







Original Article

New findings regarding predictors of Poor Corporal Integrity in Penile Implant Recipients: A Multicenter International Investigation

Chrystal Chang¹ , David W. Barham² , Zafardjan Dalimov¹, Daniel Swerdloff¹, Hossein Sadeghi-Nejad³, Robert Andrianne¹¹, Maxime Sempels¹¹, Tung-Chin Hsieh⁴, Georgios Hatzichristodoulou¹³, Muhammed Hammad², Jake Miller² , Daniar Osmonov¹⁴, Aaron Lentz⁵, Paul Perito⁶, Alfredo Suarez-Sarmiento⁶, James Hotaling⁷, Kelli Gross⁷, James M Jones⁸ , Koenraad van Renterghem¹², Sung Hun Park¹⁵, Jonathan N. Warner⁹, Matthew Ziegelmann⁹ , Vaibhav Modgil¹⁶, Adam Jones¹⁶, Ian Pearce¹⁶, Arthur L. Burnett¹⁰, Martin S. Gross⁸, Faysal A. Yafi²  and Jay Simhan¹

¹Department of Urology, Fox Chase Cancer Center, Philadelphia, PA, ²Department of Urology, University of California Irvine, Orange, CA, ³NYU Langone – NYU Grossman School of Medicine, New York, NY, ⁴Department of Urology, University of California San Diego, La Jolla, CA, ⁵Department of Urology, Duke University, Durham, NC, ⁶Perito Urology, Coral Gables, FL, ⁷Division of Urology, Department of Surgery, University of Utah, Salt Lake City, UT, ⁸Section of Urology, Dartmouth-Hitchcock Medical Center, Lebanon, NH, ⁹Department of Urology, Mayo Clinic, Rochester, MN, ¹⁰Department of Urology, Johns Hopkins University, Baltimore, MD, USA, ¹¹Service d'Urologie, Centre Hospitalier Universitaire de Liege, Liege, ¹²Department of Urology, Jessa Hospital, Hasselt, Belgium, ¹³Department of Urology, 'Martha-Maria' Hospital Nuremberg, Nuremberg, ¹⁴Department of Urology, University Hospital Schleswig Holstein, Kiel, Germany, ¹⁵Sewum Prosthetic Urology Center of Excellence, Seoul, South Korea, and ¹⁶Manchester Andrology Centre, Manchester University NHS Foundation Trust, Manchester, UK

Objectives

To evaluate the pre- and intraoperative variables that impact the integrity of the corporal bodies over time after inflatable penile prosthesis (IPP) placement, as predictors of intraoperative corporal perforation and delayed cylinder complications have not been well characterized.

Patients and Methods

We retrospectively reviewed a 16-centre multi-institutional database of IPP surgeries performed by experienced implanters from 2016 to 2021. Poor corporal integrity (PCI) was defined as intraoperative (iPCI) corporal complications or postoperative (pPCI) corporal complications. Multivariable analysis was performed to identify independent predictors of PCI, iPCI, and pPCI. Primary outcomes included intra- and postoperative corporal complications.

Results

We identified 5153 patients for analysis from 5406 IPP cases, finding 152 (2.95%) cases of PCI. On multivariable analysis, predictors of PCI included revision IPP surgery (odds ratio [OR] 8.16, 95% confidence interval [CI] 5.15–12.92; $P < 0.001$), sequential dilatation (OR 2.12, 95% CI 1.32–3.39; $P = 0.002$), coronary artery disease (CAD)/peripheral vascular disease (PVD) (OR 1.81, 95% CI 1.18–2.77; $P = 0.006$), older age (OR 1.02, 95% CI 1.01–1.04; $P = 0.013$), and corporal scarring (OR 1.58, 95% CI 1.0–2.5; $P = 0.049$). Predictors of iPCI included revision IPP surgery (OR 7.34, 95% CI 4.18–12.88; $P < 0.001$), corporal scarring (OR 2.77, 95% CI 1.64–4.69; $P < 0.001$), radiation therapy (OR 2.25, 95% CI 1.0–5.04; $P = 0.049$), and older age (OR 1.03, 95% CI 1.0–1.05; $P = 0.025$). Revision IPP surgery (OR 7.92, 95% CI 3.69–17.01; $P < 0.001$), sequential dilatation (OR 3.4, 95% CI 1.61–7.19; $P = 0.001$), CAD/PVD (OR 2.98, 95% CI 1.56–5.72; $P = 0.001$), and history of priapism (OR 3.59, 95% CI 1.08–11.99; $P = 0.038$) were predictive of pPCI.

Conclusion

Coronary artery disease/PVD, being of older age, having corporal scarring, undergoing IPP revision surgery and sequential dilatation were predictive risk factors for complications associated with PCI. Identifying patients who are at risk of having PCI may improve patient-specific counselling, consideration of referral to more experienced implanters, and surgical planning to potentially promote longer-term device viability.

Keywords

Inflatable penile prosthesis, Intraoperative complications, Postoperative complications, Corporal Integrity, Penile prosthesis erosion

Introduction

Inflatable penile prosthesis (IPP) placement is a definitive treatment for erectile dysfunction (ED) that offers high satisfaction rates for patients [1]. IPP surgery carries risks of unique and challenging intra- and postoperative complications. Although infectious complications have been thoroughly reported [2–6], non-infectious complications are poorly characterized. Increasing awareness of these complications can aid in patient counseling and preoperative planning.

Rates of intraoperative events like corporal crossover or distal/proximal corporal perforation have not been defined rigorously, but the conventional wisdom is that these occurrences are uncommon. Management of these conditions has been described elsewhere [1,7,8]. Similarly, postoperative corporal complications like impending or delayed cylinder erosion are relatively rare [9,10] but challenging to manage. No prior study has evaluated the rates of these intra- or postoperative non-infectious sequelae, or delineated risk factors that may predispose patients to such untoward events. A better understanding of these risk factors may help guide referrals of more complex cases to experienced prosthetic urologists.

We defined the term ‘poor corporal integrity’ (PCI) to include those patients who experience intraoperative corporal complications such as corporal crossover and proximal/distal perforation, or those who sustain postoperative events such as impending/actual erosions. We evaluated predictors of PCI and corporal-related complications, and we hypothesised that pre- and intraoperative variables may impact the long-term integrity of the corporal bodies, which in turn would influence device longevity.

Patients and Methods

Study Design

We retrospectively reviewed a large, multi-institutional database of IPP surgeries performed by 16 experienced implanters after an Institutional Review Board (IRB) approval was obtained (H-37856). A total of 5406 patients underwent IPP surgery between July 2016 and May 2022 at a total of 16 different institutions from the United States, Korea, and

Europe. This study was conducted based on the Declaration of Helsinki and was approved by the IRB of each centre.

Selection Criteria

Pre-defined inclusion criteria were: patients undergoing primary IPP surgery due to ED and revision cases with removal and replacement of all components of the device. Revision surgery was defined as having a history of IPP and undergoing replacement or exchange of the entire device. Patients who only had one or two components revised without replacement of the entire device were excluded. We excluded patients undergoing a salvage procedure for infection.

Study Protocol

The electronic medical records of each institution served as the primary data sources and all data were pooled for analysis. We extracted data on baseline, intra- and perioperative characteristics. PCI was defined as corporal-related complications including crossover, distal/proximal perforation, impending erosion, urethral injury, urethral or cutaneous erosion, cylinder extrusion, or deformity (such as lateral deviation). PCI was further divided into intraoperative PCI (iPCI) including crossover and perforation and postoperative PCI (pPCI) such as erosion, impending erosion, cylinder extrusion, and deformity (such as lateral deviation).

To select potential risk factors for PCI to examine, we wanted to include those that would decrease vascularity to the penis, potentially promote corporal fibrosis, and/or possibly place mechanical stress on the tunic (such as sequential dilation). We sought to examine if corporal scarring would contribute to iPCI and pPCI, and we defined it as encountering fibrosis intraoperatively, uniformly reporting it as present or not present. Regarding corporal dilation strategy, single dilation was a single pass of a dilator instrument of the surgeon’s choice (including simultaneous dilatation and measurement solely with a Furlow device), or separate dilation with an instrument followed by Furlow for measurement. Sequential dilation included various methods including serial dilatation with Hegar (Millenium Surgical Corp, Narberth, PA, USA) dilators, Brooks (Coloplast Corp, Minneapolis, MN, USA), Metzenbaum scissors, or a combination of techniques. The

last follow-up evaluation was defined as the date the surgeon performed the last clinical evaluation of the patient. Minimum follow-up required was 60 days.

Statistical Analysis

Descriptive statistics were used to summarize the data. Continuous variables were summarized as mean and SD, while categorical variables were summarized as frequencies and percentages. Chi-square and Mann–Whitney tests were used for statistical analysis for categorical and continuous variables, respectively. We included possible risk factors for PCI, such as those decreasing vascularity to the penis and/or promoting corporal fibrosis and included the following: age, coronary artery disease (CAD) or peripheral vascular disease (PVD), diabetes, and other variables. A full breakdown of all variables considered is shown in Table 1. Independent variables were selected based on both clinical and statistical significance, with a *P* value set at <0.05. The goodness of fit was assessed with Pearson and Deviance residuals.

For multivariable analysis to determine predictors of PCI, we utilised a multivariable logistic regression model and included

all significant variables found on preoperative characteristics of patients with PCI. The IBM® Statistical Package for the Social Sciences (SPSS®) version 28 (IBM Corp., Armonk, NY, USA) was used to run all statistical tests. We reported findings based on the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement.

Results

Baseline Characteristics and PCI

A total of 5406 IPP cases across 16 separate institutions were assessed. After excluding 137 salvage cases for infection and 116 cases that were not complete removal and replacement of the IPP, we identified 5153 patients for analysis (supplemental Table S1). Of these patients, there were 152 (2.95%) patients with PCI. The median (interquartile range) follow-up was 9 (2–19) months with six patients not following up after 2 months as they were content with their postoperative outcome. Between-group differences in demographic and comorbidities on univariate analysis are shown in Table 1. Patients with PCI tended to be older (aged 64.5 vs 62.6 years, *P* < 0.001), have CAD/PVD (30% vs 22%, *P* < 0.023), and be active smokers (27% vs 17%, *P* < 0.004) compared to those without PCI. Patients with PCI also seemed to have history of IPP infection (13% vs 2.6%, *P* < 0.001), history of shunt for priapism (2% vs 0%, *P* = 0.003), and to have undergone revision surgery (47% vs 14%, *P* < 0.001). Patients without PCI tended to be non-Caucasian (58% vs 40%, *P* < 0.001) and obese (49% vs 36%, *P* = 0.002) compared to those with PCI.

On multivariable analysis, predictors of PCI included undergoing revision IPP surgery (odds ratio [OR] 8.16, 95% CI 5.15–12.92; *P* < 0.001), sequential dilation (OR 2.12, 95% CI 1.32–3.39; *P* = 0.002), having CAD/PVD (OR 1.81, 95% CI 1.18–2.77; *P* = 0.006), being of older age (OR 1.02, 95% CI 1.01–1.04; *P* = 0.013), and having corporal scarring (OR 1.58, 95% CI 1.0–2.5; *P* = 0.049). Diabetes seemed to be protective (OR 0.59, 95% CI 0.38–0.91; *P* = 0.017). Table 2 summarizes these findings.

When we examined revision cases, we found a total of 781 patients. When performing multivariable analysis on revision IPP cases alone, hypertension was the only risk factor for PCI (OR 2.16, 95% CI 1.25–3.72; *P* = 0.006).

Intraoperative PCI (iPCI)

There were a total of 105 iPCI events in 100 patients. Of these, 38 (36%) were proximal perforations, 44 (42%) distal perforations, nine (8%) proximal crossovers, and 14 (13%) distal crossovers (Table 3). Five patients sustained both proximal and distal corporal complications. Additionally, 16/152 (10.5%) of the patients with PCI underwent modelling

Table 1 Preoperative characteristics of the patients with PCI (both iPCI and pPCI).

Characteristic	No PCI, N = 5001	PCI, N = 152	<i>P</i>
Age, years, mean (SD)	62.6 (10.8)	64.5 (11.1)	<0.001
Non-Caucasian Race, <i>n</i> (%)	2909 (58)	62 (40)	<0.001
Body mass index, kg/m ² , median (interquartile range)	29.8 (4.1)	28.9 (4.2)	0.007
Obese, <i>n</i> (%)	2007 (49)	47 (36)	0.002
Comorbidities, <i>n</i> (%)			
CAD/PVD	922 (22)	43 (30)	0.023
Diabetes mellitus	1678 (34)	45 (29)	0.3
Hypertension	2410 (48)	86 (56)	0.059
Immunosuppressed ^a , <i>n</i> (%)	118 (2.8)	5 (3.6)	0.6
Current smoker, <i>n</i> (%)	782 (17)	40 (27)	0.004
History of radical prostatectomy, <i>n</i> (%)	830 (17)	31 (20)	0.3
History of prostate radiation, <i>n</i> (%)	232 (5.9)	13 (8.5)	0.2
History of Peyronie's disease, <i>n</i> (%)	695 (15)	30 (20)	0.1
History of IPP infection, <i>n</i> (%)	128 (2.6)	19 (13)	<0.001
History of priapism, <i>n</i> (%)	156 (3.1)	9 (6.0)	0.1
History of shunt for priapism, <i>n</i> (%)	32 (0)	3 (2)	0.003
History of ICI, <i>n</i> (%)	1037 (25)	43 (31)	0.09
Type of surgery, <i>n</i> (%)			<0.001
Primary	4289 (86)	81 (53)	
Revision	709 (14)	73 (47)	

^aImmunosuppressed patients were defined as having the following: active treatment of solid tumour or haematological malignancies, history of solid organ transplant and taking immunosuppressive therapy, primary immunodeficiency such as severe combined immunodeficiency, human immunodeficiency virus, active treatment with steroids. Bold values statistically significant at *P* < 0.05.

Table 2 Multivariable analysis of predictors of PCI, iPCI, and pPCI.

Risk factor	PCI		iPCI		pPCI	
	OR (95% CI)	P	OR (95% CI)	P	OR (95% CI)	P
Surgery for IPP revision	8.16 (5.15–12.92)	<0.001	7.34 (4.18–12.88)	<0.001	7.92 (3.69–17.01)	<0.001
Sequential dilatation	2.12 (1.32–3.39)	0.002	1.66 (0.9–3.07)	0.107	3.4 (1.61–7.19)	0.001
CAD/PVD	1.81 (1.18–2.77)	0.006	1.25 (0.71–2.21)	0.44	2.98 (1.56–5.72)	0.001
Age	1.02 (1.01–1.04)	0.013	1.03 (1–1.05)	0.025	1.03 (0.99–1.06)	0.126
Diabetes mellitus	0.59 (0.38–0.91)	0.017	0.74 (0.43–1.27)	0.277	0.49 (0.24–1)	0.051
Corporal scarring	1.58 (1–2.5)	0.049	2.77 (1.64–4.69)	<0.001	0.48 (0.18–1.29)	0.147
Current smoker	1.52 (0.98–2.37)	0.062	1.4 (0.79–2.48)	0.25	1.62 (0.81–3.21)	0.172
Body mass index	0.97 (0.92–1.01)	0.146	0.96 (0.9–1.02)	0.159	0.99 (0.92–1.06)	0.742
Hypertension	1.31 (0.89–1.94)	0.174	1.24 (0.76–2.04)	0.384	1.39 (0.74–2.61)	0.306
History of radiation therapy	1.43 (0.71–2.89)	0.313	2.25 (1–5.04)	0.049	0.65 (0.15–2.91)	0.573
History of IPP infection	1.39 (0.71–2.73)	0.331	1.47 (0.69–3.12)	0.318	1.24 (0.32–4.82)	0.752
History of ICI	1.24 (0.8–1.93)	0.331	1.02 (0.58–1.82)	0.933	1.54 (0.78–3.04)	0.217
History of RP	0.92 (0.55–1.53)	0.736	0.94 (0.5–1.79)	0.857	0.79 (0.33–1.9)	0.598
Non-Caucasian race	0.93 (0.6–1.46)	0.763	1.04 (0.6–1.81)	0.882	0.84 (0.39–1.8)	0.655
History of priapism	1.14 (0.45–2.93)	0.779	0.51 (0.11–2.29)	0.381	3.59 (1.08–11.99)	0.038
History of Peyronie's disease	1.03 (0.62–1.7)	0.92	1.02 (0.53–1.94)	0.96	1.18 (0.54–2.54)	0.679
History of immunosuppression	1.04 (0.35–3.06)	0.949	0.33 (0.04–2.59)	0.291	2.54 (0.72–8.97)	0.147

ICI, intracavernosal injections; RP, radical prostatectomy. Bold values statistically significant at $P < 0.05$.

Table 3 The iPCI and pPCI events.

Complication	Events, n
Intraoperative PCI	105
Proximal perforation	37
Distal perforation	43
Proximal crossover	9
Distal crossover	14
Postoperative PCI	52
Erosion	13
Extrusion	30
Impending erosion	2
Deformity	7

maneuvers intraoperatively vs 501/5001 (10%) of patients without PCI.

On multivariable analysis, predictors of iPCI included revision IPP surgery (OR 7.34, 95% CI 4.18–12.88; $P < 0.001$), corporal scarring (OR 2.77, 95% CI 1.64–4.69; $P < 0.001$), history of radiation therapy (OR 2.25, 95% CI 1.0–5.04; $P = 0.049$), and older age (OR 1.03, 95% CI 1.0–1.05; $P = 0.025$). These findings are summarised in Table 2. When performing multivariable analysis on revision IPP cases alone, hypertension was the only risk factor for iPCI (OR 1.88, 95% CI 1.05–3.36; $P = 0.034$).

Postoperative PCI (pPCI)

There was a total of 52 patients with pPCI, with 13 (25%) erosions, 30 (58%) extrusions, two (4%) impending erosions, and seven (13%) deformities. These are detailed in Table 3.

On multivariable analysis, predictors of pPCI included revision IPP surgery (OR 7.92, 95% CI 3.69–17.01;

$P < 0.001$), sequential dilatation (OR 3.4, 95% CI 1.61–7.19; $P = 0.001$), having CAD/PVD (OR 2.98, 95% CI 1.56–5.72; $P = 0.001$), and having a history of priapism (OR 3.59, 95% CI 1.08–11.99; $P = 0.038$). There was one patient with iPCI who later developed a pPCI. iPCI was not found to be a significant predictor of pPCI on multivariable analysis. These predictors are described in Table 2.

Discussion

This study defines a very low (2.95%) but real risk of PCI in patients undergoing primary or revision IPP surgery that has previously not been characterized. Patients with PCI are more likely to be older, have a history of CAD/PVD and corporal scarring, or to have undergone IPP revision surgery and sequential dilatation. Notably, radical prostatectomy, radiation therapy, Peyronie's disease, and use of intracavernosal injections were not associated with PCI. Undergoing revision IPP surgery was predictive of both iPCI and pPCI, and sequential dilatation was predictive of pPCI but not iPCI. History of radiation therapy was predictive of iPCI but not PCI or pPCI. Further, encountering corporal scarring intraoperatively was predictive of iPCI, whereas patients with a history of priapism and CAD/PVD were more likely to experience pPCI. iPCI was found to not be a predictor of pPCI, as only one patient who had iPCI developed pPCI. There are only a few studies that examine risk factors for PCI – and many prior assessments combine patients with PCI with IPP mechanical failures, which confounds any possible conclusions [11–13]. These studies identified mechanical malfunction as a leading cause of device removal without paying granular attention to rates of PCI during revision surgery. In our experience, revision cases often carry the most challenging dilation when the original implant surgery was

not performed correctly. For instance, IPP placement after prior infection or repositioning poorly seated cylinders can lead to difficult cases necessitating sequential dilation or other advanced maneuvers potentially leading to perforations or crossover.

In our study, CAD/PVD was found to be predictive of PCI and pPCI. We suspect impaired vascularity would predispose patients to corporal complications. CAD/PVD provides a chronic and diffuse insult to penile vasculature. This subsequently promotes release of reactive oxygen species, which leads to oxidative stress and fibrosis of corporal smooth muscle and media of the penile arteries [14]. Higher rates of erosion and pump migration have previously been identified in patients with comorbidities that negatively affect peripheral vascular supply [15]. Impaired vascularity results in impaired healing, which would also increase the risk of PCI [15]. Our study contradicts the findings of others who found CAD/PVD to not be linked to device longevity [15,16], but these other investigations examined infection rates along with corporal complications.

We have also identified revision surgery as a strong predictor of PCI, iPCI, and pPCI. This is likely due both to mechanical forces and promotion of fibrosis over time. Fuentes and colleagues [17] suggest distal cylinder tip extrusion specifically may be the result of the chronic microtrauma stemming from repeated and/or prolonged inflation of a robust pressurised device interacting with delicate distal penile tissue over time. More than half of their patients with cylinder tip extrusion had prior implants, which likely contributed to additional long-term microtrauma. Over a quarter of their patients were found to have corporal scarring intraoperatively that was not present on initial placement [18]. Repeated surgery can therefore likely lead to weakened and fibrotic tissue. Mechanical pressure such as modelling could potentially put more stress on fibrotic tissue; however, looking at our patients with Peyronie's disease, we found that the percentage of patients who underwent modelling was the same in the PCI group and non-PCI group. Alongside the rationale that mechanical pressure could predispose patients to PCI, oversizing of implant cylinders or placing a larger implant at time of revision could also increase the risk of PCI. Wound healing after IPP implantation also involves increased production of collagen [19], which is a hallmark of fibrosis [14]. Tissue in a previously operated field is no longer as robust and healthy as that in a virgin field, as it has been subjected to repeated device inflations. Having a penile prosthesis in place can contribute to microtrauma and fibrosis long term, and thus when patients undergo revision surgery, they are at increased risk of adverse corporal sequelae.

Previously, our group reported on corporal complications in patients undergoing primary IPP placement [20]. In that study we found there was no difference in intraoperative

complications in patients who underwent sequential vs single corporal dilatation [20]. However, in our present study, we found sequential dilation and revision surgery to be associated with PCI. This is likely due to more difficult dilation in challenging revision cases such as prior IPP infections or poorly positioned cylinders, which were not included in our prior study [20].

On multivariable analysis, we noted corporal scarring to be predictive of PCI and iPCI. Fibrotic tissue tends to be less compliant, and its decreased vascularity and its relationship with perfusion may cause weaker tissue surrounding the implant [14]. Radiation is also linked to fibrosis and scarring [21], and we found radiation to be predictive of iPCI. Corporal scarring makes dilatation and penile prosthesis implantation more challenging [22,23], as tissue has higher resistance against dilators and higher rates of perforation can be encountered [24]. With fibrotic corpora, it is more difficult to create adequate space for the penile implant, which may place more stress on the implant cylinders and corpora. Over time, this added strain may increase the risk of corporal complications such as cylinder extrusion.

Patients who underwent sequential dilation were likely to have PCI and pPCI. We hypothesize that intraoperative microperforations of corpora during dilatation can manifest weeks or months later, and we anticipate that with several years' follow-up, we may identify more extrusions or erosions in our patient series. Sequential dilation was previously shown to be associated with increased corporal complications in patients undergoing virgin penile implantation and who have corpora without risk factors for fibrosis [20], and such investigations have strongly suggested single dilation be the first and only intraoperative dilatation when possible. However, once corporal scarring is encountered, the risk of iPCI is increased as there is also likely a need for sequential dilatation.

Priapism was found to be a predictor of pPCI, which is corroborated by the findings of Barham and colleagues. [25]. In that report, the majority of complications in patients with a history of priapism were related to the corpora with a high rate of corporal extrusion and erosion. Ischaemic priapism causes smooth muscle necrosis [26,27], which lends to fibrosis and corporal scarring. It may thus be more difficult to create an adequate space for the cylinders and over time the cylinders will erode or migrate through weak points in the tunica.

Interestingly, iPCI was not a predictor of pPCI. It should be noted that the iPCI cases were all identified at the time of surgery and appropriately corrected. Thus, our study demonstrates that corporal crossover or perforation does not lead to pPCI when identified and rectified during surgery. Surgeons should be cognizant of iPCI in at-risk patients to prevent an unrecognized crossover or perforation that would

likely necessitate a revision surgery. We believe that CAD/PVD, undergoing revision surgery, and sequential dilation are clinically significant. Corporal scarring was predictive of iPCI and not pPCI, and as iPCI was not found to be predictive of pPCI, we would argue that intraoperative corporal scarring should not lead to delayed corporal-related complications.

Understanding risk factors for PCI to prevent complications and ensure long-term device viability is also important from a healthcare cost prevention standpoint, as explantation can be costly and decreases rates of patient satisfaction [11]. As the relationship between improved patient outcomes and higher penile implant surgical volume is well studied [28], our study may also help identify when a potentially challenging case may need referral to a more experienced implanter.

Urologists should counsel patients with a history of CAD/PVD or those undergoing revision implantation regarding the higher risks of corporal-related complications following IPP surgery. If a patient has a history of CAD/PVD or is to undergo revision surgery, the urologist should recommend that patients should be on the lookout for signs and symptoms postoperatively, such as skin changes and signs of erosion/deformity. Intraoperatively, we suggest that single dilation be performed, when possible, with conversion to sequential dilation if needed for fibrosis. If sequential dilation is utilized, the surgeon should be cognizant of the risk of PCI and monitor postoperatively.

A strength of our study is that it is the largest database of patients undergoing IPP surgery, and we rigorously characterize PCI in a large subcohort of 152 patients. A large sample size is needed to examine these rare events of iPCI and pPCI. While our study may describe new findings regarding PCI, it is not without limitations, one of which is its retrospective nature. There is heterogeneity amongst the surgeons performing IPP surgery in this series. Due to the retrospective nature of our study and the involvement of 16 different implant surgeons, we are unable to make generalizable comparisons between surgeons regarding dilation techniques including extent of dilation. In our dataset, we were not able to account for indication for revision and thus mechanical malfunctions were included in revision cases. However, if this were to bias our results, we would expect it would be harder to detect a significant finding. Although we have previously described how sequential dilation increases complication rates in tissue without risk factors for fibrosis [20], we did not exclude these patients in the present study. Also, there may be an increased detection in complications with patients with erosions or deformities, as they may have been more likely to follow up regularly and over a longer period of time. As increased time from initial IPP placement seems to be a risk factor for cylinder extrusion [17], our study would benefit from longer-term follow-up to help identify the most refractory cases of PCI over an even longer period of time.

Conclusion

Our multicenter analysis found that CAD/PVD, being of older age, having corporal scarring, undergoing IPP revision surgery and sequential dilation were predictive risk factors for complications associated with PCI. Revision surgery was predictive of both intraoperative and postoperative adverse corporal sequelae. Recognizing risk factors for PCI preoperatively can allow for improved patient-specific counselling, possible referral to a more experienced implanter, and changes in surgical strategy to potentially promote longer-term device viability.

Disclosure of Interests

(1) Chrystal Chang, no conflict. (2) David W. Barham, no conflict. (3) Zafardjan Dalimov, no conflict. (4) Daniel Swerdloff, no conflict. (5) Martin S. Gross, consultant for Coloplast. (6) Hossein Sadeghi-Nejad, no conflict. (7) Robert Andrienne, no conflict. (8) Maxime Sempels, no conflict. (9) Tung-Chin Hsieh, no conflict. (10) Georgios Hatzichristodoulou, no conflict. (11) Muhammed Hammad, no conflict. (12) Jake Miller, no conflict. (13) Daniar Osmonov, consultant for Coloplast, Intuitive Surgical, Fidelis. (14) Aaron Lentz, speaker, consultant, preceptor for Coloplast and Boston Scientific. (15) Paul Perito, consultant for Coloplast, Boston Scientific, Urofill. (16) Alfredo Suarez-Sarmiento, no conflict. (17) James Hotaling, no conflict. (18) Kelli Gross, no conflict. (19) James M. Jones, no conflict. (20) Koenraad van Renterghem, no conflict. (21) Sung Hun Park, no conflict. (22) J. Nicholas Warner, no conflict. (23) Matthew Ziegelmann, consultant for Endo Pharma. (24) Vaibhav Modgil, no conflict. (25) Adam Jones, no conflict. (26) Ian Pearce, no conflict. (27) Arthur Burnett, consultant for Coloplast and Boston Scientific. (28) Faysal A. Yafi, consultant for Coloplast, Cynosure, Antares Pharma, Clarus Pharmaceuticals, Acerus Pharma. (29) Jay Simhan, consultant for Boston Scientific, Coloplast. I accept the responsibility for the completion of this document and attest to its validity on behalf of the co-authors. Chrystal Chang, 13 January 2024.

Sources of Funding

None.

References

- Levine LA, Becher EF, Bella AJ et al. Penile prosthesis surgery: current recommendations from the international consultation on sexual medicine. *J Sex Med* 2016; 13: 489–518
- Montague DK, Angermeier KW, Lakin MM. Penile prosthesis infections. *Int J Impot Res* 2001; 13: 326–8
- Hebert KJ, Kohler TS. Penile prosthesis infection: myths and realities. *World J Mens Health* 2019; 37: 276–87
- Gross MS, Phillips EA, Carrasquillo RJ et al. Multicenter investigation of the micro-organisms involved in penile prosthesis infection: an analysis of

- the efficacy of the AUA and EAU guidelines for penile prosthesis prophylaxis. *J Sex Med* 2017; 14: 455–63
- 5 Gross MS, Reinstatler L, Henry GD *et al.* Multicenter investigation of fungal infections of inflatable penile prostheses. *J Sex Med* 2019; 16: 1100–5
 - 6 Barham DW, Pyrgidis N, Gross MS *et al.* AUA-recommended antibiotic prophylaxis for primary penile implantation results in a higher, not lower, risk for postoperative infection: a multicenter analysis. *J Urol* 2023; 209: 399–409
 - 7 Clavell-Hernández J. Proximal extracapsular tunneling: a simple technique for the Management of Impending Cylinder Erosion and Complications Related to corporal dilation. *Sex Med* 2021; 9: 100379
 - 8 Antonini G, Busetto GM, Del Giudice F *et al.* Distal corporal anchoring stitch: a technique to address distal corporal crossovers and impending lateral extrusions of a penile prosthesis. *J Sex Med* 2017; 14: 767–73
 - 9 Minervi A, Ralph DJ, Pryor JP. Outcome of penile prosthesis implantation for treating erectile dysfunction: experience with 504 procedures. *BJU Int* 2005; 97: 129–33
 - 10 Carson CC, Mulcahy JJ, Govier FE. Efficacy, safety, and patient satisfaction outcomes of the AMS 700CX inflatable penile prosthesis: results of a long-term multicenter study. *J Urol* 2000; 164: 376–80
 - 11 Li K, Brandes ER, Chang SL *et al.* Trends in penile prosthesis implantation and analysis of predictive factors for removal. *World J Urol* 2019; 37: 639–46
 - 12 Chan EP, Punjani N, Campbell JD, Abed H, Brock G. Indications for penile prosthesis revision: lessons learned to limit technical causes of reoperation. *J Sex Med* 2019; 16: 1444–50
 - 13 Mirheydar H, Zhou T, Chang DC, Hsieh TC. Reoperation rates for penile prosthetic surgery. *J Sex Med* 2016; 13: 129–33
 - 14 Gonzalez-Cadavid NF. Mechanisms of penile fibrosis. *J Sex Med* 2009; 6 (Suppl 3): 353–62
 - 15 Miller JA, Bennett NE Jr. Comparing risk factors for adverse outcomes in virgin inflatable penile prosthesis implantations and revisions: a retrospective cohort study. *Sex Med* 2020; 8: 388–95
 - 16 Lotan Y, Roehrborn CG, McConnell JD, Hendin BN. Factors influencing the outcomes of penile prosthesis surgery at a teaching institution. *Urology* 2003; 62: 918–21
 - 17 Fuentes JL, Yi YA, Davenport MT, Bergeson RL, Ward EE, Morey AF. Long-term sequelae of inflatable penile prosthesis: clinical characteristics of patients who develop distal cylinder tip extrusion. *Transl Androl Urol* 2020; 9: 38–42
 - 18 Wynn TA. Cellular and molecular mechanisms of fibrosis. *J Pathol* 2008; 214: 199–210
 - 19 Kim J, Drury R, Morenas R, Raheem O. Pathophysiology and grayscale ultrasonography of penile corporal fibrosis. *Sex Med Rev* 2022; 10: 99–107
 - 20 Chang C, Barham DW, Dalimov Z *et al.* Single dilation in primary inflatable penile prosthesis placement is associated with fewer corporal complications than sequential dilation. *Urology* 2023; 181: 150–4
 - 21 Golan R, Patel NA, Sun T, Barbieri CE, Sedrakyan A, Kashanian JA. Impact of pelvic radiation therapy on inflatable penile prosthesis reoperation rates. *J Sex Med* 2018; 15: 1653–8
 - 22 Wilson SK, Delk JR, Mulcahy JJ, Cleves M, Salem EA. Upsizing of inflatable penile implant cylinders in patients with corporal fibrosis. *J Sex Med* 2006; 3: 736–42
 - 23 Martínez-Salamanca JI, Mueller A, Moncada I, Carballido J, Mulhall JP. Penile prosthesis surgery in patients with corporal fibrosis: a state of the art review. *J Sex Med* 2011; 8: 1880–9
 - 24 Pearlman AM, Terlecki RP. Proximal corporal perforation during penile prosthesis surgery: prevention, recognition, and review of historical and novel management strategies. *J Sex Med* 2018; 15: 1055–60
 - 25 Barham DW, Chang C, Hammad M *et al.* Delayed placement of an inflatable penile prosthesis is associated with a high complication rate in men with a history of ischemic priapism. *J Sex Med* 2023; 20: 1052–6
 - 26 Zacharakis E, Raheem AA, Freeman A *et al.* The efficacy of the T-shunt procedure and intracavernous tunneling (snake maneuver) for refractory ischemic priapism. *J Urol* 2014; 191: 164–8
 - 27 Zacharakis E, Garaffa G, Raheem AA, Christopher AN, Muneer A, Ralph DJ. Penile prosthesis insertion in patients with refractory ischaemic priapism: early vs delayed implantation. *BJU Int* 2014; 114: 576–81
 - 28 Henry GD, Kansal NS, Callaway M *et al.* Centers of excellence concept and penile prosthesis: an outcome analysis. *J Urol* 2009; 181: 1264–8

Correspondence: Jay Simhan, Fox Chase Cancer Center, Department of Urology, 333 Cottman Avenue, Philadelphia, PA 19111, USA.
e-mail: jsimhan@gmail.com

Abbreviations: CAD, coronary artery disease; ED, erectile dysfunction; IPP, inflatable penile prosthesis; IRB, Institutional Review Board; OR, odds ratio; (i)(p)PCI, (intraoperative) (postoperative) poor corporal integrity; PVD, peripheral vascular disease.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Number of penile prosthesis cases per institution.