Original Article

A global, propensity-score matched analysis of patients receiving inflatable penile prostheses and the risk of complications, infections, and re-interventions

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Background: Over 25,000 men undergo inflatable penile prosthesis (IPP) placement yearly to treat erectile dysfunction (ED). Although various comorbidities are hypothesized risk factors for complications, this remains incompletely understood. Our objective was to utilize multi-institutional data to characterize risk for reintervention, complications, and infections in patients with common suspected risk factors undergoing IPP placement.

Methods: We queried the TriNetX database for adult men who underwent IPP placement from 2003–2023 utilizing Current Procedural Terminology (CPT) codes. We examined the impact of diabetes mellitus (DM), hypertension (HTN), nicotine use, radiation therapy (RT), radical prostatectomy (RP), and urethral surgery [urethroplasty, artificial urinary sphincter (AUS), male urethral sling (MS)] on clinical outcomes defined by International Classification of Diseases 10th Revision (ICD-10) codes. Our primary outcome was need for reintervention based on CPT codes. Secondary outcomes included overall rates of complication and infection utilizing ICD-10 codes. Analytics were performed using TriNetX to calculate risk ratios (RRs) and Kaplan-Meier (KM) survival. We evaluated outcomes overall and for each individual comparison cohort using the remaining demographic variables to perform propensity score matching (PSM).

Results: In a total of 11,026 patients there was an overall 13.5% risk of undergoing at least one reintervention, with some undergoing multiple based on CPT codes. KM analysis showed a median IPP survival of 18.2 years and a projected 10- and 20-year survival probability at 70.6% and 48.4% respectively. Overall complication rate was 19.3% with a 5.2% rate of infection based on ICD codes. Patients with history of urethral surgery were at higher risk of both IPP complication and re-intervention. When further analyzing type of re-intervention, patients with a history of smoking, prior RP, and prior AUS/MS placement had higher rates of device removal. Patients with a history of diabetes were less likely to undergo IPP replacement at the time of explant. There were no identified risk factors for IPP infection.

Conclusions: This is the largest cohort of patients ever evaluated and can help guide patient selection and counseling. There was a higher rate of IPP complications than previously reported, but this may be due to different reporting parameters. History of prior urethral surgery conferred a higher risk of complications and re-intervention. These results can help guide patient selection and counseling.

Keywords: Erectile dysfunction (ED); inflatable penile prosthesis (IPP); complications; re-intervention

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Introduction

Erectile dysfunction (ED) affects at least 40 million men in the United States (1). The pathogenesis of ED is multifactorial, and most is organic in nature without a distinct identifiable cause (2). While some develop ED due to an iatrogenic cause such as radical prostatectomy (RP) or another radical pelvic surgery, others develop ED due to comorbidities such as diabetes mellitus (DM), vascular disease, Peyronie's disease (PD), and spinal cord injury (2). Treatments exist for ED range from non-invasive options such as pharmacological management and vacuum erection devices to more invasive options, such as intracorporal injections or implantation of an inflatable penile prosthesis (IPP). While most patients start with less invasive options, IPP placement remains the gold standard treatment for severe or medically refractory ED, with more than 20,000 patients treated successfully each year (2,3).

Despite advances in procedural technique and device manufacturing with antimicrobial-coated implants being introduced in the early 2000s, complications remain an inherent risk of device implantation and significantly increase patient morbidity and mortality (3). It is therefore imperative for urologists to counsel their patients on the risk of IPP failure. Unfortunately, the hypothesized risk factors for implant infection, complication, and re-intervention (removal, repair, replacement) are still incompletely understood.

Current outcomes data are mostly limited to single institutional studies from high volume centers (4), state-wide database analyses (5), and systematic literature reviews (6-11), which identified DM and immunosuppression as heightened risk factors for device infection, while the development of infection-resistant coatings was associated with lower infection rates (10). Because of this, we sought to understand the impact of various patient factors on the risk of device failure and complications by leveraging a large, multi-national research database. By broadening our sample size, we aimed to discover the impact of various patient demographic factors on IPP outcomes in a diverse population which can help guide patient selection and counseling with the aim of improving outcomes for all. Utilizing a multi-institutional data set, we sought to investigate the relationship between post-operative IPP complications (infection, re-intervention, revision) and baseline patient demographics such as the presence of DM, smoking status, and prior radiation to the pelvis. We present this article in accordance with the STROBE reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-23-412/rc).

Highlight box

Key findings

- Median inflatable penile prosthesis (IPP) device survival was 18.2 years with 10-year survival 70.6%.
- Overall device complication rate was 19.3%, re-intervention rate 13.5%, and infection rate 5.2%.
- History of prior urethral surgery (urethroplasty, artificial urinary sphincter, male urethral sling) was associated with higher complication rate and device re-intervention rate.
- History of diabetes was not associated with higher rates of complication or infection.

What is known and what is new?

- Our study found similar IPP device survival rates to prior studies, but a higher rate of complications than previously reported.
- History of urethral surgery has not been previously analyzed or reported as a risk factor, but found here to be associated with higher rates of complication and re-intervention.

What is the implication, and what should change now?

- Patients with history of prior urethral surgery should be counseled on the increased risk of complication or re-intervention. Future studies should focus on indication for re-intervention in patients with a history of urethral surgery to further guide patient counseling.

Methods

We used the TriNetX electronic health records (EHRs) data which were collected from its member healthcare organizations (HCOs) using an optimized clinical research framework (i2b2). The TriNetX EHR data contain historical data from over 100 million patients located in 69 HCOs across 19 countries (institution names were not identified but mostly within the United States). TriNetX analyzes patient data up to 20 years prior to the analysis

date [2003–2023], therefore we excluded those undergoing the index event over 20 years ago, and included data on demographics, medical diagnoses, procedures, lab values, vital signs, and medications. Given the de-identified nature of this dataset, our study was deemed exempt from Institutional Review Board approval.

Our initial cohort included all adult (greater than or equal to 18 years old) men with complete data undergoing IPP implant surgery [Current Procedural Terminology (CPT) 54401, 54405] which was set as our index event. Final analysis was run on January 26, 2023. Our primary outcome was the need for re-intervention at any point after implantation (defined by CPT 54406, 54408, 54410, 54411, 54400, 54415, 54416, 54417). Secondary outcomes included overall device complication and specifically infection defined by International Classification of Diseases 10th Revision (ICD-10) codes (T83 for all complications and T83.6 for infection). A full definition of each CPT and ICD code is included in Table S1. We assessed all outcomes as events that occurred starting day one after the index event. Potential patient risk factors, chosen based on previous literature on genitourinary implants and clinical experience, included age, body mass index (BMI), race, ethnicity, diabetes (DM, ICD E08-E13), hypertension (HTN, ICD I10-I16), smoking history (ICD Z87.891, F17.21), history of radiation therapy (RT, ICD Z92.3), history of RP (CPT 55840, 55845, 55866) history of urethroplasty (CPT 53400, 53405, 53410, 53415, 53425), and history of artificial urinary sphincter (AUS) or male urethral sling (MS) implantation (CPT 53445, 53440).

We evaluated our outcomes first on the overall IPP population. We then analyzed each risk factor individually (i.e., patients with DM against patients without DM) and utilized patient age and all other remaining variables for propensity score matching (PSM). All analyses were performed internally via TriNetX on demographic data which calculated risk ratios (RRs) and Kaplan-Meier (KM) survival after PSM was performed with significance set at P values of <0.05. TriNetX has developed their own platform so that users can perform PSM directly on their website which runs logistic regression based on user-specified variables of interest to obtain a list of propensity scores and then uses 1:1 greedy nearest-neighbor PSM to obtain the matched cohort. Covariates used for matching were a priori selected for their relationship on the outcome and included age, race, ethnicity, presence of HTN, radiation history, urethral sling history, prior urethroplasty, prostatectomy, history of renal transplant, smoking status, and presence of diabetes. Sample sizes following PSM were nearer to the smaller of each pair of cohorts. Notably, when less than 10 patients experience an outcome, TriNetX rounds the value to 10 to protect patient anonymity.

Ethical consideration

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was deemed exempt from institutional review board approval or informed consent given the de-identified nature of the registry.

Results

We identified 11,026 patients who underwent IPP implantation 20 years prior to the date of analysis. The average age at surgery was 62.2 years (±10.3) and the average age at time of analysis was 67.5 years (±10.6). The majority of patients were White (57%) and not Hispanic or Latino (71%). The overall complication rate for any procedure was 19.3%, the re-intervention rate was 13.5%, and the device infection rate was 5.2%.

Cohort demographics are included within *Table 1*, arranged before and after PSM. We found no significant effects on reintervention, complication or infection outcome from the effect of diabetes, HTN, smoking status, RT or RP. Those with history of prior urethroplasty had a higher rate of complications (30.3% *vs.* 11.1%, P<0.01, RR =2.7) and re-intervention (22.2% *vs.* 10.1%, P=0.02, RR =2.2). History of prior AUS implantation or MS placement was also significantly associated with a higher rate of complications (30.8% *vs.* 18.3%, P<0.01, RR =1.7) and device re-intervention (18.2% *vs.* 13.6%, P=0.02, RR =1.3). There were no significant risk factors identified for the outcome of device infection.

Rates of IPP re-intervention are reported in further detail within *Table 2*, examining sub-categories of re-intervention including device removal (CPT 55406, 54415), repair (CPT 54408), removal with replacement (CPT 54410), and replacement through an infected field (CPT 54411, 54417). The crude rate of removal was 3.6%, repair 2.9%, removal with replacement through a sterile field 7.7%, and replacement through an infected field 1.5%, with some patients needing multiple repeat interventions. When analyzed by CPT code, various demographic factors showed association with increased rate of re-intervention. HTN (3.6% *vs.* 3.0%, P=0.02, RR =1.2), history of smoking

Table 1 Risk of re-intervention, complication, or infection following inflatable penile prosthesis implantation

Variables	N before PSM	N after PSM	% re-intervention (CPT codes 54406, 54408, 54410, 54411, 54400, 54415, 54416, 54417)	% complication (ICD codes T83)	% infection (ICD code T83.6)
Total population	11,026	–	13.5	19.3	5.2
Diabetes					
Yes	3,972	3,403	12.2	19.5	5.5
No	7,054	3,403	13.5	18.8	5.1
Values	–	–	RR =0.9, P=0.1	RR =1.0, P=0.44	RR =1.1, P=0.52
HTN					
Yes	6,660	3,478	12.7	18.9	5.3
No	4,366	3,478	13.7	17.8	4.4
Values	–	–	RR =0.92, P=0.19	RR =1.1, P=0.25	RR =1.20, P=0.08
Smoking					
Yes	2,626	2,604	12.1	19.6	5.5
No	8,400	2,604	12.8	18.5	5.3
Values	–	–	RR =0.95, P=0.48	RR =1.1, P=0.32	RR =1.1, P=0.67
RT					
Yes	430	426	12.4	22.5	4.7
No	10,596	426	10.6	19.5	5.4
Values	–	–	RR =1.2, P=0.39	RR =1.2, P=0.27	RR =0.87, P=0.64
RP					
Yes	1,030	973	15.0	21.6	5.2
No	9,996	973	12.5	18.3	4.5
Values	–	–	RR =1.2, P=0.11	RR =1.2, P=0.07	RR =0.1.2, P=0.46
Urethroplasty					
Yes	104	99	22.2	30.3	10.1
No	10,922	99	10.1	11.1	10.1
Values	–	–	RR =2.2, P=0.02	RR =2.7, P<0.01	RR =1.0, P>0.99
AUS/MS					
Yes	688	671	18.2	30.8	7.5
No	10,338	671	13.6	18.3	5.1
Values	–	–	RR =1.3, P=0.02	RR =1.7, P<0.01	RR =1.5, P=0.07
White					
Yes	6,316	4,379	14.3	19.3	5.4
No	4,710	4,379	13.0	19.8	5.6
Values			RR =1.1, P=0.08	RR =1.0 P=0.50	RR =0.97, P=0.67

PSM, propensity score matching; CPT, Current Procedural Terminology; ICD, International Classification of Diseases; HTN, hypertension; RR, risk ratio; RT, radiation therapy; RP, radical prostatectomy; AUS, artificial urinary sphincter; MS, male urethral sling.

Table 2 Inflatable penile prosthesis re-intervention, broken down into removal, removal and replacement (with or without an infected field) and repair

Variables	N before PSM	N after PSM	% removal (CPT code 54406, 54415)	% removal and replacement (CPT code 54410)	% removal and replacement through an infected field (CPT code 54411, 54417)	% repair (CPT code 54408)
Total population	11,026	–	3.66	7.69	1.54	2.88
Diabetes						
Yes	3,972	3,403	3.7	6.0	1.4	2.5
No	7,054	3,403	3.3	7.5	1.7	2.8
Values	–	–	RR =1.1, P=0.32	RR =0.82, P=0.02	RR =0.78, P=0.2	RR =0.9, P=0.5
HTN						
Yes	6,660	3,478	3.6	6.7	1.8	2.6
No	4,366	3,478	3.0	7.2	1.3	3.0
Values	–	–	RR =1.2, P=0.02	RR =0.93, P=0.42	RR =1.4, P=0.1	RR =0.86, P=0.27
Smoking						
Yes	2,626	2,604	4.5	5.3	1.2	3.0
No	8,400	2,604	3.2	6.5	1.6	3.0
Values	–	–	RR =1.4, P=0.02	RR =0.82, P=0.08	RR =0.73, P=0.19	RR =1.0, P>0.99
RT						
Yes	430	426	4.0	5.9	2.3	2.8
No	10,596	426	3.1	5.6	2.3	2.3
Values	–	–	RR =1.3, P=0.46	RR =1.0, P=0.88	RR =1.0, P>0.99	RR =1.2, P=0.67
RP						
Yes	1,030	973	4.9	6.7	1.3	3.5
No	9,996	973	3.0	5.9	1.3	3.1
Values	–	–	RR =1.7, P=0.03	RR =1.1, P=0.45	RR =1.0, P>0.99	RR =1.1, P=0.61
Urethroplasty						
Yes	104	99	11.1	10.1	10.1	10.1
No	10,922	99	10.1	10.1	10.1	10.1
Values	–	–	RR =1.1, P=0.8	RR =1.0, P>0.99	RR =1.0, P>0.99	RR =1.0, P>0.99
AUS/MS						
Yes	688	671	7.8	8.0	1.5	4.2
No	10,338	671	3.9	6.6	1.9	3.6
Values	–	–	RR =2.0, P<0.01	RR =1.2, P=0.29	RR =0.8, P=0.5	RR =1.2, P=0.57
White						
Yes	6,316	4,379	4.1	7.1	1.6	3.2
No	4,710	4,379	3.4	7.2	1.5	2.3
Values	–	–	RR =1.2, P=0.10	RR =0.99, P=0.90	RR =1.1, P=0.67	RR =1.4, P=0.02

PSM, propensity score matching; CPT, Current Procedural Terminology; RR, risk ratio; HTN, hypertension; RT, radiation therapy; RP, radical prostatectomy; AUS, artificial urinary sphincter; MS, male urethral sling.

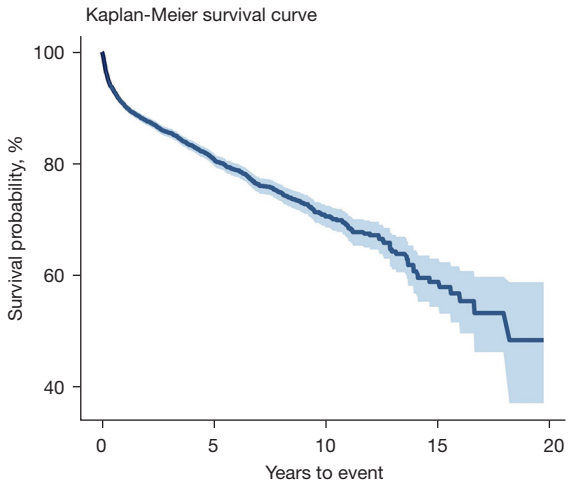

Figure 1 Inflatable penile prosthesis device Kaplan-Meier survival curve (no need for re-intervention).

(4.5% *vs.* 3.2%, P=0.02, RR =1.4), prior RP (4.9% *vs.* 3.0%, P=0.03, RR =1.7), and prior AUS/MS placement (7.8% *vs.* 3.9%, P<0.01, RR =2.0) were all associated with a higher rate of device removal. Patients with diabetes were less likely to undergo replacement of their device at time of explant than those without diabetes (7.5% *vs.* 6.0%, P=0.02, RR =0.82). White patients had a higher rate of device repair compared to non-White patients (3.2% *vs.* 2.3%, P=0.02, RR =1.4). None of the subgroups showed a significantly increased risk for removal and replacement through an infected field.

Simple survival analysis via the KM method showed a median IPP survival (freedom from re-intervention identified CPT codes for operative re-intervention) of 18.2 years, with an estimated 10- and 20-year survival probability at 70.6% and 48.4% respectively and their estimated 95% confidence intervals (*Figure 1*).

Discussion

Our aging sexually active population with increasing chronic health issues makes examining the impact of comorbidities on IPP implantation more important than ever. Additionally, the literature lacks a consensus and offers weak guidance for counseling related to IPP device survival, reinterventions, complications, and infection. This led us to perform a large-scale retrospective investigation of patient IPP implant data from a global network spanning over 20 years, with the hopes of improving our knowledge of patient counseling and helping guide future prospective studies. To our knowledge, this is the largest study to date looking at various risk factors for IPP complications, infections, and reinterventions.

Consistent with the literature, the TriNetX Kaplan-Meier 20-year survival in the TriNetX overall cohort was 48.4% for reinterventions (12). Additionally, this data showed complications for the overall cohort at 19.3%, well above previous reports. Recent studies show varying rates of complications as high as 5% (13,14) with a substantial decrease since the introduction of antimicrobial-coated materials in the early 2000s (3,7). The difference in complication rate between our study and others likely comes from the method of classification. In this study, using a broad ICD-10 code allowed us to capture a wide range of complications. Additionally, our study encompasses data from a large variety of institutions and surgeons whereas the majority of the prior data come from high volume single institution studies and meta-analyses (4,6). Prior studies have shown that high volume surgeons have fewer iatrogenic failures and prosthesis removal procedures compared with low-volume surgeons (15-18). Capturing lower volume implanters in our study may play a role in the overall higher complication rate compared to previous studies. Given these findings, the clinical implication of a higher than reported rate of adverse outcomes for patients with these selected features cannot be excluded.

Interestingly, out of all the patient risk factors evaluated, only a history of prior urethral surgery (urethroplasty, AUS, MS) was associated with a higher rate of complications and overall need for re-intervention. To our knowledge, this has not been analyzed as a possible risk factor in prior studies. We hypothesize that this may be due to an increased risk of urethral injury due to prior urethral manipulation and scar tissue and an increased risk of future urethral erosion due to poorer urethral tissue quality. Despite no studies specifically looking at prior urethral surgery as a risk factor for IPP explantation, there was a retrospective study published in 2019 looking at reoperation outcomes in men who underwent dual implantation of an IPP and AUS compared to each individually, which showed a higher likelihood of IPP reoperation at 1 and 3 years in those who underwent dual implantation (19). Other studies have shown a higher risk for infection with concomitant procedures such as simultaneous AUS insertion or repair of urethral perforation (20). We believe this is a novel finding that may raise caution or call for more thorough pre-operative counseling in patients with prior urethral interventions. As urethral tissue quality may be compromised, future studies

looking at indications for reintervention in patients with history of prior urethral surgery could help further guide patient counseling and provide more concrete data.

In an attempt to further understand risks for re-intervention, we evaluated device removal, repair, replacement, and replacement through an infected field individually. Overall, we found a higher incidence of device removal and replacement through a sterile field and repair alone compared with device removal, infection, and reimplantation through an infected field. Thus, it is likely that patients undergo re-intervention more commonly for mechanical failure than infection, consistent with clinical practice. When comparing the different subgroups, device removal alone was associated with the most risk factors, with history of smoking, prior RP, and prior AUS/MS placement all associated with an increased risk of device removal. It is likely that those undergoing IPP removal without replacement are having this done due to infection or device erosion. History of smoking and prior AUS/MS placement may place patients at a higher risk for poor tissue quality and healing and in turn place them at higher risk of infection or erosion. In regard to history of RP, this population has a higher chance of having stress urinary incontinence and thus a higher likelihood of having prior AUS or MS placement which was also found to be a risk factor for device removal. When looking at need for IPP repair alone, only White race was predictive for need for device repair. Although the majority of published IPP data focus on infection risk, a cross-sectional analysis published by Li *et al.* in June 2018 focused on predictive factors for IPP removal and notably reported non-black race as a predictive factor for explantation (15).

Of the comorbidities analyzed, DM has been the most disputed potential risk factor for complications or infections with IPP implants and there is significant discrepancy in the literature regarding DM as a risk factor. This is an important consideration since in our overall cohort 36% had a diagnosis of DM prior to IPP implantation. A large meta-analysis reported similar rates of infection in those with DM and those without in recent studies8. Alternatively, a systemic review of the literature published by Dick et. al. in October 2021 described two studies that reported a significant difference in rate of infection when compared with mean hemoglobin A1c (HbA1c), whereas two other studies showed no significant difference (6). In comparison, both an analysis of a large statewide database published by Lipsky *et al.* in March 2019 and a meta-analysis published by Gon *et al.* in March 2021 reported a higher risk of IPP infection in those with DM (5,7). Our dataset showed no increased risk for those with DM related to overall reintervention, complications, or infections. However, we did find that patients without DM were more likely to undergo reimplantation at the time of device explanation. This may be due to the fear of increased risk of infection with reimplantation at the time of explant as well as the fear of increased infection in those with diabetes given conflicting data in the literature. Limitations to our study include a lack of A1C data for those with DM. Given discrepancies across the literature, and the lack of a clear risk in this larger, multicenter study, a prospective study would help with more definitive guidance. Additionally, future studies would be improved with the inclusion of A1C or diabetes control stratification.

For those receiving an IPP, HTN is another comorbidity under controversy. While discussed less frequently than DM in the literature, HTN was recently cited as a risk factor for infection after IPP based on a single institution retrospective chart review (11). This is important, as in the TriNetX network, 60% of patients undergoing IPP implantation carried a diagnosis of HTN preoperatively. However, the data from the TriNetX network showed no increased risk of reintervention, complication, or infection for those with HTN.

Our study based on TriNetX network data has important limitations. First, it contains issues inherent to "big data" networks and retrospective analyses in that the investigators do not have control over the data collection process. Second, the data were supplied by high-volume medical centers, which limits generalizability. The data relied on charting with correct and complete use of ICD and CPT codes, a process prone to input errors. Additionally, the data did not capture patients lost to follow-up or reestablishing care at an organization outside of the provider systems in TriNetX network. Another limitation is that the study does not include the degree of disease for the comorbidities as potential risk factors. It does not differentiate for example between well-controlled *vs.* poorly controlled diabetes or HTN. Finally, propensity matching analysis lowers the sample size of each of our cohorts and thus reducing the power of the study compared to multivariate regression analysis. However, considering our sizable number of matched samples, the ability to isolate one variable at a time via propensity matching was worth this trade-off. It is also possible there is overlap between device complication and infection, such as if the device erodes. One surgeon may describe this as an infection, another may describe as a

complication, and a third may describe as both, without an ability to distinguish between these scenarios based on the data in TriNetX. These factors may limit the applicability of our results. Importantly, our work was not designed to answer causal questions. Our study is retrospective in nature and cannot resolve the threat of confounding from an unknown causal variable. However, despite these limitations, we were able to provide the largest series of IPP patients to our knowledge.

Given the insights provided by this large network of data and the inconsistencies throughout the literature, this can help guide patient discussions related to decisions and expectations with IPP implantation. However, like other investigations into this topic, this study is not without potential data collection limitations. Definitive guidance related to the comorbidities studied here would benefit from well-controlled prospective studies.

Conclusions

In this multi-institutional analysis of complications after IPP surgery, we found higher rates of IPP complications than previously reported, possibly related to our use of a broader definition with a wider variety of ICD codes. We found device reintervention rates to be similar to previous literature at 48.4% at 20 years, and similarly, infections were consistent with previous literature at 5.3%. Patients with a personal history of urethral surgery (urethroplasty, AUS, MS) had higher rates of reintervention, possibly due to an increased risk of urethral injury from scar tissue or poorer urethral tissue quality. Future studies looking at specific indications for reintervention in this population can guide further patient counseling and anticipate likelihood of device failure or need for further intervention. Importantly, we found that patients with diabetes or HTN did not have higher rates of complications, infections, or reinterventions, in opposition to the existing literature. Given these discrepancies, we advocate for further prospective studies to help with optimal patient IPP guidance and counseling.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was deemed exempt from institutional review board (IRB) approval or informed consent given the de-identified nature of the registry.

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