during use. These components can be incorporated into a single device, or separated as in two-piece and three-piece inflatables (figure 2). The original inflatable devices were plagued by mechanical problems, but these have been addressed in numerous revisions and current models have proven reliability, at least in the short term. Recently a large study of the Mentor Alpha-1 inflatable penile prosthesis showed 93% freedom from complications at 2 years.<sup>8</sup> All devices allow increase in penile girth during erection, and some make claims for increased length. Inflatable devices require increased time for insertion and therefore are perhaps not suitable for those in whom a longer operation may be hazardous or those at high risk of infection. The main consideration, however, is that of increased cost (over £3000 versus approximately £700 for semi-rigid devices). Concealment is easier with these devices, although patients must be aware of the likelihood of auto-inflation during the first three months. This occurs because the intra-abdominal reservoir is compressed by intra-abdominal pressure, forcing fluid into the cylinders. After 3 months a fibrous capsule has usually formed around the reservoir, which prevents transmission of abdominal pressure, so it is important in this early period to ensure that the reservoir remains at its maximal capacity. A lockout valve has been designed for the Mentor Alpha-1 prosthesis to achieve this aim and has shown promising early results in preventing auto-inflation.<sup>9 10</sup>

**Which patients should be considered**

Most patients considered for implantation of penile prostheses will be those with organic causes of erectile dysfunction who have failed to respond to or not tolerated conservative options. In patients with Peyronie's disease who also suffer from erectile dysfunction (usually due to distal flaccidity), a penile prosthesis can allow correction of the deformity as well as restoring erection.<sup>11-12</sup> A penile prosthesis may be the only method of treating patients with penile fibrosis following priapism or usage of intracavernosal injections.

**Pre-operative counselling**

To maximise satisfaction from penile prosthesis insertion, full and accurate pre-operative counselling of the patient and partner is mandatory. This will prevent unrealistic expectations, which are the major reasons for complaints. As insertion of a prosthesis involves replacement of the patients' cavernosal tissue with loss of any residual erectile function, surgery should only be considered when all non-invasive methods of achieving a natural erection have been exhausted.

Both patient and partner should be aware that the erection achieved with a prosthesis is a compromise. The glans penis will not be affected by any type of implant, and will remain flaccid unless there is some residual erectile function from the corpus spongiosum. The implant erection may necessitate a need for some modification of positions for sexual intercourse. Although erection is not directly related to libido or orgasm, many patients do have difficulty achieving orgasm when first using their prosthesis. They should be counselled that it could take up to a year for this to resolve. Concealment can be a problem with semi-rigid prostheses. Patients with inflatable devices must be warned about auto-inflation.

Complications of prosthetic surgery (see below), in particular infection, mechanical failure and the possibility of prolonged penile pain in the postoperative period must be explained to prospective patients. If complications do occur, revision surgery is possible, but it should be stressed that this is more difficult and has an increased complication rate.

### Pre-operative counselling before penile prosthesis insertion

- this therapy is suitable when all other methods have failed
- two types of prosthesis: semi-rigid and inflatable
- not a natural erection, in particular decreased length and glans unaffected
- concealment can be a problem with semi-rigid devices
- mechanical failure and complications do occur

#### Box 3

### Complications of penile prosthesis insertion

- mechanical failure approximately 5% in 5 years
- infection rate 1% if no additional risk factors but rises in diabetics or with revision surgery
- deformity or prosthesis erosion due to incorrect length or migration

#### Box 4

### The operation

Improvements in anaesthesia and peri-operative care, together with increasing surgical experience and expertise, mean that modern penile prosthetic surgery is a much safer and less morbid procedure than in the past. Semi-rigid prostheses may be inserted under local anaesthetic and are therefore very suitable for patients who are poor anaesthetic risks. Even with inflatable devices, refinements in technique mean it is now possible to offer this type of surgery as a day case procedure to suitable patients.<sup>13</sup> Patients are usually able to begin using both types of implant about 6 weeks after surgery. With inflatable devices, regular inflation is required in the first few months to prevent the development of a constrictive capsule around the cylinders and therefore maximise penile dimensions.

### Complications of implant surgery

There are three main groups of complications seen after penile prosthesis insertion, mechanical failure, infection, and problems related to migration or incorrect sizing of the prosthesis (box 4).

#### MECHANICAL FAILURE

This usually occurs with inflatable prostheses and is a rare complication for a modern semi-rigid device. Studies of the long-term reliability of inflatable penile prostheses are difficult to interpret because of the large number of different types of devices used. The continued evolution of prosthetic types means that large series of a single device are unusual. However, a recent overview of the available data suggested that there is a 5% mechanical failure rate at 5 years.<sup>14</sup> Occasionally it is possible to repair a prosthesis or replace a defective part but in most cases a new device needs to be implanted.

#### INFECTION

Infection is the most feared complication of penile prosthetic surgery. All surgeons follow strict protocols in an effort to minimise infection and these will typically include screening for sub-clinical infections pre-operatively, a meticulous aseptic preparation and prophylactic antibiotics. Patients at particular risk of infection are diabetics, paraplegics with condom type urine drainage and those who have had previous penile prosthetic surgery. Infection rates vary from 1% for primary procedures in non-diabetics to 18% in diabetics undergoing revision surgery.<sup>15</sup> The most common causative organism is opportunistic *Staphylococcus epidermidis* and most infections present 3–12 months after surgery. Typically, symptoms are of pain, induration and penile oedema, with purulent drainage from the wound being a late sign. Indeed infection should be considered as a cause in all prosthesis patients who develop chronic penile pain. In the presence of infection the prosthesis is usually removed and re-implantation performed at a later date after infection has been eradicated. Some surgeons, however, perform a salvage procedure for chronic infections. In these cases the wound is copiously irrigated with antibiotics and a new implant placed immediately. They claim that this prevents loss of penile length and the severe fibrosis associated with delayed re-implantation.<sup>16</sup>

#### INCORRECT SIZING

For long-term success it is essential that implanted prostheses are of the correct size. When implants are too short the glans can be hyper-mobile and droop at the end of the prosthesis. This is described as the supersonic transport (SST) deformity, because of its resemblance to the nose of Concorde! Overlong prostheses can also be a problem, and with semi-rigid rods erosion can occur. Some inflatable cylinders that are too long can produce an S-shaped deformity. Also a recent study using magnetic resonance imaging showed that 12 of 14 penile prosthetic patients with prolonged penile pain had buckling of the cylinders due to using a prosthesis that was too long.<sup>17</sup> Revision surgery is required in cases where incorrect sizing or migration has occurred.

### Revision surgery

Revision surgery is usually very difficult, mainly due to extensive corporal fibrosis. Often multiple incisions are required and a downsized prosthesis needs to be placed, needless to say the complication rate is higher. In spite of this good results are reported and if performed by surgeons experienced in the management of revision surgery, replacement of a failed prosthesis, even when marked fibrosis is present, can be successful in approximately 80% of cases.<sup>18</sup>

### The cost of various treatment options available for erectile dysfunction

#### Penile prosthesis\*:

- semi-rigid: £ 690–760 +VAT
- inflatable: £2438–3392 + VAT

#### Alprostadil\*\*:

- intracavernosal (10 µg): £ 1848
- intra-urethral (250 µg): £ 2388

Viagra (50 mg)\*\*: £ 1158

Vacuum device: £ 250

\* Price for device only, and does not include cost of operation

\*\*Based on use four times per month over 5 years

#### Box 5

## Results of treatment

There are two main components to assessing the results of surgery. Firstly, it is important to know how long the prosthesis is likely to last and secondly, there is the more critical issue of patient and partner satisfaction, ie, is the prosthesis still being used. The latter is strongly influenced by the quality of pre-operative counselling. Unfortunately there are no large prospective studies pertaining to the results of penile prosthesis insertion. The larger retrospective studies (>100 patients) that have been done show that over 90% of implants will still be functioning after 2 years. Estimates of patient and partner satisfaction range from 70 to 85%.<sup>14</sup> This compares well with other treatment modalities. For example, in a recent study after a mean follow-up of 5.4 years, 70% of patients were still using their prosthesis compared to 41% using intracavernosal injections.<sup>19</sup> The importance of patient counselling was illustrated by a report on goal-directed treatment of impotence, where 377 patients were given information about all treatment modalities and then chose their own treatment.<sup>20</sup> Twenty-seven patients chose penile prostheses and all except one (96%) were satisfied with the result.

## Cost considerations

Penile prostheses are expensive, and with increasing cost concerns in healthcare, this is an important issue. Typical costs for both semi-rigid and inflatable devices and for other therapies used in erectile dysfunction are shown in box 5. It is clear that if penile prosthetic surgery is successful, it can be a highly cost-effective method of treatment, especially in the younger patient. It is important to also realise that most patients who require penile prosthesis insertion have failed all conservative options.

## Conclusions

There is no doubt that doctors are going to see an increasing number of men seeking treatment for erectile dysfunction. With the emergence of new therapeutic options, it is important that in each patient every appropriate option is explored, as the benefits of successful treatment to patient and partner can be immense. There is no doubt that penile prosthetic surgery will continue to have an important role in this regard.

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