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**Dr. Jihad Anad Khalef**

CABU, FIBMS, Urology Senior lecturer, Department of Surgery, College of Medicine, AL-Iraqia University, Baghdad, Iraq

## Outcomes of implantation of penile prosthesis, prospective interventional study

**Dr. Jihad Anad Khalef**

### Abstract

**Background:** Penile prostheses, introduced as the first effective organic treatment for erectile dysfunction over three decades ago, have an important role in the treatment of erectile dysfunction when other non-prosthetic treatment options have proven unsatisfactory.

**Objective:** The aim of this case series is to measure the outcomes; complications and satisfaction, of using malleable penile device prosthesis in treatment of men with severe erectile dysfunction.

**Methods:** We prospectively reviewed medical records for 34 patients underwent implantation of penile prosthesis in the period from December 2014 to October 2016 in Ghazi Al-Hariri surgical specialities hospital medical city complex and Al-Jadria and Al-Mustansiria private hospitals in Baghdad to identify risk factors, indication and outcome of malleable penile prosthesis placement at our institution.

**Results:** Malleable penile prosthesis for 34 men with severe erectile dysfunction. Their ages range (25-62) year, causes of ED are vasculogenic (52.9%), DM (29.4%) (if patient diabetic >5 years), trauma (11.7%), pyerionies disease (5.9%), two of the cases which has severely uncontrolled DM has right prosthesis removed after a month and the other remaining intact because of infection (5.9%), four cases have erosion for corpora and removed (11.7%). The married couples who are completely satisfied are 8 in number, 2 unsatisfied and 16 of them partially satisfied. The mean operation time was 90 minutes, decrease to 25 minutes in last operation.

**Conclusion:** Penile prosthesis is effective in terms of satisfaction of the patients and their partners and has a reasonable complications for men with severe erectile dysfunction.

**Keywords:** Outcomes, implantation, penile, prosthesis, prospective

### Introduction

ED is defined by a National Institutes of Health consensus panel as the inability to achieve or maintain an erection sufficient for satisfactory sexual performance<sup>[1]</sup>. Worldwide estimates of ED prevalence range from 2% in men younger than 40 years to 86% in men 80 years or older<sup>[2]</sup>. The majority of patients with ED have at least one significant cardiovascular risk factor (e.g., hypertension, diabetes mellitus, smoking, or hyperlipidemia). Therefore, vasculogenic ED may be the harbinger of a systemic vasculopathic state<sup>[3]</sup>. Other important factors include heavy alcohol consumption, obesity, and physical activity<sup>[4]</sup>. A close link exists between ED and pelvic surgery, with rates ranging up to 80%. In this case, radical prostatectomy, cystectomy, and radical pelvic surgery are considered. Transurethral resection of the prostate plays an unclear role<sup>[5]</sup>. ED is highly prevalent, the incidence is strongly age-related, and it is progressive and under treated<sup>[5]</sup>. The world population is rapidly aging. Study in US show increase of cost of ED treatment from 185 million \$ in 1994 to 330million \$ in 2000<sup>[5]</sup>. One of common causes of divorce and legal marital problems so seeking solutions is important<sup>[5, 6]</sup>. Diagnosis depend on history, Physical examinations, Basic laboratory testing (A testosterone level should be performed in all men presenting with ED, Lipid profile, Assessment for diabetes with either fasting blood glucose or hemoglobin A1C.) Specialized testing, doppler study with alprostadil (caverject) injection<sup>[5, 6]</sup>. Treatment of ED is arranged in many lines according to its severity. The First-line treatment includes lifestyle modification, and modification use of some drugs. The second-line treatment includes phosphodiesterase 5 inhibitors (PDE5 inhibitors) such as sildenafil, tadalafil, and var denafil; and vacuum erection devices. The third-line treatment includes intracavernous and intraurethral (alprostadil) injection therapy. Surgeries including prosthesis are considered the fourth-line therapy<sup>[7]</sup>. So implantation of a prosthesis is the final line in the available options of therapy and it is in most of the times the last choice used in severe ED which do not respond to other options<sup>[7]</sup>. Being the last choice means that penile prosthesis is not an ideal procedure. It has some limitations,

### Correspondence

**Dr. Jihad Anad Khalef**

CABU, FIBMS, Urology Senior lecturer, Department of Surgery, College of Medicine, AL-Iraqia University, Baghdad, Iraq

and even failures. Patient are partner counselling and discussions about the procedure and its limitations is integral. Provided the patient with realistic expectations is essential to achieved more rate of satisfaction. Patient should be informed that the Sensitivity, ejaculatory abilities, and sexual drives are usually un- changed but may not be similar to what they experienced years ago. At the same time, the procedure may result in a smaller erected pe-nis than the original one. Patient should under- stand that implantation of a penile prosthesis is a permanent option, and it would be difficult to use or reuse alternative treatments like oral drugs, injections, or vacuum devices after the removal of the implanted prosthesis which may be required due to infection, mechanical failure and erosion [8]. There are many penile prosthesis used for this purpose, their implantation in its place has many surgical approaches like penoscro-tal approach, infrapubic approach, subcoronal approach, and perineal approach. Type of the prosthesis going to be implanted, and surgeon experience and preferences would determine the suitable surgical approach [9]. Intra-operatively, surgeon may experience some complications. Corporeal crossover may occur which can be recognized by the appearance of unilateral bulky penis after the implantation of the device [10]. Preformation is another expected complication which may occur proximally, distally and into the urethra [11]. Post operatively, patient may have the following complications: erosion of the prosthesis cylinder through the glans or into the urethra; 11 glans deformity or supersonic transport deformity [12, 13]; infection which is the most common and possibly the most catastrophic complication of prosthetic implantation which may need removal of the device [13, 14]. And penile necrosis which is fortunately rare [15]. Penile prosthesis as a surgical option for men with end stage erectile dysfunction who have failed treatment with pharmacotherapies including oral medications, intracavernous injections, intraurethral vasoactive agents as well as external vacuum devices. The main outcome of implanting a penile prosthesis is to allow males to have penetrative sexual intercourse benefiting the patient and their partner. As such, the best measure of clinical effectiveness is patient- partner satisfaction surveys [16]. Using penile prosthesis in Iraq for treatment of severe ED is a new procedure, and we failed to find any published study in this field on reviewing the Iraqi literature. So we aimed, in this case series, at identifying the outcomes, complications and satisfaction in men who complain from severe ED that were treated by malleable penile device (MMP).

### Patients and Methods

We prospectively reviewed the medical records of 34 patients with severe erectile dysfunction who were undergone implantation of penile prosthesis at Ghazi Al-Hariri Surgical Speciality Hospital, Medical City complex, Al-Jadiriya, and Al-Mustansiria Private Hospitals in Baghdad from December 2014 to October 2016.

### Ethical issues

The study was conducted according to the agreement of the above hospitals. Written consent was taken from all participants in this study.

### Definition of the case, inclusion and exclusion criteria

In this study we enrolled all patients who were suffering from severe erectile dysfunction and underwent penile prosthetic implantation in the above hospitals during the studies period.

Severe ED was defined in our study as failure to achieve erection at all or failure to maintain it to complete a satisfactory penetration despite using medical treatment. In our hospitals, we advised penile prosthesis for those with organic causes for erectile dysfunction as confirmed by Doppler ultrasound. The device was not advised if the patient can have at least two or more sexual intercourse a month with or without medical treatment.

### Patient workup before operation

All patients have undergone a routine preoperative evaluation by history, physical examination and investigations. Investigations have included serum electrolytes, clotting factors, an electrocardiograph, a chest X-ray and a urine examination and culture to exclude any surgical contraindication. The confirmation of the diagnosis of ED was made by Doppler ultrasonography with Caverject injection. We use a 5-10 Hz transducer to image the penis 5-10 minutes. This was done by injection 20 micrograms of prostaglandin E1 and study of arterial and venous flow rate. Cavernous artery peak systolic velocity (PSV) > 30 cm/s is considered normal. PSV 25-30 cm/s suggests mild arterial insufficiency, while a PSV < 25 cm/s indicates severe arterial insufficiency. Cavernous vein end diastolic velocity (EDV) is considered normal if it is < 3 cm/s. In isolated vena-occlusive disease, the EDV > 3 cm/s. U/S is used to assess corporal diameter. The surgery, its benefits and potential risks and complications were explained to the patient. The realistic outcomes were provided to the patient before the surgery.

### Procedure

The patient admitted to hospital a day before the surgery. After removal of pubic hair by using hair removal foam, a fugidine® (Clotrimazole) antifungal cream and genidine® (gentamycin) cream were applied on the area. Parenteral targocid® (teicoplanin) 200mg and meronim® (meropenim) 1g were injected at the time of induction as a prophylaxis and then teicoplanin 200 mg once daily and meropenem 1g three times daily were continued for 3-5 days postoperatively. In our study, we have used the malleable penile device (MMP) from Coloplast for all patients. The surgeries were done under general anaesthesia or spinal anaesthesia according to the anaesthetist's decision. A Foley's catheter was introduced into the bladder to drain urine after injecting 10 cc of povidone iodine inside the urethra. The procedure was performed under full aseptic technique; alcohol, hibitane, and povidone iodine were used for this purpose. We used penoscrotal approach in all patients through a 5-6 cm midline longitudinal incision at the level of the penoscrotal angle. It provides an excellent approach to corpora cavernosa and corpus spongiosum. After identifying the corpus spongiosum by blunt dissection, the corpora at both sides are prepared. A pair of parallel stay sutures is applied to the tunica albuginea of each corpora. Longitudinal corporal incision 2-3 cm is done. A blunt tipped corporal dilator is used for dilating cavernous tissue. Starting from 8-mm up to 13- mm. A dilator is immersed in 500 ml of saline contained 160 mg gentamicin. The corporal length is measured using special metallic sound and length of prosthesis is cut accordingly. The prosthesis is inserted in the corpora. The same procedure is repeated on other side. Corporal incision is closed using number 1 vicryl suture. Corporal incision is closed using 3/0 vicryl suture. Dressing is done by cotton and bandage. Patients were discharged from the hospital 3-5 days postoperatively. Foley's catheter was

removed at 5th postoperative day and starting oral antibiotics; ciprofloxacin tablet 500 mg twice a day and coamoxyclov capsule 625 mg three times daily for a period of 2 weeks. Since almost all patients have pain after penile prosthesis implantation, oral analgesics like diclofenac 50 mg twice a day was prescribed for the painful period. Sexual activity can be resumed no sooner than 6 weeks after implantation, and only if there is no more pain. In the case of continuing pain or severe soreness, resuming sexual activity is delayed for another

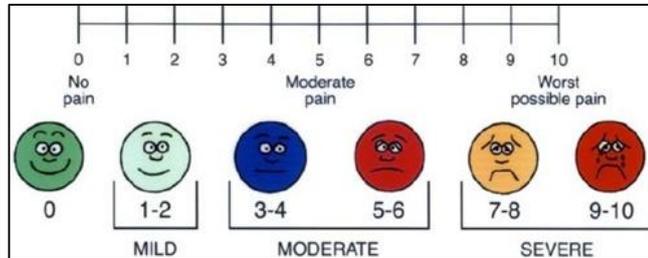


Fig 1: Visual analogue scale

2-4 weeks. The patient are learned how to flex the penis and instructed to use olive oil as a lubricant to prevent dyspareunia.

**Outcomes**

Patients were followed up for six months on regular intervals by the surgeon and his assistants through hospital visits and phone calls. In these follow up visits, we examined for development of complications and the patient’s and his partner’s satisfaction.

The complications were surgical wound infections which was diagnosed clinically by the presence of fever with redness and swelling with or without discharge; erosion which occurs due to pressure necrosis of the skin leading to displacement of the prosthesis either to the other side or to the outside; Persistent and intractable pain was defined as the pain severe enough to necessitate the use of analgesics and or narcotic after 2 weeks. Assessment of satisfaction of the patient and his partner was done by using the visual analogue scale (VAS) (See figure 1) which is composed of ten grades from completely satisfied to unsatisfied. For simplicity we grouped the patient’s response into three parts; satisfied when the score is 1 or 2, partially satisfied when the score is 3 to 6 and unsatisfied when the score is above 6. For assessment of the partner’s satisfaction we have asked the patient to quantify his partner’s satisfaction on the same scale as the direct question of the partner about her sexual satisfaction may be embarrassing.

**Statistical analysis**

Data were displayed in tables as numbers and percentages. Age was shown as mean plus/ minus standard deviation.

**Results**

The malleable penile prosthesis was performed successfully in 34 men. Mean age of participants is (43.9±11.5), with a range of (25-62) year. Table 1 shows the causes of ED, vascular cause is the commonest 18/34 (52.9%).

Table 1: Causes of erectile dysfunction

Causes	No.	Percentage
Vascular (smoking, hyperlipidemia...)	18	52.9%
DM	10	29.4%
Trauma	4	11.7%
Pyeronies disease	2	5.9%

Table 2 shows the complications following surgery. Surgical wound infection is the commonest complication 4/34 (8.3%), two of the patients with infection were having severe uncontrolled diabetes mellitus and they did not respond to antibiotics and treatment was by extraction of the prosthesis after a month of the surgery. The other two patients have responded successfully to conservative therapy with vancomycin. Two patient had erosion, in both of them the erosion was to the other side. Both were treated by manual correction and they are doing well on follow up. I the first week nearly all patients have suffered from pain and they need NSAIDs. In 22 patients (62%) the pain was extended into the second week which urge to continue NSAIDs for another week. Only 1 patient has shown severe intractable pain which needed narcotics. This patient has also supersonic transport deformity occurred due to excessive length of the prosthesis.

Results of sexual satisfaction was interpreted for 26 patients because we excluded the two patients in whom the prosthesis has been extracted due to severe infection the other 6 patients were also excluded because they were unmarried at that time and they have undergone this procedure because they were wishing to marry in the future.

Table 2: The complications post

Complication	No.	%
Wound infection	4	8.3
Erosion	2	4.2
Uncontrolled pain	1	2.1
Supersonic transport deformity	1	2.1
Total	8	16.7

Figure 2 shows that eight patients has complete satisfaction (30.7%), two patients (7.6%) were unsatisfied, and 16 patients (61.5%) were partially satisfied. While figure 3 shows that partners are more satisfied as 20 (76.9%) of them were completely satisfied and only 6 (23%) partners were partially satisfied and none were unsatisfied.

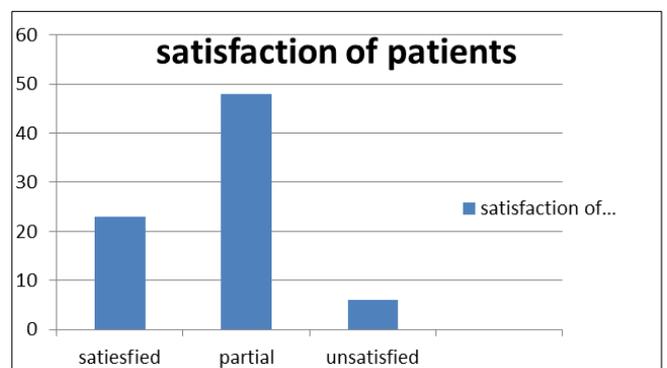


Fig 2: Patient satisfaction



Fig 3: partner satisfaction

### Discussiona

After the failure of oral drugs and intra-cavernous injections, placement of a penile prosthesis is the final option for patients with severe ED [17, 18]. In a study at University of Sao Paulo Medical School, Sao Paulo, Brazil 2010 [19], about 45% of candidates for penile prosthesis (MMP) had diabetes, 25.9% had previously undergone radical prostatectomy (RP), and 64% had hypertension. The exchange (extraction) was performed in 5.7% for fracture, inadequate size, or extrusion (erosion). A total of 24.5% of men had immediate postoperative pain, 7.9% had local infection, and 8.6% had other complications. One hundred twenty patients (86.3%) rated their level of satisfaction as good, excellent or very good, which was similar to the percentage of the partners. The mean follow-up was 40 months. The difference in rate of infection between studies can be attributed to local causes in the setting of operating theatres, and to different number of patients included in each study. Satisfaction rate in our study is higher due to good education for both of patients and their partners about the realistic outcomes with the careful selection of the patients. Very low level of prostatectomy in our series can be probably explained on the fact that, in our community, those in whom sexual activity is of much concern are more reluctant to accept prostatectomy when it is indicated due its potential effect on future sexual potency, at the same time those who develop severe ED due to prostatectomy do not seek for treatment of the ED once it develops. Another study by Salama [20]. A total of 50 patients who underwent the insertion of AMS 650 and Acu-form (which are types of malleable) penile prostheses and their partners were evaluated by a retrospective clinical record review, as well as patient and partner questionnaires. In all, 70% of the patients and 57% of the partners were satisfied with the prosthesis. There was an increase in frequency of intercourse, sexual desire, and ability to achieve orgasm. The explanation for a rate of infections such as that found in this study may be related to several factors, such as the first experience, low economic and social conditions of some patients and may therefore have a higher susceptibility to infections and careless personal hygiene during the postoperative period. Patients and their partners seemed, overall, to be satisfied with the prostheses. A total of 86.3% of men and 84.2% of the partners was satisfied with the results of surgery. These numbers are very encouraging, especially as the prostheses were generally the only possible method of treatment left to treat ED in those patients [21]. Dissatisfaction appeared to be related to the new feeling of unnatural sexual relations. With prosthesis, foreplay is no longer necessary for the start of erection. Patient

dissatisfaction may be also related to premature ejaculation which is unresolved post implant [22]. The dissatisfaction of partners may be related to the fact that, for some partners, the sexual experience does not fully meet the expectations that they had prior to the time of surgery. These unrealistic expectations probably reflect a lack of appropriate counselling prior to surgery in some patients [23]. Previous studies [24, 25] have found that the satisfaction rate among the partners is lower than ours. One factor that could explain the relatively high satisfaction rate among the partners in our study is that we depend on the patients themselves to quantify their partners' satisfaction rather than direct interview of the partners due to social reasons. And this can overestimate the satisfaction rate.

### Conclusion

Implantation of penile prosthesis is an option for the treatment of patients with sever ED. It is a safe procedure with relatively low complication rate. Both patients, and partners' satisfaction rate are high specifically when they are carefully selected and reasonably given a realistic expectations.

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  19. List of abbreviations ED Erectile dysfunction MPP Penile prosthesis CNS Central nervous system NPT Nocturnal penile tumescence PDE5 Phosphodiesterase inhibitor AMS American Medical Systems SST Supersonic transport NSAID Non-steroidal anti-inflammatory VAS Visual analogue scale Rho A GTP binding protein GTP Guanosine triphosphate cGMP Cyclic guanosine monophosphate PKG Protein kinase G Ca<sup>2+</sup> Calciumion.
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