Penile Implant Surgery

Contemporary Challenges and Controversies

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Preface

For decades penile implants have been considered the most effective treatment for severe and medication-refractory erectile dysfunction. There remains great interest in this treatment modality as the number of procedures is expected to increase over time with our aging population globally. However, implant surgery is associated with the potential for complications, and a high level of expertise is required to identify and manage these problems during and after surgery.

This book provides a comprehensive and illustrated resource to the most salient aspects of penile implant surgery, ranging from indications to long-term complications. Having an international authorship of world authorities, chapters are aimed to address common concerns, such as patient and device selection, key steps in operative technique, pain control, management of residual penile deformity, and prevention and management of infection. It also provides a step-by-step guide for specific scenarios such as penile fibrosis and neophalloplasty. Rarely discussed issues such as lengthening procedures, operating on anticoagulated patients, and medicolegal aspects are also discussed.

Penile Implant Surgery: Contemporary Challenges and Controversies is intended for both beginners and the most advanced audience, which includes, but is not limited to, residents and fully trained urologists, fellows, and practitioners in sexual medicine and reconstructive urology.

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Chapter 1
Patient and Device Selection

Pramod Krishnappa, Esaú Fernández-Pascual, and Juan Ignacio Martinez-Salamanca

Penile prosthesis (PP) has become the standard of care in the management of refractory erectile dysfunction (ED). The success of a surgery is half completed even before the start of the surgery if one knows how to select the patients and devices diligently.

There are several aspects which need to be considered before doing the PP surgery to maximise the patient-partner satisfaction and to be medicolegally safe. Patients should be given a realistic overview of the entire procedure, outcomes and possible complications so that they know what to expect following the surgery.

A legal database review published in 2014 by Sunaryo et al. [1] about PP malpractice litigation revealed that 42% of cases (17/40) led to indemnity payment to the plaintiff with a mean settlement of US$335,000 and a mean indemnity award of US$831,050. The other important and alarming findings were error in surgical decision-making (48% of cases), informed consent (31%) and postoperative infection (31%) which were the top three reasons for above claim.

A detailed preoperative discussion about the entire surgical procedure and taking signature on a detailed informed consent form is of major importance. This chapter gives a detailed outline of the issues that need to be resolved before attempting a PP surgery to make the outcomes better for the patient and also for the treating doctor.

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Patient Selection

Modifiable Risk Factors

Identifying risk factors of the patient is a top priority as some of these can be optimised before the planned PP surgery.

Smoking

There is level 1 evidence to say that smoking increases surgical site infections (SSI) [2].

As there is no published data on the adverse effects of smoking in PP surgery outcomes, we have derived established conclusions from other surgical specialities. Smokers with 11 or more pack-years had significantly increased deep surgical-site infection ($p < 0.01$) and reoperations in plastic surgery procedures [3].

Adding onto this data, studies from gastrointestinal surgery group have shown that smoking (odds ratio = 1.506, 95% confidence interval 1.131–2.004, $P = 0.005$) was an independent risk factor for postoperative complications [4].

Smoking cessation should ideally be done 4 weeks prior to the planned surgery to reduce the complications [2].

Diabetes Mellitus (DM)

A high-quality population-based data reiterated the fact that DM is an increased risk for inflatable penile prosthesis (IPP) infection [5]. The New York State-wide Planning and Research Cooperative System (SPARCS) database was searched from 1995 to 2014, and 14,969 patients underwent initial IPP insertion. Infectious complications were experienced by 3% (133/4478) of diabetic patients and 2% (210/10,491) of non-diabetic patients ($P < 0.001$) controlling for age, race, comorbidities, insurance status, annual surgeon volume and era of implantation.

The reasons for the higher implant infection rates among diabetics have been numerous. Le et al. have shown in diabetic animal models that adverse tissue healing and subsequent fibrosis around the implants can prevent the optimal functioning of the implants [6].

In a biochemical model of penis/prosthesis complex, Gefen et al. noted poor corporal elasticity of diabetic penis leading to persistent penile pain due to nerve stimulation or ischaemia in regions of compressed vascular tissue [7].

A multicentric study assessed the relation between HbA1C levels and PP infection rates in 902 PP procedures [8]. They found that infection rates were 1.3% with HbA1c level of <6.5%, 1.5% for 6.5–7.5%, 6.5% for 7.6–8.5%, 14.7% for 8.6–9.5% and 22.4% for >9.5% ($P < 0.001$). The study concluded that a threshold HbA1c level of 8.5% is suggested for clinical use to identify patients at increased infection risk.

Most authors agree that HbA1c below 8.5% is reasonably good level for PP surgery [9, 10].

Obesity

Lifestyle changes are associated with improvement in sexual function in about one third of obese men with erectile dysfunction at baseline [11].

Before attempting PP surgery, patient should be advised to lose at least 10% of body weight and to observe any spontaneous improvement in erectile function.

Chronic inflammation and dysmetabolism observed in visceral obese patients negatively influence postoperative outcomes [12].

There may be technical challenges in an obese individual with respect to placing the skin incision, operating table dimensions and appropriate placement of scrotal pump for the patient to handle it comfortably in postoperative period.

Akin-Olugbade et al. noted that those men with body mass index >30 undergoing PP surgery have lower satisfaction rates than the general PP population [13].

Pre-existing Basic Infection Screening

Fungal Infection in the Groin

Penoscrotal and groin examination should involve examining specifically for active fungal infections [14]. Candida infections were seen in 11.1% of cultures isolated from infected PP in a multicentric study, and fungal flora can be eliminated with oral fluconazole before surgery [15].

Nasal Swab Testing for Staphylococcus aureus

The commonest organism isolated from PP infection is *Staphylococcus aureus* [16].

More than 80% of healthcare-associated *S. aureus* infections are endogenous [17, 18].

In a randomised, double-blind, placebo-controlled, multicentre trial published in 2010, patients prior to surgery were randomly assigned in a 1:1 ratio to either active treatment with mupirocin ointment 2% in combination with chlorhexidine gluconate soap, 40 mg/mL or placebo ointment in combination with placebo soap. The infection rates were significantly lesser in mupirocin-chlorhexidine group (3.4% vs 7.7%) [19].

But there is no study that has analysed the role of nasal screening treatment and its benefits in reduction of PP infection. Hence it would be difficult to make a statement on this aspect. Not many prosthetic urologists do nasal screening routinely.

Urine Culture

The common sense in any prosthetic surgery is not to have any focus of infection anywhere in the body. It is practically difficult to rule out all asymptomatic infections.

It would be advisable to do preoperative urine culture in all PP surgeries from medicolegal standpoint although there is some controversy about its true value [20]. Kavoussi et al. found only a 20% (1/5) match between the germ isolated in the urine culture and that obtained from the infected PP. [21] It should be noted that all these patients were intervened with artificial urinary sphincter (AUS) implants, and not with PP. The surgical site in the case of PP surgery is closer to the urinary catheter, while in the case of AUS, the access route is usually perineal.

Katz et al. did a survey which revealed that routine urine culture was not performed by 40% and 50% of Sexual Medicine Society of North America (SMSNA) and International Society of Sexual Medicine (ISSM) members, respectively [22].

Despite this, the current prosthetic implant guidelines recommend preoperative urine culture [23].

Age

Elderly age should not be a restricting factor for penile implant surgery.

Multivariate analysis by Shabsigh et al. on a cross national survey on male health issues noted that older men (60–75 years) consistently reported that they did not seek treatment because they felt ED was a normal part of ageing [24].

Chung E et al. reported that men aged ≥75 years had satisfactory outcome with IPP surgery with no statistically significant difference identified across device survival and satisfaction rates compared to men aged <75 years [25].

Adolescent and teen cancer rates are increasing, particularly thyroid, testicular and non-Hodgkin lymphoma (NHL) cancer. Ultrasound evidence of corporal fibrosis has been observed in adolescent with NHL following cyclophosphamide and doxorubicin chemotherapy [26].

These youngsters with cancer will have their own concerns about ED at a very early age which will bother them mentally and physically. We may soon get to see increase in the number of PP surgeries in less than 30-year-old individuals [27].

HIV Status

The dilemma whether HIV increases postoperative infection rates continues to exist without robust data. A meta-analysis of HIV patients receiving orthopaedic implants was published by Kigera et al. and the group noted that the pooled risk ratio of infection in the HIV patients when compared to non-HIV patients was 1.8 (95% confidence interval [CI] 1.3–2.4) [28].

Moran et al. also showed that HIV seropositivity should not preclude PP placement in appropriately selected men. The reoperation rates in HIV cohort were similar to non-HIV cohort [29].

In contrast to above findings, in a cross-sectional analysis from Premier Perspective Database of 13 years period, Li et al. noted that HIV-positive status was predictive for PP removals due to infectious causes [30]. There could be association between immune dysregulation and the likelihood of PP removal.

There is contrasting evidence about the outcomes in HIV-positive patients. Our suggestion would be to counsel about the additional risk of PP infection in HIV positive individuals when CD4 T-cell counts <300 [31].

Solid Organ Transplantation (SOT)

It is estimated that the prevalence of ED in patients with a liver, renal and heart transplant is 40–86%, 54–66% and 71–78%, respectively [32].

Higher risk of prosthetic infection due to long-term immunosuppression is the worrisome factor in SOT recipients.

A retrospective study was done by Sun et al. which involved 26 SOT-IPP and 26 age-matched IPP recipients without SOT. Transplants included the heart [3], liver [2], kidney only [16] and kidney and pancreas [4]. The study reported no significant difference in PP infection rates (4% vs 0%, $P = 1.00$) and reoperation rates (11.5% vs 11.5%, $P = 1.00$) when comparing patients with SOT with non-SOT controls [33].

The non-infective concerns in these SOT recipients are that the placement of reservoir may be difficult due to adhesions and fibrosis of the previous pelvic surgical planes.

A 2020 systematic review also opined the same and highlighted that the SOT patients who have received a PP may benefit from the presence of an urologist during any subsequent intra-abdominal surgery to decrease the risk of intraoperative or perioperative complication of the existent PP. [34]

The classical teaching few decades back was to prefer PP without reservoir and hence to avoid three-piece IPP in SOT patients [35].

With improvements in surgical expertise and increase in high-volume centres, it is no longer the same. Recent papers have reported no differences in IPP reoperation rates between two-piece and three-piece IPP models [33, 34].

A submuscular (ectopic) placement of the reservoir to avoid visceral or bladder injury may be considered in pelvic grafts [36].

Although the criteria of Barry [37] published in 2007 on the treatment of ED in renal transplant recipients have been generally accepted, they need to be analysed in detail.

Barry [37] proposed the following recommendations for PP surgery in kidney transplant recipients:

- Stable graft function for at least 6 months
- Low doses of maintenance immunosuppressants
- PP with low probability of device malfunction

- No intra-abdominal components to avoid confusion of the reservoir with the bladder in the event of subsequent kidney transplantation
- Minimal tissue dissection
- No skin or urinary tract infections
- Use of prophylactic antibacterials (parenteral, intraurethral and topical)
- Postoperative broad spectrum oral antibacterials for 1–2 weeks

Although most of the above recommendations have an obvious reason either to avoid infections or abnormal scarring in high-risk patients, the decision to use two-piece or malleable PP to avoid implantation of the intra-abdominal reservoir is based on an analysis of the results of 46 transplant recipients, of which 4 had malfunction of the prosthesis (this was not a side effect related to the fact of being a kidney transplant recipient) and the other 4 had injury of the PP in subsequent surgeries [35]. These complications cannot be due the location of the reservoir but of the surgeons' skills and experience.

Neurological Impairment

Reports from 1980s have showed increased incidence of PP infection in spinal cord injury (SCI) patients in view of recurrent urinary tract infection resulting due to long-term urinary stasis or indwelling urinary catheters [38, 39].

Zermann et al. recommended IPP in neurologically impaired patients because of the lower risk of erosion. Malleable PP had 18% risk of erosion in this study, whereas none was seen with three-piece IPP [40].

Malleable PP, despite its drawbacks of being difficult to conceal and unattractive, has the advantage of being economical in patients who have resting tremors or limited hand movements. Kim et al. obtained different data from SCI patients: of the 48 patients who received malleable PP in SCI, erosion occurred in 2 patients (4.2%) and 2 patients required PP removal due to infection [41].

Simultaneous Artificial Urinary Sphincter (AUS) Implantation

Preliminary papers about doing synchronous dual implants (PP + AUS) have showed encouraging results [42–44]. Rolle et al. compared those who underwent synchronous implants (group 1, $n = 15$) with those who underwent two-stage surgery (group 2, $n = 8$). This Italian study noted that the 92% in group 1 and 95% in group 2 experienced "great improvement" ($P > 0.05$) on Patient Global Impression of Improvement. All group 2 patients stated they would have preferred synchronous surgery. No major complications were noted in either group [42].

Steve Wilson described this technique in 2001, but when he was asked in 2018 about the top 5 lessons that he learned from his 45-year practice in the field of

prosthetic urology, he said: "The fifth thing I wish I had known: even though I invented the dual implant via 1 incision, I now discourage it. Experience has taught me to do the implants separately" [45]. The main reason to avoid this single incision dual implant is that when something goes wrong, usually all components from both implants must be removed. This could be avoided if dual implants are inserted through scrotal and perineal incisions separately.

Revision Surgery

Patients with the following scenarios need to be counselled thoroughly about the realistic outcomes as the revision surgeries tend to be more difficult than the primary surgery and are associated with increased infection rates:

- Prior surgical intervention for priapism without primacy placement of PP [46]
- Corporal fibrosis following PP removal due to PP infection [47, 48]
- Prolonged use of intracavernosal injection [49]
- Two retroperitoneal reservoirs already in place
- Thinned out glans and PP erosion

Counselling

Patient and Partner Involvement

Cayan et al. noted higher patient satisfaction rates in the IPP group when compared to malleable PP group (99.2% vs 90.3%). The partner dissatisfaction rates were higher in malleable than IPP group (11.2% with malleable PP, 3.8% with two-piece IPP and 3.3% with three-piece IPP) [50].

Hence involving the partner in preoperative discussions may help ease the matters in postoperative phase as well [51].

Trost et al. defined a simple mnemonic: "CURSED patient" which stands for Compulsive, Unrealistic, Revision, Surgeon Shopping, Entitled, Denial and Psychiatric. Psychological issues with most difficult IPP patients include obsessive/compulsive tendencies, unrealistic expectations, those undergoing revision surgery, those seeking multiple surgical opinions, feelings of entitlement, patients in denial of their prior erectile/sexual function and current disease status or those with other psychiatric disorders [52].

Timed intelligent management of such patients will help improve outcomes and prevent unnecessary law suits.

Pre- and postoperative psychosexual counselling by qualified psychologists may improve postoperative sexual activity and erotic function for both patients and partners following PP surgery [53, 54].

In a patient suspected to have "CURSED" traits, the psychosexual counselling in PP patients should address the following aspects to have a psychologically sound patient at the end of the procedure: the impact of diagnosis, body image issues, fears relating to the surgical procedure and its outcome, the risk of excessive expectations and consequent disillusionment, relationship issues and communication problems [55].

Consent Form

Having a valid informed signed consent form is the first step to medicolegally ensure that one has explained about the positive and negative outcomes of the PP surgery.

Detailed consent forms for PP surgery can be accessed from SMSNA [56] and a document published by Kovac et al. [57]

Device Selection

The majority of high-volume prosthetic urologists would consider a three-piece IPP as the first preference in PP surgery in a virgin uncomplicated case considering the pros and cons of a three-piece IPP.

A three-piece IPP consists of a pair of corporal cylinders, scrotal pump and abdomino-pelvic reservoir. A two-piece IPP (AMS Ambicor™) consists of a pair of corporal cylinders and a scrotal pump. During prosthesis recycling, the pump transfers the solution from small reservoirs located at the proximal end of each cylinder, into each cylinder shaft, thereby causing an erection [58].

The Following Are the List of Currently Available PP Models of Two Major Companies

Boston Scientific (Marlborough, MA, USA)

- Three-piece IPP: AMS 700™ CX (Controlled Expansion) (Fig. 1.1), AMS 700™ LGX (Length Girth Expansion), AMS 700™ CXR (Controlled Expansion Restricted)
- Two-piece IPP: AMS Ambicor™ (Fig. 1.2)
- Malleable: Tactra™ (launched in 2019) (Fig. 1.3)

Fig. 1.1 AMS 700CX

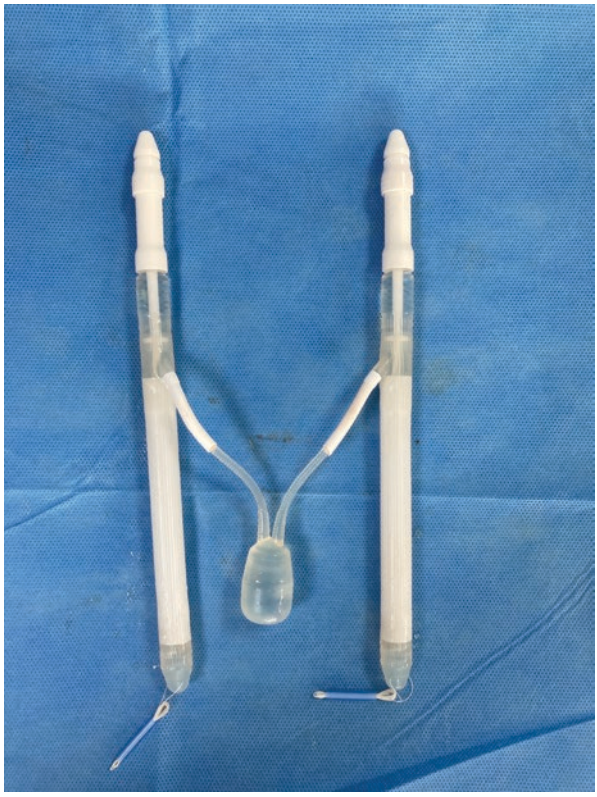

Fig. 1.2 AMS Ambicor

Coloplast (Minneapolis, MN, USA)

- Three-piece IPP: Titan® Touch, Titan® Touch Narrow Base (Fig. 1.4)
- Malleable: Genesis® (Fig. 1.5)

A preliminary study published in 2013 by Chung et al. showed that the AMS 700™ CX and Coloplast Titan® achieved similar clinical outcomes and patient satisfaction rates in Peyronie's disease treatment and modelling procedure [59].

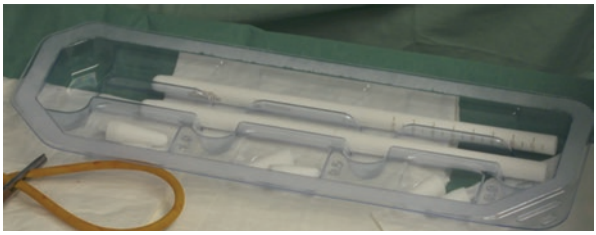

Fig. 1.3 Tactra

Fig. 1.4 Titan Touch

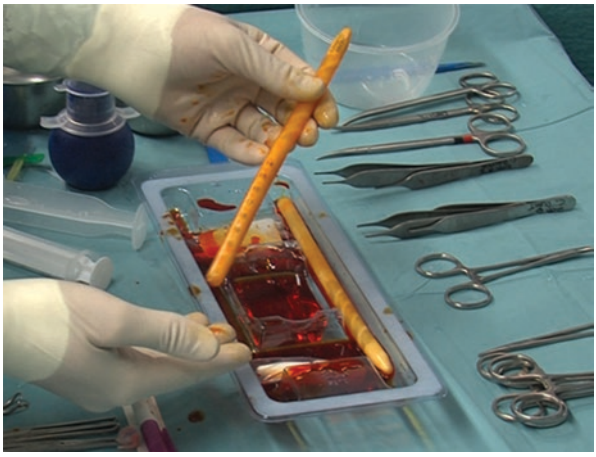

Fig. 1.5 Genesis

Approach

The three-piece IPP models are different for penoscrotal (PS) and infrapubic (IP) approaches. The ones used for PS approach will have shorter scrotal pump tubing length compared to the IP models.

AMS Ambicor™ two-piece IPP has only PS option. Malleable PP doesn't differ based on the approach.

Reservoirs

- Boston Scientific: Spherical and Conceal™
- Coloplast: Cloverleaf™ with lockout valve

The new reservoir designs such as Conceal™ flat reservoir from Boston Scientific and Cloverleaf™ from Coloplast are specially designed for ectopic placement of reservoir (between fascia transversalis and abdominal muscles).

More details about the reservoirs and surgical approaches will be dealt in the upcoming chapters.

The Following Are Some of the Tips in Choosing the Right Device (PP) in Specific Clinical Scenarios

- It is preferable to use AMS 700™ CXR or Titan® Touch Narrow Base in corporal fibrosis and post-radiotherapy cases where corporal dilatation is difficult [60].
- AMS 700™ CX and Titan® Touch which have high-pressure cylinders are preferred for manual modelling in Peyronie's disease [61].
- AMS 700™ LGX is not ideal for penile straightening in scarred corporal bodies, because the lengthening property of these cylinders does not allow for the development of sufficient axial rigidity [62].
- Although few studies [63, 64] claim that AMS 700™ LGX preserves the penile length to some extent, the same has not been observed in a recent study where Wallen et al. observed increase in stretched penile length in only six (23.1%) patients [65].
- Both AMS 700™ and Titan® have antibacterial properties. AMS 700™ has InhibiZone® which is an antibiotic coating impregnated with rifampin and minocycline, whereas Coloplast Titan is coated with polyvinylpyrrolidone (PVP), a hydrophilic substance that retains the antibiotic when dipped in any antibiotic solution. It is difficult to specify which PP offers least infection rates as PP infection depends on so many preoperative, intra-operative and postoperative factors. Dhabuwala et al. noted infection rates of 4.4%, 1.3% and 0% for

Titan® PP coated with vancomycin/gentamycin, InhibiZone-impregnated AMS 700™ PP and Titan® PP coated with rifampin/gentamicin solution, respectively [66].

- In a biomechanical cadaveric pilot study conducted by Wallen et al., the AMS 700™ CX showed the best rigidity in the shortest phallus (with three-point flexure testing) and the Titan® showed slightly better rigidity in the longest phallus and the phallus with mild Peyronie's disease [67].
- Two-piece IPP is best suited in kidney transplant recipients [37].
- Malleable PP are preferred (i) as a "bridge-course" or salvage therapy to prevent complete corporal fibrosis in PP infection or priapism to help easy placement of IPP later; [68] (ii) in those having manual dexterity issues (significant hand tremors) which may hamper handling of scrotal pump; (iii) in patients with Peyronie's disease who require lengthening techniques in which it is important to keep the penis in traction as long as possible in order to maintain the gained length; and (iv) in those unable to afford for IPP, which is mostly the case in many countries where insurance companies do not cover PP surgeries [69].

Table 1.1 summarises the patient and device selection factors that should be considered preoperatively to achieve better results.

Table 1.1 Preoperative decision-making factors

Patient factors	HbA1c less than 8.5
	Urine culture
	Screen for any obvious active infection: groin
	Psychosexual counselling in "CURSED patients"
	Written informed detailed consent
	Involve partner in discussions wherever possible
	Stop antiplatelets 1 week prior to surgery
	Quit smoking at least 4 weeks prior to surgery
	Body mass index <30, preferably
	Previous surgeries (urethral, penile, scrotal, pelvic)
	Low-dose immunosuppression protocols in transplant recipients, if feasible
Device factors	AMS 700™ CXR or Titan® Touch Narrow Base: in severe corporal fibrosis
	AMS 700™ CX and Titan® Touch: for manual modelling in Peyronie's disease
	Avoid doing synchronous dual implants through single incision (in early phase of your career)
	Malleable PP: patients with manual dexterity issues or as bridge-course option in priapism and infection
	Very large phallus: Titan® Touch
	Ectopic reservoir placement: use Conceal™ or Cloverleaf™

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Chapter 2
Critical Analysis of Maneuvers to Reduce Infection in Penile Implant Surgery

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Introduction

Erectile dysfunction (ED) has been defined as the inability to have and/or sustain an erection sufficient for intercourse [1]. Conditions commonly associated with ED include diabetes mellitus, hypertension, hyperlipidemia, coronary artery disease, obesity, and prostate cancer treatment [2]. While most of those entities are markers of cardiovascular risk, not all have been associated with increased risk of infection with surgical implants [3].

Prosthetic devices are a well-established form of treatment for medically refractory erectile dysfunction. Postoperative infection is the most feared complication of genitourinary prosthetic surgery. In the USA today, most experts report the incidence of infection during the initial implant is only 1–3%, but traditional replacement/revision surgery has had a 10–18% risk [4–6].

Multiple product enhancements during the last 25 years have resulted in markedly decreased mechanical failure rates. In fact, most authorities now believe the devices are more often revised for non-mechanical failure factors such as infection and cylinder issues than mechanical reasons [4–6]. Despite these mechanical improvements, infection has remained a significant complication in prosthetic surgery.

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