

Clinical Experience

Outcome of implanting penile prosthesis for treating erectile dysfunction: experience with 42 cases

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Abstract

Aim: To report a short-time result of three-piece inflatable penile prosthesis (IPP) implantation on treating patients with organic erectile dysfunction (ED). **Methods:** Three-piece IPPs were implanted in 42 Chinese patients with ED refractory to systemic treatment between May 2002 and May 2004. The etiologies of ED were neurogenic (28 with paraplegia and seven with traumatic nervi-erigentes injury); congenital venous leakage (5 cases), fibrosis of corpus cavernosum (1 case) and Klinefelter's syndrome (1 case). The follow-up period ranged from 24 to 57 months. **Results:** Implantation procedures were successfully performed upon all 42 patients. The length of implanted prosthesis was from 13 cm to 18 cm, and the diameter was 1 cm. The implanted prosthesis was made by the Medical Instrumentation Company of Muping (Muping, Shandong, China). Localized infection occurred in only one patient and mechanical complications occurred in five patients. Coitus could be performed in 41 cases (97.6%). Three patients with congenital venous leakage made their spouses pregnant after implantation. **Conclusion:** Implantation of three-piece IPP is an effective and safe modality for treating patients with ED. It can be well accepted by Chinese patients because of its efficacy. (*Asian J Androl* 2007 Sep; 9: 716–719)

Keywords: treatment; erectile dysfunction; penile prosthesis; implantation

1 Introduction

The development of medicine and technology has made it possible to provide new therapeutic modalities for patients with ED refractory to systemic treatment. The implantation of inflatable penile prostheses (IPP) for the treatment of erectile dysfunction (ED) has been widely practiced in the world. As third-line therapy for ED, the

numbers of implants continue to rise as the population of men treated for ED increases [1]. During the past 30 years, the development of penile prosthesis has ranged from single-piece IPP to three-piece IPP, and from non-inflatable prosthesis to inflatable prosthesis. Since the 1970s, implantation of three-piece IPP has been considered the gold standard for the treatment of ED [1].

From the 1990s, some urologists began to treat ED patients in China with the implantation of three-piece IPP (AMS Company, Minnetonka, NI, USA; or Mentor Company of America, Santa Barbara, CA, USA), and excellent therapeutic efficacy was achieved. We present our experience of treatment of patients with ED by implantation of three-piece IPP.

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2 Materials and methods

Forty-two Chinese ED patients were enrolled in this study between May 2002 and May 2004. Among them 35 were neurogenic ED, including 28 with paraplegia and seven with traumatic nervi-erigentes injury. The rest included five cases with congenital venous leakage (failure to store), one with fibrosis of corpus cavernosum, and one with Klinefelter's syndrome. The age of the patients was between 23 and 75 years, with an average of 37.2 years. The International Index of Erectile Function (IIEF-5) [2] was used to evaluate all patients, and severe ED (scores < 11) was diagnosed to all patients. Before operation, nocturnal penile tumescence testing (NPT), Color Doppler flow imaging (CDFI), cavernosography and sacral nerve sensory evoked potential (SSEP) were performed, and serum chemistry panel and hormone profile were collected.

2.1 Preoperative preparation

The sizes of bilateral penile corpus cavernosum, penile lateriflexion and curvature were assessed before implantation. The degree of the fibrosis of corpus cavernosum was also evaluated. Patients and their spouses were completely informed that implantation of penile prosthesis was to obtain erection, and this erection would not be completely the same as those naturally produced. All patients consented to the procedure. Prophylactic antibiotic (ciprofloxacin 500 mg, twice daily) was used for 3 days consecutively before implantation.

2.2 Three-piece IPP

The three-piece IPP used in this study was made by the Medical Instrumentation Company of Muping (Muping, Shandong, China). This kind of prosthesis was developed from 1992 to 1994. It was designed according to the characteristics of Chinese men. The prosthe-

sis was made from silastic, consisting of a pair of intracorporeal cylinder, a fluid reservoir and a scrotal resipump. The three parts are connected by a conduit (Figure 1). The tissue compatibility and safety of the prosthesis was tested in animals and humans and approved, and there was no extravasation or leakage (Table 1). The device has been used to treat patient with ED since 1997. Although its material is a little harder than imported products, it is accepted well by patients.

2.3 Surgical procedure

Continuous epidural anesthesia was used in our study. At the connection of penis and scrotum, a transverse incision of approximately 4 cm in length was used. Incision was performed in each layer from the skin to penile



Figure 1. The penile prosthesis (the Medical Instrumentation Company of Muping, Muping, China) was made from silastic and consists of two cylinders, a fluid-storing reservoir and a resipump. The three parts are connected by a conduit.

Table 1. The results of animal and human experiments for testing tissue compatibility and safety of the prosthesis.

Detected items	Results
Cytotoxicity	I degree
Skin sensitization	No sensitization
Intradermic stimulation	No stimulation
Implantation	Histology reaction according with the regulation of GB/T16175-1996
Ames test	Negative
Bacterium	No bacterium growth

corpus cavernosum. Hypodermis and dartos were split at the urethral laterally. Four stay-sutures with 1-0 SAS were placed at each penile corpus cavernosum to form two rows. In between, an incision was carried out vertically on the penile corpus cavernosum. The penile corpus cavernosum was dilated with a cervix dilator (diameter 8–13 mm, Pratt size 25–33) from the basilar part of glans penis to crura penis. The length of the tunnel in the penile corpus cavernosum was measured with a cylinder embolus, and should have been 0.5–1.0 cm longer than the penile prosthesis. The management of the other side was the same. After choosing suitable penile prosthesis, the prosthesis was inserted into the penile corpus cavernosum and the incision was closed with four stitches. The fluid-storing reservoir was placed into the prevesical space. Then the mediastinum of the scrotum was divided and the resipump was put in. After being filled with 40 mL 10% Cystografin, the fluid-storing reservoir was connected to the resipump. The resipump was pressed repeatedly to ensure the successful erection of penis. As soon as the release system of the resipump was pressed, the penis became flaccid. This manipulation was carried out 3–4 times to confirm the installation position was correct and there were no mechanical troubles. Drainage stayed in the scrotum before the wound was closed, and the penis was maintained in semi-erectile status. The procedures were all performed by the same surgeon.

2.4 Postoperative management

Broad-spectrum antibiotic (ciprofloxacin, 500 mg, twice daily) was used to prevent infection for 7 days. Estrogen and hemostatic drugs were used routinely post-operation. Care was taken postoperatively to observe whether there was redness, swelling, hematoma or necrosis. The drainage was pulled out on the 4th day post-operation and the Foley catheter was left in for 7–8 days to prevent contamination of the wound from urine. The scrotum was elevated to reduce edema. All patients were discharged within 8 days post-operation. In 6–8 weeks after discharge, patients were instructed on how to inflate and deflate the device.

3 Results

The procedure was successfully performed upon all 42 patients. The whole procedure took approximately 90–150 min, with an average of 110 min. The length of the

implanted penile prosthesis was 13 cm for one case, 14 cm for five cases, 15 cm for 18 cases and 16 cm for 18 cases. The diameter of implanted prosthesis was 1 cm. Postoperative follow-up lasted for 24–57 months, and 39 months on average. Localized infection that may have been caused by fluid extravasation of the prosthesis occurred in one paraplegia patient at the 11th month after implantation, which resulted in removal of the whole set of penile prosthesis. Fluid extravasation of penile prosthesis, which led to removal of the resipump, was found in another paraplegia patient. Mechanical complication occurred in three non-paraplegia patients, and the penis was maintained in semi-erectile status, which was enough to perform sexual intercourse. Paraplegia patients adopted the woman-up position during intercourse. The rate of mechanical failure was 11.9% (5/42). The effect of intercourse was satisfactory (subjectively) and the intercourse rate achieved was 97.6% (41/42), which is higher than that previously reported [3, 4]. Psychogenic ejaculation occurred in three patients. Four patients with congenital venous leakage had normal ejaculation after the treatment. Three spouses fell pregnant.

4 Discussion

The treatment of ED has been revolutionized with the introduction of orally active phosphodiesterase inhibitors, which are successful in 70%–80% of men [5]. However, there remains a group of men in whom conservative treatment fails and surgical insertion of a penile prosthesis is required. Thus we reported our experience with implantation of a prosthesis, made by the Medical Instrumentation Company of Muping (Muping, China), for the treatment of patients with ED.

Infection and mechanical failures are the main complications of the implantation of IPP [6–12] and some studies even report infection as the most troublesome complication [1]. By using prophylactic antibiotics pre-implantation, rigorous procedure, and careful observation, the postoperative recovery was smooth. There was no infection in our group at the early stage of post-operation. Only one patient had infection in the 10th month postoperatively. In order to prevent infection, all patients were asked to take antibiotics orally for 3 days every 3 months postoperation, especially for the paraplegia patients, to prevent the infection of retentive urine. Although there were 28 ED patients with paraplegia in this study, the infection rate was as low as 4.76%, which

was lower than that of other reports [3]. The key of the IPP implantation is to choose an appropriate intracorporeal cylinder with suitable length and diameter. The length of penile corpus cavernosum of the Klinefelter's syndrome patient was only 14 cm, this is very small. As a result, IPP was only implanted into one cavernosum. The length of the patient's penis was maintained at 4–5 cm post-operation and 10–14 cm at erection.

Patients and their spouses were informed that the erection after implantation would be somehow different from those naturally produced. Nerve reflection existed pre-operation would not be affected by implantation. Paraplegia patients adopted a woman-up position during sexual intercourse and the effect was satisfactory. To avoid the resipump in the scrotum stretching excessively and the fluid-storing reservoir being displaced, patients were instructed to pay attention to the strength of inflation and deflation of the device. The displacement of the device may have been the cause of extravasation of IPP and mechanical failures in two patients.

In the 1980s, the incidence of mechanical failures in inflatable penile prosthesis was 10%–20%. In recent years, this figure has dropped with the development of technology. Choi *et al.* [13] reported their experience of treating ED patients with three-piece inflatable penile prosthesis in South Korea; the incidence of mechanical failures in 3 years was 10%. Lewis [14] reported that the incidence of mechanical failures on AMS700CXM was 5.5% on average. The incidence of mechanical failures in this study was 11.9% (5/42), including two cases of fluid extravasation that led to localized infection in one case, and pump failures occurred in another three cases at the 18th and 27th month after implantation. The penis with pump failures was maintained in semi-erectile status and intercourse could still be performed successfully. Floccules were found in the fluid of two prostheses by B-ultrasonograph, indicating that the obstructed valves caused by floccule might lead to pump failures. Shortening the exposure time of the fluid to the air may prevent the formation of floccule. In addition, the improvement of the prosthesis quality will be helpful in preventing the incidence of mechanical failures.

In summary, a satisfied result was achieved with implantation of three-piece IPP to treat Chinese ED patients. The tissue compatibility and quality of the pe-

nile prosthesis used in this study was proved effective and can thus be accepted by patients.

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