A Retrospective Cohort Study on Surgical Outcomes of Penile Prosthesis Implantation Surgery in Transgender Men After Phalloplasty

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OBJECTIVES To assess surgical outcomes of penile prosthesis implantation in transgender men who underwent phalloplasty.

PATIENTS AND METHODS Transgender men who underwent penile prosthesis implantation after phalloplasty between January 1989 and September 2018 were retrospectively identified. A chart study was performed recording patient demographics, perioperative complications, and reoperations.

RESULTS A total of 32 patients were identified: 22 underwent free radial forearm flap, 5 anterolateral thigh, 4 anterolateral thigh/free radial forearm flap, and 1 fibular flap phalloplasty. The median age at prosthesis implantation was 36 (range 21-59) years, the mean BMI 25.9 ± 4.0 kg/m^2. At first implantation, 16 inflatable (AMS Dynaflex (n = 13), AMS Ambicor (n = 3)) and 16 malleable (Coloplast genesis (n = 14), AMS Spectra (n = 2)) prostheses were placed. Of these, 5 (16%) were removed/replaced because of infection, 2 (6%) because of leakage, 2 because of extrusion, 2 because of dislocation, 2 because of dysfunction, and 1 (3%) because of pain. The postoperative course was completely uneventful in 10 (31.3%) patients. Of all implanted prostheses, including revision procedures (n = 45), 21 (44%) were surgically replaced or removed.

CONCLUSION Prosthesis explantation, replacement, or revision surgery occurs frequently after penile prosthesis implantation. Patients need to be well-informed preoperatively on these complication rates. UROLOGY 132: 195–201, 2019. © 2019 Elsevier Inc.

Genital gender affirming surgery in transgender men includes metaidoioplasty and phalloplasty. An important reason for choosing the phalloplasty procedure over metaidoioplasty, is the wish to engage in penetrative sexual intercourse. Multiple surgical techniques can be utilized for phalloplasty surgery. The most commonly performed procedure is the free radial forearm flap (FRFF) phalloplasty.[1-3] Several other flaps can be used, such as the abdominal flap, the (pedicled) anterolateral thigh (ALT) flap, latissimus dorsi flap, the superficial circumflex iliac artery flap, and the free fibula flap (with or without bone graft).[4-8] A combination of flaps has also been described.[9-11] In phalloplasty surgery, an aesthetically pleasing phallus with the possibility of voiding in standing position can often be achieved. However, the neophallus could lack the rigidity that is needed for penetrative sexual intercourse.

Nowadays, patients deemed eligible for erectile prosthesis implantation are typically at least 1 year after phalloplasty surgery, have no urethral problems, are not awaiting secondary corrections of the phalloplasty or scrotoplasty and have a neophallus that is sensate, to an extent that protective sensitivity is present.

The aim of this study was to assess the surgical outcomes of erectile prosthesis implantation in transgender men who underwent phalloplasty.

PATIENTS AND METHODS

Retrospective Chart Study

In the period January 1988 to September 2017, a total of 170 patients underwent phalloplasty at our institution. All

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transgender men who underwent erectile prosthesis implantation after phalloplasty, from January 1989 until September 2018, were retrospectively identified from our hospital registry. A single-center retrospective chart review was performed, recording patient demographics (type of phalloplasty procedure performed, other medical and surgical history, comorbidity, age at surgery, body mass index (BMI) and use of medication, alcohol, nicotine and/or drugs), perioperative characteristics (date of surgery, prosthesis characteristics, surgical technique, surgery duration, length of hospitalization), intra- and postoperative complications (intraoperative complications, short-term postoperative complications, such as infections, bleeding, necrosis, and prosthesis-related complications) and reoperations.

Current Operative Technique

Over time, the surgical technique for penile prosthesis implantation has changed in our center and worldwide. Here we describe the current technique, in which a Coloplast Genesis prosthesis is implanted which is covered by a vascular prosthesis (Dacron). The skin in the genital region is shaved after intubation. Subsequently, the genital region is scrubbed with soap and meticulous disinfection is performed with chlorhexidine and povidone-iodine. A second-generation cephalosporin is administered intravenously as antibiotic prophylaxis. In patients who underwent phalloplasty with urethral lengthening, a transurethral catheter is placed.

In case of implantation of two cylinders, two parascrotal incisions are made. When placing only one cylinder, one parascrotal incision is made, or an incision at the dorsal base of the phallus is made. The ventral and proximal part of the ramus superior is freed from surrounding tissue. Two nonresorbable Prolene 2.0 sutures are placed through the periosteum, to enable firm fixation of the implant base later in the procedure.

The phallus is dilated to approximately 1 cm underneath the top of the phallus. It is important to leave a sufficient amount of subcutaneous fat between the implant and the top of the phallus to prevent implant erosion. After single-flap phalloplasty, dilatation of the phallus is performed in the middle of the shaft. After double-flap phalloplasty, the location of the prosthesis is easily dissected between the two flaps. The length of the cavity is measured with the Furlow inserter.

The measured length and width of the phallus are decisive for the size of the implants and these are trimmed according to the measured length. A rear tip extender is not necessary. The penile prosthesis and vascular prosthesis (Dacron) are rinsed with a rifampicin/gentamicin solution. The base of the prosthesis is covered by the vascular prosthesis, and fixed to the pubic bone with nonresorbable sutures. At the end of the procedure, skin quality and tissue viability are checked. Dermis and subcutaneous tissues are approximated and epidermis is closed with resorbable sutures.

Patient Satisfaction

All consenting patients, with a prosthesis in place, were asked to complete a combined questionnaire. The questionnaire consisted of the Cantril's Ladder of Life Scale (a single-item indicator of well-being, in which a patients rates life satisfaction between 0 and 10) and a self-created questionnaire with seven questions pertaining to sexuality and satisfaction with the operative result. Patients were asked to grade their satisfaction on a Likert scale from 0 (not satisfied) to 5 (totally satisfied). Additionally, patients were asked to grade the operative end result on a scale from 1 to 10.

Statistical Analysis

IBM SPSS software Version 20 for Windows (IBM Corp., Armonk, NY) was used for all statistical analyses. For patient demographics, Gaussian continuous variables were presented as means with standard deviations, non-Gaussian continuous variables were presented as medians with ranges and categorical variables were presented as frequencies and percentages

Ethical Statement

This retrospective chart study was exempt from institutional review board approval. The study on patient-reported outcomes was approved by our local medical ethical committee (METC, reference number 2018625). All photographed patients provided written informed consent for use of the photographic material. All included patients provided written informed consent for retrospective use of their medical data.

RESULTS

Patient Demographics

From January 1989 until September 2018, a total of 32 patients were retrospectively identified that underwent penile prosthesis implantation. Patient demographics are presented in Table 1. Twenty-two patients underwent FRFF (for an example, Fig. 1), 5 ALT, 4 ALT/FRFF, and 1 fibular flap phalloplasty. Two patients underwent penile prosthesis implantation in the same session as the phalloplasty procedure.

Table 1. Patient demographics

Total Patients, *n*	32
Median age at phalloplasty, y (range)	32 (19-57)
Phalloplasty type, *n* (%)	
FRFF	22 (68.8%)
ALT	5 (15.6%)
ALT + FRFF	4 (12.5%)
Fibula	1 (3.1%)
Median age at prosthesis implantation, y (range)	36 (21-59)
Mean BMI, kg/m^2 ± SD	25.9 ± 4.0
History of smoking, *n* (%)	16 (50%)
Prosthesis placement, *n* (%)	
Immediate during phalloplasty	2 (6.3%)
Delayed	30 (93.8%)
Median time between phalloplasty and prosthesis implantation, y (range)	2.3 (1.0-19.0)
Originally implanted prosthesis, *n* (%)	
Total	32 (100%)
- Inflatable	
AMS Dynaflex	13 (40.6%)
AMS Ambicor	3 (9.4%)
- Malleable	
AMS Spectra	2 (6.3%)
Coloplast Genesis	14 (43.8%)
All implanted prostheses, including revision procedures, *n* (%)	
Total	45 (100%)
- Inflatable	
AMS Dynaflex	18 (40%)
AMS Ambicor	4 (8.9%)
- Malleable	
AMS Spectra	2 (4.4%)
Coloplast Genesis	21 (46.7%)

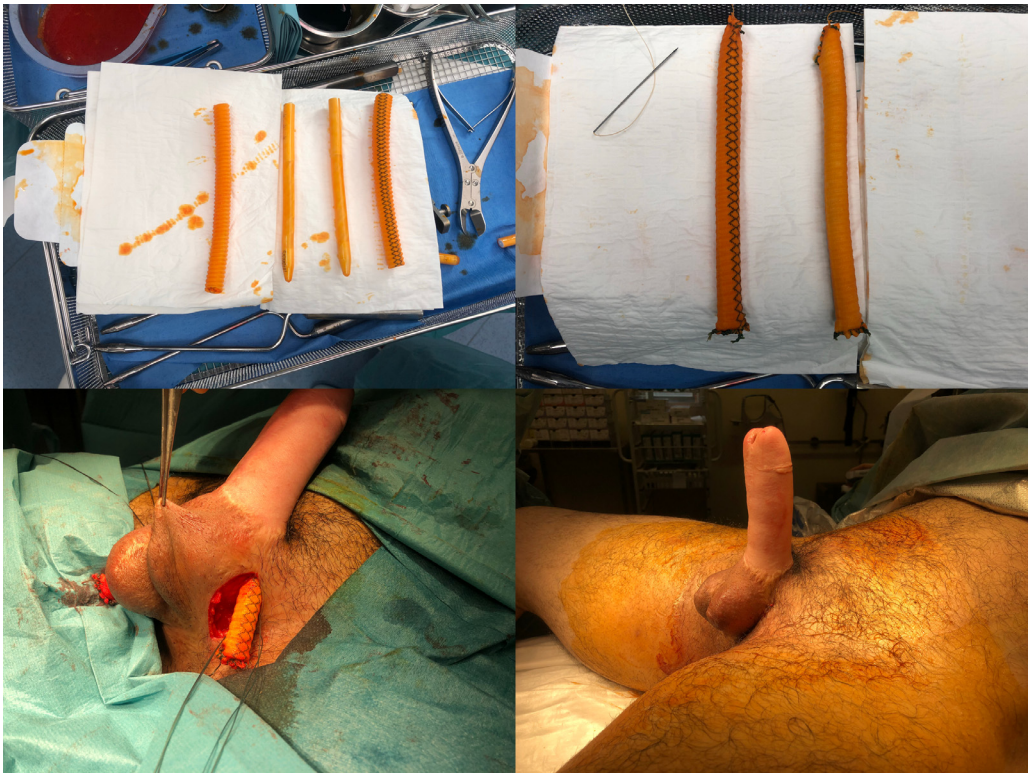

Figure 1. Implantation of Coloplast Genesis noninflatable, semi-rigid penile implant in a transgender male after free radial forearm flap phalloplasty. **Left upper:** Coloplast Genesis and Dacron prostheses. **Right upper:** the Coloplast prosthesis is inserted into the Dacron sock. **Left lower:** Fixation to the pubic bone. **Right lower:** Postoperative result. (Color version available online.)

Retrospective Chart Study

A total of 45 prostheses were implanted in 32 transgender men. The median postoperative follow-up was 4.6 years (range 0.4-23.9). Of 32 originally implanted prostheses, 16 were surgically removed or replaced after a median of 1.1 years (range 7 days-18.8 years). Five (15.6%) were explanted because of infection. Of all implanted prostheses ($n = 45$), 21 (44%) were surgically removed or replaced. Eight (17.8%) were explanted because of infection. The postoperative course was uneventful in 10 patients. At last follow-up, 24 (75%) patients had a penile prosthesis in place, while 8 (25%) did not. An overview of postoperative complications is presented in Table 2. Individual cases are presented in Table 3.

Patient Satisfaction

A total of 14 out of a possible 24 (58%) patients with a penile prosthesis in place completed the questionnaire. They rated their life satisfaction 7.8±1.3 out of 10. An overview of questionnaire outcome is presented in Supplementary Table 1.

DISCUSSION

Genital gender affirming surgery alters feelings of gender dysphoria. In phalloplasty surgery, implanting a penile prosthesis is often the last surgical step in the transition process. In this article, we reported on 32 transgender men who underwent penile prosthesis implantation between 1989 and September 2018. At last follow-up, 24 (75%) patients had a penile prosthesis in place. Revision surgery was performed in 21 (65.6%) patients. Of a total of 45 implanted prostheses, 8 were removed because of infection. A total of 14 out of a possible 24 (58%) patients with a penile prosthesis in place completed the questionnaire. They rated their life satisfaction 7.8 ± 1.3 out of 10.

An overview of literature published on the subject is presented in Supplementary Table 2.[12-19] All published

Table 2. Overview of postoperative complications

Originally Implanted Prosthesis	
Total, *n* (%)	32 (100%)
Surgically removed or replaced, *n* (%)	16 (50%)
Infection, *n* (%)	5 (15.6%)
Leakage, *n* (%)	2 (6.3%)
Extrusion, *n* (%)	2 (6.3%)
Low-grade infection, *n* (%)	2 (6.3%)
Dislocation, *n* (%)	2 (6.3%)
Disfunction, *n* (%)	2 (6.3%)
Pain, *n* (%)	1 (3.1%)
All implanted prostheses (including revision procedures)	
Total, *n* (%)	45 (100%)
Surgically removed or replaced, *n* (%)	21 (44%)
Infection, *n* (%)	8 (17.8%)
Leakage, *n* (%)	3 (6.7%)
Extrusion, *n* (%)	3 (6.7%)
Low-grade infection, *n* (%)	2 (4.4%)
Dislocation, *n* (%)	2 (4.4%)
Disfunction, *n* (%)	2 (4.4%)
Pain, *n* (%)	1 (2.2%)

Table 3. Overview of included patients and postoperative complications

Case #	Age at Implantation	Phalloplasty	With Urethral Lengthening?	Time After Phalloplasty (Years)	History of Smoking	BMI	Type Prosthesis Originally Implanted	Postoperative Complications and Reoperations	Prosthesis in Place at Last FU?	Clinical FU (Years)
1	36	FRFF	Yes	1.8	Yes	22.6	AMS Dynaflex	+9 mo Prosthesis dislocation, for which adhesiolysis and surgical refixation +3.5 y Prosthesis leakage, for which new prosthesis implantation *AMS Dynaflex* +13.2 y Prosthesis leakage, for which new prosthesis implantation *Coloplast Genesis* +16.3 y Prosthesis infection, for which prosthesis explantation	No	23.3
2	42	FRFF	Yes	3.2	Yes	33.6	AMS Dynaflex	+18.5 y Prosthesis dysfunction, for which revision was planned. Intraoperatively was a low-grade infection observed, so only explantation was performed. +19.0 y New prosthesis placement *(Coloplast Genesis)* +19.2 y Prosthesis infection, for which prosthesis explantation	No	19.6
3	43	FRFF	Yes	19.0	Yes	31.1	Coloplast genesis	+1.9 y Prosthesis extrusion, for which prosthesis explantation +4.5 y New prosthesis placement *(AMS Dynaflex)* +4.8 y Prosthesis extrusion, for which prosthesis explantation	No	4.8
4	24	FRFF	Yes	0.0	Yes	21.0	AMS Dynaflex	+8 mo Prosthesis infection, for which prosthesis explantation +1.2 y New prosthesis placement *(Coloplast Genesis)*	Yes	23.9
5	39	FRFF	Yes	0.0	No	19.0	AMS Dynaflex	+4.0 y Prosthesis leakage, for which new prosthesis implantation *AMS Dynaflex*	Yes	4.5
6	31	FRFF	Yes	1.8	No	26.3	AMS Dynaflex	None	Yes	8.5
7	30	FRFF	Yes	2.2	Yes	28.0	AMS Dynaflex	+9.7 y Prosthesis dysfunction, patient did not wish further surgery	Yes	18.3
8	36	FRFF	Yes	1.4	Yes	23.2	AMS Dynaflex	None	Yes	6.4
9	51	FRFF	Yes	2.2	No	22.3	AMS Dynaflex	None	Yes	18.2
10	41	FRFF	Yes	1.1	No	23.9	AMS Dynaflex	None	Yes	2.1

Continued

Table 3. Continued

Case #	Age at Implantation	Phalloplasty	With Urethral Lengthening?	Time After Phalloplasty (Years)	History of Smoking	BMI	Type Prosthesis Originally Implanted	Postoperative Complications and Reoperations	Prosthesis in Place at Last FU?	Clinical FU (Years)
11	30	FRFF	Yes	10.3	Yes	35.5	AMS Ambicor	+2 mo Infection and leakage of prosthesis, for which prosthesis explantation	No	10.3
12	50	FRFF	Yes	1.0	No	28.0	AMS Dynaflex	+7 d Prosthesis extrusion, for which prosthesis explantation +2.4 y New prosthesis placement *(AMS Dynaflex)*	Yes	4.0
13	25	FRFF	Yes	2.2	Yes	22.7	Coloplast genesis	+7 mo Prosthesis infection, for which prosthesis explantation	No	0.6
14	34	FRFF	Yes	3.3	Yes	27.0	Coloplast genesis	None	Yes	0.4
15	30	FRFF	Yes	3.0	Yes	29.2	AMS Dynaflex	+14 d Prosthesis infection, for which prosthesis explantation +6 mo New prosthesis placement *(AMS Dynaflex)*	Yes	21.3
16	23	FRFF	No	2.8	No	24.2	Coloplast genesis	None	Yes	2.8
17	42	FRFF	Yes	5.1	No	28.7	AMS Spectra	None	Yes	6.0
18	43	FRFF	Yes	2.4	Yes	32.7	AMS Ambicor	None	Yes	1.5
19	47	FRFF	Yes	2.0	Yes	22.4	Coloplast genesis	+1.2 y Prosthesis dislocation, for which new prosthesis implantation *Coloplast Genesis*	Yes	2.1
20	56	FRFF	Yes	14.0	No	23.7	AMS Ambicor	+8.4 y Prosthesis dysfunction, for which new prosthesis implantation *AMS Ambicor* +10.5 y Pump dislocation, for which surgical refixation	Yes	11.3
21	42	FRFF	Yes	3.2	Yes	33.6	AMS Dynaflex	+18.8 y Low-grade prosthesis infection, for which prosthesis explantation +19.0 y New prosthesis placement *(Coloplast Genesis)* +19.2 y Prosthesis infection, for which prosthesis explantation	No	19.6
22	21	FRFF	Yes	1.6	No	23.6	Coloplast genesis	+1 y Prosthesis dislocation, for which surgical refixation	Yes	1.0
23	43	ALT	No	3.2	Yes	25.3	AMS Spectra	+2.4 y Prosthesis dislocation, for which surgical refixation	Yes	5.7
24	24	ALT	No	2.1	No	27.1	Coloplast genesis	+8 mo Prosthesis dislocation, for which surgical refixation	Yes	1.6
25	49	ALT	No	3.6	Yes	23.1	Coloplast genesis	1.9 y Prosthesis dysfunction, for which new prosthesis implantation *Coloplast Genesis*	Yes	2.0

Continued

Table 3. Continued

Case #	Age at Implantation	Phalloplasty	With Urethral Lengthening?	Time After Phalloplasty (Years)	History of Smoking	BMI	Type Prosthesis Originally Implanted	Postoperative Complications and Reoperations	Prosthesis in Place at Last FU?	Clinical FU (Years)
26	28	ALT	Yes	2.5	No	21.7	Coloplast Genesis	+10 mo Prosthesis dislocation, for which new prosthesis implantation	Yes	1.2
							Coloplast Genesis			
27	29	ALT	Yes	1.7	No	23,0	Coloplast genesis	None	Yes	0.7
28	59	ALT+FRFF	Yes	1.5	No	22,6	Coloplast genesis	+5 mo Prosthesis dislocation, for which surgical refixation	Yes	0.7
29	42	ALT+FRFF	Yes	1.6	Yes	26,8	Coloplast Genesis	+4 mo Prosthesis dislocation, for which surgical refixation	Yes	3.8
30	36	ALT+FRFF	Yes	5.8	No	27.3	Coloplast Genesis	+12 d Surgical site infection, for which oral antibiotics +11 mo Penile pain when using the prosthesis, for which explantation	No	1.1
31	26	ALT+FRFF	Yes	4.5	No	26.3	Coloplast Genesis	+3.8 mo Prosthesis infection, for which prosthesis explantation	No	0.5
32	24	Fibula	Yes	2.1	No	22.1	AMS Dynaflex	None	Yes	21.1

ALT, anterolateral thigh flap; BMI, body mass index; FRFF, free radial forearm flap; FU, follow-up.

research is of retrospective nature. Current research on clinical outcomes of penile prosthesis implantation in transgender men reports predominantly on inflatable prostheses after FRFF phalloplasty. Most literature focusses on hydraulic prostheses, but a wide array of prostheses and phalloplasty subtypes are reported. In the larger recent studies, explantation due to infection was described to occur in 6%-12% of procedures, with varying follow-up times. In our series, 17.8% of prostheses were explanted due to infection. Why this is higher than described in literature is probably mostly a result of the inclusion period of our study, which dates back to 1989.

In our institution, patients can choose between hydraulic and malleable devices. Current literature on penile prostheses in transgender men primarily focusses on the uses of hydraulic devices. In general, inflatable prostheses are considered superior to malleable prostheses, because it produces rigidity and flaccidity which resembles the biological penis.[19] However, patient-factors, patient-preferences and surgeon-preferences may greatly influence the choice of prosthesis. Theoretically, inflatable prostheses are at higher risk of material fatigue, which may negatively influence the life duration of these prostheses. On the other hand, malleable prostheses may cause a more constant pressure on the surrounding tissue, which may consequently lead to a higher risk of erosion and subsequent prosthesis extrusion. High numbers of complications and secondary procedures are recorded after penile prosthesis implantation in transgender men after phalloplasty. Still, transgender men are willing to undergo these procedures, giving the impression that not the number of surgeries but the end result determines patient satisfaction and quality of life.

As mentioned before, a penile prosthesis is implanted if patients are at least 1 year after phalloplasty, protective sensitivity of the neophallus is present, and patients are not waiting for any type of surgery of the phallus and/or scrotum. The time frame of 1 year is chosen, because that is considered the time of recovery of the sensitivity of the phallus. It is postulated that sensitivity of the phallus helps to protect a patient from extrusion of the implanted penile prosthesis. Less sensitivity of the phallus is considered a contraindication for implantation of the penile prosthesis. However, no data is available on this relation.

Genital gender affirming surgery is increasingly being performed as a single stage procedure. For example, (1) removal of internal and/or external female genitalia, (2) free or pedicled flap phalloplasty, (3) urethral lengthening, (4) scrotoplasty, and (5) insertion of testicular implants, are performed in a single session in certain centers.[20,21] Historically, immediate prosthesis implantation during the phalloplasty procedure was performed twice in our series. In current literature and in our center, this is now no longer standard practice. Postoperative wound dehiscence, which at a minor extent can be expected, and/or infection may lead to early prosthesis infection. Therefore, prosthesis implantation is now no longer performed as "immediate" procedure. Currently, patients are deemed eligible for prosthesis implantation if the

phalloplasty procedure was a minimum of 1 year before and after recovery of the sensitivity of the phallus.

In our center, phalloplasty surgery was traditionally performed using FRFF or abdominal flaps. With the increase of surgical experience and expertise, now a wider range of flaps is available for this surgical procedure, including ALT flaps, superficial circumflex iliac artery flaps, and a combination of flaps. Which flap constitutes the perfect acceptor site for a penile prosthesis is unknown. In literature, it is noted that more complications arise after implantation of a hydraulic device in infraumbilical pubic flaps when compared to the FRFF, probably because multiple cylinders are necessary. For malleable prostheses, there are no data available. It is noteworthy that current literature focusses primarily on prosthesis implantation in FRFF or suprapubic and/or abdominal flaps.

Until recently, penile prostheses used in the transgender population were designed for use in the nontransgender population. In the last years, several prostheses designed for the transgender population were put on market (eg, Zephyr ZSI 100 FTM Malleable and Zephyr ZSI 475 FTM Inflatable penile prosthesis).[18,19] It will be interesting to review the surgical outcomes and patient-reported outcomes after implantation of these prostheses in larger patient groups.

One of the strengths of this study is that it focuses on a subject which is scarcely reported on, but may be of significant importance to the transgender population. A second strength is that this research provides data on malleable prosthesis implantation instead of inflatable prosthesis implantation, a group that is sometimes neglected in literature. Another strength is that a long clinical follow-up time is reported. Weaknesses of the study comprise the retrospective nature and the small size of the studied population. Quality of life and sexual function outcomes are reported in this study, but standardized, validated questionnaires are lacking for this specific population. Preoperative data on sexual health and life satisfaction was not available.

CONCLUSION

Prosthesis explantation, replacement, or revision surgery occurs frequently after penile prosthesis implantation. Patients need to be informed preoperatively on these complication rates.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.urology.2019.06.010.

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