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INVITED REVIEW

Operational Andrology

Penile prosthesis implant in the special populations: diabetics, neurogenic conditions, fibrotic cases, concurrent urinary continence surgery, and salvage implants

Eric Chung^{1,2,3}

Penile prosthesis implant (PPI) remains an effective and safe treatment option for men with erectile dysfunction (ED). However, PPI surgery can be associated with a higher risk of complications in certain populations. This article provides a critical review of relevant publications pertaining to PPI in men with diabetes, significant corporal fibrosis, spinal cord injury, concurrent continence surgery, and complex salvage cases. The discussion of each category of special populations includes a brief review of the surgical challenges and a practical action-based set of recommendations. While specific patient populations posed considerable challenges in PPI surgery, strict pre- and postoperative management coupled with safe surgical practice is a prerequisite to achieving excellent clinical outcomes and high patient satisfaction rate.

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INTRODUCTION

Penile prosthesis implant (PPI) is indicated in men with severe erectile dysfunction (ED) refractory to conventional medical therapy and wish to have a more permanent solution. Advances in the last four decades in terms of device technology and techniques have made PPI an effective treatment with excellent clinical safety record, mechanical durability, and patient satisfaction rate. However, PPI remains an invasive surgery, with potential significant complications that may have long-term implications.^{1,2}

While the primary goal of PPI surgery aims to restore erection, it also carries additional cosmetic and psychosocial consequences. Preoperative patient counseling is essential to address any unrealistic expectations and adequately inform patients of potential surgical complications in order to optimize postoperative satisfaction.³ Furthermore, there is strong evidence to suggest that high-risk populations such as men with uncontrolled diabetes mellitus, immunosuppression, corporal fibrosis (e.g., Peyronie's disease [PD] or priapism), and spinal cord injury (SCI) and men who are undergoing salvage PPI surgery, are at greater risk of prosthetic complications, especially device infection and erosion. The aim of this review article is to provide an evidence-based and expert opinion overview on the clinical outcomes of PPI surgery in these special populations.

MATERIALS AND METHODS

A critical review of all relevant publications pertaining to PPI was conducted in Medline and Embase databases, using keywords

“penile prosthesis implant,” “diabetics,” “neurological,” “spinal cord injury,” “Peyronie's disease,” “corporal fibrosis,” “priapism,” “urinary incontinence,” “infected,” and “salvage” cases. A detailed surgical description related to PPI surgery was excluded from this review. The discussion of each category of special populations also includes a brief review of surgical challenges and a practical action-based set of recommendations on surgical options.

DISCUSSION

Diabetic men

In general, diabetics are at higher risk of infection, and infectious diseases are more frequent and serious in patients with uncontrolled diabetes mellitus. The greater frequency of infections in diabetic patients is related to the underlying hyperglycemic environment that favors immune dysfunction (e.g., damage to neutrophil function, depression of the antioxidant system, and humoral immunity), micro- and macro-angiopathies, neuropathy, and decrease in the antibacterial activity of urine as well as the greater likelihood of coexisting medical comorbidities and the need for medical interventions.

In one of the earliest PPI publications on diabetic men, Bishop *et al.*⁴ evaluated a possible cause-and-effect relationship between the degree of diabetic control and the risk of infection complicating PPI surgery and found that prosthetic infection occurred in 31% of the poorly controlled versus 5% of the adequately controlled patients ($P < 0.001$). Of the 32 diabetic men, 13 (40.6%) were poorly controlled with glycosylated

¹AndroUrology Centre, Brisbane, QLD 4000, Australia; ²University of Queensland, Princess Alexandra Hospital, Brisbane, QLD 4000, Australia; ³Macquarie University Hospital, Sydney, NSW 2109, Australia.

Correspondence: Dr. E Chung (ericchg@hotmail.com)

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hemoglobin (HbA1c) level of >11.5%, with four prosthetic infections in this group, whereas in the remaining 19 controlled diabetics (HbA1c <11.5%), only one infection occurred. The impact of HbA1c on prosthetic infection was further explored by Wilson *et al.*,⁵ which showed that prosthetic infection developed in 10 diabetics (8.7%) and 11 nondiabetics (4.0%) after PPI surgery in 389 patients. Interestingly, there was no increased infection rate observed in diabetics with high fasting sugars or diabetics on insulin, with no statistically significant increased infection risk with increased levels of HbA1c among all patients or among only the diabetics. In fact, there was no meaningful difference in the median or mean level of HbA1c between the infected and noninfected patients regardless of the diabetic state.

In a more recent study, Habous *et al.*⁶ showed that higher mean HbA1c levels were associated with higher prosthetic infection, *i.e.*, 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% ($P < 0.001$), with no significant difference detected between malleable and inflatable devices. Predictors defined on multivariable analysis were PD, high body mass index, and high HbA1c level, while a high-volume surgeon had a protective effect with reduced infection risk. An HbA1c threshold level of 8.5% appeared to predict prosthetic infection with a sensitivity of 80% and a specificity of 65%. Similarly, Cangunen *et al.*⁷ found that the infection rate among diabetics was 0.67% and the prevalence of prosthesis infection among patients with HbA1c $\leq 9\%$ was 0.9%, compared with 0 among patients with HbA1c >9%. However, there was no meaningful difference in the median or mean level of HbA1c in the infected and noninfected diabetic patients. The authors concluded that the use of HbA1c values may not be a true indicator to identify and exclude those who might be prone to increased risk of prosthesis infections.

Using a state-wide database on men who underwent initial PPI insertion from 1995 to 2014, Lipsky *et al.*⁸ reported that the overall infection rate was 2.3% (343/14 969), with infectious complications experienced by 3% (133/4478) of diabetic patients and 2% (210/10 491) of nondiabetic patients ($P < 0.001$). Diabetes was associated with a statistically significantly increased PPI infection risk on multivariable analysis controlling for age, race, medical comorbidities, insurance status, annual surgeon volume, and the era of implantation (hazard ratio: 1.32, 95% CI: 1.05–1.66, $P = 0.016$).

Based on manufacturer's database comparing the infection-related revisions for antibiotic-impregnated and nonimpregnated implants, Mulcahy and Carson⁹ reported the initial revisions due to infection as 1.47% of antibiotic-impregnated versus 4.17% of nonimpregnated implants. At 7 years, the rate of infection-related revisions was statistically significantly lower for antibiotic-impregnated (1.62%) than for nonimpregnated implants (4.24%; log-rank $P < 0.0001$). Diabetic men had a statistically significantly higher rate of revisions due to infection at 7 years (1.88%) than men without diabetes (1.53%; log-rank $P = 0.0052$).

A systematic review and meta-analysis on prosthetic infection in antibiotic-coated PPI¹⁰ showed a significant advantage of using coated compared to noncoated inflatable penile prostheses to prevent postoperative device infection. For noncoated versus coated prostheses, the infection rate was 2.32% versus 0.89% ($P < 0.01$), including 0.63%, 0.55%, 4.42%, and 1.11% for minocycline/rifampin, rifampin/gentamycin immersion, vancomycin/gentamycin immersion, and hydrophilic coatings, respectively. Infection-retardant coatings that allow antibiotics to elute off the device components can decrease the incidence of device infection by approximately 50%. In a more recent systematic review, Christodoulidou and Pearce¹¹ found no statistically

significant increase in the risk of infection in patients with diabetes mellitus. The authors reported higher infection rate (ranging from 5.5% to 20%) in patients with diabetes mellitus who underwent PPI, prior to the 1990s. The implementation of antibiotic-coated implants in 2001 has resulted in lower infection rates (*i.e.*, approximately 2%) in patients with diabetes mellitus. The latest and largest case series by Eid *et al.*¹² reported an infection rate of 0.46% with antibiotic-coated implants and novel “no touch” technique in a cohort of 1511 cases, out of which 41% were patients with diabetes mellitus.

Patients with diabetes require specific consideration in planning PPI surgery. While clinical guidelines at present do not recommend diabetes screening in patients being assessed for all types of elective surgery, routine blood sugar level test is considered a standard investigation for men with ED. Failure to identify and manage diabetes and hyperglycemia states preoperatively invariably increases the risk of intra- and postoperative complications. It may be necessary to delay elective surgery to facilitate the management of poorly controlled diabetes. While there is no evidence-based guideline published that precludes surgery above a certain value for HbA1c, most studies advocate an HbA1c below 8%–9% for PPI surgery. Strict perioperative glycemic control and close monitoring are paramount to avoid diabetic-related complications. The role of perioperative antibiotic prophylaxis in PPI surgery is well documented, and published literature supports the use of antibiotic-coated devices. Postoperatively, diet and usual diabetes medications should be restarted as soon as possible, often under the guidance of an endocrinologist or diabetic nursing teams.

Neurologic group

Published literature on the clinical outcomes of PPI surgery among neurogenic men is limited. In contrast to inflatable three-piece PPI, the malleable or semi-rigid prosthesis is thought to be a more ideal option among SCI patients who are often physically handicapped with poor hand dexterity, limited range of mobility, and muscle fatigue. Malleable implant is thought to have a lower mechanical failure rate than inflatable PPI due to its “simple” design and ease of surgery. However, the lack of sensation among SCI men may predispose those with a malleable implant to have a delayed identification and presentation of prosthetic complications such as device erosion and extrusion from chronic pressure sores.

Compared to nonneurogenic men, the complication rates are often higher in the neurogenic group. Kim *et al.*¹³ reported complications in eight out of 48 patients (16.7%), with 50% related to infections. Other complications were erosion in two patients (4.2%), uncontrolled penile pain owing to excessive prosthesis length in one patient (2.1%), and supersonic transporter (SST) deformity in one patient (2.1%). The use of PPI in neurologically impaired patients was explored in a larger retrospective heterogeneous study by Zermann *et al.*,¹⁴ and the authors presented a 17-year period of PPI surgery of 147 semi-rigid (Jonas), 113 self-contained inflatable (Dynaflax), and 33 inflatable three-piece (AMS 700) prostheses in 245 neurologically impaired patients, with 43 revisions undertaken for technical reasons and prosthetic infection (5% or 12 patients). The perforation rate was higher for semi-rigid device (18.1%) compared to an inflatable three-piece prosthesis (0).

In addition to penile erection, PPI may have an additional benefit with urinary control in neurogenic men. In another study, Kimoto and Iwatsubo¹⁵ showed the use of PPI for urinary management in 51 patients (62%), for sexual dysfunction in 10 patients (12%), and for both purposes in 21 patients (26%). Ninety-three percent of the patients who used the implant for urinary management and 64% of the patients who used it for sexual dysfunction were satisfied. However,

there were high complication rates with three extrusions and nine surgical removals due to pain, the difficulty of catheterization, and infection (the complication rate was 13.3%). In another study, it reported that both diabetic and SCI males complained of poorer body image postimplant surgery when compared with a normative sample.¹⁶

Neurogenic men undergoing PPI should be counseled regarding the higher prosthetic revision and complication rates. Discussion on the advantages and disadvantages between malleable and inflatable PPI should be conducted based on the patient's physical characteristics, sexual needs, and cost. Regular monitoring for impending prosthetic erosion and presence of autonomic dysreflexia signs may signal the underlying prosthetic-related pain and infection in SCI patients.

Corporal fibrosis - PD and ischemic priapism

The presence of significant corporal fibrosis can pose a substantial technical challenge to PPI surgery both in terms of corporal dilation and a higher risk of prosthesis infection and malfunction.¹⁷ Causes of corporal fibrosis include PD, complications from an infected implant with device explant, postpriapism, and prolonged use of intracavernosal therapy. Corporal dilation in the setting of corporal fibrosis often requires an increased effort to break through the effect of the fibrotic plaque(s) and a higher likelihood of corporal perforation.

In one of the largest studies on PPI in men with acute ischemic priapism, Ralph *et al.*¹⁸ reported that immediate insertion of a penile prosthesis was a relatively straightforward surgery. Malleable penile prosthesis was inserted in 43 patients and a three-piece inflatable implant in 7 patients, with subsequent elective exchange from malleable to an inflatable device performed in 6 patients. After a median follow-up of 15.7 (range: 4–60) months, 42 patients were able to resume successful sexual intercourse. Prosthesis infection occurred in three patients (6%), which was managed by explantation and delayed reinsertion, while a further six patients needed revision surgery.

Higher rate of intraoperative complications in postpriapism men was also confirmed by Durazi and Jalal,¹⁹ and in their series, corporeal dilation was difficult due to extensive corporeal fibrosis, resulting in urethral injury in two patients. Furthermore, of the prosthesis implanted, 11 were malleable, 4 were two-piece, and 2 were three-piece AMS prostheses, highlighting that inflatable three-piece PPI may not be possible in this group. Furthermore, Sedigh *et al.*²⁰ found that all patients with an inflatable prosthesis complained of a temporary reduction in penile sensitivity likely related to previous distal corporal shunts. However, early insertion of a penile prosthesis appeared to be safe in patients with no significant loss of penile length; neither apical erosion nor extrusion was recorded.

In a separate study, Sansalone *et al.*²¹ reported 18 patients with severe penile contracture and corporal fibrosis who underwent simultaneous corporeal reconstruction and placement of a penile prosthesis. A malleable penile prosthesis has been inserted in four patients and a three-piece inflatable device in the remainder. Revision surgery was required in four patients (elective exchange to the three-piece inflatable device in three patients and upsizing of the implant in one patient) after an average follow-up of 26 (range: 6–36) months. Although all patients were able to achieve penetrative sexual intercourse, four patients were partially dissatisfied because of significant penile shortening. In expert hands, simultaneous penile prosthesis implantation and corporal reconstruction of severely scarred corpora yield satisfactory results.

Conventionally, multiple corporotomies and excavation were performed to remove fibrotic tissue from the tunica albuginea, but this was associated with variable success rates.^{22,23} Special tools such

as cavernotomes (Carrion-Rossello, Minneapolis, MN, USA) and Uramix (Lansdowne, PA, USA) (*i.e.*, double-bladed cavernotomes with linear blades) allow for tunneling and creation of corporal channel with/without an inward–outward movement²⁴ to create a large enough tunnel to accommodate the prosthetic cylinder. In cases of severe corporal fibrosis, a downsized implant may be then selected. Although these smaller implants may cause a loss of penile length and girth, they can expand the tunnel over time and allow for implantation of a regular sized prosthesis if needed in future.²⁵ The AMS 700 CXR or Coloplast Titan narrow-based cylinder can be used if corporal dilation is <12 mm in size. Although some patients are satisfied with narrow cylinders, Wilson *et al.*²⁶ reported the feasibility of subsequent cylinder upsizing after 1 year with narrow cylinders. Prolonged inflation over an 8–12-month period results in expansion of the cylinder cavity, permitting standard-sized cylinders in all patients.

Other “novel” techniques include complete excavation of fibrosed corporal tissue, extracorporal transeptal entry, and the use of endoscopic instruments for optical corporotomy and transcorporal resection. Montague and Angermeier²⁷ described complete excavation of fibrosed corporal tissue with extended corporotomies along the ventral aspect of each corpus cavernosum, using a plane of dissection between the fibrotic corporal tissue and the inner surface of the tunica albuginea, resulting in core removal of nearly all fibrotic intracorporal tissues. Cylinders are laid into the empty corporal bed, and the tunica albuginea is closed primarily. Nine patients who had undergone this procedure were identified. The operative notes and medical records were reviewed, and telephone interviews confirmed that successful outcomes were achieved in all the nine patients. Corporal excavation permits penile prosthesis implantation in men with severe intracorporal fibrosis, usually resulting from priapism or previous removal of infected penile prostheses.

Shaer and Shaer²⁸ described a novel extracorporal technique by bending the malleable implant into a U shape at the midshaft penis, with the two limbs of the rod placed toward the glans. The tips of the U are anchored under the glans. The procedure allowed acceptable coital relationship and concealment in nine out of ten cases. The same group²⁹ also proposed another novel technique with optical corporotomy and transcorporal resection of the fibrosed corpora cavernosa under vision in six patients who exhibited diffuse fibrosis of the corpora cavernosa.

In addition to intracorporal fibrosis, the presence of tunical plaque in men with PD may cause substantial residual curvature after PPI surgery. In one of the largest series of PPI comparing the two main penile prostheses, Chung *et al.*³⁰ found that PPI with modeling can provide permanent penile straightening without an increased risk of revision surgery. While there was no statistically significance in device survival between the two devices, the trend favored AMS 700 CX (Boston Scientific, Minnetonka, MN, USA) over Titan (Coloplast, Minneapolis, MN, USA), with the 5-year Kaplan–Meier estimates of mechanical survival of 91% versus 87% ($P > 0.05$) and that most men (79%) reported high satisfaction following PPI.

The general recommendation for PPI in the PD group is manual penile modeling of inflated cylinders for a clinically significant curvature after PPI surgery and if a residual curve $>30^\circ$ remains after penile modeling, then various surgical techniques, including plaque-releasing incision and/or grafting, can be considered. Corporal fibrosis presents a surgical challenge and requires surgical experience and specialized techniques to manage appropriately.^{31,32}

Concurrent urinary continence surgery

If the implants are not placed synchronously, the AUS is usually placed first followed by a penile prosthesis, in the event of urethral

injury precluding both prostheses preparation and implantation. In a sequential device implant, care is taken to avoid damaging the AUS cuff when subsequently placing the penile cylinders. Review of previous surgical records including preoperative imaging is often necessary to avoid intraoperative surprises so that placement of the second implant can be performed for the pump and reservoir on the contralateral side. The incision should be performed away from the existing device, with meticulous surgical dissection and the use of a cutting current to avoid damage to any components of the first device.

In one of the earliest reports of concurrent PPI with male sling surgery, Rhee³³ reported that concurrent placement of a semi-rigid or inflatable penile implant at the time of male sling was not associated with any perioperative complications and complete satisfaction in all four patients with continent status and erectile function at 1-year follow-up. In a more recent study, Gorbatiy *et al.*³⁴ showed that dual penile prosthesis and male sling implantation can be performed through a single perineal incision which is safe, efficient, and cost-effective. While the operative time for dual implants was double of either implant alone, dual implantation was associated with approximately \$9000 in savings.

The trans-scrotal approach allows for concurrent AUS and PPI surgery. Kendirci *et al.*³⁵ showed that synchronous dual prosthetic implantation was associated with excellent clinical outcomes with minimal complication rates. Of the 22 men who underwent synchronous AUS and PPI surgery, there were four reported complications with two urethral erosions and two reservoir migrations, of which one underwent revision. Similarly, Rolle *et al.*³⁶ showed that synchronous AUS and PPI surgery is feasible and safe and as effective as the two-stage procedure, with better acceptance by patients. There was no significant difference in pain score, continence rate, erectile function score, and patient satisfaction rate.

Mancini *et al.*³⁷ reported that dual implantation produces encouraging outcomes in patient satisfaction, ease of use, and functionality that are equal to those found after the placement of either PPI or AUS alone, and most men will encourage others and undergo dual implants if given the choice again. In a different study, Segal *et al.*³⁸ concluded that dual implants did not increase the adverse outcomes compared to implantation of a single prosthesis. However, men treated with combined implantation had greater mean age and were at greater risk for prostate cancer diagnosis and treatment and at a lesser risk for PD than men who received an inflatable penile prosthesis alone (each $P < 0.05$). Although the operative time was statistically significantly longer for the combined procedure than for the inflatable penile prosthesis alone and the AUS alone (mean: 218.1 min vs 145.9 min and 114.7 min, respectively, $P < 0.0001$), the rate of device infection, erosion, or malfunction did not increase, irrespective of combined or staged procedures ($P > 0.05$).

In a cost-analysis study, Sellers *et al.*³⁹ reported that dual implantation in a single-stage procedure statistically significantly reduced (24.7%) the operative time ($P < 0.05$, mean: 113 min) compared with the total time for the individual procedures (PPI, average of 78 min; AUS, average of 72 min; total 150 min), and that it was associated with approximately \$7000 cost savings compared with individual procedures. However, Patel *et al.*⁴⁰ found that compared with men who received a penile prosthesis alone, those PPIs and an AUS had a higher likelihood of undergoing inflatable penile prosthesis reoperation at 1 year (OR: 2.08, 95% CI: 1.32–3.27, $P < 0.01$) and 3 years (OR: 2.60, 95% CI: 1.69–3.99, $P < 0.01$), but no difference was detected for AUS reoperation rate.

Salvage cases

Unfortunately, prosthetic infection remains unavoidable despite of advances in device design, surgical techniques, and strict patient selection.⁴¹ There is very limited published literature on the role of prosthesis salvage in the setting of dual prostheses. Salvage penile prosthesis was popularized by Brant *et al.*⁴² and has largely replaced the role of delayed salvage surgery.⁴³ The benefits from immediate salvage are the preservation of both implants and prevention of penile shortening.

With a prosthetic infection or erosion, classic management involves removal of all hardware with thorough irrigation of the infected spaces. This method invariably resulted in corporal fibrosis and loss of penile size. The role of traction therapy either with an external penile mechanical extender or a vacuum erection device, either utilized preoperatively⁴⁴ or postoperatively,⁴⁵ has been shown to improve the penile size and patient satisfaction rate. However, the mechanical application can be tedious and requires strict patient compliance to be effective with an expected small gain in penile length and girth.

In order to avoid significant corporal fibrosis that can make a subsequent implant challenging, an immediate salvage procedure with a three-piece prosthesis has been advocated (when possible). However, there has been recent interest in using malleable device or biomaterials during salvage procedure to serve as a temporary space-filling implant (or cast) in order to prevent fibrosis and allow for delayed conversion to inflatable prosthesis with easy access to the interior of the corporal body for placing the new cylinders and maintaining the length of the erection. In some instances, patients may be satisfied and find the malleable rods sufficient for sexual intercourse.

Mulcahy revolutionized the concept of salvage surgery based on Scott's preliminary reports,⁴⁶ to incorporate a cocktail of betadine, hydrogen peroxide, and kanamycin/bacitracin antibiotic solution. Mulcahy's pioneering approach has expanded and challenged the role of immediate salvage surgery in prosthetic infection. Specific contraindications to a salvage operation include tissue necrosis, diabetic patients with purulence in the corporal bodies, rapidly developing infections, and erosion of the device cylinders. In his original series,⁴² 10 out of 11 patients underwent successful prosthesis salvage operation and immediate replacement of an infected penile prosthesis. In 2000, Mulcahy reported his long-term salvage success with 82% long-term infection-free rate.⁴⁷ Mulcahy proposed the role of preoperative antibiotics in these select cases to eradicate the surrounding tissue infection prior to the salvage attempt.⁴⁸ In a more recent study, Peters *et al.*⁴⁹ reported that all six diabetic patients with prosthetic infection successfully underwent salvage surgery, with placement of a malleable replacement device in five patients and elective conversion to a PPI in one patient 7 months after his salvage procedure. One patient received a PPI during salvage according to his preference.

The use of biomaterials to provide temporary cast was first reported by a Miami group⁵⁰ with the use of a synthetic high-purity CaSO_4 mixed with antibiotics. Data in reference to CaSO_4 show that this product dissolves in approximately 4–6 weeks and both patients underwent delayed implantation with no infection.

The role of biofilm and the presence of "innocuous" bacteria within the biofilm are subject of interest in any prosthetic surgery. Henry *et al.*⁵¹ confirmed the presence of positive cultures within visible biofilm and confocal micrography showed the bacterial presence on clinically uninfected inflatable penile prostheses at revision surgery. Of the 148 patients, 97 (66%) had positive bacterial swab cultures of the fluid around the pump or biofilm, and a total of 124 isolates were cultured. Of the 65 implant capsule tissue cultures obtained before

washout, 28 (43%) were positive for bacteria, whereas 16 (25%) obtained after revision washout were positive. This study showed that revision washout can decrease the bacterial load on implant capsule tissue at revision surgery.

The impact of immediate salvage surgery on corporal length preservation in patients presenting with penile implant infections was explored by Lopategui *et al.*,⁵² and the authors found that most patients can expect to lose 15%–30% of penile length irrespective of age, diabetes, type of infecting organism, and time to reimplantation. Among the successful salvaged cases, there was a mean 0.6 (95% CI: 0.20–1.1) cm reduction in total corporal length compared to a mean 3.7 (95% CI: 2.9–4.5) cm total corporal length loss in those with delayed reimplantation. In patients who underwent delayed reimplantation, the total corporal length reduction was directly proportionate to the initial penis size of the patient.

CONCLUSION

Since the introduction of modern PPI in the early 1970s, the surgical landscape for PPI has changed dramatically.⁵³ While specific patient populations pose considerable challenges in PPI surgery, strict preoperative management coupled with safe surgical practice is a prerequisite to better clinical outcomes and high patient satisfaction rate. Scientific innovations in PPI technology and surgical techniques have provided critical improvements, resulting in improved device survival and low complication rates even in high-risk populations.

COMPETING INTERESTS

The author declares no competing interests.

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