# Comparison of Penile Prosthesis Cultures Within Individual Patients After Removal/Replacement and Subsequent Salvage

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#### ABSTRACT

**Introduction:** Infection rates for virgin inflatable penile prostheses (IPPs) range from 1 to 3%; however, this can increase to 7-18% after IPP revision or removal/replacement (RR) for mechanical malfunction. Although studies have reported various RR and salvage cultures, limited data are available that directly compare microorganisms after each of these procedures within the same patient. Comparison of these cultures may determine if the infection is due to a persistent microorganism or new inoculation.

Aim: Our aim is to characterize prosthesis cultures within individual patients who develop infection after RR.

**Methods:** We retrospectively reviewed patients undergoing various IPP procedures at our institution from September 2002 to August 2018. RR procedures were determined by current procedural terminology codes 54,410 or 54,416. Infection, defined as salvage or explanation without replacement for infectious reasons, was described by current procedural terminology codes 54406, 54411, 54415, or 54417. Inclusion criteria consisted of IPP infection after RR and the presence of both RR and salvage cultures within the same patient. Owing to the small cohort size, only descriptive statistics were used.

Main Outcome Measures: Characterization of removal/replacement and salvage cultures is the main outcome measure of this study.

**Results:** A total of 202 non-infected RR procedures were performed with 9 cases (4%) of IPP infection after RR identified. Four (44%) of the RR cultures were positive and contained gram-positive (44%) and gram-negative (11%) organisms. In comparison, salvage cultures grew gram-positive bacteria (66%), gram-negative bacteria (33%), and/or fungal elements (33%). A direct comparison of the RR and salvage cultures indicated that only 2 patients (22%) grew similar organisms.

**Conclusions:** The risk of IPP infection after RR and modified washout is low. In this small series, gram-positive bacteria were most common at the time of RR and salvage. The increased incidence of fungal infections may indicate a need to modify RR protocols. Larger multi-institutional studies are needed to further investigate this relationship. Chandrapal J, Harper S, Davis LG, et al. Comparison of Penile Prosthesis Cultures Within Individual Patients After Removal/Replacement and Subsequent Salvage. Sex Med 2020;8:783–787.

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Key Words: Penile Prosthesis; Infection; Cultures; Removal Replacement; Salvage

## INTRODUCTION

With approximately 20,000–30,000 implant surgeries per year, the inflatable penile prosthesis (IPP) is the standard treatment of erectile dysfunction in men refractory to medical and

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injection therapies.<sup>1,2</sup> Although the overall IPP longevity is favorable, implant infection poses a significant concern to even the most experienced prosthetic surgeon. Reported infection rates in virgin IPPs range from 1 to 3%; however, this increases after removal/replacement (RR) or revision for non-infectious reasons and can be as high as 18% within certain patient populations.<sup>3,4</sup>

Although others have reported operative and infection culture results, limited data are available that compare microorganisms within the same patient. This could be useful in identifying whether the infection is due to a persistent microorganism or new inoculation, which may influence antibiotic treatment or operative technique. Thus, we aimed to characterize prosthesis cultures within individual patients who develop infection after RR.

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#### MATERIALS AND METHODS

After institutional review board approval, we used the Duke Enterprise Data Unified Content Explorer to identify potential participants for this study. We included subjects undergoing IPP procedures at our institution from September 2002 to August 2018. RR procedures were identified by current procedural terminology codes for removal and replacement of all component(s) of a multicomponent IPP at the same operative session (54410) or removal and replacement of non-inflatable penile prosthesis (semirigid) or IPP (selfcontained) at the same operative session (54416). Infection, defined as salvage or explantation without replacement for infectious reasons, was described by current procedural terminology codes for removal of all components of a multicomponent IPP without replacement of prosthesis (54406), removal and replacement of all components of a multicomponent IPP through an infected field at the same operative session, including irrigation and debridement of infected tissue (54411), removal of non-inflatable penile prosthesis (semirigid) or IPP (selfcontained) without replacement of prosthesis (54415), or removal and replacement of non-inflatable penile prosthesis (semirigid) or IPP (self-contained) through an infected field at the same operative session, including irrigation and debridement of infected tissue (54417). The electronic medical record of this preliminary cohort was evaluated to obtain the final study cohort. Inclusion criteria consisted of IPP infection after RR and the availability of both RR and salvage cultures within the same patient. Patients with IPP extrusion were considered infected owing to prosthesis exposure. Cultures were obtained from the IPP reservoir balloon, cylinder, and pump. During all RRs, a modified washout procedure was performed. The modified washout consisted of catheter-directed Bacitracin irrigation into the proximal and distal corpora, pump space, and reservoir space. From the medical record, we collected demographic factors including age at prosthesis infection, body mass index (kg/m<sup>2</sup>), and race (white, black); comorbidity factors at the time of RR including diabetes, hypertension, coronary artery disease, peripheral vascular disease, chronic kidney disease, Charlson Comorbidity Index (CCI), and smoking history; and treatment history including prior radiation, immunosuppression, previous history of pelvic or penile surgeries, device type, corporal fibrosis, duration of oral antibiotics, and type of postoperative oral antibiotics after RR. For each infection, the original RR culture organisms and subsequent salvage culture organisms were captured.

Owing to the small number of infections, only descriptive statistics were used. Medians and associated interquartile ranges (IQRs) were used to summarize continuous variables, whereas categorical variables were summarized with counts and percentages. Data were manipulated and summarized using R, version 3.5.1.

### RESULTS

A total of 932 subjects underwent IPP procedures during the study time frame, and 202 subjects were identified as RR. After individual chart review, subjects were excluded for having IPP revision without RR, no salvage procedure, explantation because of non-infectious etiology, or absence of RR or salvage cultures. The final study cohort consisted of 9 (4%) cases resulting in IPP infection. The median (IQR) of age and body mass index of the patients were 57 (54, 70) and 27.8 (26, 32), respectively. Five (56%) were white patients, and 4 (44%) were black. The median (IQR) Charlson Comorbidity Index was 3 (2, 4), and the most common comorbidity was hypertension in 7 (78%) patients. No patients were on immunosuppression at the time of RR. Five patients (56%) were current or former smokers with a pack history ranging from 2.5 to 44 pack/year. Median (IQR) number of previous pelvic or penile surgeries was 2 (2, 4), and 2 (22%) patients had a history of radiation after IPP placement (Table 1). Within the infective cases, the American Medical System prosthesis was the most common IPP placed at RR (CX [n = 5,56%] and LGX [n = 1, 11%]) followed by the Coloplast Titan (n = 3,33%), Significant corporal fibrosis was identified in 3 (33%) patients, based on a coding modifier. Postoperative antibiotics were given for a median (IQR) duration of 10 (5,14) days with a fluoroquinolone being the most prescribed one (n = 5,56%) (Table 2).

RR cultures contained gram-positive (44%) and gram-negative (11%) organisms. In comparison, salvage cultures grew gram-positive bacteria (66%), gram-negative bacteria (33%), and/or

 Table 1. Demographics for patients with prosthesis infections after

 RR

Characteristic	Infections (N = 9)
Age (y), Median [IQR]	57 [54,70]
BMI, Median [IQR]	27.8 [26, 32]
Race, n (%)	
White	5 (56%)
Black	4 (44%)
Comorbidities, n (%)	
Diabetes	2 (22%)
Hypertension	7 (78%)
CAD	3 (33%)
PVD	2 (22%)
CKD	2 (22%)
Charlson Comorbidity Index, Median [IQR]	3 [2, 4]
Smoking History, n (%)	
Never	4 (44%)
Former	3 (33%)
Current	2 (22%)
Smoking pack/y, [min,max]	15 [2.5, 44]
History of radiation, n (%)	2 (22%)
Immunosuppression, n (%)	0
Number of previous pelvic and penile surgeries, Median [IQR]	2 [2, 4]

 $\mathsf{BMI} = \mathsf{body}\ \mathsf{mass}\ \mathsf{index};\ \mathsf{CAD} = \mathsf{coronary}\ \mathsf{artery}\ \mathsf{disease};\ \mathsf{CKD} = \mathsf{chronic}\ \mathsf{kidney}\ \mathsf{disease};\ \mathsf{IQR} = \mathsf{interquartile}\ \mathsf{range};\ \mathsf{PVD} = \mathsf{peripheral}\ \mathsf{vascular}\ \mathsf{disease};\ \mathsf{RR} = \mathsf{removal/replacement}.$ 

Table 2. Operative characteristics	and	postoperative	antibiotic
therapy after RR			

	Infections (N = 9)		
Types of IPPs, n (%)			
AMS CX	5 (56%)		
AMS LGX	1 (11%)		
Coloplast Titan	3 (33%)		
Modifier for corporal fibrosis, n (%)	3 (33%)		
Duration of oral antibiotics (d), Median [IQR]	10 [5, 14]		
Postoperative oral antibiotics after RR, n (%)			
Bactrim	2 (22%)		
Bactrim/Rifampin	1 (11%)		
Fluoroquinolone	5 (56%)		
Clindamycin	1 (11%)		

 $\mathsf{AMS}=\mathsf{American}$  Medical System;  $\mathsf{IPPs}=\mathsf{inflatable}$  penile prostheses;  $\mathsf{RR}=\mathsf{removal/replacement.}$ 

fungal elements (33%) (Figure 1). No culture growth was seen in 5 (56%) patients at the time of RR and 1 (11%) patient at the time of salvage (Table 3). Of the 9 infections, 3 (33%) had both positive RR and salvage culture for comparison. A direct comparison of the RR and salvage cultures in this group had 2 patients (22%) who grew similar organisms. Within this group, 1 patient had pan-sensitive cultures and the other did not have susceptibilities performed as this is not routinely performed at our institution for gram-positive bacteria other than *Staphylococcus aureus* or *Enterococcus* species because of a low antibiotic resistance pattern.

### DISCUSSION

At our institution, we found a 4% infection rate after IPP RR. Within RR cultures, 44% contained gram-positive bacteria and 11% grew gram-negative bacteria. Salvage cultures demonstrated gram-positive bacteria, gram-negative bacteria, and fungi at 66%, 33%, and 33%, respectively. When directly comparing RR and salvage cultures in individual patients, we found that only 2 patients grew similar microorganisms.

Reported infection rates after IPP revision or RR are higher than virgin procedures. While virgin cases have reported infection rates of 1-3%, revision or RR cases can be as high as 18%.<sup>3,5</sup> At our institution, the infection rate after RR was 4%, which is consistent with the current literature. In one of the larger, multicentered studies, Henry et al<sup>4</sup> analyzed 214 clinically uninfected IPP revisions and reported a subsequent infection rate of 5.7%. Compared with historical infection rates, this is a significant reduction and can be attributed to the introduction of antibiotic-coated implants, improvement in sterile surgical techniques, and antibiotic coverage.

Historically, IPP infections were most commonly caused by gram-positive bacteria, such as Staphylococcus species found on the skin.<sup>3,6</sup> This is reasonable given the handling of the prosthesis during implantation, the close proximity of the implant to the skin, and the manipulation required for pump activation. However, more contemporary studies report a wider range of microbes, including gram-negative bacteria and fungal elements.<sup>7,8</sup> In our cohort, gram-negative bacteria were present in 11% and 33% of RR and salvage cultures, respectively. In addition, 33% of patients grew Candida species at the time of salvage. This trend of atypical microorganisms found in IPP infections is consistent with the literature. Dawn et al performed a literature review of organisms characterized at the time of revision and found an increase in both clinically uninfected and infected implants with fungi, Escherichia coli, and Enterococcus species. These microbes are not limited to prosthetic revision surgery but can also be found during salvage. In a 25-center, multi-institutional retrospective study, Gross et al<sup>8</sup> reviewed intraoperative cultures obtained at explantation or Mulcahy

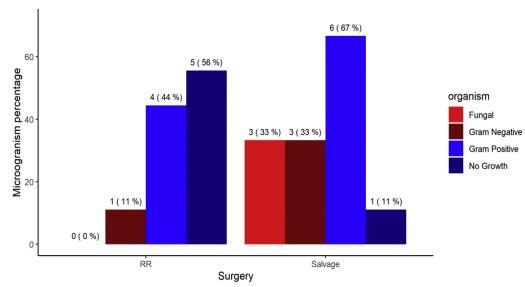


Figure 1. Culture data from RR and salvage. RR = removal/replacement.

Patient	Removal replacement cultures	Salvage cultures
1	<ul> <li>Enterococcus faecalis*</li> <li>Pseudomonas aeruginosa<sup>†</sup></li> </ul>	<ul> <li>Enterococcus faecalis*</li> <li>Pseudomonas aeruginosa<sup>†</sup></li> </ul>
2	<ul> <li>Coagulase-negative Staphylococcus<sup>‡</sup></li> <li>Streptococcus viridans<sup>5</sup></li> </ul>	<ul> <li>Coagulase-negative Staphylococcus<sup>‡</sup></li> <li>Streptococcus viridans<sup>5</sup></li> </ul>
3	Coagulase-negative     Staphylococcus	• Candida glabrata
4	<ul> <li>Coagulase-negative Staphylococcus</li> <li>Streptococcus viridans</li> </ul>	None
5	None	<ul> <li>Bacteroides</li> <li>Peptostreptococcus</li> <li>Streptococcus viridans</li> </ul>
б	None	<ul> <li>Coagulase-negative Staphylococcus</li> <li>Klebsiella</li> <li>Streptococcus viridans</li> </ul>
7	None	<ul> <li>Candida albicans</li> <li>Staphylococcus aureus</li> </ul>
8	None	<ul> <li>Group B Streptococcus</li> <li>Streptococcus viridans</li> </ul>
9	None	• Candida albicans

RR = removal/replacement.

\*<sup>,†</sup>Pan-sensitive.

<sup>‡,§</sup>No susceptibilities were performed.

salvage and found gram-negative and *Candida* species in 39% and 11% of positive cultures, respectively. Taken together, these studies demonstrate the emergence of non-traditional pathogens and suggest that expanded coverage of antimicrobial therapies to include gram-negative bacteria and fungi may be needed.

Despite the association, the presence of positive cultures may not lead to clinical infections. A multicenter study by Henry et al<sup>6</sup> reported a 70% positive culture rate in patients with clinically uninfected penile prostheses. Similarly, Silverstein et al<sup>9</sup> examined penile prostheses under confocal scanning laser microscopy from patients undergoing IPP revision or removal for mechanical malfunction and found positive cultures in 80% of patients. These studies suggest that the presence of microorganisms may not lead to clinical infections, and the lack of infection could be attributed to a combination of microbe virulence and host immune mechanisms.

One unique aspect of our study is the sample size. This study assessed 202 IPP revision procedures, which is one of the largest cohorts reported for this procedure at a single institution. Second, we performed a direct comparison of RR and salvage cultures. Other studies performed similar culture analyses but did not directly compare these cultures within the same patient. Of the patients who developed IPP infection after RR, only 2 patients had identical cultures at RR and salvage. As these species did not demonstrate antibiotic resistance, the findings suggest that the similar cultures were attributed to either microbial persistence or reinfection with the same microbes.

Our study has several limitations. This study was limited and underpowered by the small cohort of patients undergoing IPP RR and subsequent salvage. This reflects the overall low prevalence of IPP infections and inconsistent collection of cultures on salvage. Patients who underwent IPP procedures at our institution could have been lost to follow-up or presented to other hospitals for prosthesis-related care, resulting in potential underreporting of infections. However, as our electronic health record system receives information from outside hospitals and were included in our review; this limitation is assumed to be minor. A limitation of the electronic health record is that abstracted information may be subject to incorrect coding or mislabeling. To avoid this, each chart was manually reviewed to validate the inclusion and exclusion criteria.

Characterization of RR and salvage cultures within individual patients helps determine if IPP infection after RR could be attributed to persistent or new microorganisms and may influence surgical field disinfection techniques at the time of RR. As this study was limited by a small sample size and low disease prevalence, future directions include expansion to a multiinstitutional phase to increase study power.

## CONCLUSION

At our institution, infection after IPP RR is rare and consistent with the reported rates within the literature. Most infections after RR were not similar to the organism cultured at the time of replacement. The increased incidence of gram-negative bacteria and fungi may indicate a need to modify RR protocols with broader antimicrobial treatment to cover these emerging microorganisms.

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## REFERENCES

- 1. Burnett AL, Nehra A, Breau RH, et al. Erectile dysfunction: AUA Guideline. J Urol 2018;200:633-641.
- Santucci R, Bandukwala N. Penile prosthesis implantation Medscape [updated 8/31/16. Available at: https://emedicine. medscape.com/article/446761-overview#a5. Accessed May 28, 2019.
- Wilson SK, Delk JR 2nd. Inflatable penile implant infection: predisposing factors and treatment suggestions. J Urol 1995; 153(3 Pt 1):659-661.

- Henry GD, Donatucci CF, Conners W, et al. An outcomes analysis of over 200 revision surgeries for penile prosthesis implantation: a multicenter study. J Sex Med 2012;9:309-315.
- 5. Montague DK, Angermeier KW, Lakin MM. Penile prosthesis infections. Int J impotence Res 2001;13:326-328.
- Henry GD, Wilson SK, Delk JR 2nd, et al. Penile prosthesis cultures during revision surgery: a multicenter study. J Urol 2004;172:153-156.
- 7. Dawn LE, Henry GD, Tan GK, et al. Biofilm and infectious Agents present at the time of penile prosthesis revision surgery: Times are a Changing. Sex Med Rev 2017;5:236-243.
- 8. Gross MS, Phillips EA, Carrasquillo RJ, 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; 14:455-463.
- Silverstein AD, Henry GD, Evans B, et al. Biofilm formation on clinically noninfected penile prostheses. J Urol 2006; 176:1008-1011.