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Perioperative Outcomes and Complications of Primary versus Revision Penile Prosthesis Surgery: A Retrospective Single-Center Cohort Study

Anton Moderegger

anton.moderegger@uksh.de

UKSH Campus Lübeck https://orcid.org/0009-0003-4805-3099

Alexander Reese

Matchima Huabkong

Oleksandr Boiko

Hendrik Fender

Axel Merseburger

Daniar Osmonov

University Hospital Schleswig-Holstein, Campus Lübeck https://orcid.org/0000-0003-4963-9158

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Abstract

Background

Implantation of an inflatable penile prosthesis is the surgical gold standard for medically refractory erectile dysfunction. While perioperative outcomes of primary implantation have been well characterized, comparative data on revision surgery are limited, particularly during the early implementation phase of a new institutional program.

Patients and Methods

In this retrospective single-center cohort study, all consecutive primary implantations and revision procedures with complete perioperative documentation performed at our institution between April 2024 and July 2026 were analyzed (74 primary implantations, 34 revision procedures). Perioperative outcomes and postoperative complications – assessed using the Clavien-Dindo classification and a composite device-failure endpoint (mechanical failure, new penile deviation, revision, or explantation) – were compared between groups using the Wilcoxon rank-sum test and Fisher's exact test. Multivariable linear and logistic regression were used to adjust for baseline differences.

Results

Revision surgery required significantly longer operative time than primary implantation (median 78 vs. 56 minutes, $p < 0.001$), an effect that persisted after multivariable adjustment (+ 19.3 min, 95% CI 10.1–28.6, $p < 0.001$). Length of hospital stay was also longer after revision surgery ($p = 0.018$). Overall complication rates (Clavien-Dindo ≥ I) were numerically higher after revision surgery (32.4% vs. 20.3%) but did not reach statistical significance ($p = 0.226$), nor did major complications (11.8% vs. 4.1%, $p = 0.203$) or the device-failure endpoint. Explantation occurred exclusively after revision surgery (2/34 vs. 0/74).

Conclusion

Revision surgery for penile prosthesis is significantly more time-consuming than primary implantation and shows a consistent, though not statistically significant, trend toward higher rates of general and device-specific complications. These findings should inform patient counseling, operative planning, and resource allocation, even within an established program led by an experienced implant surgeon.

Introduction

Erectile dysfunction (ED) is a common condition, and for men in whom conservative and pharmacological treatments fail, implantation of an inflatable penile prosthesis represents the surgical gold standard, offering reliable restoration of erectile function with high rates of patient and partner satisfaction[1–3].

Beyond the index procedure, however, a clinically relevant proportion of patients will eventually require revision surgery over the lifetime of their device – because of infection, mechanical failure, erosion, unsatisfactory reservoir or cylinder positioning, or a new penile deformity[4,5]. Revision surgery is generally considered more technically demanding than primary implantation, owing to corporal fibrosis, scarring, and distorted anatomy from the index procedure, and has been associated in prior series with longer operative times and a higher risk of perioperative complications[6,7].

At our institution, a structured penile prosthesis program following a standardized surgical technique and perioperative pathway was established in April 2024. While short-term outcomes of primary implantation within this program have been favorable, the perioperative profile of revision surgery performed during the same early implementation period has not yet been characterized.

The aim of the present study was therefore to compare perioperative outcomes and postoperative complications between primary implantation and revision surgery within the same consecutive institutional cohort, in order to inform patient counseling, operative planning, and resource allocation for revision procedures.

Patients and Methods

Study Design and Patient Population

This retrospective single-center cohort study included all consecutive patients with complete perioperative and operative documentation who underwent penile prosthesis surgery – primary implantation or revision – at the Department of Urology, University Hospital Schleswig-Holstein, Campus Lübeck, between April 2024 and July 2026. The study was approved by the responsible institutional ethics committee (approval no. 2026 – 315).

All procedures followed a standardized surgical technique and perioperative pathway, including a routine postoperative day-one sonographic examination of the implant pocket [8].

The analysis cohort comprised 108 patients: 74 primary implantations and 34 revision procedures. All procedures, both primary and revision, were performed by a single experienced implant surgeon.

Data Collection

Clinical data were retrospectively extracted from the institutional clinical information system. Patient characteristics included age, height, weight, body mass index (BMI), ASA classification, diabetes mellitus, arterial hypertension, anticoagulation, active smoking, immunosuppression, and Peyronie's disease. Implant characteristics included manufacturer, model, and total implant length including the rear tip extender. Perioperative variables included operative time, length of hospital stay, and catheter and drain duration.

With the exception of the postoperative complication-type field (by design only populated when a complication occurred, and therefore structurally blank for 47/108 patients rather than missing at random), no missing data were observed for any of the analyzed variables; consequently, no imputation was required.

Study Size

No formal a priori sample size or power calculation was performed. All consecutive, fully documented patients who underwent penile prosthesis surgery at our institution during the study period were included, representing a convenience sample determined by clinical caseload rather than a pre-specified target size. The resulting sample size, particularly for the revision subgroup (n = 34) and the device-failure endpoint (5 events in the revision group), limits statistical power for the complication analyses (see Limitations).

Bias

Several potential sources of bias were considered. Primary implantation and revision surgery are not randomly allocated but reflect the clinical indication for surgery (confounding by indication); measured baseline differences between groups (ASA classification, Peyronie's disease) were addressed through multivariable adjustment, but unmeasured factors related to the underlying reason for revision (e.g., degree of corporal fibrosis, cause of prior device failure) could not be accounted for. In addition, Clavien-Dindo grading and complication coding were performed by the treating clinical team as part of routine documentation rather than by reviewers blinded to group assignment, which may have introduced non-differential information bias.

Endpoints

The primary endpoint was perioperative outcome, in particular operative time, compared between primary implantation and revision surgery. Secondary endpoints were length of hospital stay, catheter and drain duration, and postoperative complications.

Postoperative complications were assessed using two complementary endpoints. First, the Clavien-Dindo classification (overall complications, grade ≥ I; major complications, grade ≥ III) captured general perioperative morbidity requiring a therapeutic intervention. Second, because the Clavien-Dindo classification does not capture prosthesis-specific problems that have not (yet) triggered a formal intervention – such as an early mechanical issue or a new penile deviation – a composite “device failure” endpoint was defined a priori, comprising mechanical failure, new penile deviation, revision, or explantation.

Statistical Analysis

Categorical variables are presented as absolute and relative frequencies. Continuous variables are presented as mean ± standard deviation or median (interquartile range, IQR), depending on their distribution.

Continuous variables were compared between groups using the Wilcoxon rank-sum (Mann-Whitney U) test; categorical variables were compared using Fisher's exact test. Given the exploratory nature of the baseline and complication-type comparisons, p-values were not adjusted for multiple testing and should be interpreted as descriptive.

Multivariable linear regression was used to assess the independent association between group (primary vs. revision) and operative time, adjusting for Peyronie's disease – which differed between groups at baseline – as well as age and BMI. Multivariable logistic regression was used to assess the independent association between group and each complication endpoint, adjusting for age, BMI, Peyronie's disease, active smoking, and diabetes mellitus.

All statistical analyses were performed using R (R Foundation for Statistical Computing, Vienna, Austria). A two-sided p-value < 0.05 was considered statistically significant. This manuscript was prepared following the STROBE guidelines for cohort studies.

Results

Study Cohort

Between April 2024 and July 2026, 108 consecutive penile prosthesis procedures with complete perioperative documentation were performed at our institution and included in this analysis: 74 primary implantations and 34 revision procedures (Table 1).

Baseline characteristics were well balanced between groups except for ASA classification and, at a trend level, Peyronie's disease. The revision group included a lower proportion of ASA I and a higher proportion of ASA II patients (p = 0.037), while Peyronie's disease was more common among primary implantations (17.6% vs. 2.9%, p = 0.060) (Table 1).

Table 1

Baseline patient characteristics of primary implantation and revision surgery cases. Continuous variables are shown as mean ± SD; categorical variables as n (%). Continuous variables were compared with the Wilcoxon rank-sum test, categorical variables with Fisher's exact test.

Variable	Primary implantation (n = 74)	Revision surgery (n = 34)	p value
Patient characteristics			
Age, years	57.6 ± 11.9	58.2 ± 13.8	0.887
BMI, kg/m²	27.8 ± 4.3	27.8 ± 3.7	0.942
ASA classification			**0.037**
ASA I	23 (31.1%)	4 (11.8%)	
ASA II	40 (54.1%)	27 (79.4%)	
ASA III	11 (14.9%)	3 (8.8%)	
Comorbidities			
Diabetes mellitus	21 (28.4%)	9 (26.5%)	1.000
Arterial hypertension	34 (45.9%)	18 (52.9%)	0.539
Anticoagulation	5 (6.8%)	2 (5.9%)	1.000
Active smoking	25 (33.8%)	12 (35.3%)	1.000
Peyronie's disease	13 (17.6%)	1 (2.9%)	0.060

ASA = American Society of Anesthesiologists; BMI = body mass index.

Perioperative Outcomes

Revision surgery required significantly longer operative time (median 78 vs. 56 min, $p < 0.001$) and a longer hospital stay ($p = 0.018$) than primary implantation, whereas catheter and drain duration did not differ significantly between groups (Table 2, Fig. 1).

Table 2

Perioperative outcomes of primary implantation and revision surgery. Continuous variables are shown as median (IQR).

Variable	Primary implantation (n = 74)	Revision surgery (n = 34)	p value
Operative time, min	56.0 (IQR 47.0–66.5)	78.0 (IQR 63.5–89.8)	< 0.001
Length of hospital stay, days	3.0 (IQR 3.0–4.0)	3.0 (IQR 3.0–5.0)	0.018
Catheter duration, days	2.0 (IQR 2.0–3.0)	2.0 (IQR 2.0–3.0)	0.210
Drain duration, days	2.0 (IQR 2.0–3.0)	2.0 (IQR 2.0–3.0)	0.266

Figure 1. Operative time and length of hospital stay by group. Box plots show the median, interquartile range, and individual data points for the 74 primary implantations and 34 revision procedures.

In multivariable linear regression adjusting for Peyronie's disease, age, and BMI, revision surgery remained independently associated with a longer operative time (+ 19.3 min, 95% CI 10.1–28.6, $p < 0.001$), while none of the adjustment variables reached significance (Table 5).

Postoperative Complications

Overall (32.4% vs. 20.3%) and major (11.8% vs. 4.1%) complication rates were numerically higher after revision surgery, without reaching statistical significance (Table 3).

Table 3
Postoperative complications according to the Clavien-Dindo classification, by group (Fisher's exact test).

Outcome	Primary implantation	Revision surgery	p value
Overall complications (Clavien ≥ I)	15 (20.3%)	11 (32.4%)	0.226
Major complications (Clavien ≥ III)	3 (4.1%)	4 (11.8%)	0.203

The most frequent implant-specific complication in both groups was hematoma/bleeding, attributable in part to the routine postoperative day-one sonographic examination, which also detected small, subclinical hematomas that were managed conservatively. Explantation occurred exclusively after revision surgery (2/34 vs. 0/74); the remaining complication types are detailed in Table 4.

Table 4
Implant-specific postoperative complications by group. Patients may have more than one complication; percentages refer to the respective group size.

Complication	Primary implantation	Revision surgery
Infection	1 (1.4%)	1 (2.9%)
Hematoma/bleeding	12 (16.2%)	6 (17.6%)
Early mechanical failure	4 (5.4%)	0 (0.0%)
Erosion	1 (1.4%)	1 (2.9%)
Revision	2 (2.7%)	2 (5.9%)
Explantation	0 (0.0%)	2 (5.9%)
Readmission < 90 days	1 (1.4%)	0 (0.0%)
Impaired wound healing	3 (4.1%)	1 (2.9%)
New deviation	4 (5.4%)	1 (2.9%)
Urinary retention	1 (1.4%)	2 (5.9%)

Multivariable Analysis

Table 5
Multivariable linear regression for operative time, adjusted for Peyronie's disease, age and BMI.

Term	Estimate (min)	95% CI	p value
Intercept	58.23	23.09 to 93.37	0.001
Revision surgery	19.30	10.05 to 28.55	< 0.001
Peyronie's disease	-2.48	-15.31 to 10.35	0.702
Age	0.04	-0.30 to 0.38	0.819
BMI	0.02	-1.01 to 1.05	0.973

Crude and multivariable-adjusted odds ratios were similar for both complication endpoints, indicating limited confounding by the measured covariates; revision surgery was not significantly associated with either endpoint (Tables 6a, 6b). Active smoking showed a consistent, non-significant trend toward higher odds of both outcomes in the adjusted models.

Table 6
a. Crude (univariable) and multivariable-adjusted logistic regression for overall postoperative complications (Clavien ≥ I). The adjusted model controls for age, BMI, Peyronie's disease, smoking and diabetes mellitus. Reference category for all binary covariates: No.

Term	OR	95% CI	p value
Revision surgery (crude, unadjusted)	1.88	0.74 to 4.70	0.176
Revision surgery (adjusted)	2.00	0.75 to 5.33	0.161
Age	0.97	0.93 to 1.01	0.116
BMI	1.06	0.95 to 1.19	0.308
Peyronie's disease	1.04	0.20 to 4.15	0.956
Active smoking	2.08	0.81 to 5.39	0.126
Diabetes mellitus	1.24	0.41 to 3.58	0.687

Table 6

b. Crude (univariable) and multivariable-adjusted logistic regression for device failure (mechanical failure, new deviation, revision or explantation), independent of Clavien-Dindo grade. The adjusted model controls for age, BMI, Peyronie's disease, smoking and diabetes mellitus. Reference category for all binary covariates: No.

Term	OR	95% CI	p value
Revision surgery (crude, unadjusted)	1.25	0.36 to 3.94	0.715
Revision surgery (adjusted)	1.31	0.35 to 4.51	0.672
Age	0.97	0.92 to 1.02	0.238
BMI	1.05	0.90 to 1.20	0.513
Peyronie's disease	1.18	0.16 to 5.94	0.850
Active smoking	3.15	0.98 to 10.71	0.056
Diabetes mellitus	1.10	0.25 to 4.21	0.894

Discussion

In this retrospective single-center comparison, revision surgery for penile prosthesis was associated with a significantly longer operative time than primary implantation, an effect that persisted after adjustment for baseline differences. While overall and major complication rates, as well as a composite device-failure endpoint, were numerically higher after revision surgery, these differences did not reach statistical significance in this moderately sized cohort.

Even within a program led by an already experienced implant surgeon, revision surgery constituted a distinct and more demanding clinical entity, requiring approximately 35% more operative time than primary implantation. This is consistent with the general surgical principle that revision procedures are technically more challenging than de novo implantation, owing to corporal fibrosis, scar tissue, and altered anatomy from the index procedure, and mirrors a propensity-score-matched comparison in which revision implants were likewise associated with longer operative time and a higher overall complication rate than primary implants [6,7]

Another important finding of our study concerns operative time. Prolonged operative time has been described as a modifiable risk factor for postoperative infection following IPP implantation[9]. In our cohort, the median operative time for primary IPP implantation was 56 minutes, significantly shorter than the operative time observed in the revision surgery group. The relatively short operative time in our primary implantation cohort may therefore represent an important factor contributing to the favorable postoperative outcomes observed in this group.

Notably, general perioperative morbidity as captured by the Clavien-Dindo classification and prosthesis-specific device failure both showed a consistent trend toward higher rates after revision surgery, without

reaching statistical significance, which likely reflects the moderate sample size of the revision subgroup (n = 34) rather than a true absence of effect. Complication rates observed here are broadly consistent with contemporary multicenter registry data [10] although direct comparison is limited by differing case mix and complication-capture strategies. This is illustrated by the observation that explantation – arguably the most severe device-specific outcome – occurred exclusively after revision surgery (2/34 vs. 0/74), even though this difference could not be formally tested given the small event count. We would caution against interpreting the non-significant complication comparisons in this study as evidence of equivalent safety between primary implantation and revision surgery; rather, they should be viewed as hypothesis-generating and in need of confirmation in larger, ideally multicenter, cohorts.

A very specific finding of our study is the duration of drain placement after IPP implantation. This parameter was slightly longer than that reported in previous studies. This difference is attributable to the specific postoperative protocol of the operating surgeon. Based on his previous experience, as published in the International Journal of Impotence Research[11], the clinical protocol is to maintain the drain for 48–72 hours postoperatively. This approach was developed to substantially reduce the rate of postoperative hematoma without increasing the overall infection rate.

Our current data support this hypothesis and confirm the safety and potential benefit of prolonged drain placement within this specific clinical protocol. Although the overall infection rate in our cohort was slightly higher than that reported in the current literature, the infection occurred in only one patient, who had diabetes mellitus. Therefore, the observed infection rate should be interpreted with caution, particularly given the presence of this important patient-specific risk factor.

The revision group differed from the primary implantation group with respect to ASA classification and, at a trend level, the prevalence of Peyronie's disease. The reasons for this baseline imbalance remain speculative, as information on whether revision cases had originally undergone primary implantation at our own institution or elsewhere was not systematically captured in the present dataset (see Limitations).

The overall number of complications should be interpreted in the context of two important considerations. First, most patients referred to our center represent complex and challenging cases, often with extensive medical and surgical histories, and are referred from other European centers for specialized treatment. Therefore, the patient population included in our cohort may inherently carry a higher risk of postoperative complications than a standard primary IPP population. Second, the relatively modest number of patients may have contributed to an apparently high overall complication rate, as even a small number of adverse events can substantially influence the reported percentage. These factors should therefore be taken into account when interpreting the complication profile of our cohort.

From a practical perspective, these findings have direct implications for surgical planning: revision surgery should be scheduled with adequate operative time (approximately 20–30% longer than for

primary implantation, based on our data), and, given the numerically higher complication rates, patients should be counseled accordingly and postoperative surveillance intensified.

Prior series have similarly reported that revision penile prosthesis surgery is associated with longer operative times and elevated complication rates compared with primary implantation, particularly in the presence of corporal fibrosis or prior infection [5,6]. Our findings are broadly consistent with this literature, while extending it to the specific context of a newly established institutional program.

These findings were obtained in a single, recently established academic penile prosthesis program under the direction of one experienced lead implant surgeon, with a comparatively small and homogeneous surgical team, in a healthcare system where penile prosthesis surgery is concentrated in relatively few centers [12]. The magnitude of the observed differences in operative time and complication rates between primary and revision surgery may not generalize directly to high-volume, long-established programs, to centers with multiple independent implant surgeons, or to non-academic settings with different case mix, referral patterns, or perioperative protocols. External validation in larger, multicenter cohorts is therefore warranted.

Limitations

This study has several limitations. First, its retrospective, single-center design and moderate sample size – particularly for the revision subgroup (n = 34) and the device-failure endpoint (5 events in the revision group) – limit statistical power and the precision of the multivariable estimates, which should be interpreted with caution given the wide confidence intervals. Second, information on whether revision cases had originally undergone primary implantation at our own institution or elsewhere was not available, precluding a more detailed analysis of revision etiology and its relationship to the index procedure. Third, only early perioperative endpoints were assessed; no data on implant survival, long-term functional outcomes, or patient-reported outcomes are available. Finally, the Clavien-Dindo classification and the device-failure endpoint, while complementary, do not fully capture the multidimensional nature of prosthesis-related morbidity, and future studies should incorporate functional and patient-reported endpoints.

A post-hoc power calculation illustrates the extent of this limitation: at the observed allocation ratio (74 primary implantations to 34 revision procedures), detecting the difference in overall complication rates (20.3% vs. 32.4%) with 80% power would require approximately 470 patients (322 primary, 148 revision), and detecting the difference in major complication rates (4.1% vs. 11.8%) would require approximately 412 patients (282 primary, 130 revision). These figures should inform the sample size planning of future, ideally prospective multicenter, studies designed to confirm or refute the complication differences observed here.

Conclusion

In this single-center comparative analysis, revision surgery for penile prosthesis required significantly more operative time than primary implantation, and showed a consistent, though not statistically significant, trend toward higher rates of general and device-specific complications. These findings should inform patient counseling, operative scheduling, and postoperative surveillance for revision procedures, even within an established program led by an experienced implant surgeon, and warrant confirmation in larger, multicenter cohorts.

Declarations

Other Information

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Conflicts of Interest

D. Osmonov has served as a consultant for Boston Scientific, Coloplast Porgès, and Rigicon. The remaining authors declare no conflicts of interest relevant to this work.

Author Contributions

Conceptualization: A. Moderegger, D. Osmonov, H.E. Fender. Data collection: A.S. Reese, M. Huabkong, A. Moderegger. Statistical analysis: A. Moderegger. Manuscript preparation: A. Moderegger. Manuscript revision: all authors. Supervision: D. Osmonov, A.S. Merseburger.

Ethics Statement

This study was approved by the responsible institutional ethics committee (approval no. 2026-315). The study was conducted retrospectively on routinely collected clinical data; the requirement for individual informed consent was waived due to the retrospective nature of the study.

Data Availability

The datasets analyzed during the current study are available from the corresponding author on reasonable request, subject to institutional and data protection approval.

STROBE Statement

This manuscript has been prepared with reference to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guideline for cohort studies. A completed STROBE checklist is provided as a separate supplementary document.

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Figures

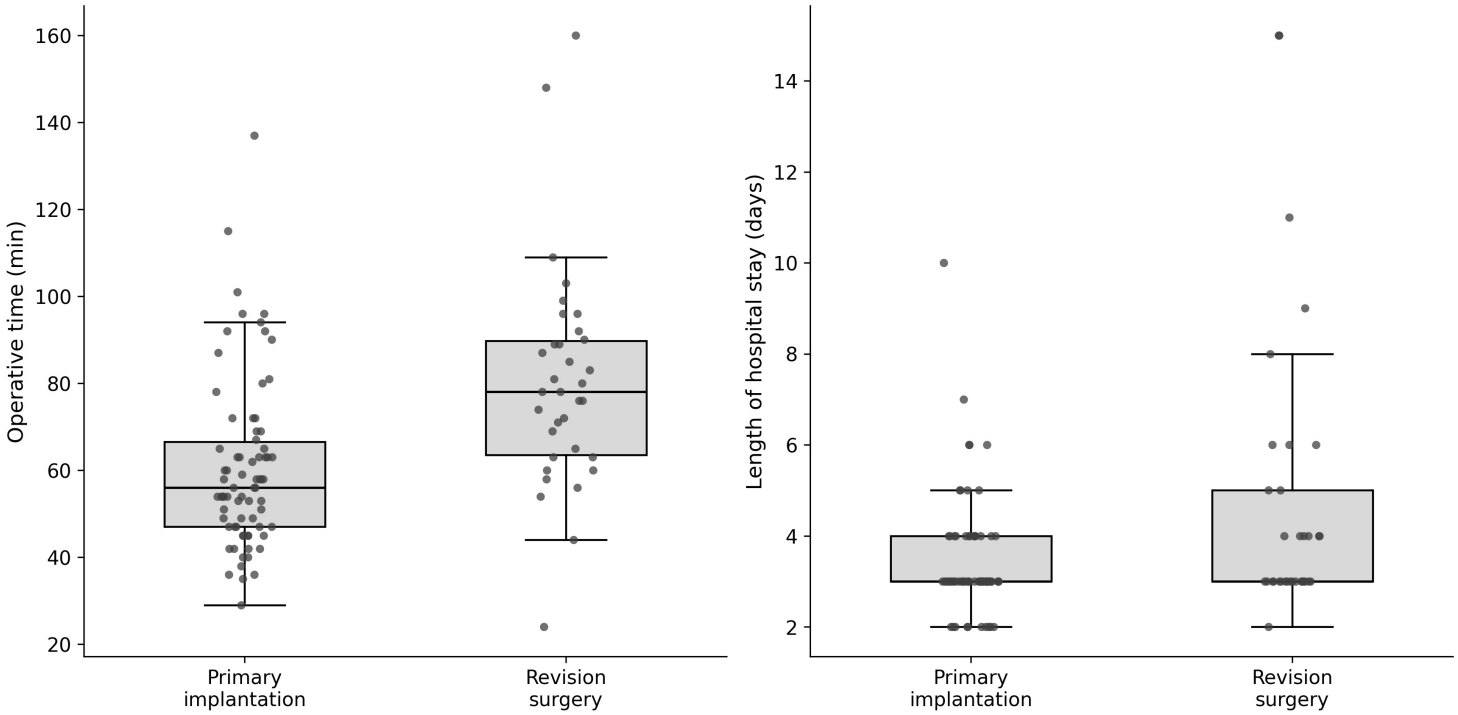


Figure 1

Operative time and length of hospital stay by group. Box plots show the median, interquartile range, and individual data points for the 74 primary implantations and 34 revision procedures.