Penile implants in the treatment of organic impotence

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ABSTRACT

Objective: To evaluate the reliability and safety of penile implants in the treatment of organic impotence at the Saudi Aramco - Dhahran Health Center.

Methods: A series of 108 cases of organic impotence that underwent 125 penile implantation procedures between 1988 and 1997 was reviewed. The follow-up period ranged between 6 months and 10 years. The mean age was 57.9 years (range 26-76). The prostheses used were AMS (American Medical System) inflatable (92 cases) and malleable (16 cases).

Results: There were no complications in 86 patients, (80%) who had functioning prostheses all through the follow-up period. Revision of the implants was required in 13 patients (14%). The causes of revision were severe infection, intolerable pain from an oversized malleable prosthesis, and dysfunction of the inflatable prostheses. Removal of the implant was necessary in severe infection, intolerable pain, and extrusion of the prosthesis. All 9 patients (8%) had inflatable prostheses and refused a second implant. There was no single mortality among our series. The overall procedure complications involved 26 out of 125 procedures (21%). It was shown that malleable penile prostheses have significantly lower procedure complications than the inflatable ones ($p<0.05$).

Conclusion: Penile implants are reliable and safe modality of treatment for organic impotence with acceptable morbidity.

Keywords: Impotence, treatment, prosthesis, penile implants.

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The penile prosthesis represents a satisfactory but a second-line treatment for organic erectile dysfunction. Alternatives, such as psychosexual counseling, external vacuum-constriction devices, intracorporial injection of vasoactive agents,[1] and recently the transuretheral suppositories[2] need to be considered in the management of men with impotence. Oral and transcutaneous medications have been tested with excellent success rates.[3] Vascular reconstructive procedures continue to play a role in selected cases.[4] In this study, we have reviewed the experience of the use of penile implants at Saudi Aramco - Dhahran Health Center over the past 10 years for evaluation of their safety and reliability.

Methods. A series of 108 patients with erectile dysfunction underwent 125 penile implant procedures between January 1988 and April 1997. The mean patient's age at presentation was 57.9 (± 9.69) years, ranging from 26 to 76 years. The prostheses used were AMS 600 malleable (21 procedures) and Hydroflex/Dynaflex inflatable (104 procedures). A complete urological and sexual history was obtained and all candidates underwent physical examination. Routine laboratory evaluation included measurement of serum testosterone, follicular stimulating hormone (FSH), luteinizing hormone (LH), and prolactin (PL); blood glucose and urine analysis. All patients underwent nocturnal

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penile tumescence evaluation using the Snap-Gauge test. Penile Doppler color flow studies, dynamic infusion cavernosometry and cavernography, nerve conduction studies and psychological counseling were carried out as indicated. All patients received appropriate literature about the treatment options and their risks and benefits. After verbal discussion, written informed consent was obtained prior to surgery. All patients had sterile urine cultures carried out preoperatively and all received peri-operative prophylactic antibiotics. The approach for insertion was left to the preference of the surgeon, (sub-coronal in 54 patients and peno-scrotal in 54 patients). Uretheral catheters were used during each procedure; these are normally removed within 24 hours. Information about the reliability and complications associated with the implant were obtained from the medical records and telephone interview of patients. The patient outcome was considered satisfactory when the patient was able to have satisfactory intercourse. Complications were examined in detail, with particular reference to postoperative pain, infection, erosion and the subsequent need to remove the prosthesis. These complications were statistically correlated with the type of prosthesis and the underlying patients risk factors using the chi-square, Fischer exact P value and the unpaired Student's t test calculations.

Results. All 108 patients were contacted during a mean follow-up of 46.1 (+ 27.8) months, ranging from 6 to 118 months. The mean age at presentation was 57.9 (+ 9.7) years, ranging from 26 to 76 years. The cause of erectile dysfunction was found to be multifactorial in a large number of cases (54%), other causes are listed in Table 1. Diabetes mellitus was the most common finding in our study population (62%); other underlying medical conditions are listed in Table 2. There were no complications reported in 86 patients (80%) who had a satisfactorily functioning prosthesis throughout the follow-up period; inflatable devices were used in 71 cases and malleable devices were used in 15 cases. Removal of the prosthesis was required in 22 patients (21%). Thirteen patients (12%) required replacement of their implants- once or twice (total of 17 procedures) - with satisfactory results. The last 9 patients refused replacement of their prosthesis after removal. The underlying causes for implant replacements and removal are shown in Tables 3 and 4. Early replacement of the implant was required in 2 cases. The first case had severe peri-prosthesis (Dynaflex) infection, whereas the second case had severe pain due to an oversized malleable prosthesis. Late dysfunction of inflatable prostheses was the reason for replacement in 11 patients. Malleable devices were used in 2 cases of early replacement, whereas patients who presented with delayed dysfunction of

Table 1 - Etiology of erectile dysfunction

Causes of erectile dysfunction	Number of patients (n=108) %
Multifactorial*	58 (54)
Neurological	16 (15)
Endocrinal	2 (2)
Vascular	2 (2)
Peyronie's disease	3 (3)
Priapism	1 (1)
Idiopathic	26 (24)

*Patients had several underlying etiological factors

Table 2 - Underlying medical conditions.

Medical conditions	Number of patients (n=108)* (%)
Diabetes melitus	67 (62)
Hyperlipidemia	43 (40)
Hypertension	37 (34)
Coronary disease	21 (19)
Cerebrovascular disease	2 (2)
Sickle cell disease	1 (1)
Hodgkin disease	1 (1)
Obesity	8 (7)
Smoking	27 (25)

*Some patients had several medical conditions

Table 3 - Causes of replacement.

Medical conditions	Number of patients (n=108)* (%)
Early	
Infection	1 (1)
Severe pain**	1 (1)
Late	
Dysfunction*	11 (10)
Total	13 12

*All inflatable **Malleable

Table 4 - Causes of removal of the prosthesis*.

Medical conditions	Number of patients (n=108)* (%)
Early	
Infection	6 (5.5)
Severe pain**	1 (1)
Late	
Severe pain	1 (1)
Extrusion	1 (1)
Total	9 (8)

*All inflatable

an inflatable prosthesis were given a second chance with another inflatable device (11 cases). Among the redo cases, dysfunction of the second device occurred in 4 cases. Those required reinsertion of a third prosthesis using (3) malleable and (1) inflatable. Removal of implants was necessary in 9 patients after the first procedure because of severe peri-prosthesis infection (5 cases), intolerable pain (3 cases) and late extrusion (1 case). All these cases had inflatable prostheses and refused reinsertion of a second device.

Among the 125 insertions performed in our institute, there were 26 instances of major procedure complications (21%), and these are listed in Table 5. Statistical analysis had shown that only the type of implant correlates significantly with the overall complication rate. Malleable penile prostheses seem to have a lower procedure complication rate than inflatable devices ($P<0.05$). None of the underlying patient's risk factors was found to correlate statistically with the procedure complication rates.

Table 5 - Procedure complications.

Procedure complications	Insertions (n=125) (%)
Minor	
Urine retention	6 (5)
Pain	5 (4)
Mild infection	1 (1)
Hematoma	3 (2)
Total	15 (12)
Major	
Severe pain	3 (2)
Infection	7 (6)
Extrusion	1 (1)
Dysfunction	15 (12)
Total	26 (21)

Discussion. Sexual impotence is an age-and disease-dependent disorder of great prevalence.[5,6] The currently recommended first line of treatment is non-surgical, according to the American Urological Association guidelines.[7] Penile prosthetic surgery continues to be a valid treatment option with an incomparable high index of satisfaction if not complicated.[8-10] Like other prosthetic implants, however, penile prostheses present various risks related to the surgical procedure, the presence of a foreign body, the mechanics of the device and the psychological reaction to the prosthesis.

In our series, the majority of cases had multifactorial etiology (54%) or idiopathic impotence (24%). Those cases had initially gone through psychosexual counseling with adjuvant non-surgical modalities of treatment. Most of our patients found intracorporial papaverine inconvenient or impractical. The experience with erection devices was disappointing. Therefore, penile prostheses were found to be a more suitable option for our patient population until a more convenient and effective modality proves itself in practice.

Among the 108 patients, there were 22 instances of major complications resulting in either ultimate removal of their devices (9 patients i.e. 8%) or exchange (13 patients, i.e., 12%), whereas none of those with minor complications required device removal or replacement. Infection and mechanical malfunction accounted for most of the revision procedures. Our infection rate was 6% (8/125 procedures), all of which were in patients with inflatable prostheses. Reports in the literature describe infection rates between 1% and 11%.[8-14] The risk factors for infection in patients receiving penile implants have been discussed in detail,[12-14] and the most important ones appear to be a history of urinary tract infection, neurogenic bladder, spinal cord injuries,[14] diabetes mellitus,[8] and extreme obesity. None of these factors was found statistically to be of significance as a high risk for infection in our study group. Salvage of the implant was achieved in one patient who had superficial wound infection that was controlled with antibiotics. In the remainder of cases (7 patients,) the prostheses had to be removed and replacement was required only in one case using a malleable prosthesis. Postoperative pain was recognized in 8 instances among the 125 procedures (6%). Most of the patients responded very well to deflation trials of inflatable devices (4 patients), 1 patient required removal of one of the inserted malleable rods to relieve pain, and 3 patients requested removal of the whole device but refused replacements. The only case of implant extrusion was a 65-year old diabetic who refused to have another prosthesis because of social reasons. The

mechanical prosthetic dysfunction reported in our series included leakage, pump or valve malfunction and the concord deformity secondary to short devices. These were reported in 11 patients (10%) and amounted to 12% of the procedure complications (15/125 procedures). In all instances, we were able to restore function by replacement of a second inflatable prosthesis (4 patients had replacement of the prosthesis twice). Our overall results are comparable to those reported by different authors,[8-15] which ranges between 4.5% and 44% of cases in 5-years follow-up.

In conclusion, organic erectile dysfunction remains a worldwide problem involving about 15% of the population in the United States. Non-surgical treatment is still considered the first line therapy for such cases. New oral therapy has shown promising results when properly used. Penile implants should be concluded only after failure of medical treatment. Careful preoperative assessment and education of the patient, proper device selection and strict asepsis including antimicrobial prophylaxis are essential for obtaining a successful outcome after surgery. Newer therapeutic modalities continue to evolve and they deserve further research trials and reporting.

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