

## Distinguishing Failure to Cure From Complication After Penile Prosthesis Implantation

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### ABSTRACT

**Background:** A successful penile prosthesis implantation (PPI) surgery can be defined by outcomes beyond the absence of complications.

**Aim:** To introduce the concept of failure to cure (FTC) in the context of PPI to more accurately gauge post-operative outcomes after PPI.

**Methods:** Consecutive patients from our sexual function registry who underwent PPI from January 2011 to December 2013 were analyzed. Demographics, previous treatment of erectile dysfunction, comorbidities, social history, postoperative problems (POPs), and surgical outcomes were tabulated. Patients completed the International Index of Erectile Function (IIEF) and the Erectile Dysfunction Inventory of Treatment Satisfaction questionnaires. We defined a complication, according to the Clavien-Dindo classification, as any deviation from the ideal postoperative course that is not inherent in the procedure and does not constitute an FTC. FTC was defined as a POP that was not a complication. The  $\chi^2$  tests, t-tests, or Wilcoxon rank-sum tests were used.

**Outcomes:** Patient-reported and objective outcomes after PPI.

**Results:** Our enrollment consisted of 185 patients, and we contacted 124 (67%). Of these, 16 (12.9%) had a POP requiring reoperation. Eight patients developed surgical complications (three infections, four erosions, and one chronic pain). Eight patients had FTC (four malpositions and four malfunctions). Factors that correlated with POPs were previous PPI, body mass index higher than 30 kg/m<sup>2</sup>, and previous treatment with intracorporal injections ( $P < .05$  for all comparisons). Patients who had POPs scored significantly lower on the IIEF erectile function and intercourse satisfaction domains ( $P < .05$  for the two comparisons), but not on the orgasmic function, sexual desire, and overall satisfaction domains ( $P > .05$  for all comparisons).

**Clinical Implications:** POPs after PPI surgery can be more accurately categorized using the Clavien-Dindo classification of surgical complications to more clearly distinguish surgical complications from FTC.

**Strengths and Limitations:** Limitations of our study include its retrospective approach. Our series included a large proportion of patients treated for prostate cancer, which limits the generalizability of our findings. We also had a relatively short median follow-up time of 27 months.

**Conclusions:** Patient-reported outcome assessments can vary greatly from what physicians determine to be successful PPI. An assessment of POPs encompasses more than just complication rates; it also reflects FTC. Even when POPs occur, patients can still derive satisfaction if they are correctively managed. Factors that possibly predispose to POPs include previous PPI surgery, body mass index greater than 30 kg/m<sup>2</sup>, and history of intracorporal injections. **Pineda M, Burnett AL. Distinguishing Failure to Cure From Complication After Penile Prosthesis Implantation. J Sex Med 2017;XX:XXX–XXX.**

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**Key Words:** Penile Prosthesis; Satisfaction; Complications; Infection; Outcomes

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### INTRODUCTION

Penile prosthesis implantation (PPI) is an option for patients with erectile dysfunction (ED) who have failed, have contraindications for, or decline first- and second-line therapies.<sup>1</sup> It is conventionally understood that PPI has high patient satisfaction and low complications rates.<sup>2,3</sup> Satisfaction ratings are reported to be in the range of 79% to 98%, suggesting that patients are

uniformly pleased with their outcomes after PPI.<sup>4–6</sup> Unfavorable surgical outcome rates (infectious plus mechanical malfunction) are reported to be 8% to 20%.<sup>4–7</sup>

Despite these statistics, it is unclear what constitutes a “complication” of PPI surgery. Dindo and Clavien<sup>8</sup> defined a surgical complication as “any deviation from the ideal postoperative course that is not inherent in the procedure and does not comprise a failure to cure.” They further stated that “if the original purpose of surgery has not been achieved, this is not a complication but a ‘failure to cure’ (eg, residual tumor after surgery).”<sup>9</sup> Thus, success for PPI surgery can be defined by outcomes beyond the absence of complications. A successful result can be determined by whether the outcome meets all ideal criteria, including ease of use and patient satisfaction.

In this report, we examine patient determinants of outcomes after PPI surgery. Our primary focus was patient-reported assessments of determinants of successful surgery. We also registered patient demographic and clinical factors and evaluated whether these variables influence patient reporting of outcomes.

## METHODS

This study derives from our ongoing institutional sexual function registry (institutional review board approval ID NA\_00068547) composed of a subset of patients who were consecutively enrolled from January 2011 to December 2013. This database subset consisted of 185 patients treated by four surgeons at our institution. Patients might have had previous PPI surgery.

Patient demographics, previous medical and surgical treatment of ED, comorbidities, social history, postoperative problems (POPs), and surgical outcomes were tabulated. All patients completed the International Index of Erectile Function (IIEF) questionnaire at enrollment. After PPI surgery, patients completed the IIEF and the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) unless they required device explantation during follow-up. Questionnaire completion postoperatively required clinic or telephone follow-up with assistance by evaluators other than the primary surgeons. Chart review and patient interview by telephone were done to update PPI status and use.

We conceptualized a POP with PPI as a surgical complication or a failure to cure (FTC; [Figure 1](#)). We defined a surgical complication as any deviation from the ideal postoperative course that is not inherent in the procedure and does not constitute an FTC and graded it based on the Clavien-Dindo classification of surgical complications.<sup>9</sup> According to this definition, surgical complications of PPI include device infections, erosions, and chronic pain. FTC was defined as a category of POPs that includes malposition or mechanical malfunction or difficult operation of the device, lack of natural feeling of the erection, and patient dissatisfaction.

Univariate analyses were performed using  $\chi^2$  tests for categorical data and t-tests or non-parametric alternative Wilcoxon rank-sum tests for continuous data.

## RESULTS

Our enrollment consisted of 185 patients. We were able to contact only 124 patients (67%) directly, and this represents the cohort represented in this report. Chart review of the remaining 61 patients did not show any postoperative surgical complications. The average age for the cohort was 63 years (range = 26–82). The median time from surgery to follow-up was 27 months (range = 15–72).

Approximately half the patients had vascular disease or prior prostate cancer surgery among diverse comorbidities ([Table 1](#)). Prior prostate cancer surgery was the second most common risk factor after hypertension. Our series had a relatively low rate of diabetes at 12%.

All patients in this cohort underwent three-piece inflatable PP surgery. Before PPI, patients commonly tried different less invasive options. Approximately three of four patients used phosphodiesterase type 5 inhibitors, half used intracorporal injections (ICIs), and one third used vacuum erection devices. The other ED therapies used before PPI are listed in [Table 1](#).

Of the 124 patients contacted, 16 (12.9%) underwent reoperation, including 8 for surgical complications and 8 for FTC ([Table 2](#)). All eight patients who had a surgical complication and one patient with malposition of his device (ie, FTC) underwent explantation without replacement. Seven patients classified as having FTC underwent device removal and replacement. Five of 18 patients (27%) who had a prosthesis before presenting to our institution developed a surgical complication or FTC at our institution. In contrast, 11 of 111 patients (9%) without prior PPI developed a surgical complication or FTC ( $P < .05$ ). POP rates varied by surgeon, with the surgeon who performed the most procedures having the lowest POP rates ([Table 3](#)).

### Patient- and Disease-Specific Outcomes

Eleven of 44 patients (25%) with obesity (body mass index  $> 30 \text{ kg/m}^2$ ) had a surgical complication or FTC compared with 5 of 80 non-obese patients (6%;  $P < .01$ ). Of 60 patients who were administered ICIs, 12 (20%) had a surgical complication or FTC compared with 4 of 64 (6%) who never used ICIs ( $P < .05$ ). Use of other treatment modalities (ie, phosphodiesterase type 5 inhibitors, vacuum erection devices, and intra-urethral pharmacotherapy) did not correlate with the development of surgical complication or FTC.

White patients had a higher rate of surgical complication or FTC (17.6%) than non-white patients (6.5%), although this difference was not statistically significant ( $P = .056$ ). Diabetes status was not found to have statistical significance: 17% of men with diabetes had a surgical complication or FTC compared with

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