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Penile Prosthesis Implantation Revision Surgery: Feasibility and Safety

Penil Protez İmplantasyonu Revizyon Cerrahisi: Uygulanabilirlik ve Güvenlik

Short Title: Penile Prosthesis Implantation Revision Surgery (Penil Protez İmplantasyonu Revizyon Cerrahisi)

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Abstract

Objective: This study aims to evaluate the feasibility and safety of penile prosthesis implantation (PPI) revision surgery in a high-volume center.

Materials and Methods: We retrospectively analyzed data from 30 patients undergoing PPI revision between January 2021 and September 2024, performed by two experienced andrology-trained surgeons at two centers. Patient demographics, comorbidities, surgical details, and complications were recorded. Quality of life was assessed at three months using the Quality of Life and Sexuality with Penile Prosthesis (QoLSPP) questionnaire. Complications were classified using the Clavien-Dindo system.

Results: Revision indications included non-functioning prostheses (33.3%), visible deformity (16.7%), inadequate inflation (20%), conversion from malleable to inflatable penile prosthesis (IPP) (13.3%), and infection (16.7%). Infrapubic (40%) or penoscrotal (60%) approaches were used. Mean operative time was 101.8 minutes, hospital stay was 2.1 days, and follow-up was 9 months. Complications (Clavien-Dindo Grade I-II) included orchitis (10%), wound infection (6.7%), and scrotal/perineal ecchymosis (13.3%), all resolved conservatively. Staphylococcus epidermidis was the most common pathogen in infections. Patients transitioning to IPPs reported high QoLSPP scores.

Conclusion: PPI revision surgery, when performed by skilled surgeons, is safe and effective, with high patient satisfaction, particularly for IPP transitions. Larger studies with longer follow-up are needed to assess long-term outcomes.

Keywords: penil prosthesis, revision surgery, patient satisfaction, malleable penil prosthesis, inflatable penil prosthesis

Özet

Amaç: Bu çalışma, yüksek hacimli bir merkezde penil protez implantasyonu (PPI) revizyon cerrahisinin uygulanabilirliğini ve güvenilirliğini değerlendirmeyi amaçlamaktadır.

Gereçler ve Yöntemler: Ocak 2021 ile Eylül 2024 arasında PPI revizyonu geçiren 30 hastanın verileri retrospektif olarak analiz edilmiştir. Operasyonlar, androloji alanında deneyimli iki cerrah tarafından iki merkezde gerçekleştirilmiştir. Hasta demografisi, komorbiditeler, cerrahi detaylar ve komplikasyonlar kaydedilmiştir. Yaşam kalitesi, üç ayda Penil Protez ile Yaşam Kalitesi ve Cinsellik (QoLSPP) anketi ile değerlendirilmiştir. Komplikasyonlar Clavien-Dindo sistemiyle sınıflandırılmıştır.

Bulgular: Revizyon endikasyonları arasında çalışmayan protez (%33,3), görünür deformite (%16,7), yetersiz şişme (%20), malleable protezden şişirilebilir penil proteze (IPP) geçiş (%13,3) ve enfeksiyon (%16,7) yer almıştır. İnfrapubik (%40) veya penoskrotal (%60) yaklaşımlar kullanılmıştır. Ortalama operasyon süresi 101,8 dakika, hastanede kalış süresi 2,1 gün ve takip süresi 9 ay olmuştur. Komplikasyonlar (Clavien-Dindo Grade I-II) orşit (%10), yara enfeksiyonu (%6,7) ve skrotal/perineal ekimoz (%13,3) şeklindeydi ve tümü konservatif yöntemlerle düzelmiştir. Enfeksiyonlarda en sık Staphylococcus epidermidis saptanmıştır. IPP'ye geçen hastalar yüksek QoLSPP skorları bildirmiştir.

Sonuç: Deneyimli cerrahlar tarafından yapılan PPI revizyon cerrahisi güvenli ve etkilidir; özellikle IPP'ye geçiş yapan hastalarda yüksek memnuniyet sağlar. Uzun vadeli sonuçları değerlendirmek için daha büyük ve uzun takipli çalışmalara ihtiyaç vardır.

Anahtar kelimeler: penil protez, revizyon cerrahisi, hasta memnuniyeti, tek parçalı penil protez, şişirebilir penil protez

Introduction

Penile prosthesis implantation (PPI) is a highly effective treatment for men with erectile dysfunction (ED) who fail first- and second-line therapies [1]. The modern inflatable penile prosthesis (IPP) era began in 1973 when Brantley Scott reported implanting silicone bodies, a reservoir, and a control pump in five patients [2]. Early IPPs, while effective for organic ED, had mechanical failure rates up to 50% within five years [3]. Prosthesis infection, a severe complication in andrological surgery, increases morbidity and healthcare costs, exceeding initial implant costs by over six times [4]. Infection rates range from 2% for primary implantations to 18% for replacements [5].

Despite high patient satisfaction with IPPs, issues like discomfort, inadequate inflation, deformity, palpable abnormalities, or painful intercourse may require revision surgery [6]. Revision surgery effectively addresses infections, mechanical failures, or patient dissatisfaction, with most patients satisfied post-revision [7]. Most patients undergoing IPP replacement report satisfaction and need no further intervention [8]. However, revision surgery carries higher risks of infection and complications than primary surgery [9], posing challenges for patients, surgeons, and healthcare systems [10]. This study evaluates the feasibility and safety of PPI revision surgery.

Materials and Methods

Following ethics committee approval from Başakşehir Çam ve Sakura City Hospital Ethics Committee (Approval No:05032025.81). We retrospectively analyzed data from patients undergoing PPI between January 2021 and September 2024. A total of 30 patients who underwent penile prosthesis revision surgery were included in the study. Surgeries were performed by two experienced surgeons with andrology fellowship training at two centers. We recorded age, body mass index (BMI), comorbidities, surgical history, prostate surgery, pelvic radiation therapy, ED duration before initial PPI, and prior ED treatments.

Patients received standardized antibiotic prophylaxis consisting of ceftriaxone 1 g, vancomycin 500 mg, and fluconazole 150 mg, administered per institutional guidelines. This regimen was selected based on local microbiological data identifying Staphylococcus epidermidis as a prevalent pathogen in prosthetic infections, combined with the elevated infection risk in revision surgeries compared to primary implantations, as supported by Mulcahy et al. [11]. Ceftriaxone and vancomycin were chosen to provide broad-spectrum coverage against gram-positive and gram-negative organisms, while fluconazole addressed

potential fungal contamination, particularly in patients with comorbidities such as diabetes mellitus. Antiplatelet therapy was stopped preoperatively per departmental guidelines. Patients had either malleable penile prostheses (PP) or IPPs. Before revision, a 15-minute povidone-iodine skin preparation was performed. Surgeons chose infrapubic or penoscrotal approaches based on preference. IPPs were implanted in all revisions, with drains placed at the surgeon's discretion. For infection-related revisions, swab cultures from the device surface and peri-prosthetic area were collected, sealed in tubes, and sent for microbiological analysis. We recorded operative time, perioperative bleeding, drain volume, drain duration, and hospital stay.

Sexual intercourse was permitted six weeks post-surgery. Quality of life (QoL) was assessed at three months using the Quality of Life and Sexuality with Penile Prosthesis (QoLSPP) questionnaire, covering functional, relational, social, and self-image domains. Responses used a Likert scale (0 = "never" to 5 = "always"), with higher scores indicating better outcomes. Complications were classified using the Clavien-Dindo system.

Statistical Analysis

Categorical variables were reported as frequencies (n) and percentages (%). Continuous variables were expressed as means or medians. Data were analyzed using IBM SPSS Statistics, version 28.0 (Armonk, NY, USA).

Results

We evaluated 30 patients undergoing PPI revision, with a mean age of 58.0 ± 7.5 years and a mean follow-up of 9 ± 3.4 months. Demographic and perioperative data are shown in **Table 1**. Six patients (20%) had prior radical prostatectomy for prostate cancer; none received radiotherapy. No preoperative penile deformities were noted. Six patients (20%) had malleable PP, and IPPs were implanted in all revisions. Revision indications included non-infectious causes in 25 patients (83.3%): non-functioning prosthesis in 10 (33.3%), visible deformity in 5 (16.7%), inadequate inflation in 6 (20%), and conversion from malleable PP to IPP in 4 (13.3%). Five patients (16.7%) underwent revision due to infection.

Infrapubic incisions were used in 12 patients (40%) and penoscrotal in 18 (60%). Mean operative time was 101.8 ± 20.0 minutes. Drains were placed in 15 patients (50%), with a mean drain volume of 54.3 ± 15.0 mL. Mean hospital stay was 2.1 ± 0.7 days. Staphylococcus epidermidis was the most common microorganism (3 patients), followed by Escherichia coli and Proteus mirabilis. All complications were Clavien-Dindo Grade I or II, including orchitis

in 3 patients, wound infection in 2, and scrotal/perineal ecchymosis in 4, all resolving with conservative treatment.

Patients transitioning from malleable PP to IPP reported high QoLSPP scores at three months: functional (21/25), relational (16/20), personal (18/20), and social (13/15).

Discussion

Penile prostheses are designed to provide durable functional outcomes and sufficient rigidity for sexual intercourse, yet mechanical failures or infections often necessitate revision surgery. Our study demonstrates that revision surgery, performed by experienced andrology-trained surgeons, is a safe and effective solution for addressing infections, erosions, mechanical failures, or patient dissatisfaction [7]. Mechanical issues, such as fluid leakage or valve dysfunction, were the primary reasons for revision in our cohort, affecting 10 patients with non-functioning prostheses and 6 with inadequate inflation. These findings align with reported mechanical failure rates ranging from 0% to 56% in large series [12-15], with fluid leakage identified as the most common cause [16]. Since the introduction of IPPs in 1973, mechanical and medical complications have been well-documented [2], underscoring the importance of ongoing advancements in device design to enhance durability.

Prosthesis infection, though rare with rates of 0.5–9% [17-19], remains a significant concern due to its devastating consequences, including prolonged recovery and high healthcare costs. In our study, Staphylococcus epidermidis was the most frequently isolated pathogen in infection-related revisions [20], consistent with the literature suggesting that infections often stem from intraoperative contamination of the implant cavity [16]. The absence of short-term infections post-revision in our cohort highlights the efficacy of rigorous sterile techniques and standardized antibiotic prophylaxis. In our cohort, all five infection-related revision cases underwent complete removal of the infected prosthesis, followed by thorough irrigation and immediate replacement with inflatable penile prostheses, adhering to the Mulcahy salvage protocol [11]. This approach was chosen based on the expertise of fellowship-trained surgeons, patient preference for restoring full functionality, and the absence of systemic infection, which aligns with successful outcomes reported in select series [11,21]. These findings suggest that IPP replacement in infection-related revisions is feasible in high-volume centers, though we acknowledge the need for long-term follow-up to assess durability and reinfection rates [21]. However, our 9-month average follow-up limits conclusions about long-term infection rates. Lotan et al. reported significantly lower durability for replacement prostheses compared to

primary implants (5-year survival: 42% vs. 71%), with infection rates reaching 18.8% for revisions [9]. This disparity emphasizes the need for meticulous surgical planning and patient counseling regarding the higher risks associated with revision procedures.

Our study's complications, including orchitis (3 patients), wound infections (2 patients), and scrotal/perineal ecchymosis (4 patients), were all Clavien-Dindo Grade I or II and resolved with conservative management. These minor complications support the need for adaptable postoperative care pathways to optimize outcomes [22]. The low severity of complications in our cohort may reflect the expertise of fellowship-trained surgeons and the use of standardized protocols, such as povidone-iodine skin preparation and antibiotic prophylaxis. Nevertheless, the higher complication risk in revision surgery compared to primary implantation [9] warrants careful patient selection and preoperative optimization, particularly for those with comorbidities like diabetes mellitus (46.7%) or cardiovascular disease (56.7%), which were prevalent in our cohort.

Patient satisfaction is a critical metric for assessing PPI success. Our patients transitioning from malleable PP to IPP reported high QoLSPP scores across functional, relational, personal, and social domains, suggesting that IPPs significantly enhance quality of life. This finding is particularly relevant for patients seeking improved functionality and aesthetic outcomes. However, revision patients generally face a higher risk of dissatisfaction than those undergoing primary implantation [10]. Caire et al. reported a 58.3% satisfaction rate for revised IPPs, notably lower than the >90% satisfaction for primary implants, though 75% of patients would undergo the procedure again [10]. These data highlight the importance of managing patient expectations, especially for those undergoing revision for non-mechanical reasons, such as visible deformity or inadequate inflation. In our study, the high satisfaction among patients converting to IPPs may be attributed to improved device performance and the expertise of the surgical team, but the short follow-up period limits our ability to assess long-term satisfaction trends.

The 9-month follow-up in our study provides valuable insights into short-term outcomes but restricts our understanding of long-term prosthesis durability and complication rates. Mechanical failures often manifest beyond five years [12-15], and infection risks may persist over time [9]. Future studies with extended follow-up are essential to evaluate the durability of revised IPPs and the sustainability of patient satisfaction. Additionally, the retrospective design and lack of a control group are notable limitations, as they hinder our ability to compare revision outcomes with primary implantations or alternative treatments. Despite these constraints, our

findings from a high-volume center underscore the feasibility of revision surgery when performed by skilled surgeons. Larger, prospective studies are needed to identify predictors of successful revision outcomes, such as patient comorbidities, surgical techniques, or device characteristics.

Conclusion

PPI revision surgery, performed by experienced andrology-trained surgeons, is safe and effective. Patients transitioning from malleable PP to IPP report high satisfaction, highlighting the procedure's potential to improve QoL.

Ethics Committee Approval: Ethical approval for this study was obtained from Başakşehir Çam and Sakura City Hospital Clinical Research Ethics Committee (Approval number and date: 05032025.81 and 24.03.2025).
Informed Consent: An informed consent was obtained from all the patients.
Publication: The results of the study were not published in full or in part in form of abstracts.
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References

[1] Brinkman MJ, Henry GD, Wilson SK, Delk JR 2nd, Denny GA, Young M, et al. A survey of patients with inflatable penile prostheses for satisfaction. J Urol 2005;174(1):253-7. https://doi.org/10.1097/01.ju.0000161608.21337.8d

[2] Brantley Scott F, Bradley WE, Timm GW. Management of erectile impotence Use of implantable inflatable prosthesis. Urology 1973;2(1):80-2. https://doi.org/10.1016/0090-4295(73)90224-0

[3] Gregory JG, Purcell MH, Standeven J. The inflatable penile prosthesis: Failure of the rear tip extender in reducing the incidence of cylinder leakage. J Urol 1984;131(4):668-9. https://doi.org/10.1016/S0022-5347(17)50569-8

[4] Balen A, Gross MS, Phillips EA, Henry GD, Munarriz R. Active Polysubstance Abuse Concurrent With Surgery as a Possible Newly Identified Infection Risk Factor in Inflatable

Penile Prosthesis Placement Based on a Retrospective Analysis of Health and Socioeconomic Factors. J Sex Med 2016;13(4):697-701. https://doi.org/10.1016/j.jsxm.2016.01.010

[5] Kansal NS, Henry GD, Mulcahy JJ. Salvage surgery for penile prosthesis infection. Curr Sex Health Rep. 2008;5(3):115-9. https://doi.org/10.1007/s11930-008-0021-x

[6] McPhail EF, Nehra A, Bruner BC, Kawashima A, King BF, Kim B. MRI and its role in the evaluation and surgical decision making in patients with challenging IPP presentations: Descriptions of MRI findings and algorithm for patient management. BJU Int 2012;109(12):1848-52. https://doi.org/10.1111/j.1464-410X.2011.10683.x

[7] Henry GD, Donatucci CF, Conners W, Greenfield JM, Carson CC, Wilson SK, et al. An outcomes analysis of over 200 revision surgeries for penile prosthesis implantation: a multicenter study. J Sex Med 2012;9(1):309-15. https://doi.org/10.1111/j.1743-6109.2011.02524.x

[8] Bettocchi C, Palumbo F, Spilotros M, Lucarelli G, Palazzo S, Battaglia M, et al. Patient and partner satisfaction after AMS inflatable penile prosthesis implant. J Sex Med 2010; 7(1 Pt 1):304-9. https://doi.org/10.1111/j.1743-6109.2009.01499.x

[9] Lotan Y, Roehrborn CG, McConnell JD, Hendin BN. Factors influencing the outcomes of penile prosthesis surgery at a teaching institution. Urology 2003;62(5):918-21. https://doi.org/10.1016/S0090-4295(03)00665-4

[10] Caire AA, Boonjindasup A, Hellstrom WJG. Does a replacement or revision of an inflatable penile prosthesis lead to decreased patient satisfaction. Int J Impot Res 2011;23(2):39-42. https://doi.org/10.1038/ijir.2011.1

[11] Brant MD, Ludlow JK, Mulcahy JJ. The prosthesis salvage operation: immediate replacement of the infected penile prosthesis. J Urol 1996;155(1):155-7. https://doi.org/10.1016/s0022-5347(01)66580-7

[12] Wilson SK, Wahman GE, Lange JL. Eleven years of experience with the inflatable penile prosthesis. J Urol 1988;139(5):951-2. https://doi.org/10.1016/S0022-5347(17)42726-1

[13] Woodworth BE, Carson CC, Webster GD. Inflatable Penile Prosthesis: Effect of Device Modification on Functional Longevity. J Urol 1987;137(6):232A. https://doi.org/10.1016/s0022-5347(17)75665-0

[14] Goldstein I, Bertero EB, Kaufman JM, Witten FR, Hubbard JG, Fitch WP, et al. Early experience with the first pre-connected 3-piece inflatable penile prosthesis: the Mentor Alpha-1. J Urol 1993;150(6):1814-8. https://doi.org/10.1016/S0022-5347(17)35903-7

[15] Lewis RW. Long-term results of penile prosthetic implants. Urol Clin North Am 1995;22(4):847-56. https://doi.org/10.1016/s0094-0143(21)00698-4

[16] Henry GD, Wilson SK, Delk JR 2nd, Carson CC, Wiygul J, Tornehl C, et al. Revision washout decreases penile prosthesis infection in revision surgery: a multicenter study. J Urol 2005;173(1):89-92. https://doi.org/10.1097/01.ju.0000146717.62215.6f

[17] Chung E, Van CT, Wilson I, Cartmill RA. Penile prosthesis implantation for the treatment for male erectile dysfunction: Clinical outcomes and lessons learnt after 955 procedures. World J Urol 2013;31(3):591-5. https://doi.org/10.1007/s00345-012-0859-4

[18] Gross MS, Phillips EA, Carrasquillo RJ, Thornton A, Greenfield JM, Levine LA, 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(3):455-63. https://doi.org/10.1016/j.jsxm.2017.01.007

[19] Best JC, Clavijo RI. Best practices for infection prevention in penile prosthesis surgery. Curr Opin Urol 2020;30(3):302-8. https://doi.org/10.1097/MOU.0000000000000744

[20] Montague DK. Periprosthetic infections. J Urol 1987;138(1):68-9. https://doi.org/10.1016/S0022-5347(17)42992-2

[21] Wilson SK, Delk JR 2nd. Prevention and treatment of complications of inflatable penile prosthesis surgery: a review article. Arch Esp Urol 1996;49(3):306-311. https://pubmed.ncbi.nlm.nih.gov/8702353/

[22] Wintner A, Lentz AC. Inflatable Penile Prosthesis: Considerations in Revision Surgery. Curr Urol Rep 2019;20(4):18. https://doi.org/10.1007/s11934-019-0881-9

Table 1. Demographic and perioperative characteristics of patients undergoing ppı revision surgery (n=30)

Parameter	Value
Age (years)	58.0 ± 7.5
Body mass index (BMI, kg/m²)	27.4 ± 4.0
Comorbidities, n (%)	
- Diabetes mellitus (DM)	14 (46.7%)
- Smoking	18 (60.0%)
- Cardiovascular disease	17 (56.7%)
Radical prostatectomy history, n (%)	6 (20.0%)
Malleable penile prosthesis, n (%)	6 (20.0%)
Revision indication, n (%)	
- Non-functioning prosthesis	10 (33.3%)
- Visible deformity	5 (16.7%)
- Inadequate inflation	6 (20.0%)
- Malleable to IPP conversion	4 (13.3%)
- Infection	5 (16.7%)
Surgical approach, n (%)	
- Infrapubic incision	12 (40.0%)
- Penoscrotal incision	18 (60.0%)
Operative time (minutes)	101.8 ± 20.0
Post-operative drain placement, n (%)	15 (50.0%)
Drain volume (mL)	54.3 ± 15.0
Hospital stay (days)	2.1 ± 0.7
Complications, n (%)	
- Clavien-Dindo Grade I	4 (13.3%)
- Scrotal/perineal ecchymosis	4 (13.3%)
- Clavien-Dindo Grade II	5 (16.7%)
- Orchitis	3 (10.0%)
- Wound infection	2 (6.7%)

Notes: Continuous variables are presented as mean ± standard deviation (SD). Categorical variables are presented as frequency (percentage). BMI: Body Mass Index; DM: Diabetes Mellitus; IPP: Inflatable Penile Prosthesis. Drain volume and revision indications were included based on study results. Radical prostatectomy history and malleable penile prosthesis data were added from study text.