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ORIGINAL ARTICLE

Sexual Function

# Outcome of penile prosthesis implantation: are malleable prostheses an appropriate treatment option in patients with erectile dysfunction caused by prior radical surgery?

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The aim of our study was to evaluate the outcome of penile prosthesis implantation in patients with various comorbidities as a cause of erectile dysfunction (ED). The data of 181 patients who underwent surgery between 1998 and 2012 in two centers were evaluated. The mean age of the patients was 52.2 years (range: 31–71 years). The study group contained 162 patients (89.5%) with malleable prostheses and 19 (10.5%) with inflatable implants. All patients were re-evaluated 1 month later to assess prosthesis function and complications, and further re-examinations were performed if needed. Satisfaction was defined as having satisfactory intercourse and happiness with the device in general. The follow-up period was at least 12 months for each patient. The postoperative complication rate was 32% ( $n = 58$ ). The number of complications with inflatable and malleable prostheses was 7 (3.9%) and 51 (28.1%), respectively. Overall, 21 prostheses (11.6%) had to be removed because of various complications and patient dissatisfaction. Patients with prior radical surgery had higher extraction rates ( $\chi = 14.606$ ,  $P < 0.05$ , Chi-square test). The main reasons for removal were erosion ( $n = 11$ ; 6.1%) and infection ( $n = 3$ ; 2.1%). With respect to satisfaction during intercourse, we found that 104 (57.5%) patients described themselves as very satisfied with the prosthesis, while 21 (11.6%) were unsatisfied. The high explantation rate in patients with prior surgery was remarkable in our study. Our results revealed that a malleable prosthesis should not be the preferred type of implant for patients with prior surgery.

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## INTRODUCTION

Surgical implantation of a prosthesis is the preferred option for definitive treatment of erectile dysfunction (ED) for men who do not respond to or are unwilling to consider pharmacologic or less-invasive treatment methods.<sup>1</sup> Studies have estimated that more than half of men aged 40–70 years suffer from some form of ED, with nearly 50% of men between 60 and 70 years having moderate to severe ED.<sup>2</sup> Oral phosphodiesterase type-5 inhibitors are the preferred first-line treatment for men with ED. Approximately, 25%–30% of patients will not be benefited from these medications and will therefore be advised to undergo intracavernosal injection, which is associated with a high drop-out rate. At least 10%–15% patients with ED will be candidates for penile prosthesis implantation (PPI).<sup>3</sup> Penile prosthesis implants have the highest satisfaction rates among treatment options for ED. Penile prostheses can be grouped into inflatable and noninflatable devices. Noninflatable prostheses are less expensive and more durable, but they are more likely to erode because of permanent erection. Inflatable devices offer the advantage of flaccid and erect states, but mechanical failure occurs at higher rates than for malleable devices because of their complex structure. Nevertheless, technical improvements in the

devices and in surgical techniques have made PPI an effective treatment for refractory ED.<sup>4</sup> The efficacy and safety of various types of penile prostheses have been reported by prominent centers.<sup>5</sup> Due to improved placement techniques and devices, most complications are related to medical problems rather than mechanical failure. The aim of this study was to evaluate the clinical outcomes and surgical complications after penile prosthesis implantation performed at our institution in patients with various causes of ED. We analyzed complications, mechanical failures, and the satisfaction status of patients after PPI.

## MATERIALS AND METHODS

### Study population

This study included 198 patients suffering from end-stage ED of various etiologies who underwent surgery at either of two different research and education hospitals between 1998 and 2012. Seventeen patients were excluded because they were lost during follow-up. The remaining 181 patients' records were evaluated. Indications for PPI were failure or intolerance of medical treatment, confirmation of ED by Doppler ultrasound or cavernosography, and severe ED. All procedures were performed by three senior surgeons or under the supervision of these

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surgeons. The data of these patients were reviewed to determine ED etiology, comorbid medical diseases, type of prosthesis, perioperative complications, postoperative outcome, and patient satisfaction. The diseases contributing to their ED are presented in **Table 1**. The most common comorbidities observed were diabetes mellitus ( $n = 81$ ; 44.5%), organic dysfunction ( $n = 46$ ; 25.4%), and radical surgery ( $n = 29$ ; 16.1%).

### Procedural course and data characteristics

The mean age of the patients was 52.2 years (range: 31–71 years). Our study population contained 162 patients (90.0%) with malleable prostheses and 19 (10.0%) with inflatable implants (**Table 2**). All men underwent medical and psychiatric consultation, as was performed routinely before the surgery. The operative field was disinfected with povidone–iodine the night before the operation and 10 min before the surgical intervention. Most ( $n = 142$ ; 78.9%) of the malleable prostheses were implanted through a penoscrotal incision, and the inflatable devices were implanted through infrapubic ( $n = 13$ ; 7.2%) or penoscrotal ( $n = 6$ ; 3.3%) incisions. Preoperative antibiotic prophylaxis, such as vancomycin, was given the night before the surgery and for 3 days postoperatively. Oral antibiotic prophylaxis with ciprofloxacin was continued through the 7<sup>th</sup> postoperative day. The implant and operation fields were irrigated with gentamicin 240 mg in saline prior to implantation. The corpus cavernosum usually was dilated with Hegar dilators, though an Otis urethrotome was necessary in two cases. A Foley catheter was inserted at the end of the procedure and removed 1 day later. The patients were discharged 3–5 days postoperatively.

Various complications, including re-implants and explants, were recorded in detail (**Tables 3 and 4**). All patients were re-evaluated

**Table 1: Primary causes of ED in the study group**

Disease	Patient, n (%)
Diabetes mellitus	81 (44.7)
Vascular diseases	46 (25.4)
Radical pelvic surgery	29 (16.0)
Other reasons	25 (13.8)
Pelvic trauma	9 (5.0)
Priapism	5 (2.8)
Peyronie's disease	5 (2.8)
Penis fracture	3 (1.7)
Venous surgery	1 (0.6)
Pelvic radiotherapy	1 (0.6)
Vertebra fracture	1 (0.6)

ED: erectile dysfunction

**Table 2: Type of implanted penile prosthesis**

Prosthesis type	n (%)
Malleable	
Mentor Acu-Form	50 (27.6)
AMS 600–650M	35 (19.4)
Mentor malleable	30 (16.6)
Coloplast	28 (15.5)
Promedon	9 (5.0)
Mentor genesis	9 (5.0)
Self-contained inflatable	
AMS Dynaflex	3 (1.7)
Three-piece inflatable	
Coloplast Titan	7 (3.9)
Mentor alpha-1	2 (1.1)
AMS 700	8 (4.4)

1 month later for prosthesis function and complications, and further re-examinations were performed if needed. The follow-up period was at least 12 months for each patient. The reasons for prosthesis explantation were classified as erosion, infection, mechanical failure, or any functional complication. Satisfaction during intercourse and general happiness with the prosthesis were also assessed. Satisfaction was defined as having satisfactory intercourse and happiness with the device in general.

### Statistical analysis

Data were analyzed with SPSS version 20.0 statistical software (SPSS Inc., Chicago, IL, USA). Comparability between groups was tested using the independent samples *t*-test for continuous variables and the Chi-square test for categorical variables.

## RESULTS

The outcomes of 181 patients were evaluated. Six of the surgeries were secondary procedures. Re-implantations were performed in patients with infection ( $n = 2$ ), SST deformity ( $n = 1$ ), mechanical failure ( $n = 3$ ), and bilateral urethral perforation ( $n = 1$ ).

**Table 3: Peri-and post-operative complications**

Perioperative complications	n (%)	Note
Urethra perforation	6 (3.3)	During dilatation
Cavernosal crossover	9 (6.2)	During dilatation
Crural perforation	2 (1.1)	During dilatation
Postoperative complications		
Superficial wound infection	17 (9.4)	Resolved with antibiotherapy
Hematoma	2 (1.1)	Located on scrotum, proximal penis
Dehiscence of glans penis	15 (8.3)	Resolved after 1 month
Pain during intercourse	5 (2.8)	Persisted after 1 year
Bending during intercourse	10 (5.5)	Dissolved after few months
Lower urinary tract symptoms	4 (2.2)	Could sustain intercourse
Soft glans	6 (3.3)	History of TURP in two patients
	4 (2.2)	

**Table 4: Complications in different comorbidity groups that lead to explantation**

Primer comorbidity	Extracted, n (%)	Reason for explantation
Diabetes mellitus	5 (2.8)	Leakage from the reservoir ( $n=1$ ) after 18 months ( $n=1$ ) Inflation dysfunction of left prosthesis after 5 years (self-contained prosthesis) ( $n=1$ ) Pump dysfunction ( $n=1$ ) after 10 years Penile necrosis ( $n=1$ ) SST deformation after 3 months ( $n=1$ )
Vascular causes	4 (2.2)	Prosthesis infection ( $n=2$ ) Distortion due to early koitus (12 <sup>th</sup> day) ( $n=1$ ) Left scrotal erosion ( $n=1$ )
Radical surgery	8 (4.4)	Erosion ( $n=8$ )
Radical prostatectomy	5 (2.8)	
Radical cystectomy	3 (1.7)	
Other comorbidities	4 (2.2)	
Penile fracture	1 (0.6)	Prosthesis infection ( $n=1$ )
Priapism	1 (0.6)	Erosion ( $n=1$ )
Peyronie's disease	1 (0.6)	Dissatisfaction about the device ( $n=1$ )
Pelvic trauma	1 (0.6)	Erosion ( $n=1$ )
Total	21 (11.6)	

SST: super sonic transporter

Perioperative complications, including urethral perforation, cavernosal crossover, and crural perforation, were identified in 17 (9.4%) patients (Table 3). Bladder perforation was not observed in our study group. In a patient with diabetes, only one side of the prosthesis was able to be inserted. All intraoperative complications were resolved during surgery, and the operations were completed successfully. The overall postoperative complication rate was 32.0% ( $n = 58$ ). Complication rates of inflatable and malleable prostheses were 3.9% ( $n = 7$ ) and 28.1% ( $n = 51$ ), respectively. Details about the number, course, or reasons of complications are listed in Table 3.

In the 11 cases (6.1%) with erosion, the complication was observed in a median time of 13 weeks (1–50 weeks). Eight of these patients had a history of radical surgery; three were patients with prior cystectomy (1.7%) and five were patients with prior prostatectomy (2.8%). A further three cases with erosion were patients with priapism (0.6%), cardiovascular disease (0.6%), and pelvic trauma with urethral injury (0.6%). In eight cases, erosion was identified on one side, while two prostheses were excreted bilaterally, and erosion of the scrotum due to the pump occurred in one case 4 months postoperatively. The last patient also complained about ongoing perineal pain. All prostheses were extruded from the glans penis, and one of these was a re-implanted device. Overall, 21 prostheses (11.6%) had to be removed because of various complications and dissatisfaction (Table 4). Four of the 21 explanted prostheses were inflatable devices, and none of these were in patients with prior radical surgery. Infection of the prosthesis was identified in three malleable devices. The time to the onset of prosthesis infections (1.7) was 13, 22, and 52 weeks (median time = 32.3) postoperatively.

The rate of prosthesis extraction independent of the reason for removal was significantly higher in patients with prior radical surgery as the primary comorbidity ( $\lambda = 14.606$ ,  $P < 0.05$ , Chi-square test). The group with prior radical surgery accounted for 42.9% of all explantations. Likewise, the erosion rate was different among groups based on prior radical surgery ( $\lambda = 24.837$ ,  $P < 0.01$ , Chi-square test), and 70.0% of the patients who had erosion were in the group that had received prior radical surgery. With respect to groups of comorbidity compared with complications encountered, no significant association with postoperative complication rate was detected ( $\lambda = 5.157$ ,  $P > 0.05$ , Chi-square test). Age was not a risk factor for the development of postoperative complications ( $P > 0.05$ ,  $t = -1.355$ ,  $t$ -test).

With respect to satisfaction during intercourse, we detected that 104 (57.5%) patients described themselves as very satisfied with the prosthesis, 48 (26.5%) indicated that they were satisfied, and 21 (11.6%) were not happy with the prosthesis implantation at all (Table 5).

**Table 5: Intercourse frequency and satisfaction rates**

Characters	Value
Mean time to first intercourse, day (range)	54 (9–150)
Intercourse rate (weekly frequency of sexual activity), $n$ (%)	
0–1	63 (36.2)
2	90 (51.7)
3	14 (8)
4	7 (4)
Patient satisfaction, $n$ (%)	
Very satisfied	104 (57.5)
Satisfied	48 (26.5)
Not satisfied	21 (11.6)

## DISCUSSION

The main purpose of this study was to present the outcomes after prosthesis surgery. Prosthesis infection is one of the main complications of PPI surgery, with an incidence between 1.6% and 13.3%.<sup>6,7</sup> Various causes of infection have been described in the literature, and most prostheses become infected in the first year after operation. The time to occurrence of infection in our study was similar to those reported previously, with all infections presenting within 1 year after surgery.<sup>8</sup> Infection rates are more common in revision surgeries than in primary PPI.<sup>7</sup> Jarow<sup>9</sup> found infection rates of 1.8% and 13.3% for primary and secondary procedures, respectively. With regard to infection in re-implanted patients in our study, none of the infected patients were repeat surgeries. The low number of re-implanted patients in our data set cannot provide meaningful statistics. Factors that impair host resistance to infection, including poor antibiotic penetration due to capsule formation around the previous implant and poor wound healing, were thought to be related to an increased risk of infection during revision surgery.<sup>10</sup>

Antibiotic-impregnated prostheses have been introduced in recent years. Mulcahy and Carson<sup>11</sup> reported a significantly lower rate of infection-related revisions for antibiotic-impregnated prostheses than for nonimpregnated implants in diabetic patients ( $P < 0.01$ ).

The incidence of prosthesis infection was 1.7% in our study. Diabetes was not a predisposing factor for prosthesis infection, and none of the infected prostheses were identified in patients with diabetes. Similarly, no correlation between diabetes and penile prosthesis infection was reported by Montague *et al.*<sup>12</sup> who reported a 2% incidence of prosthesis infection in nondiabetic patients and a 2.2% incidence in diabetics.

Patients with perioperative complications such as urethral perforation, crural perforation, and cavernosal crossover were identified with a higher incidence in our study (9.4%) compared with other studies (4.8%).<sup>13</sup> All perioperative complications were resolved during the operation, and the procedure was completed successfully. Nevertheless, in four patients with perioperative urethral perforation and in one case with cavernosal crossover, erosion requiring extraction developed in the postoperative period.

Superficial wound infections (13%) resolved after treatment with broad-spectrum antibiotics. Our rate of superficial infections was relatively high. Minervini *et al.*<sup>13</sup> reported in their study with 504 patients an infection rate of 6%. Minor complications such as hematoma were treated conservatively and caused no long-term sequelae. Strict adherence to antimicrobial prophylaxis, cleansing of the perineal skin, intraoperative surgical shaving, povidone scrubbing, limited operating room traffic, and good postoperative care are advised to reduce infection rates. North American experts have published a consensus report about the prevention, management, and research of infection associated with penile prostheses. They recommend six factors for the prevention of infection. Two factors were related to perioperative systemic antibiotic prophylaxis and antiseptic cleansing of the skin. They reported superior protection with alcohol-based antiseptic preparation versus povidone-iodine. For antibiotic prophylaxis, they recommend intravenous antibiotic during hospitalization for at least 24 h after surgery and oral antibiotic prophylaxis for 5–14 days afterward.<sup>14</sup> In our practice, we routinely used povidone-iodine for cleansing, we did not shave intraoperatively, and oral and intravenous antibiotic prophylaxis was not given for more than 7 days postoperatively. However, in our opinion, the high rate of infection in our study was more affected by other factors such as the high number of operations that are performed in our operation room,

the high circulation of patients in our clinic, inadequate postoperative care because of low staff numbers, and the low socio-economic status of our patients.

Mechanical failure was found in 3 of the 13 inflatable prostheses. These failures occurred at 3, 61, and 119 months after implantation. One of these cases was a self-contained prosthesis, in which the left cylinder did not inflate after 61 months. The two other cases involved the pump and reservoir, although it was not clear whether these failures were due to leakage. Malleable prostheses are known to be more durable than inflatable devices, and the likelihood of mechanical failure may be lower than in inflatable prostheses. Lotan *et al.*<sup>15</sup> reported that the survival rate of malleable prostheses was 87% compared with 50% for inflatable prostheses. This difference can be explained by the mechanical complexity of inflatable prostheses and the simple design of malleable prostheses. The probability of failure was found to be higher in more complex devices.<sup>16</sup> Mechanical failures of malleable prostheses, such as breaks, were not observed in our study group. The reported overall percentage of mechanical failure of malleable prostheses is approximately 1.7% in the literature.<sup>17</sup>

Satisfaction with the prosthesis was not evaluated in detail in our report. Our patients were asked during control visits if they were very satisfied, satisfied, or unsatisfied with the prosthesis in general. A validated questionnaire with detailed questions was not performed. Other studies used the validated questionnaire, "The Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS)" to establish satisfaction rates after implantation and found patient satisfaction rates of 97%, 81%, and 75% for AMS 700CX, AMS Ambicor, and AMS 600–650, respectively.<sup>18</sup> The use of this type of standardized assessment material for satisfaction will help to determine comparable results for different centers.

A relationship between previous radical surgery and complications was not observed in our patient group. However, the relationship between erosion and radical surgery was remarkable. Erosion is known to be one of the disadvantages of malleable prostheses compared with inflatable devices.

The erosion rate of prostheses in our study was higher in patients with prior surgery compared to other comorbidities ( $P < 0.01$ ). Related to this observation, explantation numbers were higher in the prior radical surgery group. In addition, it should be emphasized that there was no relation between complication rates and the groups of comorbidities. This was another point that led us to think that erosion was related to radical surgery. The reason for the higher erosion rates in prosthesis implantations after radical surgery may be due to the cavernosal fibrosis that occurs after surgery. Iacono *et al.*<sup>19</sup> reported intensive cavernosal fibrosis in prostatectomized patients due to local hypoxia. A reduction in the number of elastic and smooth muscle fibers and an increase in collagen tissue were observed in the corpus cavernosa. Studies also have demonstrated that cavernosal fibrosis sets in after radical prostatectomy, and the vascular and neurological causes of fibrosis cannot yet be specified.<sup>19,20</sup>

Our findings suggest that radical surgery is related to intense cavernosal fibrosis with a consequence of higher perioperative and postoperative complication rates, especially in malleable prostheses. We did not evaluate patients with erosion or other complications according to the different brands of implanted devices. We have the opinion that erosion was related more to comorbidity and the type of prosthesis. Most of the implants were malleable prostheses, which are known to carry a higher risk for erosion. We could not correlate the high erosion rate with factors other than radical surgery because the number of erosions in other groups of comorbidity was low.

Other authors have reported on the safety of three-piece inflatable prosthesis in patients with prior radical prostatectomy. They evaluated the postoperative complication rate after three-piece penile prosthesis implantation in patients with and without prior radical prostatectomy. The estimate of probability, by the Kaplan–Meier method, of no mechanical failure after 5 years in the postradical surgery group was higher than that observed in the other group. The postoperative complication rates in the radical surgery group and the other group were 11% and 16%, respectively. This study concluded that a three-piece inflatable prosthesis can be placed safely in postradical surgery patients through a standard scrotal transverse incision without complications and with favorable outcomes.<sup>21</sup>

The low-economic status of our patients and the high costs of inflatable devices led our patients to choose malleable prostheses, despite the known advantages of inflatable prostheses. These devices are still the more commonly implanted devices at our institution. With regard to patients with prior radical surgery who are candidates for a penile prosthesis, our study revealed unfavorable outcomes. Our study showed higher erosion rates in the postradical surgery group, although the postoperative complication rate was not different from other comorbidity groups. Finally, we think that other reports with regard to malleable prosthesis implantation in patients with postradical surgery ED are needed.

#### AUTHOR CONTRIBUTIONS

CS collected data, has helped in study design, helped to draft the manuscript, and has performed proofreading. OO has made contributions in the design of the manuscript, in analyzing the data, in interpreting the data, in sequence alignment, and in writing the manuscript. MB has helped in revision and design of the manuscript and has made proofreading. UY has made contributions in collecting the data and revision of language. TK has given final approval of the version to be published and has helped in the study design. All authors read and approved the final manuscript.

#### COMPETING INTERESTS

All authors declare no competing interests.

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