


Primary versus revision implant for inflatable penile prosthesis: A propensity score-matched comparison

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Abstract

Inflatable penile prosthesis (IPP) provides excellent outcomes after virgin implants. However, few data on IPP after revision surgery are available.

This study aimed at comparing the outcomes of IPP in patients undergoing primary or revision implant surgery. Patients who underwent revision implant surgery (Group 1) between 2013 and 2020 were identified. Overall, 20 patients (Group 1) could be matched with a contemporary matched pair cohort of surgery-naive patients (Group 2) in a 1:1 ratio. Patients in Group 2 had a significantly shorter operative time [median (IQR): 84 (65–97) vs. 65 (51–75) min; $p = .01$] and lower rate of overall complications (25% vs. 10%; $p = .01$). Of note, mean (*SD*) scores for the Quality of Life and Sexuality with Penile Prosthesis (QoLSPP) questionnaire demonstrated high satisfaction and IPP efficacy in both Groups 1 and 2: functional domain [3.9 (1.0) vs. 4.0 (1.2); $p = .4$], personal [3.9 (1.1) vs. 4.0 (1.1); $p = .3$], relational [3.8 (1.3) vs. 3.9 (1.1); $p = .5$] and social [3.9 (1.1) vs. 4.0 (1.2); $p = .2$].

These results suggest that in experienced hands, IPP offers high satisfaction to both patients and partners even in the setting of revision implant. However, it is mandatory to inform those patients about the increased risk of perioperative complications.

KEYWORDS

erectile dysfunction, inflatable penile prosthesis, revision implant surgery, virgin primary implant

1 | INTRODUCTION

Inflatable penile prosthesis (IPP) implantation represents the gold standard treatment in patients with erectile dysfunction (ED) refractory to conventional medical therapy or who prefer a permanent solution (Hatzimouratidis et al., 2018; Levine et al., 2016). To date, there is an abundance of the literature demonstrating that IPP offers high satisfaction levels to both men and partners with a low risk

of complications (Akakpo et al., 2017; Barton et al., 2019). However, results cannot be generalisable across multiple subpopulations of ED patients. Although IPP provides excellent outcomes when performed in selected cases (primary implantation, no other factors such as diabetes, immunosuppression or concomitant surgeries), anatomic variation (e.g., fibrotic corpora after previous penile surgery) and concurrent comorbidities can give rise to suboptimal outcomes of which both surgeons and patients should be cognizant.

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Nevertheless, IPP is increasingly being offered to these higher risk populations, particularly patients undergoing revision implant surgery. In fact, in daily clinical practice, it is not uncommon for men to receive IPP after prior penile implant (Akakpo et al., 2017; Barton et al., 2019). That is because device failure, infectious and other complications do occur, requiring reoperation and prosthesis replacement (Kava et al., 2007).

Although several studies have reported the outcomes of IPP so far, benefits and consequences of IPP after revision implant surgery have not yet been reported fully (Akakpo et al., 2017; Barton et al., 2019; Hatzimouratidis et al., 2018; Kava et al., 2007; Levine et al., 2016). The aim of this study was to compare the outcomes of IPP in patients with or without primary implant at our institution.

2 | METHODS AND METHODS

2.1 | Data source, study design and population

Data of implanted patients were extracted from our prospectively maintained password-secured database. Patients with urinary incontinence, previous urethral surgery and lack of follow-up data were excluded from the study. Patients with prior implant surgery who underwent IPP implantation between 2013 and 2020 were identified and compared with a contemporary matched pair cohort of patients undergoing primary implant surgery.

2.2 | Surgical Technique

All procedures were performed by an experienced single surgeon with the minimally invasive infrapubic approach (Perito, 2008; Perito & Wilson, 2013; Wilson & Delk, 1994). Hospital ethics committee approval was obtained according the ethical principles of the Declaration of Helsinki. Informed consent was obtained from all patients to participate in the study.

According to recent guidelines, accurate alcohol-based intra-operative scrub and antibiotic prophylaxis were used to prevent perioperative infections (Levine et al., 2016; Wolf et al., 2008). A Foley catheter was inserted before surgery and then removed at discharge. An AMS 700 LGX (AMS) three-piece IPP was implanted in all patients, except those with significant fibrosis requiring narrower cylinders (AMS 700™ CXR). In cases where a supplementary surgical access for reservoir placement was necessary because of post-surgical adhesions, it was placed in the subcutaneous space, when the patient's anatomy allowed, or between the transversalis fascia and rectus abdominis muscle according to previously published techniques (Karpman et al., 2013; Perito & Wilson, 2011; Smaldone et al., 2006;).

A scrotal drainage was left in place and removed on the 1st post-operative day. Patients were instructed to wait 4 weeks after the discharge (on the 1st post-operative day) before using the IPP (Knoll et al., 2009).

2.3 | Measurements

Clinical and surgical data were recorded. Validated self-administered questionnaires were employed to evaluate post-prosthesis sexual life at 6 months follow-up. At this time of follow-up, patients are expected to have an adequate expertise in using the prosthesis, and post-operative complaints including pain or swelling are generally resolved (Tefilli et al., 1998).

In particular, questionnaires included are as follows: Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) (Althof et al., 1999), International Index of Erectile Function (IIEF-SF) (Rhoden et al., 2002), Quality of Life and Sexuality with Penile Prosthesis (QoLSPP) (Caraceni & Utizi, 2014). Specifically, as the QoLSPP was developed by Caraceni et al. in 2014, patients operated prior to this date were contacted and asked to fill the questionnaire during the early 2015.

Complications were evaluated using the modified Clavien classification (Dindo et al., 2004). All patients had a 12 months minimum follow-up.

2.4 | Statistical analysis

Propensity score matching was carried out to reduce the effect of inherent differences between the groups. The cohorts were balanced according to age, ED duration, BMI, Charlson Comorbidity Index score, socioeconomic status, diabetes presence and follow-up length.

Categorical variables are reported as frequency and percentage, and continuous variables as median and interquartile range (IQR) or mean and standard deviation (SD). The Mann-Whitney and chi-square tests (or the Fisher exact test) were used to compare continuous and categorical variables among groups. Statistical analysis was performed using SPSS v.23.0 (IBM). All reported *p* values are two-sided, and statistical significance was set at $p < .05$.

3 | RESULTS

Of all 87 included patients, 20 with revision implant surgery (Group 1) could be matched with primary implant patients (Group 2) in a 1:1 ratio. In Group 1, 12 patients underwent revision due to infection and 7 due to malfunction, and 1 had a malleable prosthesis replacement with IPP. Specifically, 6 patients underwent salvage procedure by applying Mulcahy's approach (Mulcahy, 2000a).

Patient characteristics are summarised in Table 1. In Group 1, unilateral proximal corporal perforation was observed in 1 patient (5%) intra-operatively. Concerning post-operative complications, minor (Clavien grade ≤ 2) events were represented by 1 (5%) grade 1 (decreased penile sensitivity) in Group 1 and 1 (5%) Grade 2 (diffused penile pain) in Group 2. Major (Clavien grade ≥ 3) complications included 1 infection (5%) and 1 erosion (5%) in Group 1, leading to implant removal 10 and 18 months after surgery, respectively. In

TABLE 1 Baseline and perioperative characteristics of patients with (Group 1) or without (Group 2) prior implant surgery

	Group 1 (n = 20)	Group 2 (n = 20)	p
Age, years, median (IQR)	63 (61–72)	64 (60–71)	.5
BMI*, kg/m ² , median (IQR)	27 (23–29)	27 (25–30)	.4
Charlson Comorbidity Index, n (%)			.2
0	6 (30)	7 (35)	
1	6 (30)	5 (25)	
2	5 (25)	5 (25)	
≥3	3 (15)	3 (15)	
ED duration, months, median (IQR)	31 (16–45)	32 (14–46)	.2
Socio-economic status, n (%)			.3
High	11 (55)	10 (50)	
Low	9 (45)	10 (50)	
Diabetes mellitus, n (%)	4 (20)	5 (25)	.3
Previous pelvic surgery, n (%)			.1
For prostate cancer	4 (20)	6 (30)	
For bladder cancer	1 (5)	1 (5)	
Previous pelvic radiation therapy	2 (10)	2 (10)	.6
Operative time, min, median (IQR)	84 (65–97)	65 (51–75)	.01
Follow-up length, mo, median (IQR)	38 (28–51)	37 (29–43)	.5
Complications, n (%)	5 (25)	2 (10)	.01
Decreased penile sensitivity	1 (5)	–	
Penile pain	–	1 (5)	
Corporal perforation	1 (5)	–	
Infection	1 (5)	–	
Erosion	1 (5)	–	
Device malfunction	1 (5)	1 (5)	

*Body mass index.

both groups, a device malfunction occurred in 1 patient and was treated with implant replacement after 22 (Group 1) and 38 (Group 2) months, respectively.

No patients had complications graded higher than 3 within Clavien Scale score. One patient (5%) in both Groups 1 and 2 ($p = .9$) showed a prolonged length of stay (>1 day). Details on IPP utilisation and perceived anatomical variations are shown in Table 2. Overall, no differences were observed concerning both the return

TABLE 2 Use of the device and perceived anatomical variations in patients with (Group 1) or without (Group 2) prior implant surgery

	Group 1 (n = 20)	Group 2 (n = 20)	p
First activation after surgery, n (%)			.2
<4 weeks	1 (5)	4 (20)	
>4 but <6 weeks	8 (40)	7 (35)	
6 or more weeks	11 (55)	9 (45)	
Frequency of device utilisation, n (%)			.3
On daily basis	1 (5)	2 (10)	
More than once a week	6 (30)	8 (40)	
Once a week	9 (45)	8 (40)	
Once a month or less	4 (20)	2 (10)	
Self-estimated variations of the penis, n (%)			
In length			.6
No variation	7 (35)	6 (30)	
Gained	2 (10)	4 (20)	
Lost	11 (55)	10 (50)	
In circumference			.2
No variation	13 (65)	15 (75)	
Gained	3 (15)	2 (10)	
Lost	4 (20)	3 (15)	

to sexual activity and device utilisation (both $p > .2$). However, although patients were encouraged to activate IPP after 4 weeks post-operatively, 4 (20%) men in Group 2 were able to resume sexual activity earlier, whereas in Group 1 only one (5%) patient was able to restart prior to the 4th post-operative week ($p = .01$). Specifically, sexual activity was resumed by the majority of patients after 6 weeks [11 (55%) and 9 (45%) patients in Groups 1 and 2, respectively; $p = .1$]. A similar frequency of IPP activation was observed among the groups ($p = .2$), with most men (80% and 90%, respectively; $p = .2$) using the device at least once a week.

About perceived changes in the penis size, a self-estimated variation in the penile length was observed in 13 (65%) and 14 (70%) patients in Groups 1 and 2 ($p = .6$). Conversely, changes in the penis circumference were reported only in 7 (35%) patients in Group 1 and 5 (25%) patients in Group 2 ($p = .2$) (Table 2).

In both groups, a high level of treatment satisfaction was observed, with a mean (SD) score of 73.9 (21.7) and 74.1 (21.4) according to the EDITS questionnaire, respectively ($p = .6$). Interestingly, a high overall partner's satisfaction was also observed (Table 3). Similarly, favourable results among Groups 1 and 2 were demonstrated by the QoLSPP scores: functional domain [3.9 (1.0) vs. 4.0 (1.2); $p = .4$], personal [3.9 (1.1) vs. 4.0 (1.1); $p = .3$], relational [3.8 (1.3) vs. 3.9 (1.1); $p = .5$] and social [3.9 (1.1) vs. 4.0 (1.2); $p = .2$] (Table 3).

	Group 1 (n = 20)	Group 2 (n = 20)	p
QoLSPP domain			
Functional, mean (SD)			.4
Prosthesis adequacy	4.0 (1.1)	4.1 (1.0)	
Ease/simplicity of use	3.9 (1.2)	4.1 (0.9)	
Duration of implant	4.0 (1.3)	4.1 (1.3)	
Penile rigidity	3.5 (1.4)	3.3 (1.2)	
Fulfilment of expectations	3.8 (1.6)	3.9 (1.3)	
Personal, mean (SD)			.3
Sexual desire	3.8 (1.2)	3.9 (1.1)	
Liveliness and wit	4.2 (1.1)	4.2 (1.2)	
Security	4.1 (1.3)	4.2 (0.9)	
Sexual experience	3.9 (1.3)	4.0 (0.8)	
Relational, mean (SD)			0.5
Well-being of the couple	3.9 (1.2)	4.0 (1.1)	
Frequency of orgasms	3.7 (1.4)	3.8 (1.2)	
Frequency of sexual intercourse	3.8 (1.3)	3.9 (1.3)	
Partner satisfaction	3.4 (1.5)	3.4 (1.1)	
Social, mean (SD)			0.2
Daily life	3.9 (1.1)	4.0 (1.3)	
General well-being	4.0 (0.8)	3.9 (1.0)	
Feeling like others	3.9 (1.1)	4.0 (1.3)	
EDITS score, mean (SD)			
Patient	73.9 (21.7)	74.1 (21.4)	0.6
Partner	72.9 (23.9)	73.0 (22.0)	0.5
IIEF-5 score, mean (SD)	20.1 (6.0)	20.2 (5.9)	0.7

Abbreviations: EDITS, Erectile Dysfunction Inventory of Treatment Satisfaction; IIEF, International Index of Erectile Function; QoLSPP, Quality of Life and Sexuality with Penile Prosthesis.

4 | DISCUSSION

IPP implantation offers excellent results when performed in selected patients (Akakpo et al., 2017; Barton et al., 2019; Hatzimouratidis et al., 2018; Kava et al., 2007; Levine et al., 2016). In contrast, in high-risk populations, such as men with corporal fibrosis or those undergoing revision procedures, it might become a surgical challenge with suboptimal outcomes (Hatzimouratidis et al., 2018; Henry, Donatucci, et al., 2012; Levine et al., 2016; Martinez-Salamanca et al., 2011).

Currently, sparse data exist on the benefits, risks and consequences in high-risk men undergoing revision surgery after IPP implant. Specifically, previous reports have included perioperative results and complications (Carvajal et al., 2020; Chung, 2020; Scherzer et al., 2019). Of further clinical relevance, no study has investigated functional outcomes and level of satisfaction after IPP insertion in this surgical population so far. Notably, even if the IPP is successfully placed without any complications, implant results may not fulfil post-surgical expectations. Therefore, although surgeons

consider the implantation a surgical victory, patients remain dissatisfied, which severely affects men functionally and psychologically. In addition, most of the previous studies reporting on the IPP implant have used nonvalidated tools to assess functional outcomes and patient satisfaction after surgery. Specifically, they were mostly assessed by tools such as the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) or the International Index of Erectile Function (IIEF) that have been designed and validated to assess treatment options, other than the IPP. Therefore, they result in inaccurate assessments of sexual satisfaction and patient quality of life after IPP placement.

The present study represents the first report comparing the safety and efficacy of IPP implantation in patients undergoing primary or revision implant surgery. In our experience, IPP implantation confirmed to be feasible also in the setting of revision surgery (Carvajal et al., 2020; Chung, 2020; Scherzer et al., 2019). However, as expected, re-operative cases showed a longer operative time ($p = .01$), corroborating what emerges from the available literature (Carvajal et al., 2020; Chung, 2020; Scherzer et al., 2019).

TABLE 3 Efficacy of IPP and satisfaction level in patients with (Group 1) and without (Group 2) prior implant surgery

Despite several technical refinements and improvement in device reliability and durability, IPP implantation remains associated with potential significant morbidity (Carvajal et al., 2020; Chung, 2020; Scherzer et al., 2019). Also, primary implantation is associated with lower complication rates (OR 0.35 95% CI 0.25–0.49 I² = 19%) than the revision procedure (Carvajal et al., 2020). Specifically, available studies show infection rates after revision surgery ranging from 8% to 12% (Carvajal et al., 2020; Chung, 2020; Henry, Donatucci, et al., 2012; Martinez-Salamanca et al., 2011; Scherzer et al., 2019), and the risk is positively correlated with the operative time (Carvajal et al., 2020).

According to previous reports, in the present series, surgery-naïve patients had a lower complication rate ($p = .01$), together with shorter operative time ($p = .01$). Overall, our complication rates appear to be higher than other series (Carvajal et al., 2020; Chung, 2020; Henry, Donatucci, et al., 2012). However, in our study, we employed a strict methodology for collecting data that might partly explain the reported higher rates of complications. Specifically, first, complications were evaluated both during the perioperative phase and the entire follow-up length. Second, any deviation from the perioperative standard was classified as a complication, including the events that required no treatment. In particular, our patients undergoing nonprimary surgery had a higher rate of major complications including corporal perforation, infection and erosion ($p = .01$). Indeed, as previously demonstrated, they represent relatively common complications in the setting of fibrotic corpora or revision surgery (Carvajal et al., 2020; Chung, 2020; Henry, Donatucci, et al., 2012; Mooreville et al., 1999; Scherzer et al., 2019;). Mooreville et al. (1999) reported intra- and post-operative perforations in 31% and 25% of patients after IPP placements into fibrotic corpora, respectively. More recently, Henry, Donatucci, et al. (2012) observed that infection or impending extrusion/erosion occurs in 5.7% of cases with revised prostheses: if the IPP is replaced, it develops in 5% of patients, as compared with 9.1% when it is not replaced.

In our study, patients were discouraged to use the IPP prior to 4 weeks after surgery. Nonetheless, some patients used the IPP earlier (Table 2). In particular, a quicker return to sexual function was observed in men with primary implant ($p = .01$). Otherwise, Henry, Brinkman, et al. (2012) and Goldstein et al. (1997) reported that 41% and 25% of patients resumed sexual activity prior to the 4th post-operative week, respectively. This figure might be due to a wider adherence to physician's prescriptions by the patients. Also, it could be also affected by the lower number of patients in our study.

Overall, levels of satisfaction after IPP implant are related to several factors, including the cosmetic outcome, perioperative complications, ease of use and partner acceptance (Carvalho et al., 2015; Hatzimouratidis et al., 2018).

In our study, the EDITS (Althof et al., 1999) and IIEF (Rhoden et al., 2002) questionnaires were administered 6 months post-operatively to assess the satisfaction level in both patients and partners (Grande et al., 2018). In our experience, both patients with or without primary implantation experienced a high level of

general satisfaction, also when considering the domain of sexual intercourse frequency (Vakalopoulos et al., 2013). Specifically, according to Vakalopoulos findings, in both groups, satisfaction levels in partners were closely related to patient ones (Vakalopoulos et al., 2013).

However, the use of questionnaires not developed for IPP patients leads to improper estimation of outcomes after surgery. To overcome this bias, in the present study, we employed the QoLSPP questionnaire (Caraceni & Utizi, 2014). Our findings confirm that IPP implantation has a positive impact both on patients and partners QoL as demonstrated by the perceived fulfilment of expectations, satisfaction with the implant and overall well-being ($p > .1$ for all) among the groups.

Among determinants of post-surgical satisfaction, the perception of penile shortening represents the main cause of dissatisfaction after implant. However, it is unclear why the IPP efficacy is significantly lower in those patients (Akakpo et al., 2017). According to Mulcahy (2000a), it might be due to decreased penile sensitivity and ejaculatory disorders. Although altered sensitivity might negatively affect the erectile function, the role of ejaculatory problems remains unclear (Akakpo et al., 2017).

In light of this, Mulcahy first described the salvage procedure to avoid difficult revision surgery and penile shortening (Mulcahy, 2000a). This approach has shown success as high as 82% (Mulcahy, 2000b). Specifically, in the present study, we observed similar rates of penile shortening in patients with or without virgin primary implant ($p = .6$).

Our study has some limitations. First, the analysis is retrospective. Second, all procedures were performed by an experienced single surgeon, and thus, our results cannot be translated to all patients receiving IPP. Third, our analysis includes a relatively small number of cases.

In conclusion, in experienced hands IPP placement confirms to be an effective treatment option for erectile dysfunction, showing high satisfaction levels both in patients and partners even after revision implant surgery. However, it is mandatory to adequately inform and warn those patients about the increased risk of complications after surgery.

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CONFLICTS OF INTEREST

None of the contributing authors have any conflict of interest, including specific personal and financial interests or relationships and affiliations, relevant to the subject matter or materials discussed in the manuscript.

AUTHORS' CONTRIBUTIONS

Protocol/project development (GBDP, AL, AS, CC), data collection or management (GDL, AEM, AL, MM, GA, IDG, SS), data analysis (GBDP, AS), manuscript writing/editing (GBDP, AS, PG, EDB, SS, MM), approval of the submitted and final versions (all).

ETHICS APPROVAL

Hospital ethics committee approval was obtained, and it conforms to the provisions of the Declaration of Helsinki.

CONSENT TO PARTICIPATE

All patients gave written informed consent to have their data collected in our institutional database and used for present and future studies.

CONSENT FOR PUBLICATION

All patients gave written informed consent to have their data published in the present and future studies.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author, upon reasonable request. The data are not publicly available due to privacy or ethical restrictions.

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