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#### **Authors**

Huynh, Linda

Osman, Mohamad

Yafi, Faysal

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INVITED REVIEW

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# Risk profiling in patients undergoing penile prosthesis implantation

Linda M Huynh, Mohamad M Osman, Faysal A Yafi

Penile prosthesis implantation is the gold standard of surgical therapy for patients with medication-refractory erectile dysfunction. However, this umbrella definition includes significant heterogeneity and associated risk profiles that should be candidly discussed and addressed perioperatively. Factors associated with operative success and patient satisfaction are often surgery specific; however, risk profiling via patient selection, preoperative optimization, proper device selection, and intraoperative consideration are highly correlated. Some examples of common risk profiles include comorbidity(ies) such as cardiovascular disease, diabetes mellitus, prior abdominal surgery, Peyronie's disease, and psychological risk factors. Similarly, integration of surgeon- and patient-amenable characteristics is key to decreasing risk of infection, complication, and need for revision. Finally, patient risk profiling provides a unique context for proper device selection and evidence-based intraoperative considerations.

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**Keywords:** patient selection; penile prosthesis; risk factors

## INTRODUCTION

Penile prosthesis (PP) implantation is the gold standard of surgical therapy for patients refractory to pharmacological therapies, such as phosphodiesterase type 5 (PDE-5) inhibitors.<sup>1–3</sup> While these procedures are often associated with high levels of patient satisfaction,<sup>4–6</sup> risks for complications remain.<sup>7,8</sup> In addition, given the elective nature of PP implantation, there also exists a significant risk for disconnect between preoperative expectations and postoperative reality – a balance which places unique pressures on informed patient consent, preoperative counseling, and risk profiling.<sup>9,10</sup>

The goal of this review is to explore common risk profiles for patients undergoing PP implantation, in addition to other factors of patient satisfaction and operative success. In doing so, this review will discuss patient selection, pertinent risk factors, preoperative optimization, device selection, and intraoperative considerations.

## PATIENT SELECTION AND PERTINENT RISK FACTORS

Although patient selection for PP implantation is typically straightforward due to patient preference, there are many nuances that require significant attention.<sup>9,10</sup> Both the American Urological Association (AUA) and the International Society of Sexual Medicine (ISSM) guidelines recommend pursuing PP implantation as an intervention for end-stage erectile dysfunction (ED) and, especially, for patients refractory to conservative therapies.<sup>11,12</sup> However, this umbrella definition creates significant heterogeneity within the patient population, as it potentially includes patients with ED as a result of other medical comorbidities such as cardiovascular disease, diabetes mellitus, radical prostatectomy, Peyronie's disease, or psychological conditions.<sup>13–16</sup> Even further, a diagnosis of ED may be indicative of underlying comorbidities that ought to be addressed prior to prosthetic

surgery.<sup>14–16</sup> These added layers of complexity further emphasize the need for evidence-based practices during patient selection and preoperative risk counseling.

### History of cardiovascular disease

ED is more common in the elderly population<sup>17,18</sup> and often occurs with cardiovascular disease.<sup>13</sup> A diagnosis of ED can be indicative of underlying coronary artery disease (even in younger patients) and places this population at an increased risk for future cardiovascular events.<sup>19</sup> While there are no validated tools to estimate risk of cardiovascular complications during PP implantation, several nomograms exist for preoperative cardiovascular assessment and general postoperative management.<sup>20,21</sup> Knowledge of these risk stratification tools, such as the CHADS<sub>2</sub> and CHA<sub>2</sub>DS<sub>2</sub>-VASc (congestive heart failure, hypertension, age [ $\geq 75$  years], diabetes mellitus, and stroke [vascular disease, age (65–74 years), and sex category]) scores,<sup>22,23</sup> can be useful referents within the context of patient selection and preoperative counseling during PP implantation. These nomograms and their threshold values are summarized in **Table 1**.

Further, given that penile prosthetic surgery is classified as a high risk for bleeding, special attention needs be paid to patients utilizing antiplatelet and/or anticoagulant (AP/AC) medications.<sup>24</sup> In particular, significant cardiovascular conditions requiring AP/AC use include congestive heart failure, atrial fibrillation, deep vein thrombosis, coronary stents, mechanical heart valves, or pulmonary embolism.<sup>25,26</sup> In an effort to mitigate the risk of complications of urologic interventions on patients managed with AP/AC, the AUA and International Consultation on Urological Disease (ICUD) recently published recommendations for nonurgent procedures in patients utilizing AP/AC. Their guidelines are summarized in

**Table 2.**<sup>27</sup> While PP implantation was not previously recommended for men utilizing anticoagulants, the AUA and several other organizations now generally regard this procedure to be safe in this population.<sup>27,28</sup>

### History of diabetes mellitus

Patients with a history of diabetes mellitus are naturally at high risk for infection, due to immune dysfunction, diabetic neuropathy, and poor circulation.<sup>29–31</sup> However, it remains unclear whether diabetes and diabetic comorbidity significantly increase rates of infection after PP implantation.<sup>32–35</sup> After a study from 1992 found that patients with higher glycated hemoglobin (HbA1c) had significantly higher rates of infection, patients with poorly controlled diabetes are often considered at higher risk.<sup>32</sup> A more recent study from 2018 revisited these findings and subsequently established an HbA1c threshold of 8.5% in an effort to characterize patients and further assisted in preoperative optimization.<sup>33</sup> However, evidence continues to remain divided, as several systematic reviews confer no significant increase in infection rates.<sup>36</sup> Despite this lack of consensus, surgeons are still encouraged to optimize patient health prior to nonemergent procedures<sup>37,38</sup> and large prospective studies assessing impact of diabetic characteristics on postoperative outcomes are highly encouraged.

**Table 1: Cardiovascular risk stratification via CHADS<sub>2</sub> and CHA<sub>2</sub>DS<sub>2</sub>-VASc scores**

Survey	Condition	Point
CHADS <sub>2</sub>		
C	Congestive heart failure	1
H	Hypertension	1
A	Age ≥75 years	1
D	Diabetes mellitus	1
S <sub>2</sub>	Prior stroke or TIA or systemic thromboembolism	2
Total		6 <sup>a</sup>
CHA <sub>2</sub> -DS <sub>2</sub> -VASc		
C	Congestive heart failure	1
H	Hypertension	1
A <sub>2</sub>	Age ≥75 years	2
D	Diabetes mellitus	1
S <sub>2</sub>	Prior stroke or TIA or systemic thromboembolism	2
V	Vascular diseases	1
A	Age 65–74 years	1
S <sub>c</sub>	Sex category (female)	1
Total		9 <sup>b</sup>

<sup>a</sup>Patients with a score >2 have a 5.9%–18.2% risk of experiencing ischemic stroke per year, <sup>b</sup>Patients with a score >4 have a 6.7%–15.2% risk of experiencing ischemic stroke per year. CHADS<sub>2</sub> and CHA<sub>2</sub>-DS<sub>2</sub>-VASc: congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, and stroke–vascular diseases, age 65–74 years, and sex category. TIA: transient ischemic attack

### Previous abdominal surgery

Previous abdominal surgery can be indicative of intraoperative difficulty, especially with regard to reservoir placement.<sup>39</sup> Traditional placement prefers blind introduction of the reservoir into the Retzius space.<sup>39,40</sup> However, patients with prior abdominal or pelvic surgery are at higher risk for complications during placement; intestinal reservoir-related complications, intraoperative damage to the bladder, iliac vessels, or other surrounding structures are complications of which all implanters must be aware during reservoir placement in the space of Retzius, since they may be further exacerbated by previous surgery, radiation, or trauma.

For patients with a history of significant abdominal surgery, and potentially altered anatomy, such as history of robot-assisted laparoscopic prostatectomy, radical cystectomy, bilateral inguinal hernia repair, and/or colorectal interventions, reservoir placement in a submuscular location is preferred.<sup>40</sup> This space, which is developed above the transversalis fascia and under the rectus fascia, has proven to be both a safe and also effective alternative with high rates of patient satisfaction.<sup>40–42</sup> During preoperative counseling, these patients should be warned of the side effects of submuscular reservoirs, *i.e.*, the possibility of a palpable reservoir and the rare circumstance requiring reservoir revision secondary to herniation.

Alternatively, for patients with increased risk, Hartman *et al.*<sup>41</sup> developed an alternative surgical approach to prevent damage to the bladder and iliac vessels. As per this technique, a small, incision is made above the anterior superior iliac spine in both lower lateral quadrants, and a pocket in the potential space of the retroperitoneum was created for placement. The pump is implanted in a subdartos midline scrotal pouch. Although this method required a second fascial incision (and potential attendant increases in operative time and postoperative discomfort), there were no complications or injuries in the 62 patients in the trial. This technique was further explored by Loh-Doyle *et al.*<sup>43</sup> in patients with urinary diversion, with similar success.

### Patients with Peyronie's disease

The development of medication-refractory ED in association with Peyronie's disease is common, with PP implantation being the most popular surgical treatment.<sup>44</sup> According to the AUA guidelines, a malleable PP is often associated with higher dissatisfaction among patients and an inflatable PP is the preferred choice.<sup>45</sup> While overall patient satisfaction is high, dissatisfaction is often linked to shortened penile size, reduced sensitivity, poor concealment, and device deviation,<sup>46</sup> possibilities which should be addressed in detail during the patient selection process. Simple PP insertion is shown to resolve curvature in 33%–90% of patients, but adjunctive surgical techniques during implantation can also improve residual curvature and postoperative penile length.<sup>44–47</sup> Surgical techniques

**Table 2: Summary of the American Urological Association Guidelines on anticoagulant and antiplatelet use**

Condition requiring AC/AP use	AUA guideline for nonurgent surgeries
On clopidogrel or aspirin for secondary stroke prevention	Continue aspirin through the perioperative period
On DAPT for bare metal stent placed within 3 months of planned surgery	Do not withdraw from DAPT, wait until at least 3 months after placement of stent
On DAPT for drug-eluting stent placed within 12 months of planned surgery	Do not withdraw from DAPT, wait until at least 12 months after placement of stent
On DAPT for bare metal stent placed at least 3 months ago or drug-eluting stent placed at least 12 months ago	Consult cardiology, discontinue DAPT 10 days before the surgical procedure, restart within 7–10 days after surgery
Mechanical heart valves	Cardiology consultation
Low-dose aspirin alone for cardiac risk factors	Aspirin can be continued in perioperative period without increased risk of major bleeding
Atrial fibrillation requiring warfarin	Consult cardiology, stop warfarin 5 days before the surgical procedure, and restart 12–24 h after surgery, if the bleeding risk is acceptable

AC: anticoagulant; AP: antiplatelet; DAPT: dual antiplatelet therapy; AUA: American Urological Association



include manual penile modeling, concurrent plication for refractory curvature, endoscopic plaque resection, and plaque incision/grafting.<sup>47</sup> In patients with severe penile shortening, the double dorsoventral sliding technique can also be used to recover penile length during PP placement.<sup>48</sup> Within this context, both surgeon and patient should be aware of added complexity and ensure that expectations are managed accordingly.

### Identification of the CURSED patient

While the above-mentioned risk factors may be attenuated or treated prior to PP implantation, psychosocial risk factors and unrealistic patient expectations are difficult to overcome. As such, the identification of the “difficult patient” is critical to maintaining postoperative satisfaction and operative success. To aide, Trost *et al.*<sup>49</sup> conducted a review of cosmetic literature and illustrated seven key characteristics associated with high rates of postoperative dissatisfaction: the CURSED patient who is compulsive/obsessive, unrealistic, seeking revision, surgeon shopping, entitled, in denial, and/or psychiatric. While these characteristics may not be immediately recognizable during initial consultations, focused discussion and input from medical office staff can facilitate their surfacing. Specific examples are provided in **Table 3**. However, this list is by no means exhaustive and surgeons should trust their intuition during preoperative visits – by definition, a patient with unreasonable expectations cannot be fully satisfied, even in the setting of a great surgical outcome.

### PREOPERATIVE OPTIMIZATION AND COUNSELING

After patient selection for PP implantation, informed consent and preoperative counseling provides a formal platform to plan, anticipate, and discuss risk of complications. The risk of infection with virgin inflatable penile prosthesis (IPP) implantation ranges from <1% to 4%, increasing up to 10% in patients seeking a revision.<sup>50–52</sup> Although these risks are appreciably low in contemporary series, they are associated with significant morbidity, potential need for revision or explantation,

**Table 3: Risk factors associated with postinflationable penile prosthesis surgery dissatisfaction – compulsive, unrealistic, revision, surgeon shopping, entitled, denial, psychiatric patient**

<i>CURSED</i> factor	<i>Characteristics and examples</i>
Compulsive/obsessive	Fixated on minor changes in anatomy “Penocentric” Pathologically observant Overly detail oriented/perfectionist Inflexible
Unrealistic	Excessively optimistic Discounts possibility of complication Requires repeated assurance of successful outcomes Seeking highly specific set of outcomes
Revision	Progressive decrease in satisfaction with each revision
Surgeon shopping	Details history of other surgeons Fails to take responsibility for decisions Quick to criticize Often has experience in the medical field
Entitled	Disrespectful to office staff Demands specialized treatment and/or attention Frequent calls/visits Unreasonable scheduling requests Domineering in conversation Poorly compliant
Denial	Exaggerated memories of prior sexual characteristics
Psychiatric	Mood disorders – acceptable, if treated Personality disorders – poor candidates Penile dysmorphic disorder

CURSED: compulsive, unrealistic, revision, surgeon shopping, entitled, denial, psychiatric

psychological trauma, and financial burden.<sup>53</sup> As such, both patients and surgeons should be aware of the risk profiles that create a predisposition for infection and how to minimize the associated risks.

### Surgeon-amenable factors

The influence of surgeon experience on preoperative optimization and patient risk profiling is important to recognize. As nearly all skills are dependent on frequency of repetition, low-volume surgeons with limited specialty training are more likely to have higher complication rates and reduced operative success, as compared to higher-volume and more experienced surgeons.<sup>54–57</sup> In the context of PP implantation, a 2009 retrospective review by Henry *et al.*<sup>54</sup> found significantly shorter cylinder lengths of prostheses placed, higher complication rates, longer operative times, and shorter revision-free survival of PP implantation among low-volume surgeons. Similarly, these findings were echoed in an analysis of a national penile prosthesis database.<sup>58</sup> Recognition of correlations such as these not only allows for realistic patient counseling, but also indicates that surgeons should be able to recognize when a patient’s risk profile is ill-matched to the operation, avoid surgery in complex patients, and refer to specialized practices when appropriate. Additional training may also be warranted to improve surgical skills or to expand surgical offerings.

Similarly, the recent increase in outpatient PP implantation speaks further to surgeon-amendable factors and preoperative optimization.<sup>58</sup> While some argue that this shift toward shorter hospital stays is due to insurance reimbursement rates, others view it illustrative of increased surgeon preparedness and willingness to invest time preoperatively.<sup>58–60</sup> A 2019 study of 16 923 patients by Kirshenbaum *et al.*,<sup>61</sup> for instance, found that men with inpatient admissions within 90 days of PP implantation were 3 times more likely to be readmitted within 30 days, 1.7 times more likely to have a length of stay for 2 days or greater, and 1.7 times more likely to have device complications after PP implantation. These models are useful reminders of easily modifiable approaches to preoperative assessment and risk profiling: investment in medical optimization and, in some cases, delayed surgery can alleviate risk and improve surgical outcomes.

### Patient-amenable factors

Shared decision-making between patient and surgeon is also key to preoperative optimization and risk profiling. In this regard, controversies in the current guidelines should be discussed, among which includes perioperative use of antibiotic prophylaxis. The current AUA Best Practice Policy Statement in Antimicrobial Prophylaxis recommends <24 h of antibiotic therapy after PP insertion, citing data from orthopedic literature.<sup>62</sup> In contrast, a panel of North American expert prosthetic surgeons recommends the use of postoperative antibiotics (of varying types), from 5 to 14 days after surgery.<sup>63</sup> Even further, a popular approach is one with a “better safe than sorry” mentality, with many experts advocating for broader approaches to antibiotic prophylaxis despite lack of Level 1 evidence. Regardless of paucity in the current literature, patients should be counseled on the risks associated with postoperative antibiotic prophylaxis, in addition to the current disagreement between practice guidelines, expert opinion, and surgeon experience.

Along these lines, patients with spinal cord injuries are universally recognized to be at an increased risk for postoperative infection and are consequently more often prescribed perioperative antibiotic prophylaxis.<sup>64</sup> However, a study by Selph and colleagues at the University of North Carolina deconstructed the pathophysiology of infection in these patients into highly generalizable and patient-

amenable risk factors.<sup>64–66</sup> Risk profiles generally included those who (1) were stationary, (2) had reduced distal blood circulation, (3) had suboptimal hygiene, (4) were immunocompromised, and (5) who experienced prolonged catheterization. Similarly, a retrospective review by Balen *et al.*<sup>66</sup> further identified risk factors contributing to infection in polysubstance abusers. Rather than the substance abuse itself, the authors found that the likelihood of abuse correlated closely with low socioeconomic status, poverty, and other comorbidity – factors more likely culprit of infection.<sup>66</sup> In these settings, addressing the parts may be more effective than the whole. Patients presenting with these risk profiles should be referred to preventative measures such as discontinued steroid use, preoperative management of comorbid conditions, avoidance of indwelling catheterization, preoperative skin cleansing, and compliance with antibiotic regimens.

Perhaps more applicable to the general patient undergoing PP implantation is maintenance of a healthy lifestyle. Although patients who have never smoked and have a healthy diet are considered optimal candidates, perioperative modification of risky behaviors has also shown to be an effective strategy to increasing operative success.<sup>67,68</sup> A meta-analysis by Sorenson,<sup>67</sup> for example, demonstrated that smokers who quit smoking 4 weeks prior to surgery were able to reduce their risk of infection by over 50%. Further, balanced meals and that promote tissue healing (*i.e.*, lean meats, green and yellow vegetables, citrus fruits, dairy products, and whole wheat breads and grains) are widely recommended during the recovery process.<sup>68</sup>

### IMPACT OF PATIENT RISK PROFILES ON DEVICE SELECTION

Currently available penile prostheses have achieved high ratings in regard to safety and reliability.<sup>69</sup> While adverse events are increasingly uncommon, possibility of infection, erosion, or mechanical malfunction postimplantation still remains.<sup>47,50,53</sup> In this regard, patient risk profiling and device selection remains key to preventing adverse events, ensuring patient satisfaction, and maintaining device longevity.

#### *Patient and surgeon preference*

There are two primary manufacturers of semirigid and inflatable penile prostheses in the United States: AMS (American Medical Systems, Minnetonka, MN, USA) and Coloplast Ltd. (Peterborough, Cambs, England), each with their own uniquenesses that complement patient profiles. In general, semirigid rods are favored for their excellent mechanical reliability and ease of implant via subcoronal, penoscrotal, or infrapubic incisions.<sup>47</sup> However, these devices also have the disadvantage of an always erect penis that is not easily concealed. There are also two- and three-component inflatable devices, each also with their own advantages and disadvantages. Three-component prosthesis feel softer than two-piece devices when deflated, have better cosmetic results, and ensure more natural erections. However, these devices also have increased potential for malfunction and often require more complicated surgical approaches.<sup>70</sup> As a general guide, patient and partner generally prefer inflatable prostheses for their ability to mimic both the flaccid and erect states of a normally functioning penis.<sup>5,6,46,47</sup> While rigidity is achieved by semirigid and inflatable prosthesis alike, these differences in cosmetic result and “naturalness” of the devices drive patient preference. These priorities should be weighed against potential case complexity, surgical technique, and potential need for revisions.

#### *Advances in prosthetic implants*

Both AMS and Coloplast Ltd. have recognized the need for patient-device tailoring and infection management. AMS produces the 700™

series: the AMS 700 CX, AMS 700 LGX, and the AMS CXR. Within the context of risk profiling, the AMS CXR is the optimal choice for cases of fibrosis of corpora cavernosa, scarred corporal bodies, and stenotic proximal corpora.<sup>69–71</sup> All three models include a polymer coating, Parylene™, designed to increase device longevity; and Inhibizone™, an external layer made of minocycline and rifampin to prevent bacterial colonization. Comparable to these innovations, Coloplast Ltd. produces the alpha 1; the Titan, which adds an additional hydrophilic coating to absorb antibiotics when immersed; and the Titan narrow-base, designed specifically for scarred or fibrotic corpora. All devices of both companies employ kink-free silicone tubing and improved tubing connections to prevent mechanical failure.

#### *Clinical considerations*

Several clinical factors also determine the optimal penile prosthesis for a patient and, in this regard, patient risk profiles should be considered to maximize benefit. Older men who have limited mental or manual dexterity, for example, are often better served with semirigid implants, given the challenges associated with the pump and deflation mechanisms of inflatable devices. In contrast, patients with spinal cord injury or diminished sensation in the penis may benefit most with an inflatable device, given the potential for prolonged, excessive pressure against the prosthetic rods, which increases the likelihood of erosion.<sup>69,71</sup> Even yet, patients with Peyronie’s disease should only consider prostheses for girth expansion, as length expansion may exacerbate curvature.<sup>47</sup> A summary of advantages and disadvantages of each prosthesis is presented in **Table 4**.

Although patient-specific profiles are important to evaluate when considering intra-manufacturer devices, there is also some evidence to inform inter-manufacturer selection. In 2016, Scovell and colleagues addressed this question via biomechanical testing on the four most commonly utilized prostheses (*i.e.*, AMS 700 LGX 18 cm/22 cm versus the Coloplast Titan 18 cm/21 cm) and highlighted key differences between the manufacturers’ designs. When compared to the Coloplast Titan, the AMS 700 LGX expanded mostly longitudinally, less circumferentially, and was highly dependent on pressure.<sup>72</sup> To translate these findings to clinical practice, the AMS 700 LGX may be optimal for men who are concerned with penile length while potentially troublesome for patients who have corporal fibrosis. Similarly, the Coloplast Titan is considered to be a preferred product for men who need higher axial loading during penetration and in men concerned with a lower-hanging phallus postimplantation. Overall, this study is yet another example of the importance of patient-oriented device selection.

#### INTRAOPERATIVE CONSIDERATIONS

Finally, there are a number of intraoperative considerations that are used in an effort to reduce patient risk during PP implantation. While many of these are perhaps widespread practices, we seek to explore their advantages within specific patient populations and call for evidence-based policies to match.

#### *Preoperative use of chlorhexidine wash*

The preoperative use of chlorhexidine washes is one of the easiest and most commonly carried out preventative measures prior to PP implantation. The literature suggests reduction of surgical site infection with the use of chlorhexidine washes when compared to use of a povidone-iodine wash.<sup>73,74</sup> A 2013 prospective, randomized study of patients undergoing urological prosthetic operations found that chlorhexidine was superior to povidone-iodine in eradicating skin flora at the surgical site before prosthesis implantation.<sup>74</sup> The use of preoperative chlorhexidine washes are recommended for their ease

**Table 4: Risk profiles driving device selection – advantages and disadvantages of semirigid versus inflatable prostheses**

<i>Prosthesis</i>	<i>Advantage</i>	<i>Disadvantage</i>
<b>Semirigid</b>		
AMS 650	Diameter of stainless steel wires reduced to improve concealability and reduce spring-back	Always erect and difficult to conceal underneath clothing
AMS 600 M		
Coloplast Acu-Form	Advantageous for patients with limited dexterity	
AMS Dura II	Ability to remain fat when pushed downward	
<b>Two-piece inflatable</b>		
AMS Ambicor	Provided fluid-filled 2 cylinders, each with its own inflation/deflation valve, inflatable chamber, and reservoir	Feels harder than three-piece implants; less natural
<b>Three-piece inflatable</b>		
AMS 700 CX	Tactile pump	Require more complicated surgical approaches, have increased potential for malfunction
AMS 700 LGX	Expands longitudinally, preserves penile length	
AMS 700 CXR	Advantageous for cases with fibrosis of corpora cavernosa, scarred corporal bodies, and stenotic proximal corpora	
Coloplast Titan	Expands circumferentially, results in a higher-hanging phallus postimplantation	
Coloplast alpha 1	Pressure-independent	
Coloplast alpha 1 narrow-base	Advantageous for fibrotic corpora/smaller anatomy	

AMS: American Medical Systems

to be carried out and their superiority to povidone-iodine washes. Patients at higher risk for infection due to virulent skin flora or positive urine culture, for example, can be more persistent in the utilization of chlorhexidine wash.

#### **Surgical site hair removal**

Informed by general surgery literature, most institutions have specific policies mandating the use of electric clippers for all surgical site hair removal. However, due to the delicate, irregular, and elastic skin of the male genitalia, urologists often prefer razors.<sup>73</sup> Several randomized control trials have compared the use of electric clippers versus razors, without any evidence to support a decrease in infection for either device.<sup>75</sup> Because these trials suggest no advantage of one over the other, the Sexual Medicine Society of North American recommends surgeons be permitted to use their choice for preoperative preparation and patients be instructed not to shave or clip themselves prior to surgery.<sup>76</sup>

#### **Intraoperative antibiotics**

As with all open surgical procedures, antibiotics at the time of incision are mandatory. The American Urological Association recommends perioperative use of an aminoglycoside (or aztreonam) and a first- or second-generation cephalosporin and vancomycin. Both may be continued up to 24 h after surgery.<sup>62</sup> Alternative antibiotics include ampicillin/sulbactam, ticarcillin/clavulanate, and piperacillin/tazobactam for <24 h, given no previous bacterial colonization. While survey data show large variation in preference of antibiotic use, their use is often tailored by contraindication, side effect profiles, and patient preference.<sup>77</sup>

#### **Surgical drain placement**

To date, the efficacy and safety of closed-suction drainage of the scrotum remains a topic of debate. Those that critique placement of a surgical drain suggest an increase in risk of infection via retrograde migration of bacteria as commonly seen in wound drains of nonurologic procedures.<sup>64,65,69,70</sup> Further, closed-suction drainage systems are more invasive, require postoperative removal, and can prevent same-day discharge. These factors are weighed against decreased risk of edema, ecchymosis, and hematoma formation of the scrotum. In 2005, Sadeghi-Nejad and colleagues retrospectively reviewed 425 patients undergoing primary three-piece PP implantation with closed-suction drain placement for 12–24 h after surgery. With infection

rates comparable to other series, surgical drain placement did not significantly increase infection rates in this series. Further, this cohort benefited from low incidence of postoperative hematoma formation, swelling, and ecchymosis.<sup>78</sup> Without prospective randomized control trials on drain placement following PP implantation, benefit of closed-suction drains remains unclear. Until Level 1 evidence is found to support its use, drain placement remains a surgeon-driven preference.

#### **Sterile procedures and the “no-touch” technique**

In 2011, Eid presented the “no-touch” technique for PP implantation.<sup>79</sup> The traditional approach is employed through the penoscrotal raphe, until Buck’s fascia is reached. Then, new and unused instruments (and gloves) are utilized to cover the surgical field with a clear drape. Above the original incision site, a small opening in the drape is created where the remainder of the procedure is performed. This approach allows for minimal to no contact with the patient’s skin, surgeon’s hands, surgical instruments, and the implant. Although this “no-touch” technique increases operating time by 10–20 min and creates additional cost via new instruments, several prospective series have shown this technique to be effective in reducing risk of contamination and subsequent infection.<sup>80</sup> Given the newness of this technique, however, future studies to establish its cost-effectiveness and (potentially) refine its use are anticipated.

#### **CONCLUSIONS**

While penile prosthetic surgery enjoys high rates of patient satisfaction, the potential for complication and infection remains. Factors increasing complexity of penile prosthesis implantation range from medical comorbidity, patient- and surgeon-oriented characteristics to proper device selection and differences in intraoperative technique. In these regards, candid risk profiling is key to ensuring the best possible result.

#### **AUTHOR CONTRIBUTIONS**

LMH and MMO synthesized data, drafted, and finalized manuscript; FAY made critical revisions and finalized manuscript. All authors read and approved the final version of the manuscript and agreed with the order presentation of the authors.

#### **COMPETING INTERESTS**

FAY: Consultant, Coloplast, Boston Scientific. LMH and MMO declared no competing interests.

## REFERENCES

- 1 Scott FB, Bradley WE, Timm GW. Management of erectile impotence. Use of implantable inflatable prosthesis. *Urology* 1973; 2: 80–2.
- 2 Small MP, Carrion HM. Penile prosthesis: new implant for management of impotence. *J Fla Med Assoc* 1975; 62: 21–5.
- 3 Wilson SK, Delk JR, Salem EA, Cleves MA. Long-term survival of inflatable penile prostheses: single surgical group experience with 2,384 first-time implants spanning two decades. *J Sex Med* 2007; 4: 1074–9.
- 4 Pryor MB, Carrion R, Wang R, Henry G. Patient satisfaction and penile morphology changes with postoperative penile rehabilitation 2 years after Coloplast Titan prosthesis. *Asian J Androl* 2016; 18: 754–8.
- 5 Gentile G, Franceschelli A, Masseno P, Tuccio A, Cocci A, *et al*. Patient's satisfaction after 2-piece inflatable penile prosthesis implantation: an Italian multicentric study. *Arch Ital Urol Androl* 2016; 88: 1–3.
- 6 Akakpo W, Pineda MA, Burnett AL. Critical analysis of satisfaction assessment after penile prosthesis surgery. *Sex Med Rev* 2017; 5: 244–51.
- 7 Pineda M, Burnett AL. Penile prosthesis infections—a review of risk factors, prevention, and treatment. *Sex Med Rev* 2016; 4: 389–98.
- 8 Hartman RP, Kawashima A, Takahashi N, LeRoy AJ, King BF. Inflatable penile prosthesis (IPP): diagnosis of complications. *Abdom Radiol (NY)* 2016; 41: 1187–96.
- 9 Narang GL, Figler BD, Coward RM. Preoperative counseling and expectation management for inflatable penile prosthesis implantation. *Transl Androl Urol* 2017; 6: S869–80.
- 10 Kovac JR. Informed consent for penile prosthesis surgery. *Transl Androl Urol* 2017; 6: 881–2.
- 11 American Urological Association Education and Research, Inc. Erectile dysfunction: AUA guideline. *J Urol* 2018; 200: 633–41.
- 12 International Society for Sexual Medicine. Penile prosthesis surgery: current recommendations from the international consultation on sexual medicine. *J Sex Med* 2016; 13: 489–518.
- 13 Lane-Cordova AD, Kershaw K, Liu K, Herrington D, Lloyd-Jones DM. Association between cardiovascular health and endothelial function with future erectile dysfunction: the multi-ethnic study of atherosclerosis. *Am J Hypertens* 2017; 30: 815–21.
- 14 Bratu O, Oprea I, Marcu D, Spinu D, Niculae A. Erectile dysfunction post-radical prostatectomy – a challenge for both patient and physician. *J Med Life* 2017; 10: 13–8.
- 15 Campbell J, Alzubaidi R. Understanding the cellular basis and pathophysiology of Peyronie's disease to optimize treatment for erectile dysfunction. *Transl Androl Urol* 2017; 6: 46–59.
- 16 Chen J, Chen Y, Chen G, Dai Y, Yao Z. Altered brain networks in psychogenic erectile dysfunction: a resting-state fMRI study. *Andrology* 2017; 5: 1073–81.
- 17 Mulhall JP, Luo X, Zou KH, Stecher V, Galaznik A. Relationship between age and erectile dysfunction diagnosis or treatment using real-world observational data in the USA. *Int J Clin Pract* 2016; 70: 1012–8.
- 18 Rastrelli G, Corona G, Mannucci E, Maggi M. Vascular and chronological age in men with erectile dysfunction: a longitudinal study. *J Sex Med* 2016; 13: 200–8.
- 19 Katsiki N, Wierzbicki AS, Mikhailidis DP. Erectile dysfunction and coronary heart disease. *Curr Opin Cardiol* 2015; 30: 416–21.
- 20 Rocha E. Cardiovascular risk scores: usefulness and limitations. *Rev Port Cardiol* 2016; 35: 15–8.
- 21 Woodward M. On validation of cardiovascular risk scores. *BMJ* 2016; 354: i4483.
- 22 Chen YL, Cheng CL, Huang JL, Yang NI, Chang HC. Mortality prediction using CHADS<sub>2</sub>/CHA<sub>2</sub>DS<sub>2</sub>-VASc/R<sub>2</sub>CHADS<sub>2</sub> scores in systolic heart failure patients with or without atrial fibrillation. *Medicine (Baltimore)* 2017; 96: e8338.
- 23 Patell R, Gutierrez A, Rybicki L, Khorana AA. Usefulness of CHADS<sub>2</sub> and CHA<sub>2</sub>DS<sub>2</sub>-VASc scores for stroke prediction in patients with cancer and atrial fibrillation. *Am J Cardiol* 2017; 120: 2182–6.
- 24 Gupta AD, Streiff M, Resar J, Schoenberg M. Coronary stent management in elective genitourinary surgery. *BJU Int* 2012; 110: 480–4.
- 25 Stough WG, Patterson JH. Role and value of clinical pharmacy in heart failure management. *Clin Pharmacol Ther* 2017; 102: 209–12.
- 26 Houston BA, Kalathiyar RJ, Kim DA, Zakaria S. Volume overload in heart failure: an evidence-based review of strategies for treatment and prevention. *Mayo Clin Proc* 2015; 90: 1247–61.
- 27 Culkun DJ, Exaire EJ, Green D, Soloway MS, Gross AJ, *et al*. Anticoagulation and antiplatelet therapy in urological practice: ICUD/AUA review paper. *J Urol* 2014; 192: 1026–34.
- 28 Rahman A, Latona J. New oral anticoagulants and perioperative management of anticoagulant/antiplatelet agents. *Aust Fam Physician* 2014; 43: 861–6.
- 29 Dryden M, Baguneid M, Eckmann C, Corman S, Stephens J, *et al*. Pathophysiology and burden of infection in patients with diabetes mellitus and peripheral vascular disease: focus on skin and soft-tissue infections. *Clin Microbiol Infect* 2015; 21: S27–32.
- 30 Leung M, Leung DY. Coronary microvascular function in patients with type 2 diabetes mellitus. *EuroIntervention* 2016; 11: 1111–7.
- 31 Karki DB, Yadava SK, Pant S, Thusa N, Dangol E, *et al*. Prevalence of sensory neuropathy in type 2 diabetes mellitus and its correlation with duration of disease. *Kathmandu Univ Med J (KUMJ)* 2016; 14: 120–4.
- 32 Bishop JR, Moul JW, Sihelnik SA, Peppas DS, Gormley TS, *et al*. Use of glycosylated hemoglobin to identify diabetics at high risk for penile periprosthetic infections. *J Urol* 1992; 147: 386–8.
- 33 Habous M, Tal R, Tealab A, Soliman T, Nassar M, *et al*. Defining a glycated haemoglobin (HbA1c) level that predicts increased risk of penile implant infection. *BJU Int* 2018; 121: 293–300.
- 34 Wilson SK, Carson CC, Cleves MA, Delk JR. Quantifying risk of penile prosthesis infection with elevated glycosylated hemoglobin. *J Urol* 1998; 159: 1537–9.
- 35 Canguven O, Talib R, El Ansari W, Khalafalla K, Al Ansari A. Is HbA1c level of diabetic patients associated with penile prosthesis implantation infections? *Aging Male* 2018; 9: 1–6.
- 36 Christodoulidou M, Pearce I. Infection of penile prostheses in patients with diabetes mellitus. *Surg Infect (Larchmt)* 2016; 17: 2–8.
- 37 Wilson SK, Mora-Estaves C, Egidio P, Ralph D, Habous M. Glans necrosis following penile prosthesis implantation: prevention and treatment suggestions. *Urology* 2017; 107: 144–8.
- 38 Segal RL, Camper SB, Ma L, Burnett AL. Prediction model for penile prosthesis implantation for erectile dysfunction management. *Curr Med Res Opin* 2014; 30: 2131–7.
- 39 Bennet N, Huang IS. Inflatable penile prosthesis in the radical prostatectomy patient: a review. *F1000Res* 2018; 7: 1–8.
- 40 Dadhich P, Hockenberry M, Kirby EW, Lipshultz L. Penile prosthesis in the management of erectile dysfunction following cancer therapy. *Transl Androl Urol* 2017; 6: S883–9.
- 41 Hartman RJ Jr., Helfand BT, McVary KT. Outcomes of lateral retroperitoneal reservoir placement of three-piece penile prosthesis in patients following radical prostatectomy. *Int J Impot Res* 2010; 22: 279–83.
- 42 Perito PE. Ectopic reservoir placement – no longer in the space of the Retzius. *J Sex Med* 2011; 8: 2395–8.
- 43 Loh-Doyle J, Patil MB, Sawkar H, Wayne K, Boyd SD. 3-piece inflatable penile prosthesis placement following radical cystoprostatectomy and urinary diversion: technique and outcomes. *J Sex Med* 2018; 17: 907–13.
- 44 Shindel W, Bullock TL, Brandes S. Urologist practice patterns in the management of Peyronie's disease: a nationwide survey. *J Sex Med* 2008; 5: 954–64.
- 45 American Urological Association Education and Research, Inc. Peyronie's Disease: AUA Guideline. *J Urol* 2015; 194: 745–53.
- 46 Montorsi F, Guazzoni F, Bergamaschi F, Rigatti P. Patient-partner satisfaction with semirigid penile prostheses for Peyronie's disease: a 5-year followup study. *J Urol* 1993; 153: 1819–21.
- 47 Anaissie J, Yafi FA. A review of surgical strategies for penile prosthesis implantation in patients with Peyronie's disease. *Transl Androl Urol* 2016; 5: 342–50.
- 48 Rolle L, Ceruti C, Timpano M, Sedigh O, Destefanis P, *et al*. A new, innovative, lengthening surgical procedure for Peyronie's disease by penile prosthesis implantation with double dorsal-ventral patch graft: the "sliding technique". *J Sex Med* 2012; 9: 2389–95.
- 49 Trost LW, Baum N, Hellstrom WJ. Managing the difficult penile prosthesis patient. *J Sex Med* 2013; 10: 893–906.
- 50 Trost L, Wanzek P, Bailey G. A practical overview of considerations for penile prosthesis placement. *Nat Rev Urol* 2016; 13: 33–46.
- 51 Mandava SH, Serefoglu EC, Freier MT, Wilson SK, Hellstrom WJ. Infection retardant coated inflatable penile prostheses decrease the incidence of infection: A systematic review and meta-analysis. *J Urol* 2012; 188: 1855–60.
- 52 Wilson SK, Zumbo J, Henry GD, Salem EA, Delk JR, *et al*. Infection reduction using antibiotic-coated inflatable penile prosthesis. *Urology* 2007; 70: 337–40.
- 53 Lujan S, Rogel R, Broseta E, Boronat F. Local treatment of penile prosthesis infection as alternative to immediate salvage surgery. *Sex Med* 2016; 4: e255–8.
- 54 Henry GD, Kansal NS, Callaway M, Grisby T, Henderson J, *et al*. Centers of excellence concept and penile prostheses: an outcome analysis. *J Urol* 2009; 181: 1264–8.
- 55 Onyeji IC, Sui W, Pagano MG, Weinberg AC, James MB, *et al*. Impact of surgeon case volume on reoperation rates after inflatable penile prosthesis surgery. *J Urol* 2017; 197: 223–9.
- 56 Ziegemann M, Kohler TS, Bailey GC, Miest T, Alom M, *et al*. Surgical patient selection and counseling. *Transl Androl Urol* 2017; 6: 609–19.
- 57 McAbee KE, Pearlman AM, Terlecki RP. Infection following penile prosthesis placement at an academic training center remains low despite involvement of surgeons-in-training. *Investig Clin Urol* 2018; 59: 342–7.
- 58 Alwaa A, Harris CR, Hussein AA, Sanford TH, McCulloch CE, *et al*. The decline of inpatient penile prosthesis over the 10-year period, 2000–2010. *J Sex Med* 2015; 3: 280–6.
- 59 Mulhall JP, Bloom K. Comparison of in-patient and out-patient penile prosthesis surgery. *Int J Impot Res* 2001; 13: 251–4.
- 60 Mondaini N, Sarti E, Giubilei G, Gavazzi A, Costanzi A, *et al*. Penile prosthesis surgery in out-patient setting: Effectiveness and costs in the "spending review" era. *Arch Ital Urol Androl* 2014; 86: 161–3.

- 61 Kirshenbaum EJ, Nelson M, Hehemann MC, Kothari AN, Eguia E, *et al*. Impact of post-hospital syndrome on penile prosthesis outcomes: a period of global health risk. *J Urol* 2019; 201: 154–9.
- 62 American Urological Association Education and Research, Inc. Best practice policy statement on urologic surgery antimicrobial prophylaxis. *J Urol* 2008; 179: 1379–90.
- 63 Darouiche RO, Bella AJ, Boone TB, Brock G, Broderick GA, *et al*. North American consensus document on infection of penile prostheses. *Urology* 2013; 82: 937–42.
- 64 Elmussareh M, Goddard JC, Summerton DJ, Terry TR. Minimising the risk of device infection in penile prosthetic surgery: a UK perspective. *J Clin Urol* 2013; 6: 280–8.
- 65 Selph JP, Carsson CC 3<sup>rd</sup>. Penile prosthesis infection: approaches to prevention and treatment. *Urol Clin North Am* 2011; 38: 227–35.
- 66 Balen A, Gross MS, Phillips EA, Henry GD, Munarriz R. Active polysubstance abuse concurrent with surgery as a possible newly identified infection risk factor in inflatable penile prosthesis placement based on a retrospective analysis of health and socioeconomic factors. *J Sex Med* 2016; 13: 697–701.
- 67 Sorenson LT. Wound healing and infection in surgery. The clinical impact of smoking and smoking cessation: a systematic review and meta-analysis. *Arch Surg* 2012; 147: 373–83.
- 68 Russell L. The importance of patients' nutritional status in wound healing. *Br J Nurs* 2001; 10: S44–9.
- 69 Hossein SN. Penile prosthesis surgery: a review of prosthetic devices and associated complications. *J Sex Med* 2007; 4: 296–309.
- 70 Bettocchi C, Palumbo F, Spilotros M, Palazzo S, Saracino GA. Penile prostheses. *Ther Adv Urol* 2010; 2: 35–40.
- 71 Lazarou S, Reyes-Valejo L, Morgentaler A. Technical advances in penile prostheses. *J Long Term Eff Med Implants* 2006; 16: 235–47.
- 72 Scovell JM, Liehui G, Barrera EV, Wilson SK, Carrion RE, *et al*. Longitudinal and horizontal load testing of inflatable penile implant cylinders of two manufacturers: an *ex vivo* demonstration of inflated rigidity. *J Sex Med* 2016; 13: 1750–7.
- 73 Darouiche RO, Wall MJ Jr, Itani KM, Otterson MF, Webb AL, *et al*. Chlorhexidine-alcohol versus povidone-iodine for surgical-site antisepsis. *N Engl J Med* 2010; 362: 18–26.
- 74 Yeung LL, Grewal S, Bullock A, Lai HH, Brandes SB, *et al*. A comparison of chlorhexidine-alcohol versus povidone-iodine for eliminating skin flora before genitourinary prosthetic surgery: a randomized controlled trial. *J Urol* 2013; 189:136–40.
- 75 Grober ED, Domes T, Fanipour M, Copp JE. Preoperative hair removal on the male genitalia: clippers vs. razors. *J Sex Med* 2013; 10: 589–94.
- 76 Sexual Medicine Society of North America; Position Statements: Razors and Preoperative Preparation of the Male Genitalia. Available from: <http://www.smsna.org/V1/about/position-statements>. [Last accessed on 2019 Jun 11].
- 77 Wosnitzer MW, Greenfield JM. Antibiotic patterns with inflatable penile prosthesis insertion. *J Sex Med* 2011; 8: 1521–8.
- 78 Sadeghi-Nejad H, Ilbeigi P, Wilson SK, Delk JR, Siegel A, *et al*. Multi-institutional outcome study on the efficacy of closed-suction drainage of the scrotum in three-piece inflatable penile prosthesis surgery. *Int J Impot Res* 2005; 17: 535–8.
- 79 Eid JF. No-touch technique. *J Sex Med* 2011; 8: 5–8.
- 80 Eid JF. Penile implant: review of “no-touch” technique. *Sex Med Rev* 2016; 4: 294–300.

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