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Clinical Recommendations From the European Society for Sexual Medicine Exploring Partner Expectations, Satisfaction in Male and Phalloplasty Cohorts, the Impact of Penile Length, Girth and Implant Type, Reservoir Placement, and the Influence of Comorbidities and Social Circumstances

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ABSTRACT

Introduction: To date, several aspects of inflatable penile prosthesis (IPP) surgical procedure have been poorly studied.

Aim: The aim of this study was to review the evidence associated with IPP implantation and provide clinical recommendations on behalf of the European Society for Sexual Medicine (ESSM). Overall, 130 peer-reviewed studies and systematic reviews, which were published from 2007−2018 in the English language, were included.

Methods: MEDLINE and EMBASE were searched for randomized clinical trials, meta-analyses, and open-label prospective and retrospective studies.

Main Outcome Measure: The panel provided statements exploring patients and partner expectations, satisfaction in male and phalloplasty cohorts, the impact of penile length, girth and implant type, reservoir placement, the influence of comorbidities, and social circumstances. Levels of evidence were provided according to the Oxford 2011 criteria and graded as for the Oxford Centre for Evidence-Based Medicine recommendations.

Results: In the preoperative setting, it is fundamental to identify and interact with difficult patients with the intention of enhancing the surgeon's ability to establish the surgeon-patient relationship, reduce physical and legal risk, as well as enhancing patient satisfaction. To address this need, the mnemonic Compulsive, Unrealistic, Revision, Surgeon Shopping, Entitled, Denial, and Psychiatric ("CURSED") has been suggested to identify patients who are at high risk of dissatisfaction. The current recommendations suggest improving glycemic control in patients with diabetes. Available evidence suggests evaluating transplant recipients with the criteria of Barry, consisting of stable graft function for >6 months, avoidance of intra-abdominal reservoir placement, and low-dose immunosuppression. HIV status does not represent a contraindication for surgery. Smoking, peripheral vascular disease, and hypertension may be associated with an increased risk of revision surgery. Patients with

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spinal cord injury may receive IPP. Patients aged ≥70 years, as well as obese patients, can be offered IPP. The IPP implantation can be performed in patients with stable Peyronie's disease. Ectopic high submuscular reservoir placement can be considered as an alternative method.

Clinical Implications: There is a relevant lack of high-level data and definite conclusions in certain areas remain difficult to draw.

Strength & Limitations: All studies have been evaluated by a panel of experts providing recommendations for clinical practice. Because of lack of sufficient prospective data, some of the included studies are retrospective and this could be stated as a limitation.

Conclusion: This ESSM position statement provides recommendations on optimization of patient outcome by patient selection, and individualized peri- and intra-operative management. ESSM encourages centers to collaborate and to create prospective, multicenter registries in order to address this topic of increasing importance.
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Key Words: Penile Prosthesis; Patient Expectations; Partner Expectations; Cosmesis; Disappointment; Dissatisfaction; Penile Implantation; Comorbidity; Socioeconomic Factors; Diabetes Mellitus; Outcome; Satisfaction; Reservoir; Balloon; Phalloplasty

INTRODUCTION

Since the first report of inflatable penile prosthesis (IPP) implantation by Scott et al[1] in the early 1970s, several technological improvements in the devices have been introduced to improve the outcomes of this surgery. To date, the European Association of Urology, Guidelines for Male Sexual Dysfunction 2018, recognizes IPP implantation as the third line treatment for erectile dysfunction (ED).[2] IPPs are known to result in high patient satisfaction rates.[3–6] Technical improvement of devices and the refinement of surgical techniques have resulted in improved revision-free survival with a freedom from mechanical failure of 79.4% at 10 years and 71.2% at 15 years. Overall, 68.5% of primary penile prostheses (PPs) survived 10 years or longer without revision or explantation and 59.7% exceeded 15 years.[7] Contemporary series examining outcomes of 3-piece IPP implantation have demonstrated patient and partner satisfaction approaching 100%.[8–12]

Despite several studies exploring IPPs surgery, definite conclusions in certain areas remain difficult to make due to the following reasons:

1) The heterogeneity of models of IPP implanted as well as the variety of surgical approaches
2) The lack of well-structured prospective randomized controlled trials
3) The presence of very few scientifically validated tools to assess both patients' and partners' satisfaction rates after PP implantation

Several aspects of this surgery, including patient and partner expectations, the possible influence of patients' comorbidities and social circumstances on the surgical outcomes, and patient and partner satisfaction following the implantation, are rarely investigated. The aim of the present article is to provide the European Society for Sexual Medicine position statements on this topic, to better clarify the multiple aspects of penile prosthetic surgery, offering an evidence-based clinical framework to guide patient-tailored management of ED.

METHODOLOGY AND DEFINITIONS

We performed MEDLINE and EMBASE searches for peer-reviewed articles using the terms: penile prosthesis, patient and partner expectations, cosmesis, disappointment, dissatisfaction, penile prosthesis, penile implantation, comorbidity, socioeconomic factors, diabetes mellitus, prosthesis, outcome, satisfaction, reservoir, and phalloplasty. Studies were included if they were <10 years old and had direct relevance to the subject. Due to the limited number of prospective and randomized-controlled trial (RCT) studies on IPP surgery in male patients with ED, all studies were considered and included. Studies older than 10 years were included only if considered to be of great value to the topic with respect to the quality of the data. Data was catalogued into study type, level of evidence, number of subjects, duration of follow-up, treatment arms, and outcomes (Supplemental Table). Articles were analyzed and results summarized with all recommendations made based upon the available literature.

Overall, 130 peer-reviewed studies and systematic reviews, which were published from 2007–2018 in the English language, were included in this review. Statements were structured within 5 subcategory chapters:

I. Influence of comorbidities and social circumstances of patients in association with PP.
II. Female and male expectations of PP surgery.
III. The impact of length, girth, and implant type upon PP satisfaction.
IV. Reservoir placement and patient satisfaction.
V. Sexual satisfaction associated with PP in the context of phalloplasty surgery.

A number of issues were raised during the review process, including:

(a) poor definition of primary end points;
(b) heterogeneity in the surgical implantation technique;
(c) heterogeneity of included devices;
(d) inconsistencies in the definition of comorbidities;
(e) heterogeneity in the duration of follow-up.

Oxford criteria for levels of evidence and grades were used[13] (https://www.cebm.net/2009/06/oxford-centre-evidencebased-medicine-levels-evidence-march-2009/).

INFLUENCE OF COMORBIDITIES AND SOCIAL CIRCUMSTANCES

Diabetes Mellitus

Statement #1

We suggest optimizing glycemic control to normal hemoglobin A1c (HbA1c) levels in patients with diabetes mellitus prior to penile implant surgery (level 2; grade B).

Evidence

Uncontrolled diabetes mellitus is a risk factor for increased infection rates.[14] According to a retrospective review of the American Medical Systems (AMS; Minnetonka, MN, USA) database by Mulcahy and Carson,[15] there is an increased infection risk for PP performed in patients with diabetes. Diabetic men had a significantly higher rate of revisions due to infection at 7 years (1.88%) than men without diabetes (1.53%; $P = .005$; Table 1).[15] In contrast, other studies published in the 1990s did not find an increased risk of infection in patients with diabetes. There is conflicting data on optimal HbA1c cutoffs, which can help predict the potential increased risk of infection in patients with diabetes. In a prospective trial of 90 patients, all infections were found in patients with diabetes. There were infections in 31% of the poorly controlled vs 5% of the adequately controlled patients with diabetes. In this study, an HbA1c of 11.5% indicated patients at high risk for infection, thus, the authors proposed this as a cutoff value.[16] On the other hand, another prospective study on 389 patients found that there was no increased infection risk with increased levels of Hb1Ac. In addition, there was no difference in either the median or mean level of HbA1c in the infected and noninfected patients, regardless of diabetes.[17] A retrospective single-institution study of 300 patients with diabetes by Canguven et al,[18] found that the risk of prosthesis infection did not increase with higher HbA1c levels, with no significant difference in the mean level of HbA1c when comparing infected and noninfected patients with diabetes. The most recent and currently largest multicenter prospective study by Habous et al,[19] which included 902 penile implant procedures, found significantly higher mean HbA1c levels in patients with implant infection (9.5%) compared with patients without infection (7.8%; $P < .001$). An HbA1c threshold level of 8.5% predicted infection with sensitivity of 80% and specificity of 65%. The main critical point of the study is a higher infection rate in comparison with the known studies. Only "non-coated" implanted devices were evaluated in this series[19] (Table 1). Infection rates in patients with diabetes mellitus seem not to be different from a statistical point of view from those of the implant population at large in the antibiotic coated PP era.[20]

Remarks

Although there remains controversy whether there is a clinically relevant increased risk of infection in patients with diabetes, we emphasize that the most recent prospective and largest multicenter study has shown that diabetics with poor glycemic control are indeed at higher risk of device infection than patients with good glycemic control. Further studies are warranted to evaluate the impact of diabetes on outcomes of PP surgery.

Prior Solid Organ Transplantation

Statement #2

We suggest that patients with prior solid organ transplantation can be considered for PP implantation (level 3; grade C).

Evidence

Small case series, including <20 patients, published in the 1980s and 1990s, reported controversial findings regarding risk of infection and re-operation in patients with a history of previous solid organ transplantation. Some studies found that patients with prior solid organ transplantation had no infections of implants and no device malfunctioning.[21–23] Other studies instead found that the risk of infection and the risk of mechanical failure were increased.[24–27] A retrospective single-center study showed that the risk of infection after insertion of PP in patients with prior organ transplantation was similar to that in patients without prior organ transplantation (4.3% vs 4.2%). The risk of prosthesis malfunction was higher in transplant patients (8.7% vs 3.6%).[28] Another retrospective single-center study showed no increased risk of infection in patients with prior renal transplantation.[29] In the most recent single-center study by Sun et al,[30] 26 patients with liver, kidney, heart, and combined kidney and pancreas transplantation, and 26 controls (patients without prior solid organ transplantation) were compared. The authors found no differences in re-operation rates between the 2 groups (both 11.5%) at the 30 month follow-up. In addition, there was no difference in re-operation rates between the various

types of transplanted organs[30] (Table 1). There are few studies in the last 10 years investigating PP infection in patients with immunosuppression due to other diseases. A retrospective single-center study by Wilson and Delk,[29] including >1,000 penile implants, found that 50% of patients with infected PP had previously undergone steroid treatment for chronic autoimmune disease, such as lupus or rheumatoid arthritis.

Remarks

Evidence regarding PP implantation in patients with a history of solid organ transplantation is limited. Data on type of immunosuppression are not available. In addition, data on time between solid organ transplantation and PP are not available.

Optimal timing of PP implantation in patients with prior solid organ transplantation remains unclear. It has to be underlined that immunosuppression is more intensive during the early phase following solid organ transplantation. Recent evidence suggests, evaluating transplant recipients on immunosuppressive with the criteria of Barry,[31] which consist of stable graft function for >6 months, avoidance of intra-abdominal reservoir, and low-dose immunosuppression prior to penile implant surgery.[32]

HIV

Statement #3

We suggest offering PP surgery to patients with ED when indicated regardless of the HIV status (level 3; grade C)

Evidence

A retrospective study by Gross et al,[33] including 350 patients across 2 institutions found no difference in risk of PP infection in HIV-negative (3%) vs HIV-positive (4%) patients. Similarly, a single-center retrospective study by Davoudzadeh et al[34] of 221 patients in a single institution found no statistically significant difference in subsequent implant infection between men with HIV (8.3%) and men without HIV (5.7%; Table 1).

Remarks

Evidence regarding PP implantation in patients with HIV is limited and is derived from retrospective studies with low patient numbers.[35] Importantly, data has not yet been published in peer-reviewed journals but was presented at international meetings. Data on antiretroviral therapy and viral load suppression is not available.

Smoking

Statement #4

We suggest that smoking may be associated with an increased risk of revision surgery in patients undergoing PP implantation. We suggest encouraging patients to quit smoking (level 3; grade C).

Evidence

A retrospective Veterans' database analysis on 6,586 patients with PP surgery by Lacy et al[36] and at least 1 year of follow-up found that smoking was associated with an increased risk of revision or explant surgery following PPI (hazard ratio (HR): 1.17; 95% CI: 1.02−1.34; Table 1). Conversely, another retrospective analysis, including 152 patients from Veterans Affairs patients at a teaching institution, found no difference in the failure or revision rate according to the smoking status.[37]

Remarks

Evidence regarding PP implantation in patients who are smoking is limited and is derived from retrospective studies. Data on current vs former tobacco use are scanty.

In general, smoking seems to be associated with an increased risk of infection in patients undergoing surgery, and smoking cessation is associated with a decrease of infection risk. A systematic review and meta-analysis, including 479,150 patients, concluded that smoking cessation for at least 4 weeks prior to surgery reduces surgical site infections, but not other healing complications.[38]

Peripheral Vascular Disease and Hypertension

Statement #5

We suggest that peripheral vascular disease and hypertension may be associated with an increased risk of revision surgery in patients undergoing PP implantation (level 3; grade C).

Evidence

A retrospective Veterans' database analysis on 6,586 patients by Lacy et al[36] with PP and at least 1 year of follow-up found that peripheral vascular disease and hypertension were both associated with an increased risk of revision or explant surgery following PP implantation (peripheral vascular disease: HR: 1.25; 95% CI: 1.10−1.41; hypertension: HR 1.27; 95% CI: 1.12−1.43; Table 1).[36] In contrast, another retrospective analysis, including 152 patients, found no difference in the failure or revision rate in patients with hypertension.[37] A retrospective single-center study on 74 patients by Ji et al[39] found that hypertension did not correlate with mechanical or nonmechanical failure.

Remarks

Evidence regarding PP implantation in patients with comorbid peripheral vascular disease and hypertension is very limited and is derived from retrospective studies. Data regarding the treatment of peripheral vascular disease and control of hypertension is not available.

Further studies are warranted to evaluate the impact of peripheral vascular disease and hypertension on outcomes of PP surgery.

Spinal Cord Injury

Statement #6

We suggest that patients with spinal cord injury may receive PP, provided that bladder emptying is possible and long-term indwelling catheters are avoided. We suggest using inflatable PP in these patients (level 3; grade C).

Evidence

Overall, patients with spinal cord injury seem to be at increased risk for prosthesis infection, as demonstrated by several retrospective studies published in the 1980s and 1990s.[29,40–42] One retrospective study by Jarow,[43] however, did not find an increased risk of PP infection in patients with spinal cord injury. A more recent retrospective study by Zermann et al[44] on 245 neurologically impaired patients, including 197 with spinal cord injuries, found a device infection rate of 5% at a mean follow-up of 7 years. With respect to semirigid devices, there was 18% risk of erosion, whereas with 3-piece inflatable devices, there were no erosions. The authors concluded that PP surgery represents a safe option for the treatment of ED in patients with neurological impairment. Moreover, they recommend an IPP because of the lower risk of erosion[44] (Table 1). Other authors have suggested that patients with spinal cord injuries have unique risk factors, including possible alterations in the regional blood supply, recurrent urinary tract infections, and decreased sensation as well as impaired wound healing, that may facilitate implant erosion.[45,46] It might be helpful to minimize device infections by avoiding long-term indwelling catheters, enabling bladder emptying, and by early treatment of penile wounds and pressure sores.[46]

Remarks

Evidence regarding PP implantation in patients with spinal cord injury is low and derives from retrospective studies with low patient numbers. As pointed out by Zermann et al,[44] special attention must be paid to patient preparation, the surgical procedure, and postoperative management, as well as follow-up to ensure favorable treatment outcomes in patients with spinal cord injury (Table 1).

Age

Statement #7

Age has no impact on satisfaction rates in patients receiving IPP. We suggest offering PP to patients with ED regardless of age when indicated (level 3; grade 3).

Evidence

A retrospective single center study by Al-Najar et al[47] found that 83% of patients aged ≥70 years were satisfied with a PP, and 73% were regularly using the PP for sexual activity. Similarly, another retrospective study by Chung et al[48] found that 30 men aged ≥75 years reported satisfactory outcome with PP surgery and no difference in device survival and satisfaction rates compared with 186 men aged <75 years at 38.8 months' mean follow-up. Overall, 10% of patients aged ≥75 years had revision surgery for mechanical malfunction[48] (Table 1). A further retrospective study by Villarreal and Jones[49] on 48 patients aged ≥71 years found satisfaction rates of 86% with 1.7% infections and 1.7% hematomas at a mean follow-up of 1.5 years. The majority of patients used penile prosthesis 1−6 times per month for sexual activity.[49] Another retrospective single-center study by Kim et al[50] on 438 patients found that patients' age (<60 years vs ≥60 years) was not associated with device survival. A retrospective single-center study by Madbouly et al[51] on 54 patients aged >60 years found that the modified frailty index was not associated with adverse outcomes at 1-year follow-up (Table 1).

Remarks

Evidence regarding PP in elderly patients is very low and derives largely from small retrospective studies with low patient numbers.

Obesity

Statement #8

We suggest offering PP to patients with obesity with ED, when indicated (level 3; grade C).

Evidence

A retrospective single-center study by Kim et al[50] on 438 patients found that obesity (body mass index [BMI] ≥30 vs <30 kg/m^2) was not associated with device survival (Table 1). Another retrospective single-center study on 114 patients treated with 3-piece (Alpha-1, Mentor, MN, USA) and 2-piece (Ambicor; AMS) inflatable devices found that patients with BMI >30 had significantly lower scores on the Group Selection Questionnaire, International Index of Erectile Function (IIEF) satisfaction domain, and Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) compared with the general implant population. It is important to underline that penile concealment related to prepubic fat may contribute to patient dissatisfaction after PP surgery in patients with obesity.[52]

Remarks

Evidence regarding PP in patients with obesity is poor and derives from a single retrospective study.

Urinary Incontinence

Statement #9

Simultaneous implantation of IPP and artificial urinary sphincter (AUS) may lead to higher revision rates, and, therefore, the potential benefit of cost-effectiveness of synchronous surgery should be weighed against the potentially increased risk of revision surgery and its related costs (level 3; grade C).

Table 1. Selected studies on the influence of comorbidities and social circumstances on outcome in patients treated with PP

Title	Authors & Publications	Level of Evidence	Patients' age [years]	Number of subjects	Summary
Diabetes mellitus	Mulcahy et al[15] (2011), Eur Urol	2	Patients with impregnated penile prosthesis: 56 (mean) Patients with non-impregnated penile prosthesis: 58 (mean)	6,071 diabetic patients (impregnated penile prosthesis) 624 diabetic patients (non-impregnated penile prosthesis)	Initial revisions due to infection in 1.5% of impregnated vs 4.2% of non-impregnated group. At 7 years, the rate of infection-related revisions was lower for impregnated (1.6%) than for non-impregnated penile implants (4.2%), $P < .0001$. Diabetic patients had higher rate of revisions due to infection at 7 years (1.9%) than patients without diabetes (1.5%), $P = .005$)
	Habous et al[19] (2018), BJU Int		56 (mean)	902 implant procedures (685 (76%) malleable prosthesis vs. 217 (24%) IPP)	Overall infection rate 8.9% (80/902). Patients with implant infection had higher HbA1c levels (9.5% vs 7.8%), $P < .001$. Infection rates were: 1.3% with HbA1c <6.5%, 1.5% for HbA1c 6.5–7.5%, 6.5% for HbA1c 7.6–8.5%, 14.7% for HbA1c 8.6–9.5%, and 22.4% for HbA1c >9.5%, $P < .001$. Predictors for increased infection risk defined on multivariable analysis: PD, high BMI, high HbA1c Predictors for reduced infection risk defined on multivariable analysis: high-volume surgeon HbA1c threshold level of 8.5% predicted infection with a sensitivity of 80% and a specificity of 65%
Solid organ transplantation	Sun et al[30] (2018), Urology	3	Patients with solid organ transplantation: 53.7 (mean) Controls: 56.4 (mean)	26 (heart (3), liver (2), kidney (17), kidney and pancreas (4)) 26 controls	No difference in re-operation rates between patients with vs without prior solid organ transplantation (11.5% v. 11.5%), $P = 1.00$). No difference in reoperation rate between 2-piece vs 3-piece IPP models, $P = 0.47$. No difference in IPP re-operation rates between different solid organs transplanted
HIV	Davoudzadeh et al[34] (2016), TJ Sex Med	3	64 (mean)	221	Infection requiring explantation: HIV negative 5.7% vs HIV positive 8.3%. No difference in infection rate between HIV negative vs HIV positive patients, $P = .5$
	Gross et al[33] (2017), J Sex Med		n.s.	350 (18 HIV positive patients)	One (5.5%) of 18 HIV-positive patients had postoperative infection. No difference in infection rates between HIV-positive vs HIV-negative patients, $P = .6$

(continued)

Table 1. Continued

Title	Authors & Publications	Level of Evidence	Patients' age [years]	Number of subjects	Summary
Spinal cord injury	Zermann et al[44] (2006), J Urol	3	40.8 (mean)	245 (293 surgical procedures: 147 semirigid (Jonas), 113 self-contained inflatable (Dynaflex), and 33 inflatable 3-piece (AMS 700)	Mean follow-up of 7.2 years 195 patients were re-evaluated 43 revisions for technical reasons and infections. Infection rate was 5% (12 patients). Perforation rate was 18.1% (15 of 83 cases) for semirigid devices, 2.4% (2 of 84) for self-contained inflatable devices and 0% (0 of 28) for inflatable 3-piece devices
Age	Chung et al[48] (2014), World J Urol	3	77.1 (mean)	216 (30 patients ≥75 years)	In men ≥75 years, after an average of 18.6 months follow-up, 3 patients had IPP revision surgery due to mechanical malfunction. No difference in IPP survival between patients <75 years vs ≥75 years at 3 years follow-up
	Madbouly et al[51] (2017), The aging male		64.9 (mean)	54	One-year adverse outcomes in 43 (79.6%) patients. Modified frailty index not associated with 1-year adverse outcomes
Urinary incontinence	Patel et al[53] (2018), J Urol	3	61.5 (IPP alone) 64.4 (IPP + AUS or AUS then IPP)	11,531 IPP surgeries (98.4% (n = 11,352) IPP alone; 1.6% (n = 179) dual prostheses (IPP + AUS = 139 and IPP then AUS = 40)	Patients with IPP + AUS had higher likelihood of IPP reoperation at 1 year (OR 2.1; 95% CI: 1.3−3.3, $P < .01$) and at 3 years (OR 2.6, 95% CI 1.7−4.0, $P < .01$), compared to IPP alone. Patients with IPP + AUS did not have a higher likelihood of AUS reoperation at 1 year ($P = .76$) and at 3 years ($P = .73$), compared to AUS alone
	Segal et al[54] (2013), J Urol		IPP + AUS: 65.3 (mean) IPP: 59.9 (mean) AUS: 67.5 (mean)	55 combined procedures (IPP + AUS) 336 IPP only and 279 AUS only	Rate of device infection, erosion, or malfunction was not increased irrespective of combined or staged procedures ($P > .05$)
PD	Khera et al[65] (2018), J Sex Med	3	61.5 (mean)	1,180 (250 [21.2%] with PD)	One and 2-year data available for 177 (70.8%) and 130 (52.0%) patients. More than 80% of patients with PD satisfied or very satisfied at 1 and 2-year follow-up. More than 88% of patients with PD were using the device at 1 and 2-year follow-up. At baseline, 19.3% of men with PD reported being depressed, with a decrease to 10.5% ($P = .02$) and 10.9% ($P = .07$) at 1 and 2-year follow-up

(continued)

Table 1. Continued

Title	Authors & Publications	Level of Evidence	Patients' age [years]	Number of subjects	Summary
	Chung et al[66] (2013), J Sex Med		63 (mean)	18 patients (with IPP insertion and synchronous penile plication)	15 patients completed a postoperative satisfaction survey at a mean of 11 months follow-up. All reported improvement in overall condition and penile curvature. One patient with bi-planar deformity reported minor residual curvature. None reported continued pain or required suture release
	Kim et al[50] (2010), J Sex Med		63 (mean)	438	397 patients (90.7%) available for analysis. Mean follow-up 113 months 82 patients (20.6%) mechanical failure. Mechanical survival rate 97.6%, 93.2%, and 78.2% at 3, 5, and 10 years. Obesity was not associated with overall survival of penile prosthesis
Smoking	Lacy et al[36] (2016), Urology	3	62 (mean)	6,586	Smoking was associated with increased risk of revision or removal surgery (HR: 1.2; 95% CI: 1.0—1.3)
Peripheral vascular disease and hypertension	Lacy et al[36] (2016), Urology	3	62 (mean)	6,586	Peripheral vascular disease was associated with increased risk of revision or removal surgery (HR: 1.3; 95% CI: 1.1—1.4) Hypertension was associated with increased risk of revision or removal surgery (HR: 1.3; 95% CI: 1.1—1.4)

AUS = artificial urinary sphincter; BMI = body mass index; HbA1c = hemoglobin A1c; HR = hazard ratio; IPP = inflatable penile prosthesis; n.s. = not specified; OR = odds ratio; PD = Peyronie's disease; PP = penile prostheses.

Table 2. Patients and partners satisfaction in association with length and girth enhancement

Title	Authors & Publications	Level of Evidence	Follow-up	Number Subjects	Outcomes measures	Summary
Biomechanical comparison of IPP: A Cadaveric Pilot Study.	Wallen JJ et al[110] (2018), J Sex Med	4	-	3	Column compression modified cantilever deflection 3-point bending methods	Only the AMS LGX at less than maximum inflation was unable to consistently withstand the roughly 0.9 kg. Coloplast Titan showed slightly better rigidity than the AMS LGX and CX devices. CX showed the best rigidity in the shortest phallus. Titan showed slightly better rigidity in the longest phallus (C) and the phallus with mild PD
Complications, functional and quality of life outcomes following primary and secondary implantation of PP at a tertiary referral center.	Ralla B et al[111] (2018), Int J Impot Res	4	26	43	EDITS QLQC30	AMS 700 and Coloplast Titan. No difference in satisfaction
IPP as tissue expander: what is the evidence?	Chung PH et al[93] (2017), Int Braz J Urol	4		2,749	Change in length (cm) % change in length	1,532 AMS 700 LGX, 717 AMS 700 CX, and 500 Coloplast Titan. DOES NOT ASSESS SATISFACTION. Patients who underwent device replacement at <2 years did not experience an increase in mean cylinder length. On the contrary, patients who underwent device replacement at ≥ 2 years did experience significant increases in mean cylinder length (LGX 1.2 cm, CX 1.1 cm, and Titan 0.9 cm, $P < .001$). The mean increases in length at ≥ 2 years were similar between the 3 devices ($P = .20$). Sixty percent of patients demonstrated increases of >0.5 cm and 40% demonstrated increases of ≥ 1 cm. Titan increased 0.7 cm, 0.9 cm, 1.0 cm, and 1.3 cm at the time of device replacement 1, 2, 3, and 5 years after the initial placement, respectively. DOES NOT ASSESS SATISFACTION

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Table 2. Continued

Title	Authors & Publications	Level of Evidence	Follow-up	Number Subjects	Outcomes measures	Summary
Patient's satisfaction after 2-piece IPP: an Italian multicentric study.	Gentile Get al[115] (2016), Arch Ital Urol Androl	4	42	2005–2013	EDITS (Modified) w 5-point scale — very satisfied to not at all satisfied	Retrospective, non-randomized. 29 (69%) — Ambicor 13 (31%) — Coloplast excel 42% were extremely satisfied, 33% referred to be almost satisfied, the remaining 25% were substantially indifferent to the result. 73% of partners — fully satisfied. 7 of 42 patients (64%) reported to be fully satisfied by the device, once activated. Only 3 patients complained for the incomplete concealing of the prosthesis. One was not satisfied for the insufficient girth of the shaft; another one referred shortening of the penis, and one was unsatisfied for incomplete penile rigidity with full-activated implant. The length of the penis was reported to be increased in 13 of patients, reduced in 8 patients, and unmodified in the remaining 21. Conclusion: IPP is a feasible solution to treat severe ED. The 2-piece models are a valid option of choice, especially in the elder patient, and has low rates of intra and postoperative complications. It also offers satisfactory rates of aesthetics and functional results
Comparison of the patient and partner satisfaction with 700CX and Titan PP	Otero JR et al[104] (2017), Asian J Androl		248		EDITS and non-validated satisfaction questionnaire	Retrospective. 194 CX, 54 Titan OTR more patients satisfied with the 700CX TM than with Titan. No patient was dissatisfied or very dissatisfied after the PP implantation ($P = .0014$). Optimal Mx: while no patient with the Titan implant took longer than this time, 10% of patients with the 700CX TM implant went over this length of time ($P = .0014$). Ease deflation: 4% of patients with the 700CX TM implant were dissatisfied with the deactivation of the PP, up to 24% of the patients with the Titan implant were

(continued)

Table 2. Continued

Title	Authors & Publications	Level of Evidence	Follow-up	Number Subjects	Outcomes measures	Summary
						dissatisfied ($P = .0031$). 207 partners: although both groups would "strongly" recommend to their partners to re-implant the PP, it seems there is a greater tendency that group 700CX TM would recommend it more than group Titan with 69% vs 56%, respectively.
Prospective evaluation of patient satisfaction, and surgeon and patient trainer assessment of the Coloplast Titan one touch release three-piece IPP	Ohl DA et al[112] (2012), J Sex Med	4	113	6 and 12 months	Satisfaction	Prospective, single arm, Coloplast Titan OTR: overall satisfaction with the device was 90.6% and 90.0% at 6 and 12 months. Ease of deflation, was seen in 70.8% and 73.3%
Physician and patient satisfaction with the new 700 momentary squeeze IPP	Knoll LD et al[114] (2009), J Sex Med	4	69		Patients questioned on ease of finding and using the pump, erection quality compared with a natural one, overall satisfaction with the PP	Prospective, single arm. AMS MS pump 96% easily locating the inflation bulb and 94% deflating the device with one push of the deflation button. At 6 months, 77% of the patients were very satisfied, 9% somewhat satisfied, and 14% dissatisfied
Comparison between AMS 700™ CX and Coloplast™ titan inflatable PP for Peyronie's disease treatment and remodeling: clinical outcomes and patient satisfaction.	Chung E et al[66] (2013), J Sex Med	4	138		Surveyed on ease and frequency of use, patient and partner satisfaction, and self-esteem.	Prospective randomized, with retrospective telephone follow up. No control. AMS 700CX vs Coloplast Titan in modeling context. 88AMS, 50 Coloplast 109 (79%) patients scored at least 4 on a 5-point scale of overall satisfaction with the cosmetic and functional outcomes. The most common reason for dissatisfaction was shortened penile length with 18 (62%) patients reported a decreased penile length post-operatively. No statistically significant difference in patient usage and satisfaction rates between AMS 700 CX and Titan IPPs ($P > .05$). Eighty-two percent of patients would undergo

(continued)

Table 2. Continued

Title	Authors & Publications	Level of Evidence	Follow-up	Number Subjects	Outcomes measures	Summary
						operation again and recommend to others. >60% utilized devices more than twice a month. 80% described the inflation and deflation of IPP as easy, 80% inflated the IPP completely full for sexual penetration. More than two-thirds of patients reported greater self- confidence following IPP implantation.
Patient and partner outcome of inflatable and semi-rigid PP in a single institution.	Bozkurt IH et al[116] (2015), Int Braz J Urol	4	Minimum 1 yr	257	IIEF EDITS	Non-randomized cohort study. Not looking at differences between devices, only between malleable and inflatable. Also, mainly Ambicor 97 AMS Ambicor, 13 AMS 700 CX and 8 AMS Ultrex (AMS, Minnetonka, MN, USA) 152 patients (80 IPP, 72 SPP) could be contacted IIEF scores were 10.1 ± 4.5 and 23.4 ± 1.5 EDITS 78 ± 11 (patients) EDITS 72 ± 10 (partners)
Implantation of AMS 700 LGX PP preserves penile length without the need for penile lengthening procedures.	Negro CLet al[95] (2016), Asian J Androl	4	6 month	36	Stretched flaccid length, length at p50, p100 IIEF EDITs	Mixed etiology. A significant difference in stretched flaccid penile length was seen between 6 and 12 months ($P = .033$). 100 was also significantly increased at 6 and 12 months, with a mean 10% increase (1.3 ± 0.4 cm) from baseline to 12 months. Stretched penile length was at least 1 cm longer at 12 months than preoperative and 6 months measurements in all patients, 80% of patients satisfied with the final length. Mean stretched flaccid penile length was 13.1 ± 1.2 cm at baseline, and was greater at 6 months (13.7 ± 1.1 cm [$P = .018$]), and at 12 months (14.2 ± 1.2 cm [$P = .0001$]); a mean difference of 1.1 ± 0.3 cm at 12 months vs baseline. Mean P_{50} and P_{100} lengths were 13.1 ± 1.2 cm and 13.9 ± 1.3 cm ($P = .002$) at baseline; 13.1 ± 1.2 cm and 14.3 ± 1.3 cm ($P = .0001$) at 6

(continued)

Table 2. Continued

Title	Authors & Publications	Level of Evidence	Follow-up	Number Subjects	Outcomes measures	Summary
						months; and 13.1 ± 1.2 cm and 14.4 ± 1.3 cm at 12 months ($P = .0001$).
Prospective and long-term evaluation of erect penile length obtained with inflatable penile prosthesis to that induced by intracavernosal injection	Wang R et al[103] (2009), Asian J Androl	4		11	Erect penile length (cm) (ICI) vs length following IPP	First study to objectively show a significant decrease in erect penile length after IPP implantation when compared with that after ICI- erect penile length (mean ± SE) as induced by ICI was 13.2 ± 0.4 cm, whereas the lengths attained with IPP were 12.4 ± 0.3, 12.5 ± 0.3, and 12.5 ± 0.4 cm at the sixth week, sixth month and 1-year follow-ups, respectively.
Upsizing of inflatable penile implant cylinders in patients with corporal fibrosis	Wilson SK et al[94] (2006), J Sex Med	4		37	Length, upsizing to standard IPPs (AMS 700 CX, Mentor Alpha 1, Mentor Titan	Corporal fibrosis patients. Upon reoperation, it was possible to pass dilators of 12° mm width proximally allowing the substitution of standard-sized AMS 700 CX (23), Mentor Alpha 1 (10), or Mentor Titan (2). Additionally, corporal length measurements in the previously infected patients increased an average of 2.2° cm
Prospective evaluation of postoperative penile rehabilitation: penile length/girth maintenance 1 year following Coloplast Titan inflatable penile prosthesis.	Henry GD et al[122] (2015), J Urol	4		93	Penile length girth and number of pumps required for full inflation How satisfied w penile length? Worse, unchanged, improved	Penile measurement changes were statistically significantly improved at 12 months as compared with immediately postoperative and at 6 months. 64.5% of subjects were satisfied with their length at 1 year, and 74.2% had perceived penile length that was longer (29%) or the same (45.2%) as prior to the surgery; 61.3% and 16.1% of subjects had increased and unchanged satisfaction. All but 2 subjects (93.4%) were satisfied with the overall function and dimensions of their IPP. Coloplast Titan only.
Mechanical reliability and safety of, and patient satisfaction with the Ambicor inflatable penile prosthesis: results	Levine LA et al[97] (2001), J Urol	4	131	43.4	EDITS (Modified)	Satisfaction 90.6/82.6 Patient/Partner

(continued)

Table 2. Continued

Title	Authors & Publications	Level of Evidence	Follow-up	Number Subjects	Outcomes measures	Summary
of a 2-center study.						
Penile length alterations following penile prosthesis surgery.	Deveci et al[131] (2007), Eur Urol	4	56	1 month and 6 months	EDITS IIEF	Prospective, overall satisfaction not reported; only score change vs raw score. Unable to find a significant measured length loss despite a subjective penile length loss perceived by 72% of patients. Subjective penile length loss was more common in patients who had undergone radical prostatectomy before prosthesis implantation (32%). Men complaining of length loss had lower IIEF satisfaction domain and EDITS scores.
Outcomes and Satisfaction Rates for the Redesigned 2-Piece Penile Prosthesis	M. Luxet et al[117] (2007), J Urol	4	146	38	EDITS (Modified)	Modified EDITS (88/76) (patient/partner)
Penile Implantation in Europe: Successes and Complications with 253 Implants in Italy and Germany	A. Natali et al[5] (2008), J Sex Med	4	200	60	EDITS (modified)	AMS 700CX, AMS Ambicor, and AMS 600-650: Patient: 97%, 81%, and 75% Partner: 91%, 91%, and 75%
Patient's satisfaction after 2-piece inflatable penile prosthesis implantation: an Italian multicentric study.	G. Gentile et al[115] (2016), Arch Ital Urol Androl	4	27	42	EDITS for Ambicor only.	1% of patients (30) reported regular use of the prosthesis, at least 1 time/week, the satisfaction was good in 42% of patients (18), quite good in 33.3% (14), quite bad in 2.4% (1), very bad in 7.1% (3), and 6 patients (14.4%) did not answer. In 29 cases (69%), the AMS Ambicor device was implanted, because a Coloplast Excel model was placed in the remaining 13 (31%).
AMS three-piece inflatable implants for erectile dysfunction: a long-term multi-institutional study in 200 consecutive patients.	F. Montorsi et al[6] (2000), Eur Urol	4				Old study but large numbers 98% patient and 96% partner satisfaction rates 185 patients from a group of European institutions.

ED = erectile dysfunction; EDITS = Erectile Dysfunction Inventory of Treatment Satisfaction; EORTC QLQ-C30: The European Organisation for Research and Treatment of Cancer quality of life questionnaire; ICI = intracavernosal injection; IIEF = International Index of Erectile Function; IPP = inflatable penile prosthesis; PD = Peyronie's disease; PP = penile prostheses;

Evidence

A retrospective study by Patel et al[53] published on the New York State Department of Health Statewide Planning and Research Cooperative Database analyzing 11,531 patients who underwent PP surgery, AUS surgery, or both (n = 161) found that those with a dual treatment had a higher likelihood of undergoing revision surgery for PP at 1 year (odds ratio: 2.08; 95% CI: 1.32−3.27; $P <$ .01) and at 3 years (odds ratio: 2.60; 95% CI: 1.69−3.99; $P <$ .01) follow-up[53] (Table 1). Another retrospective study by Segal et al,[54] including 55 combined procedures, found that the rate of device infection, erosion, or malfunction was not increased when compared with staged procedures (Table 1). A prospective study by Martinez-Salamanca et al[55] on 32 patients with dual prostheses found no intraoperative complications. During follow-up, 4 device-related complications occurred, including AUS reservoir migration, urethral erosion, and distal corporal extrusion.[55] A retrospective study of 95 patients by Mancini et al,[56] including 33 with synchronous surgery, found that revision rate was not statistically different between single and dual surgery (9% vs 3%; $P =$ .6).[57] Other retrospective studies with patient numbers lower than 20 found that simultaneous implantation of IPP and AUS is safe and effective.[58] Finally, a retrospective study by Sundaram et al[59] on 304 patients with AUS found a higher rate of AUS cuff erosion in patients who also had PP placement (11.6%), when compared with patients who did not undergo simultaneous PP surgery (4.3%; $P = .037$). In addition, there was a higher rate of device removal in patients who also had PP implanted, when compared with patients without PP (17% vs 9%; $P = .044$). Importantly, in this study, patients with synchronous and staged implantation of PP and AUS were grouped together.[59] Another retrospective single-center study evaluated 39 patients treated with synchronous (33%) and metachronous artificial urinary sphincter and 3-piece inflatable penile prosthesis (AMS 700, Boston Scientific, Marlborough, MA) after radical cystectomy with neobladder. After 94 months median follow-up, 1 patient developed penile prosthesis infection and 4 patients developed artificial sphincter erosion. In each case, the infection did not involve the other device. 2 patients (5.1%) developed mechanical failure of IPP requiring revision surgery (reservoir replacement due to leak, n = 1, and cylinder replacement, n = 1). Synchronous placement of AUS and IPP were not associated with poorer device outcomes compared with patients who had metachronous placement. The authors of this study concluded that dual implantation of AUS and IPP can be performed safely in patients after radical cystoprostatectomy and neobladder without an increased risk of infectious complications, mechanical failure, cuff erosion, or revision surgery when compared with non-neobladder patients with both devices. In addition, the authors stated that neobladder patients with dual implants should be counseled regarding the risk of mechanical failure requiring surgery.[60]

Remarks

Several publications pointed out that there is a paucity of published data on combination surgery for management of both ED and male incontinence, but synchronous surgery might represent a favorable approach[61−64] (Table 1). There are currently no RCTs supporting the hypothesis that dual implantation is as safe as staged implantation of PP and AUS. Although some studies found that synchronous implantation of PP and AUS may be safe, the most recent study showed a significantly increased risk of revision surgery for PP after 1-year and 3-year follow-ups. In contrast, another recently published retrospective study found that synchronous implantation of AUS plus IPP was not associated with poorer device outcomes compared with patients who had metachronous implantation surgery. We suggest that the potential benefit of cost-effectiveness of synchronous surgery should be weighed against the potentially increased risk of revision surgery.[63]

Peyronie's Disease

Statement #10

We suggest that PP surgery is feasible in patients with Peyronie's disease (PD). We suggest that PP surgery should only be performed in the stable phase of the disease and in patients with ED not responding to medical treatment (level 3; grade B).

Evidence

Results from the Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration (PROPPER) study by Khera et al[65] demonstrated that >80% of the 250 patients who received PP surgery for ED and concomitant PD were satisfied or very satisfied and were regularly using their PP at 1-year and 2-year follow-up (Table 1). A retrospective single-center study by Chung et al[66] on 138 patients found similar device survival, patient satisfaction, and penile straightening independent of the device used. Another retrospective single-center study by Chung et al[67] on 18 patients who underwent PP insertion with synchronous penile plication found improvement in overall condition and penile curvature in all patients after a median follow-up of 11 months. Minor residual curvature was reported in 1 patient with biplanar deformity.[67] A retrospective study by Garaffa et al[68] showed that 29% of patients with PD who had been treated with PP implantation required additional intraoperative straightening procedures in order to adequately correct the residual curvature. Interestingly, modeling was more efficient in patients with IPP compared with patients with malleable PP (84% vs 54%) Similarly, Levine et al[69] found that PP surgery with straightening maneuvers in 99 men resulted in satisfaction rates of 84% at mean follow-up of 49 months. Complications included penile shortening in 3%, diminished sensitivity in 2%, difficulty operating the device in 1%, persistent curvature in 4%, superficial wound infection in 1%, and mechanical failure in 7% of patients. Overall, 13% of patients required revision surgery, including 7 replacements of PP due to mechanical failure. In 2 patients, revision was required due to pump malposition, and 2 patients underwent corporoplasty for impending distal erosion.[70] Penile shortening due to surgical treatment is a common cause of

Table 3. Studies to reservoir placement

Title	Authors & Publications	Level of Evidence	Follow up	Number Subjects	Outcomes measures	Summary
Emerging Complications Following Alternative Reservoir Placement during Inflatable Penile Prosthesis Placement: A 5-Year Multi-Institutional Experience	Hernández et al[124] (2019), J Urol	3	Mean 20.4 months	5 yr, 3 centers, RETROSPECTIVE	Revision rate for reservoir only	612 HSM, 362 SOR. 2% vs 1.3% revision rate, respectively, — Not significant
Extended Experience with High Submuscular Placement of Urological Prosthetic Balloons and Reservoirs: Refined Technique for Optimal Outcomes	Paglaria et al[120] (2018), Urology Practice	3	Mean 25.6 (1.9-93.6) months	560 1st time reservoir RETROSPECTIVE	Pain/herniation Deep pelvic complications (vascular/bladder)	619 HSM (IPP — Coloplast and AMS 344, AUS 275) 2009—2016 but only 560 first time available for review 8/399 first time HSM revised — 4 for pain, 4 for herniation 6/161 first time SOR revised — 3 for herniation, 3 for deep pelvic complications
Subcutaneous Placement of Inflatable Penile Prosthesis Reservoirs	Garber and Bickell[123] 2016 Urology	4	7-11 months	7 (1 explanted early) Average BMI 39 RETROSPECTIVE	Palpable herniation	Subcutaneous Reservoir 8/1000 Coloplast IPP single surgeon, 1/8 explanted for infection, other 7 not palpable by patient or surgeon
Does Pressure Regulating Balloon Location Make a Difference in Functional Outcomes of Artificial Urinary Sphincter?	Singla et al[121] (2015), J Urol	3	Mean 23 months	294 RETROSPECTIVE	Herniation Deep pelvic	294 AUS (HSM 154, SOR 140) No demographic difference No pain 1/140 SOR — herniation 1/140 SOR — spontaneous bladder rupture unrelated to reservoir. No problems with HSM. No difference in continence rates
Reservoir alternate surgical implantation technique: preliminary outcomes of initial PROPPER study of low profile or spherical reservoir implantation in submuscular location or traditional prevesical space	Karpman et al[122] (2015), J Urol	2	Mean 17.8 months	744 PROSPECTIVE	Herniation Palpable satisfaction	PROPPER study — AMS 700 IPP devices only 3/572 SOR — 81% very satisfied, 2 herniation, 1 capsular contracture 2/172 HSM — 85.9% very satisfied, 2 herniation. Palpability was not an issue

(continued)

Table 3. Continued

Title	Authors & Publications	Level of Evidence	Follow up	Number Subjects	Outcomes measures	Summary
High submuscular placement of urologic prosthetic balloons and reservoirs: 2-year experience and patient-reported outcomes	Chung et al[119] (2014), Urology	3	Mean 3.2 months	146 RETROSPECTIVE	Palpability Bother	Mixed AMS700, Titan and AUS 146 cases, single surgeon 80% not palpable by patient 9/146 bothered but only 2 wanted revision 2 AUS herniation. Self-reported patient satisfaction 97% AUS, 96% IPP

AUS = artificial urinary sphincter; BMI = body mass index; HSM = high submuscular; IPP = inflatable penile prosthesis; PROPPER = Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration; SOR = space of Retzius.

patient dissatisfaction. A retrospective multicenter study on 206 patients evaluated treatment-related patient-reported outcome using a nonvalidated questionnaire. Subjective loss of penile length ranging from 0.4−1.2 cm was reported in 78%, 29%, and 24% of patients who were treated with the Nesbit procedure, grafting technique, and malleable penile prosthesis implantation, respectively. Loss of penile length bothered 86%, 79%, and 82% of patients who were treated with the Nesbit procedure, grafting technique, and malleable penile prosthesis implantation, respectively.[71] Some techniques that aim at preventing penile shortening have currently been described, including the sliding-technique using double dorsal-ventral patch graft or circumferential grafting. These techniques require extensive mobilization of the urethra and the neurovascular bundle in order to allow adequate restoration of penile length and, therefore, are significantly more aggressive than simultaneous penile prosthesis implantation and tunical incision/plication.[67,71] 2 studies, including 3 and 23 patients, respectively, reported penile lengthening of approximately 3 cm at a median follow-up of 13 and 22 months, respectively, and 90−100% of patients were satisfied with functional and cosmetic results of the sliding-technique.[5,6,72,73] After a median follow-up of 37 months, a prospective multicenter study by Rolle et al[74] on 28 patients with PD with severe penile shortening and ED who have undergone the sliding-technique reported bleeding requiring a blood transfusion in 3.5% of patients and infection requiring the removal of the device in 7% of patients. The authors reported that there were no late recurrences of curvature. In this study, porcine small intestinal submucosa and acellular porcine dermal matrix were used to cover the tunical defects in patients with IPP. In patients undergoing malleable PP implantation, a collagen-fibrin sponge was used to cover the tunical defects.[74] Another study evaluated 143 patients with severe penile shortening who had undergone a modified sliding technique, including 77 patients (54%) with PD and therapy-resistant ED. The mean curvature in the PD subgroup was 45° (range 0°−100°). Patients were implanted with either malleable (n = 133) or inflatable (n = 10) devices. After a median follow-up of 10 months (range 6−18 months), there were no major complications and the curvature was resolved in all patients, although 10% of patients with malleable prosthesis were dissatisfied with postoperative girth.[75]

Remarks

Evidence regarding PP implantation in patients with PD is low and derives mainly from retrospective studies with low patient numbers and limited follow-up. Retrospective and prospective studies found that the risk of infection is not increased compared with patients without PD who receive PP surgery. There is an increased risk of perforation of the urethra in patients with PD receiving PP surgery plus modeling.[76] Further prospective and RCT studies are needed to evaluate the value of a synchronous vs staged surgical approach for the treatment of patients with ED and PD. The International Consultation on Sexual Medicine emphasizes that penile implant surgery should

Table 4. Studies to phaloplasty

Paper	N	Diagnosis	Median FU (m)	Method	Penile Prosthesis	Penetrative sex	
Falcone et al[125] (2018)	104	FTM	20	In-house questionnaire	3-piece IPP	77%	Functional and cosmetic satisfaction 88%, Partner satisfaction 60%, orgasm 61%
Leriche et al[129] (2008)	35	FTM	110	In-house questionnaire	Ambicor/ malleable	51%	
Zuckerman et al[130] (2015)	31	48% FTM	60	From notes	21 malleable, 10 IPP	81%	No differentiation IPP vs malleable
Callens et al[126] (2015)	10	Non-FTM	37	Individual psych interview	Ambicor/ Spectra	? 100%	8/10 orgasm with sex, 2/10 masturbation, satisfaction with erect length slightly more than control group but not statistically significant
Young et al[128] (2017)	9	Trauma/ Exstrophy	30	In house questionnaire, IIEF, SQOL for men, web and phone interview	? type of PP	66%	Masturbation 78%, IIEF – overall satisfaction 5/10, orgasmic 6/10, intercourse satisfaction 10.5/15, SQOL for men – 60/100 no change after PP
Falcone et al[127] (2016)	6	Trauma	51	In-house questionnaire	3 piece IPP	100%	Orgasmic 100%, satisfaction 100%

FTM = transmasculine individuals (or transgender men); IIEF = International Index of Erectile Function; IPP = inflatable penile prosthesis; SQOL = sexual quality of life.

be performed in case of stable disease and in patients with ED not responding to medical therapy.[70]

Female and Male Expectations of IPP Surgery

Statement #11

We suggest that surgeons thoroughly discuss expected postoperative outcomes with both partners prior to PP surgery, including possible complications and their management (level 3; grade B).

Evidence

Female sexual satisfaction rates play an important role in determining overall couple satisfaction following PP implantation. Over the last decade, only a few articles evaluated female partner satisfaction rates.[8,77,78] Patient dissatisfaction after PP implantation may be a consequence of partner sexual dissatisfaction. The correlation observed suggests that patients not satisfied with their PP are likely to have female partners at high risk for female sexual dysfunction.[77]

Studies have suggested a direct linear correlation between the satisfaction of the sexual partner(s) and the overall satisfaction.[78] In this analysis, there were no statistically significant differences when stratifying couples according to level of education or implant characteristics.[78] Patients experienced higher sexual relationship satisfaction (median score = 90.6) than their partners (median score = 81.2), but there was no difference in treatment satisfaction. Lower depression scores were associated with higher sexual confidence and intimacy and these were correlated with improved treatment satisfaction and sexual function. In 1 study analyzing patients undergoing PP surgery, a preoperative expectation survey was followed 4 months later with a single outcome satisfaction score of 1−100. Statistical linear regression analysis confirmed that lower preoperative expectation scores correlated almost linearly with higher satisfaction scores after surgery. The authors concluded that giving patients an accurate description of the procedure and setting realistic expectations leads to higher postoperative satisfaction rates.[79] In small groups of patients and partners who were not satisfied with the surgical result, objective analysis of the possible reasons for dissatisfaction showed a discrepancy between reality and patient expectations.[8,80,81] Accordingly, it was shown that satisfaction of patients with PP was inversely correlated with preoperative expectations.[11] There are no well-established preoperative validated scores associated with PP insertion.[82−84] This is possibly due to the fact that assessment of female and male expectations, as well as the degree of satisfaction, is multifactorial, subjective, and, therefore, extremely complex to be analyzed.[82−84] Studies evaluating satisfaction after cosmetic aesthetic surgery may give an idea of the factors that may lead to patients' dissatisfaction.[85−87] Male and female patients undergoing cosmetic procedures may expect associated improvement in quality of life, self-esteem, and overall anxiety, with satisfaction judged by not only the surgical outcome, but also by its overall impact on patient's self-esteem.[86,87] Objective clinical determinants of patient satisfaction following PP placement should take into consideration the etiology of ED, such as radical prostatectomy, PD, corporal fibrosis after priapism, diabetes, and other metabolic-related conditions, including obesity.[12,88] Other studies have considered a BMI >30 kg/m^2, previous radical prostatectomy, and PD as risk factors for postoperative dissatisfaction with PP.[52] Additional key determinants of decreased satisfaction include perceived penile length loss, decreased glans engorgement, altered penile sensation, decreased sensation during ejaculation, perioperative discomfort, cosmetic outcome/ease of concealment, difficulty to cycle the device, partner dissatisfaction, perception of unnatural feel, complications, and extent of treatment provided prior to surgery.[3,7,79] With this modest evidence and considering the psychological assessment being used in cosmetic surgery, Trost et al[89] identified 7 parameters associated with higher rates of postoperative dissatisfaction. The authors combined these parameters in the mnemonic Compulsive, Unrealistic, Revision, Surgeon Shopping, Entitled, Denial, and Psychiatric ("CURSED"). Character traits of difficult patients with PP include obsessive/compulsive tendencies, unrealistic expectations, those seeking multiple surgical options, feelings of entitlement, patients in denial of their prior erectile/sexual function and current disease status, or those with other psychiatric disorders. The authors provided this framework to identify and interact with difficult patients with PP with the intention of enhancing the prosthetic surgeon's ability to establish and strengthen the surgeon-patient relationship, reduce physical, emotional, and legal risk, as well as ultimately enhancing patient satisfaction. Perhaps this article may represent the first step toward breaking one of the many barriers in achieving a best outcome for couples having PP surgery.[52] Trost and colleagues[82] refined the CURSED pneumonic and added more important aspects. This includes setting reasonable expectations, reviewing anticipated risks, optimizing postoperative compliance to reduce complications, and providing ongoing support for the patient`s condition. Authors conclude that the incorporation of enhanced patient selection and counseling offers the possibility for improving patient's satisfaction and overall outcomes. Additionally, it may limit potential adverse consequences, including patient or personal harm, lawsuits, impaired credibility, or similar effects.[82]

Remarks

At present, standardized methods for assessment of patient and partner expectations have not been established. The CURSED assessment of preoperative expectation may assist in identifying high-risk patients. The key in understanding PP-associated dissatisfaction might be to observe the initial expectations of couples prior to surgery. The main goal is to investigate those multifactorial characteristics, such as sexual history of the couple, including their beliefs, sexual fantasies, fears, and, most importantly, expectations related to PP implantation.

A further multicenter and multidisciplinary evaluation could be initiated in order to evaluate patients' and partners' satisfaction. The influence of cultural and social factors related to the aging process and a shift in the expression of sexuality due to increased life expectancy, as well as improvement of quality of life over the last decade, increases the role of sexual medicine. Interdisciplinary treatment options are required in the care of couples to cover both psychological and surgical needs.

Inflatable Penile Implant Satisfaction — The Impact of Length, Girth, and Implant Type

Statement #12

Despite heterogeneity in the methods of measurement, it seems that overall Inflatable Penile Implant satisfaction is moderate to high (level 3; grade C).

Statement #13

Objective measures and patient perception of penile dimensions should be routinely reported in PP outcomes. In some cases, penile length can be progressively increased by the implant acting as a tissue expander (level 4; grade C).

Statement #14

Greater girth expansion may occur with longer PP in situ time (level 4; grade C).

Statement #15

Ex vivo studies suggest Coloplast Titan showed slightly better rigidity than the AMS LGX and CX devices (level 3; grade C). The AMS700CX has demonstrated the best axial rigidity (3-point flex test) in the short phallus, the Coloplast Titan is slightly better in the long phallus and in patients with PD (level 3; grade C).

Statement #16

Patients should be thoroughly counselled regarding the characteristics of each device in order to optimize satisfaction (level 4; grade 4).

Evidence

Generally, studies demonstrate moderate to high levels of patient and partner satisfaction. However, it is important to remember that there are multiple aspects of satisfaction, such as ease of inflation/deflation, appearance, usage, partner related satisfaction, as well as function, which are not universally included in reports of IPP outcomes. Many studies use validated scoring systems, such as EDITS or IIEF, however, these have not necessarily been developed specifically for the evaluation of penile implant outcomes. Validated scoring systems for PP surgery include the Quality of Life and Sexuality with Penile Prosthesis.[90–92]

Satisfaction and Length

Although no study specifically evaluated the impact of length of the implant on satisfaction outcomes, it has been reported that the length can be progressively increased by the PP acting as a tissue expander. Whereas subsequent implants can be longer by 0.9–2.2 cm, the absolute difference between each implant type is low[93,94] (Table 2). It seems that greater expansion may occur with longer in situ time[93,95] (Table 2). Even without replacement, implants may provide an increase in penile length over time by an average of 0.2 cm to 2.2 cm[80,94–97] (Table 2). Biomechanical (ex vivo) studies indicate that the AMS LGX showed an absolute increase in length of 13 mm (18 cm device) during inflation.[98] The AMS LGX is also reported to result in an increased penile length during in vivo exchange of the device, of 1.1 cm at 12 months; this finding is comparable with other PP types.[95,99] One recently published observational study on 74 patients demonstrated an increase of 3 cm of the stretched penile length when an AMS LGX 700 was implanted, followed by twice daily vacuum device therapy for 6 months.[100] Although most studies suggest an increase in length and patients may also perceive an increase in length,[80,101] the evidence is conflicted with studies also claiming a measurable decrease in length in 12% (15/122) of patients (includes both inflatable and malleable devices,[9] or in length terms, from 0.2 to 3.0 cm).[102,103] Importantly, there are significant numbers of patients (42–46%) that are dissatisfied with the appearance of their erect penis post-PP insertion[104] (Table 2). In other PP patients' groups, such as these with PD, the main reason of dissatisfaction with an implant was patient-reported length reduction.[66]

Although rear-tip extenders add length to the overall implant, an ex vivo study demonstrated their addition led to increased cylinder deflection.[105] A cadaveric study (n = 2), similarly concluded that rear-tip placement affect kinking at either the extender or within the PP, although the implants maintain their physical durability sufficient for vaginal intromission.[106] Due to the nature of these studies, no comments can be drawn, however, in relation to patient satisfaction and rear-tip extender placement.

Administration of a vasoactive agent has been utilized during intraoperative corporal measurement and compared with the flaccid stretched method of length measurement. A small study of 38 noted 82% (flaccid stretch) of patients vs 6% (vasoactive injection) reported shorter postoperative penile lengths — satisfaction was not reported.[107]

Satisfaction and Girth

Once again, evidence in this area is limited and conflicting. A recent study of 24 patients noted an increased penile circumference at 12 months of 2.4 cm[102]; satisfaction scores were not recorded. Cadaveric studies confirm the post-implant girth to be 24% greater, compared with pre-implant.[108] Other studies suggest that greater girth expansion may occur with longer PP in

situ time,[80] whereas other suggest there was no evidence of reduction in girth in inflatable devices. In this later article, although overall satisfaction was quite high, 92% 4−5 score, this was not correlated with girth and the study included both inflatable and malleable devices.[101]

Other articles have described a notable decrease of penile loss in girth of 0.5 to 2.6 cm[96,109] (Table 2). Overall, however, evidence exploring different outcomes between PP types on girth expansion are poor.

Satisfaction with Various Inflatable Implant Types

Although most of the literature is focused on patient satisfaction, 1 recent study revealed 90% (AMS700CX) and 93% (Coloplast Titan) of partners felt that sex was very good with, respectively, 90% and 97% re-recommending their partners to undergo surgery.[66] A cadaveric biomechanical study of AMS CX, LGX, and Coloplast Titan implants demonstrated similar axial compression rigidity, with the Titan showing slightly better rigidity than the AMS LGX and CX devices. The AMS CX showed the best axial rigidity (3-point flex test) in the short phallus, the Titan slightly better in the long phallus and in PD[110] (Table 2). With these physical characteristics in mind, some comparative studies show no difference in overall satisfaction, with 79% of patients reporting 4/5 on function and cosmesis scoring.[66,111] The Coloplast Titan OTR pump is associated with 85−93% overall satisfaction rates.[80,112,113] Similar rates are reported with the AMS MS pump models[114] (Table 2). One comparative study showed higher overall satisfaction rates with the AMS700CX, when compared to the Coloplast Titan, with 70.6% vs 44.4% of patients reported to be "very satisfied" on a modified EDITS score[104] (Table 2). A retrospective analysis of patients with Coloplast Titan and 2-piece AMS Ambicor PPs showed "extreme satisfaction" in 42% of cases, whereas 33% were "almost satisfied." The main limitation of this series is that outcomes are not stratified by PP type[115] (Table 2). 2-piece implants, within comparative studies, tend to show lower rates of satisfaction when compared with their 3-piece counterparts (IIEF scores 10.1 ± 4.5 for the 2-piece implants and 23.4 ± 1.5 for the 3-piece implants).[97] EDITS scores for the AMS Ambicor range between 78% and 81%,[5,97,116,117] whereas AMS700CX EDITS scores are as high as 97%.[5] Results of the large PROPPER cohort (comparing Ambicor n = 27 and AMS700 n = 1228) showed no difference in IIEF and inpatient satisfaction. The AMS LGX demonstrates EDITS of 77.8% at 12 months[95] (Table 2).

Remarks

Overall, the evidence regarding patient and partner satisfaction regarding different models of IPPs, as well as the impact of length or girth upon satisfaction levels is plagued by heterogeneous study types with low levels of evidence and derives mainly from retrospective studies with low patient numbers and limited follow-up. No face to face comparisons among different devices are available. Validated and consistent patient-related and partner-related outcome measures of satisfaction should be routinely reported in PP outcomes. A prospective European registry of PP is advisable in order to help our understanding of these surgeries, including patient-related outcomes.

Satisfaction With IPP Pump

Statement #17

Product independent satisfaction with an IPP pump function is relatively high and indicated in comparative studies as over 80% (level 4; grade C).

Evidence

Single arm studies have shown AMS MS (momentary squeeze) overall satisfaction rates of 77−86%,[104,114] with ease of inflation of 57%[66,114] (Table 2). A comparative study pooled ease of inflation of both Coloplast Titan and AMS 700 CX (MS pump) at 80%[66] (Table 2). The AMS 700 has demonstrated deflation satisfaction of 80−90%,[66,114] with dissatisfaction rates of 4%.[104] These results compare favorably against the Coloplast pump, which is associated with satisfaction and dissatisfaction rates, respectively, of 73% and 24%[104,112] (Table 2). A retrospective chart review showed improved ease of teaching and patient utilization of the newer Coloplast Titan OTR pump compared with the predecessor Genesis model.[118] A prospective single armed study of the Coloplast Titan OTR reported overall satisfaction rates of 90%, with 73% of patients reporting ease of deflation at 12 months[112] (Table 2).

Remarks

Evidence regarding the satisfaction with IPP pump is low and derives from retrospective studies with low patient numbers. Selection bias, as well as preoperative education and counseling, likely play a role in patient satisfaction. Current studies evaluated both overall satisfaction and ease of deflation, with respect to each type of device, but face to face comparisons among different devices are not available. Prospective studies based on the European registry of PP would help our understanding of pump satisfaction.

Patient Satisfaction Regarding Reservoir Placement of IPP

Statement #18

Ectopic high submuscular (HSM) reservoir placement can be considered as an alternative method of reservoir placement during IPP implantation (level 2; grade C).

Statement #19

Palpability of the HSM reservoir does not seem to be a significant factor with regard to revision surgery (level 2; grade C).

Statement #20

Subcutaneous reservoirs can be used with caution in very obese patients (level 2; grade C).

Evidence

Satisfaction with respect to reservoir placement included the following domains: palpability, pain, general satisfaction, complications, device difficulties, and location. Reservoirs from both AUS and IPP placement were included. Where a particular center had published updated data over a series of years, then only the most recent article was selected as it included all previous data unless different outcomes were assessed. Only 6 studies met these criteria.[119–124] There were various locations for reservoir placement, including space of Retzius (SOR), HSM, lateral extraperitoneal (lateral), and subcutaneous.

The University of Texas published 3 retrospective studies, where the 2014 and 2015 studies were subsets of the 2018 survey[119–121] (Table 3).

The 2014 study investigated patient's reported outcomes only in 146 patients who have undergone HSM reservoir placement with mixed cohort of AMS 700, Coloplast Titan and AUS (AMS 800) devices. Patient-reported satisfaction was 97% for AUS devices and 96% for IPP devices; 80% of reservoirs were impalpable by the patient. Of the 9 patients who were bothered by the reservoir, only 2 wanted revision surgery. There were 2 reservoir herniations in the AUS group.[119] The larger 2018 study evaluated a cohort of 560 patients who had undergone HSM or SOR reservoir placement (AMS 700, Coloplast Titan and AMS 800) for the first time. No specific patient-reported satisfaction was assessed apart from pain and herniation. In particular, pain and herniation were reported, respectively, by 4 and 4 patients in the HSM group and by 0 and 3 patients in the SOR group. There was a higher rate of deep pelvic complications in the SOR group ($n = 3$) than in the HSM group ($n = 0$).[121] The 2015 study looked at device functional outcomes for 294 AUS devices comparing approximately equal SOR and HSM placement but made no comment on patient-reported satisfaction. There was no difference in revision rate, explant rate, and continence rate[120] (Table 3).

In 2019, Hernández et al[124] published a multicenter study of 974 IPPs. Of these reservoirs, 612 were in the HSM group and 362 were in the SOR group. They confirmed that the revision rate for reservoir-related complications was low in both groups (SOR 1.3% and HSM 2.0%) and not statistically different.[124]

The large prospective PROPPER study presented 1-year follow-up data on AMS 700 devices; the reservoir had been placed in an SOR location in 221 patients and in the HSM 1 in 55. Patients reported being "very satisfied" in 81% and 85.9% of cases, respectively, and herniation occurred in 0.5% in the SOR group and in 1% in the HSM group. This difference was not statistically significant. Reservoir palpability and auto inflation were not an issue in this group of patients[122] (Table 3).

A small retrospective study presented 8 Coloplast Titan reservoirs that were placed in a subcutaneous location in the abdominal wall in patients with obesity with an average BMI of 39 kg/m^2 (range 28–49;[123] Table 3). One reservoir was removed for infection and none of the other 7 patients reported being bothered by a palpable reservoir. There was no specific study on lateral reservoir placement.

Remarks

Patient-reported satisfaction rates are very good for reservoirs and there does not seem to be any difference between SOR and HSM placement. Pain and herniation are very uncommon and there is no difference with HSM and SOR placement. There is a small but slightly higher rate of deep pelvic complications with SOR, so it would be reasonable to offer ectopic reservoir placement instead of SOR placement to avoid pelvic complications. There is no outcome data on lateral reservoir placement. A further multicenter and multidisciplinary evaluation could be initiated in order to evaluate patient and partner satisfaction in relation to the reservoir placement.

Sexual satisfaction Associated With IPPS After Phalloplasty Surgery

Statement #21

There is insufficient data to differentiate between IPP and malleable devices in relation to satisfaction rates (level 4; grade C).

Statement #22

There is a need for validated instruments for assessment but in their absence, IIEF and SQOL-Men may be useful (level 4; grade C).

Evidence

Falcone et al[125] has published the largest series of 104 transgender patients who had been administered a nonvalidated questionnaire. All patients had been implanted with a 3-piece IPP, with median follow-up of 20 months. 3 of the other series published in the literature had <10 patients, and no statistical analysis was, therefore, possible[126–128] (Table 4). These were all nontransgender patients. In the 3 largest studies, the satisfactory sexual penetration rate was between 51% and 81%.[127,129,130] It was not possible to differentiate between IPP and malleable PP as the numbers were too small[129,130] (Table 4). Callens et al[126] introduced a novel method of assessment using a psychologist to interview all the patients; all 10 patients were having penetrative sex and 80% were able to orgasm during sex[126] (Table 4). Only Falcone et al[125] evaluated partner satisfaction, reporting positive outcomes in 60% of cases. Young et al[128] used validated questionnaires for non-transgender men undergoing phalloplasty and PP (Table 2). They showed that overall satisfaction, orgasm, and intercourse satisfaction were all satisfactory. Interestingly, the sexual quality of life score for these

non-transgender men showed no difference before and after PP insertion.

Remarks

The main limit in assessing sexual satisfaction associated with PPs in phalloplasty is the lack of validated questionnaires specifically dedicated to this group of patients. Indeed, most of the authors focused their attention on the surgical outcomes of the procedure. Only a minority of them attempted to assess patient-reported outcomes through the administration of non-validated questionnaires. Therefore, among the published studies, most of them were excluded from the present review because of the lack of any satisfaction assessment. At the end of the selection process, only 6 studies were suitable for inclusion.

To date, there is a paucity of proper satisfaction data after PP implantation in phalloplasty. Further multicentric evaluation are warranted in order to confirm these preliminary data. An effort should be done to validate a dedicated questionnaire to assess the outcomes of PP placement in this category of patients.

CONCLUSIONS

A majority of the studies published on IPP deal with clinical or technical aspects of surgery, but not with associated factors, such as the patients' and partners' expectations, comorbidities, and social profiles. Over the last decades, a number of articles have described the expectations of both patients and their partners, the influence of the patients' comorbidities, as well as a variety of social aspects in association with PP. This approach should be highly encouraged and supported by multicentric prospective RCTs.

According to current findings, there is an increased infection risk in PP performed in patients with poorly controlled diabetes mellitus. The current recommendations suggest improving glycemic control in patients with diabetes planned for PP surgery.

The number of organ transplantations is growing year to year. Without doubt, patients with ED should have all treatment options, including IPP.

We suggest offering PP surgery to patients with ED when indicated, regardless of HIV status, age, and BMI. Smoking may be associated with an increased risk of revision surgery in patients undergoing PP implantation; thus, we should encourage patients to quit smoking prior to surgery. Peripheral vascular disease and hypertension may be associated with an increased risk of revision surgery in patients undergoing PP and should, thus, be adequately addressed preoperatively.

Patients with spinal cord injury may receive PP, provided that bladder emptying is possible and that indwelling catheters are avoided.

We agree with the International Consultation on Sexual Medicine that emphasizes that PP surgery should be performed exclusively in patients with stable PD and in patients with medically refractory ED.

At present, standardized methods for assessment of patient and partner expectations have not been established. The CURSED assessment of preoperative expectations can help to identify high-risk patients.

Evidence regarding patient and partner satisfaction regarding different models of IPPs, as well as the impact of length or girth upon satisfaction levels, is plagued by heterogeneous study types that evaluate different outcome measures and that have a low ($\geq$3) level of evidence. Evidence is mainly derived from retrospective studies with low patient numbers and limited follow-up. In general, overall satisfaction with various types of IPPs is comparable. Although there are manufacturing differences between the available devices, such as texture, feel, and handling; these aspects have been scientifically studied, thus, no comment can be made.

Ectopic HSM reservoir placement can be considered an alternative method of reservoir placement during the IPP implantation. Palpability of the ectopic reservoir does not seem to be a significant factor for revision surgery.

There is a need for validated instruments to assess the degree of sexual satisfaction associated with IPPs after phalloplasty surgery, however, in their absence, IIEF and SQOL-Men questionnaires may be useful. The majority of phalloplasty patients with PP currently have the ability to engage in penetrative sex.

The main disadvantages of the reviewed publications were the retrospective assessment approach with low numbers of patients, most of them summarizing only single center experience. Larger prospective multicentric epidemiological studies should be initiated and supported by relevant international societies.

The present European Society for Sexual Medicine position should be recognized as the first attempt to improve the understanding of the current situation around IPPs and to initiate further steps, such as a European IPP registry to lay the foundation for future prospective multicenter RCTs.

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SUPPLEMENTARY DATA

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