



# Overcoming barriers to immediate penile implant salvage surgery: a narrative review

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**Background and Objective:** Since immediate salvage (IS) surgery for infected penile prosthesis (PP) was introduced nearly 30 years ago, an abundance of evidence has emerged in support of its use. IS remains underutilized by the modern urologist despite its distinct advantages. While some medical literature proposes reasons for the underuse of IS, no comprehensive review attempts to address the numerous factors limiting its implementation. Our objective is to analyze the barriers to IS surgery for infected PP with the goal of expanding utilization of this technique through a practical and standardized approach for treating urologists.

**Methods:** A narrative review of available English, peer-reviewed, medical literature relevant to the barriers to IS was completed. Searches were expanded to include literature from surgical specialties in general if hypothesized barriers were incompletely described in available PP publications.

**Key Content and Findings:** The major barriers that are likely contributing to the low rates of IS for PP surgery can be broadly classified into three major categories: institutional/systemic, medical/surgical, and patient preference. Institutional/systemically driven barriers include surgeon comfort with PP surgery, low national availability of urologists, inaccessibility of prosthetics or critical ancillary staff at the time of patient presentation and limited operating room (OR) access. Medical/surgical barriers primarily relate to reinfection fears, perceived contraindications to IS, and overall patient stability at the time of presentation. Patient preference factors inhibiting IS involve loss of trust in the medical team, psychosocial distress, dissatisfaction with the initial device prior to infection and anxiety regarding postoperative recovery. Many of the identified barriers can be overcome with increased surgical training, improved patient and surgeon understanding of PP infection, or precautionary planning.

**Conclusions:** Of the factors that contribute to low utilization of IS, many are misunderstood or unknown. Recognition of these barriers may equip urologists to provide better care to patients with prosthesis infection.

**Keywords:** Infection; penile prosthesis (PP); erectile dysfunction; salvage surgery

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## Introduction

The penile prosthesis (PP) has been a reliable option for management of refractory erectile dysfunction (ED) for fifty years (1,2). Traditionally, PP was only offered in the setting of less-invasive treatment failure, however, recent guidelines recommend discussion of all ED management options early in the decision-making process (3,4). Over the last twenty years, global utilization of PP for ED has steadily increased (5).

As PP utilization has increased, prosthesis technology and complication management strategies have also evolved (1,2). Despite improvements in surgical technique and hardware, prosthesis infection, a devastating complication of PP surgery, is estimated to occur in 1–4% of virgin cases (6,7). Historically, standard of care for PP infection included broad spectrum antibiotics, complete device removal, and delayed replacement if desired. While earlier literature is available, the concept of immediate inflatable PP (IPP) salvage was popularized by Brant *et al.* in 1996 (8,9). This technique reduced corporal fibrosis and loss of penile length associated with PP explantation by immediately placing a new prosthesis after the removal of infected hardware and extensive wash-out (10). Reinfection rates following immediate salvage (IS) are low at <10% (7,11). Further development of salvage techniques, the malleable implant salvage technique (MIST) variation in particular [a variation of Mulcahy's salvage technique that utilizes a malleable PP (MPP)], have simplified the salvage procedure, reduced reinfection rates, and challenged dogma regarding contraindications to IS (11,12).

Several alternatives to IS for PP infection have been proposed but are generally considered inferior treatment options. When compared to delayed salvage, IS was shown to be more practical [one *vs.* two operating room (OR) procedures, lower cost] while having a statistically equivalent success rate (13). Conservative management of prosthesis infection has also been described but is not currently recommended by guidelines (4). As such, IS is widely considered the preferred intervention for prosthesis infection (10,14).

Despite a preference for IS amongst experts, it was only utilized for 17.3% of infected PP between 2000 and 2009 (15). Potential barriers leading to the underutilization of IS for infected PP have yet to be thoroughly explored or challenged in contemporary literature. Herein, we describe the etiology of and possible solutions to these barriers while broadly categorizing them as institutional, medical/surgical, or relating to patient preference. We present this

article in accordance with the Narrative Review reporting checklist (available at <https://tau.amegroups.com/article/view/10.21037/tau-23-509/rc>).

## Methods

A narrative review of available literature relevant to the barriers to IS was completed (using databases of PubMed, Medline, ScienceDirect, Google Scholar). Search terms included: penile prosthesis, IPP, inflatable penile prosthesis, malleable penile prosthesis, salvage, immediate, infection, treatment, explant, replacement, and barrier. It was anticipated that there would likely be a paucity of literature relevant to PP salvage specifically, therefore searches were extended to include relevant data from other medical specialties when appropriate. Only peer-reviewed publications in the English language were considered. Literature from the last 20 years was preferred but earlier studies were not excluded. All authors reviewed the included publications. The search strategy summary is outlined in *Table 1*. Referenced studies include prospective studies, meta-analysis, case series, reviews, and expert opinions. Where appropriate, author opinion and expert opinion are noted in the manuscript.

## Results

The authors of this review found that the numerous independent factors contributing to underutilization of IS for infected PP can be categorized into one of the following general considerations: institutional/systemically driven barriers, medical/surgical barriers unique to a patient's state of health or presenting condition, and barriers secondary to a patient's individual preferences for their care (*Table 2*).

### *Institutional barriers*

For IS to be possible in the first place, a urologist comfortable with PP surgery, including salvage technique, needs to be available to the patient presenting with an infection. Urology care in general is predominantly concentrated around urban centers with 62.2% of United States (US) counties having no practicing urologists and 90.0% of urologists practicing in metropolitan areas (16). Furthermore, it is estimated that only 15% of urology training programs employ a dedicated prosthetic urologist and >75% of all PP are placed by surgeons who log less than five prostheses annually (17,18). When this is

**Table 1** The search strategy summary

Items	Specification
Date of search	9/25/2023
Databases and other sources searched	PubMed, Medline, ScienceDirect, Google Scholar
Search terms used	Penile prosthesis, IPP, inflatable penile prosthesis, malleable penile prosthesis, salvage, immediate, infection, treatment, explant, replacement, and barrier
Timeframe	Up to September 2023
Inclusion criteria	Peer-reviewed publications in the English language were considered. All study types were reviewed. Studies with higher level of evidence were emphasized (if applicable)
Selection process	Selection was performed by all authors with review by the senior author prior to inclusion
Additional considerations	Searches were extended to include relevant data from other medical specialties when appropriate

**Table 2** Barriers to immediate penile implant salvage

Barrier category	Individual barrier	Comments
Institutional/systemic	Surgeon training/comfort	Formal prosthetic training in residency/fellowship in the United States is highly variable. Surgeons incorrectly assume patients must be treated urgently
	Access to urologists	The majority of United States counties do not have a practicing urologist
	Unfamiliarity with washout solutions	Consider single agent washout with Irrisept
	OR access	Securing OR space/time can be difficult, particularly in a post-COVID-19 era
	Unavailable ancillary staff	OR staff or device representatives familiar with specialized prosthesis surgery are often unavailable at the time of patient presentation
	Unavailable prosthetic devices	Many hospitals do not stock the prosthetic devices needed for IS. However, it should be noted that IS does not need to be completed on an emergent basis
Medical/surgical	Reinfection	Historical IS reinfection rates were ~18%. Surgical technique and device changes have reduced them to ~7% or less
	Historical exclusion criteria	Patients with necrotic infections, diabetic patients with purulence, severely diabetic patients, and device erosion were excluded by Mulcahy. Modern studies suggest that these patients may be safely salvaged
	Severe sepsis	The acuity of the patient's illness may prevent extended operative/anesthesia times. Surgery can be considered after 2–3 days of parenteral antibiotics
Patient preference	Loss of trust	Complications lead to loss of trust in the hospital, staff, and possibly surgeon
	Psychosocial distress	Complications can be anxiety provoking, leading patients to choose the least anxiety producing option following infection
	Dissatisfaction	Dissatisfaction with the device initially may lead patients to prefer explant without replacement, rather than IS
	Post-operative course	Postoperative course following implantation may deter patients from IS, including pain, loss of work and caregiver stress

OR, operating room; COVID-19, coronavirus disease 2019; IS, immediate salvage.

considered in the setting of low rates of PP infection, it is statistically unlikely that the average urologist will have extensive experience with PP surgery, much less salvage surgery. It is probable that many patients with PP infection present to centers with no available urology care or to centers without a urologist comfortable with IS. As this barrier precedes all others, efforts should be made to bridge the current knowledge/skill gap amongst urologists to allow for better patient access to IS. Potential solutions include increased instruction on salvage technique in residency training, attendance at cadaveric prosthesis courses, virtual instruction seminars, and improved guidelines that encourage salvage for infected PP over other treatment options (19-22).

The original Mulcahy washout protocol was complex and involved the use of multiple irrigation solutions/techniques. Surgeons' lack of familiarity with the protocol is likely a barrier to its utilization (23). Some of the extraneous steps of the original protocol, including the use of hydrogen peroxide, have since been eliminated (19). Razdan *et al.* recently showed that IS/MIST washout with a single solution [Irrisept (chlorhexidine gluconate)] is effective, demonstrating a 100% success rate with no erosion or reinfection in a limited series of four patients (24). Continued simplification of the MIST protocol will likely serve as a catalyst for wider adoption of IS.

Urologists may be detracted from IS due to a perception that the salvage procedure needs to be completed urgently, outside of normal OR hours, or before scheduled surgery/clinic can proceed. Operating at these times can be disruptive to a surgeon's schedule. Surgery is more difficult and less efficient outside of normal operational hours due to the absence of ancillary staff who are familiar with PP procedures (25). However, patients are commonly hemodynamically stable on presentation with PP infection. If stable, it is appropriate for the patient to be initiated on intravenous (IV) antibiotics and observed before proceeding to the OR electively (19).

Availability of OR time may also be leading to decreased utilization of IS (as surgeons can misinterpret infected PP/IS as an indication for urgent operative intervention) (4,19). OR availability has been particularly impacted in a post-coronavirus disease 2019 (post-COVID-19) healthcare system. While insufficient OR nursing/anesthesia staff and operating suite availability have been an ongoing problem for decades, these issues have only been exacerbated in recent years (26,27). Lack of timely access to the OR has led surgeons to delay or alternatively manage pathologies

that were traditionally treated with emergent surgery (27). While this has not been evaluated in the field of genitourinary prosthetic surgery specifically, it is reasonable to conclude this systemic problem may detract from a urologist's willingness to convert their management practices for infected PP to IS. Rather than adopting a more time intensive, unfamiliar operation, urologists may be further persuaded by this barrier to manage infected PP with explantation alone. Although it is discouraged by experts, non-operative treatment with long-term antibiotics is also described in the literature (28,29). It is unclear how frequently this treatment option is utilized but is likely still implemented by some, and potentially more attractive if OR time is difficult to secure.

A final institutional barrier to consider is penile implant inventory. Many hospitals, even those with regular PP surgery, do not have a full supply of prosthetics, but rather obtain the needed device from a sales representative pre-/intra-operatively (30). As MPPs are significantly less common nationally, it is even less likely that one of these devices would be available for IS/MIST protocol. Typically, device representatives are readily available to physicians and in most situations can provide needed supplies in a timely manner. This could be an indication to postpone surgery until all needed materials can be procured (as discussed above) but should not prohibit IS. It should also be noted that unlike IPPs, MPPs are cut to appropriate size from the standard production length at implantation and have a long shelf-life. Several MPP diameters are available. Smaller diameter implants are useful when corporal fibrosis is encountered intra-operatively (as the fibrosis can preclude placement of a larger MPP). As such, the authors recommend stocking 2-3 MPPs to be adequately prepared for IS. Three brands of MPP, Boston Scientific (Marlborough, MA, USA), Coloplast (Minneapolis, MN, USA), and Rigicon (Ronkonkoma, NY, USA), are available in the US (31). Any of these brands may be used for MIST, but the relative frequency of their use for IS nationally has not been reported (12,32). MPPs are also a useful management option for refractory ischemic priapism further justifying their place in the OR supply (33).

The barriers outlined in this section represent a significant hurdle to overcome prior to IS being offered to a patient with an infected prosthesis. Several of these are endemic to our healthcare system, while others can be overcome with improvements to urologist training/understanding, prosthetic guidelines, and surgical preparation. A temporary solution may involve urologists

specializing in prosthetic surgery to preoperatively counsel patients to return exclusively to their care if any symptoms of PP infection develop. This solution is not perfect, as many patients live considerable distances from a practicing urologist (as previously discussed) or even cross state lines for PP surgery (34). Patients are also frequently lost to follow-up, making it unlikely for them to return to their original PP surgeon. For example, Chierigo *et al.* showed that 56.4% of their 149 IPP patient cohort was lost to long-term follow up (35).

### *Medical/surgical barriers*

In addition to the institutional barriers to IS, medical and surgical factors have also limited adoption of this approach by urologists. Reinfection raises the greatest concern, as removal of an infected device with replacement in the same surgical field poses obvious risks. The long-term rate of reinfection in IS patients reported by Mulcahy in 2000 was 18%, which has fueled debate regarding the technique (8,9).

Since Mulcahy's study in 2000, advances in antibiotics, device design, and surgical technique have resulted in a significant reduction in infection risk (11,12). The advent of antibiotic impregnated devices in 2001 has led to a significant decrease in primary placement infection rates to 1–4% (36–38). Although there are no direct comparisons, it is reasonable to conclude that this reduction is conferred to IS patients as well (39). Gross *et al.* in 2016 demonstrated that salvage with a malleable device could reduce the rate of reinfection from the previously published 18% down to 7% (12). As a comparison, two-stage and one-stage revisions of periprosthetic joint infections in total knee arthroplasty have reinfection rates of 8.8% and 7.6% respectively (40). While reinfection warrants concern, current literature would suggest that the rate is low, declining, and comparable to salvage in other fields.

An additional potential contributor to low IS utilization are the exclusion criteria set forth by Brant *et al.* in 1996, which excluded patients with necrotic infections, diabetic patients with purulence, severely diabetic patients, and those with rapidly developing infections or device erosion (9). This excluded population can represent a disproportionately large number of patients that would otherwise be candidates for salvage. As previously noted, this was prior to the advent of antibiotic impregnated devices and a major shift to salvage with malleables resulting from the works of Köhler *et al.* in 2009 (32) and Gross *et al.* in 2016 (12). Subsequent works have since shown that these advances may make

it reasonable to immediately salvage many of these patients. Peters *et al.* in 2018 demonstrated 0 reinfection at 39 weeks post-operatively amongst a small population of poorly-controlled diabetic patients with purulent IPP infections (41). Chandrapal *et al.* in 2020 expanded upon this work by examining a cohort of 26 salvage patients that included 4 with exposed hardware and 9 with purulent infections (11). None of these 13 patients developed reinfection, although one immunosuppressed patient did, revealing a cohort necessitating further study (11). It is important to realize that there are very few true contraindications to IS in the modern surgical era and the historical exclusion criteria are likely antiquated.

The critically ill patient requiring PP removal poses a difficult scenario for the genitourinary surgeon. In these patients the focus is on minimization of operative/anesthetic time and removal of the source of infection. IS rates in this population are expectedly lower than in other cohorts (15). If source control with immediate device removal is not emergently indicated, patients often improve significantly with several days of parenteral antibiotics (19). Surgery with IS can be considered at this time when the patient has stabilized (19). That being said, patients presenting with sepsis requiring intensive care unit (ICU) level care represent a small overall percentage of PP infections (19). This group likely represents a minute contribution to the disparity between salvage success rates and utilization of the technique. Recent studies have suggested that there has been a shift towards infections with more virulent organisms (19,42). It will be necessary to observe if the severity of IPP infections at the time of presentation worsens. If so, this barrier may evolve.

### *Patient preference barriers*

Along with institutional and medical/surgical barriers, patients' preferences also influence whether IS occurs. When patients experience complications after surgery their self-reported perception of the care they received is negatively impacted. Patients are less likely to recommend the hospital and are more likely to perceive the hospital staff as unresponsive (43–45). Although not directly investigated in the study by Gurland *et al.*, one may theorize that if a patient is less likely to recommend the hospital, they may also be less likely to recommend the surgeon. A loss of trust in the surgical team may then cause patients to simply favor explant rather than proceeding with IS or may cause patients to present to a different hospital (avoiding the



surgeon and the surgeon's team). Given the distribution of urologists in the US (as previously discussed), the patient's new hospital of choice may not have a urologist that is comfortable performing IS.

Surgical complications can lead to significant psychosocial distress, depression, anxiety and can negatively affect a patient's quality of life (45). For example, when given the choice for management of prostate cancer, patients feeling anxious or depressed are more likely to prefer radical treatment options rather than active surveillance, as active surveillance can be anxiety producing (46,47). In the case of PP infection, the least anxiety producing option could be explantation without IS diminishing the fear for repeat PP infection. If patient anxiety is focused on erectile dysfunction, corporal fibrosis, or the loss of penile length, IS may be favored.

Patients may also prefer to not proceed with IS if they were not satisfied with the initial device. IPPs have impressive satisfaction rates ranging from 81–97% (48–50). It is difficult to interpret these rates, however, as there are varying definitions of dissatisfaction in the literature. These discrepancies lead to dissatisfaction rates that range from 0–30% with common reasons being need for explantation, loss of penile length, decreased glanular engorgement, altered sensation, pain and perioperative complications (49,51). Regardless of what the true rates of dissatisfaction are, it seems that only a small subset of this already small population of PP patients would elect for removal without replacement. In a study by Minervini *et al.*, only 26% of 54 dissatisfied men wanted their malleable prosthesis removed (48). Collectively, it is possible that a small subset of patients that were dissatisfied with their initial IPP would prefer explantation without salvage, which subsequently may lower IS rates.

Lastly, the post-operative course associated with PP surgery may deter patients from proceeding with IS. Post-operative pain after prosthetic placement is variable. The highest reported pain scores occur on post-operative day 0, with mean visual analog scale ratings ranging from 0.84–4.73 (0 indicating no pain to 10 indicating extreme pain) during the immediate post-operative period to post-operative day 1 (52). Some degree of pain is expected for up to 6 weeks, although a minority of patients can develop chronic pain lasting >2 months (53). Diabetic patients with HbA1c >8 have been described as a cohort who are at risk for more significant post-operative pain after PP surgery (54). Patients who had significant post-operative pain after first implantation may not want to undergo the intervention again. Similarly, those who had extended recoveries after

their initial PP surgery may fear recurrently burdening a caregiver or missing extended periods of work. Patients may assume that these complications are minimized with explant alone.

## Conclusions

Despite an abundance of literature supporting the use of IS, it remains underutilized. Many of the institutional, medical/surgical, and patient preference derived factors that contribute to low utilization of IS are generally misunderstood or unknown. Recognition of these barriers and how to overcome them will equip urologists to provide better care to patients with prosthesis infection.

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