Revision Washout Decreases Implant Capsule Tissue Culture Positivity: A Multicenter Study

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Purpose: Positive cultures, visible biofilm and confocal micrography confirm bacterial presence on clinically uninfected inflatable penile prostheses at revision surgery. Salvage irrigation has been proved to rescue patients with clinically infected inflatable penile prostheses. Similar washout at revision for noninfectious reasons significantly lowers subsequent infection rates. We investigated a larger series of patients for positive culture rates and evaluated implant capsule tissue culture rates before and after revision washout.

Materials and Methods: At 4 institutions a total of 148 patients with inflatable penile prostheses underwent revision surgery for noninfectious reasons between June 2001 and September 2005. Swab cultures of the fluid around the pump and visible biofilm were obtained. Also, in 65 patients a wedge of tissue from the capsule that forms around the pump was cultured. After implant removal revision washout of the implant spaces was performed and a second wedge of tissue was cultured.

Results: Of the 148 patients 97 (66%) had positive bacterial swab cultures of the fluid around the pump or biofilm. A total of 124 isolates were cultured. Of the 65 implant capsule tissue cultures obtained before washout 28 (43%) were positive for bacteria, while 16 (25%) obtained after revision washout were positive.

Conclusions: Positive cultures and visible bacterial biofilm are present on clinically uninfected inflatable penile prostheses at revision surgery in most patients. Revision washout appears to decrease the bacterial load on implant capsule tissue at revision surgery of inflatable penile prostheses for noninfectious reasons.

Key Words: penis, infection, prostheses and implants, impotence, bacteria

Prosthetic devices are a well established form of treatment for medically refractory erectile dysfunction. Postoperative infection is the most feared complication of any genitourinary prosthetic surgery. Whereas the incidence of infection with original implantation is only 1% to 3%, traditional revision surgery carries a 7% to 18% risk.[1–5] In most cases of infection associated with primary implantation bacteria are believed to be introduced at surgery.[6,7] It is believed that a capsule of tissue envelopes the implant, effectively sealing off the prosthesis within 72 hours postoperatively.[8–10]

Licht et al reported in 1995 that 43% of cultured penile prostheses and 36% of cultured artificial urinary sphincters yielded organisms from clinically uninfected devices during revision.[1] In 2003 our group reported that culture positive bacteria were found in 54 of 77 patients (70%) with clinically uninfected inflatable penile prostheses at reoperation.[8] That study also showed that IPPs with positive bacterial cultures had a shorter mechanical revision-free failure rate than IPPs with negative cultures. We also noted that several patients had visible biofilm despite no signs of clinical infection preoperatively. In 2006 Silverstein et al used scanning laser microscopy and noted that 8 of 10 IPPs removed for mechanical failure had bacteria and associated biofilm on the implants.[9]

Coated prostheses have been introduced, including the InhibiZone™ antibiotic coating of the AMS 700® penile prosthesis, consisting of a combination of rifampin and minocycline. Also, the hydrophilic Titan® coating of the Titan penile prosthesis (Coloplast, Atlanta, Georgia) absorbs whatever antibiotic solution it is dipped into. These coatings on the outside of IPPs decrease the infection rate of primary implantation surgery.[11,12]

Salvage rescue, that is vigorously washing out the implant space with an antiseptic irrigation protocol, is effective for infected IPPs.[13] Revision washout, which is a similar antibiotic irrigation protocol, decreases subsequent infection in cases of clinically uninfected IPPs.[10] Bacterial biofilm is present on the IPPs in most patients at revision surgery. We assume that salvage rescue and revision washout decrease subsequent infections by mechanically cleansing the implant spaces. A decreased bacterial presence in implant spaces after salvage rescue and revision washout is the basis for the clinical practice.

Thus, we evaluated the bacterial presence on the capsule that forms around implanted IPPs. We also investigated

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capsule tissue culture rates before and after revision washout for bacterial presence. Moreover, we reinvestigated the culture swab positivity rate of the implants as well as whether a bacterial presence on swab culture affects the longevity of the mechanical failure-free revision rates of IPPs in a larger series of patients. To our knowledge this is the first such study of the surgical capsule bacterial presence before and after lavage irrigation.

MATERIALS AND METHODS

The study was prospectively performed. It consisted of 148 patients who underwent reoperation of a penile prosthesis at a total of 4 institutions between June 2001 and September 2005. Patients underwent revision or explantation/replacement of the prostheses for mechanical failure, patient dissatisfaction or poor functional outcome. There was no clinical evidence of infection in any patients before reoperation. Institutional review board approval was obtained for the study and all patients provided informed consent before surgery. The study involved patients of varied ancestry/ethnic origins, including 1 Arab, 129 white, 15 black and 3 Hispanic men.

Upon entering the pump space, swab cultures of the fluid around the pump and any visible biofilm on the IPP were obtained. This protocol was previously described.[8] In addition, a tissue wedge was removed from the capsule that forms around the pump and sent in a sterile specimen cup for tissue grinding culture. After implant removal, revision washout of the implant spaces was performed. The implant was completely removed and in a few cases the reservoir was left behind. All implant spaces were then washed out with the antiseptic solutions of the Mulcahy salvage rescue protocol before replacement with a 3-piece IPP, as previously described.[10] After revision washout a second tissue wedge was obtained from the capsule that had surrounded the old pump and similarly sent for culture. Each set of implant capsule tissue cultures (before and after revision washout) was obtained from 65 patients.

Nonparametric revision-free duration curves were calculated using the Kaplan-Meier product limit method.[14] Patients were separated into 2 groups for analysis, including group 1—those with positive swab cultures and group 2—those with negative swab cultures. There was no demographical difference between the 2 groups. Separate curves were estimated for patients with and without bacterial presence on swab culture and the 2 curves were compared using the log rank test.[14] Data management and analysis were performed using Stata®, version 9.2.[15]

RESULTS

Of the patients 73% underwent reoperation because of prosthesis mechanical breakdown. Table 1 lists the indications for reoperation. A total of 72 patients had a Mentor Alpha®, 59 had an AMS 700, 3 had an AMS Dynaflex®, 4 had an AMS Ambicor®, one had an AMS Hydroflex®, 2 had a Mentor Titan, 1 had a Flexiflate®, 1 had a Mentor Mark II (Mentor, Santa Barbara, California) and 5 had malleable rods. Average age of the 148 patients was 65.5 years (range 33 to 91), 32% were known to be diabetic and 78% were undergoing the first revision. The mean interval to reoperation in the group was 47.9 months (range 1 to 190).

TABLE 1. *Indications for reoperation in patients who underwent culture*

Reoperation Indication	No. Pts (%)
Mechanical (tubing fracture, fluid loss)	108 (73)
Patient dissatisfaction	5 (3.4)
Chronic IPP pain	4 (2.7)
Impending cylinder erosion/lat distal tip extrusion	8 (5.4)
Tissue lengthening/fibrotic stretch	5 (3.4)
Penile deformity (SST, S shape)	9 (6.1)
Other (reservoir hernia, proximal migration, cylinder aneurysm, hematoma, pump induration)	9 (6.1)

Of the 148 patients 97 (66%) had positive bacterial cultures on swab of the fluid around the pump upon surgically entering the pump space or of any visible biofilm on the IPP. A total of 124 isolates were cultured from those 97 patients (table 2). Of the 65 implant capsule tissue cultures obtained upon initially entering the pump space 28 (43%) were positive for bacteria with 4 patients having more than 1 type of bacteria. Of the 65 implant capsule tissue cultures obtained after revision washout 16 (25%) were positive for bacteria with 2 patients having more than 1 type of bacteria (table 3 and fig. 1).

Figure 2 shows Kaplan-Meier revision-free survival curves. Overall the mean revision-free duration was 6.3 years in patients with negative culture swabs compared with 4.7 years in patients with positive culture swabs (log rank $p = 0.0162$).

DISCUSSION

Inflatable penile prostheses are a well established treatment for erectile dysfunction. In the last 30 years multiple product enhancements have produced prostheses with a markedly decreased mechanical failure rate. In fact, most authorities now believe that the devices are more often revised because of human factors, such as infection and medical problems, than because of mechanical failure.[16] Despite mechanical improvements, infection has remained a significant complication of prosthetic surgery.

Multiple studies indicate an increased risk of infection when repeat operations (revisions) are performed on genitourinary prostheses.[2–5,10,11] This increased incidence of infection associated with reoperation was postulated to be caused by decreased host resistance factors, impaired antibiotic penetration of the area due to the capsule surrounding the components and decreased wound healing related to scar formation. The organism most often responsible for the infection in reoperation is Staphylococcus epidermidis.[1] This bacterium is also the most common cause of infection during the original implantation, accounting for 35% to 80% of all positive cultures.[1,6]

Most authorities believe that genitourinary prosthetic infection is caused by contamination of the implant space at surgery. Studies show that preoperative nasal swab cultures of certain Staphylococcus species significantly correlated with postoperative surgical site wound infections.[17] Hematogenous late infections occur but rarely.[18] After adherence to the implant and colonization many bacteria, including staphylococci, produce a protective mucin coat or biofilm.[7] Bacterial adherence to IPPs by several bacterial species has been observed in the laboratory for many years.[19]

TABLE 2. *Isolates cultured from clinically uninfected IPPs*

Organism Cultured	No. Total Isolates (%)
S. epidermidis	55 (44)
S. lugdunensis	23 (18.5)
S. hemolyticus	9 (7)
S. capitis	6 (5)
Streptococcus mitis	4 (3)
Methicillin resistant *S. aureus*	2 (1.6)
S. ureolyticus	3 (2.4)
S. warneri	3 (2.4)
S. auriculris	2 (1.6)
Propionbacterium	3 (2.4)
Enterococcus faecalis	3 (2.4)
Other (*S. hominis, S. simulans, Eschericha coli,* Pseudomonas aureus, *S. shleiferi, S. bovis, S. milleri*)	11 (9)
Yeast	2
Corynebacterium	2

In 1996 Brant et al reported salvage success with clinical infections.[13] Their method, which has successfully been repeated by others since then, involves removing the infected device and sequential lavage of antiseptic solutions to sterilize the implant space, followed by immediate reimplantation of a sterile replacement device. Only after the complete implant has been removed and the entire capsular space is thoroughly irrigated is the new implant placed. We believe that the success of this technique for eradicating infection is predicated on the removal of bacteria and the biofilm by vigorous lavage of the implant spaces. To our knowledge there are no known studies to date showing that the bacterial presence is changed by lavage of the implant spaces during surgery.

Licht et al found that 40% of clinically uninfected penile prostheses and 36% of artificial urinary sphincters had low colony counts of S. epidermidis.[1] Three of the patients with positive cultures later had infection and higher colony counts of the organism were found at explantation. No patients with penile prostheses who had negative culture at reoperation showed a subsequent prosthetic infection. Therefore, ensuring that the replacement implant has a sterile environment in which to be placed at revision/replacement may lower the rate of prosthesis reoperation infection. Even better, using the salvage protocol of irrigation with antiseptic solutions at replacement, revision washout

TABLE 3. *Pump space capsule tissue grinding culture isolates before and after revision washout*

Organism Cultured	No. Isolates	
	Before Washout	After Washout
S. epidermidis	16	8
S. lugdunensis	5	4
S. ureolyticus	1	
S. shleiferi	1	
Micrococcus species	1	1
S. capitis	1	
E. faecalis	1	1
S. milleri	1	
S. auriculris	1	
S. warneri		2
S. salivarius	1	
Gram-Pos rod	2	
S. simulans		1
S. hemolyticus	1	
Proteus mirabilis	1	
S. sanguis		1

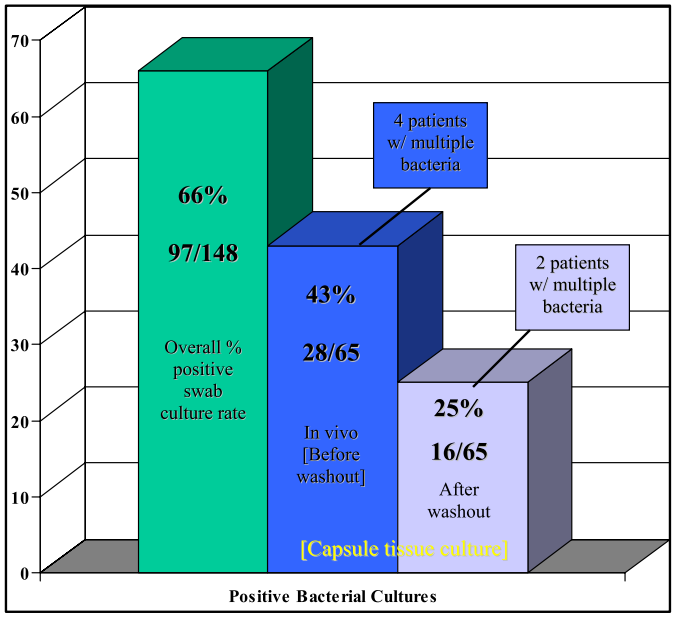

FIG. 1. Percent of positive bacterial cultures at IPP revision surgery for noninfectious reasons.

combined with insertion of an antibiotic coated prosthesis appears to help ensure a sterile environment for the new implant, while antibiotic elution could address bacterial contamination at revision surgery.[10,20] Therefore, establishing the bacterial presence/contamination on the capsule tissue before and after antiseptic lavage is valuable knowledge for the operating surgeon. Does revision washout even decrease this assumed bacterial presence on the implant space capsule tissue?

Although the washout solutions used are antiseptic, it is possible that the most important part of the washout is mechanical débridement of the bacteria/biofilm in the implant space.[10,13] Abouassaly et al reported decreased infection rates with revision washout using only a copious amount of 1 type of antibiotic solution instead of the several smaller amounts in the original salvage rescue protocol.[20] In fact, some investigators of that group now use a larger amount of 1 solution instead of several solutions. A possible future study could compare antiseptic solutions vs normal

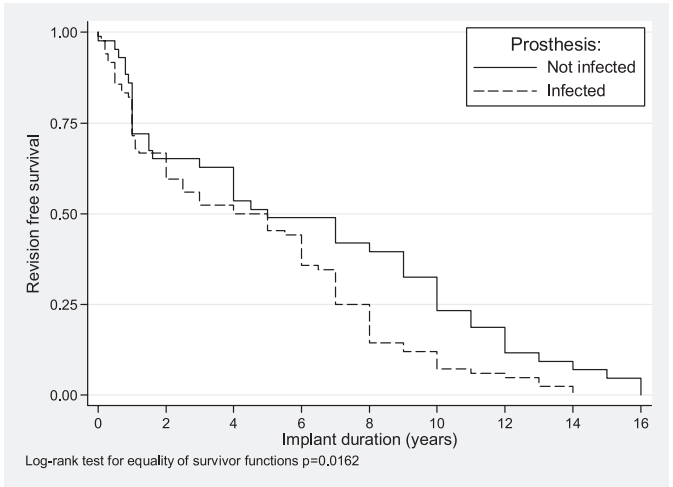

FIG. 2. Kaplan-Meier product limit estimated revision-free survival stratified by bacterial presence on culture swab.

saline as the irrigant in the washout. It is possible that some irrigants used in the original salvage rescue protocol, ie hydrogen peroxide, cause tissue irritation or poor wound healing, making patients more susceptible to infection.

Although the antibiotic coating InhibiZone, which is a combination of rifampin and minocycline on the outside of IPPs, decreases the infection rate of primary implantation surgery, it appears to have a less dramatic effect in revision cases.[10,11] The established biofilm found during revision surgery could present too overwhelming a bacterial colony count for the antibiotic coating. The amount of antibiotic used to coat the outside of the AMS 700CX InhibiZone penile prosthesis is less than a single oral pill, which is potentially enough to lower infection rates in primary surgeries but not enough to treat the established biofilm found in secondary cases. It was assumed that washing out the implant spaces to remove the biofilm and sterilize the surgical site before replacement with an antibiotic coated IPP would decrease the bacterial presence and lower subsequent infection rates.[10] Our study demonstrates that in 45% of the cases there were culture positive bacteria on the implant space capsule tissue, which were isolated upon entering the pump space. The load of bacteria present may be too much for the antibiotic coating on the newer implants to decrease the revision infection rates. However, after revision washout the rate of culture positive bacteria was decreased by almost half to 25%, indicating a decrease in the amount of bacteria present on the implant capsule after surgical lavage of the implant spaces. Moreover, the number of patients for whom culture yielded more than 1 type of bacteria decreased from 4 to only 2 after revision washout. A decreased bacterial presence appears to be the basis for the revision washout and the salvage rescue success in decreasing subsequent revision surgery infection rates. Of note, residual antibiotic fluid used during revision washout could be a contributing factor in the lower culture positive bacteria rate on the implant space capsule tissue after washout. To our knowledge our study is the first demonstrating a scientific basis for decreasing bacterial contamination after surgical antiseptic lavage.

An aspect of the data that was surprising was how many culture positive bacteria were still present on the capsules after antiseptic lavage of the implant space. A 25% rate is still quite high, in that surgeons are placing a foreign body (the IPP) against a thick capsule of tissue that has live bacteria on it. Classically prosthetic surgeons would be appalled by this concept but recognizing the almost universal presence of biofilm on implants, as defined by scanning laser microscopy at clinically uninfected revisions, maybe decreasing the bacterial load with revision washout is enough to decrease the infection rate in revision cases. However, this 25% culture positive rate indicates that perhaps revision washout should be more aggressive to try to decrease bacterial contamination even more. The patient should receive adequate systemic antibiotics before revision surgery and several liters of antiseptic lavage washout should be used. Perhaps in the future a study could be done in which the tissue surrounding the pump would be debrided, especially in patients undergoing a true salvage procedure.

A common question raised by urologists on the subject of biofilm is how high the positive swab culture rate of the fluid around the pump/visible biofilm (70%) was in our 2004 study.[8] In this study, which was much larger, the bacterial positivity rate was almost the same at 66%. Moreover, since that 2004 report the bacteria/biofilm presence on scanning laser microscopy was found to be 80%.[9] Another issue was the finding that revision-free implant survival was lower in patients with positive bacterial swab cultures than in those with negative cultures. In this larger study we found that average revision-free survival was 1.6 years less in patients with positive bacterial swab cultures than in those with negative cultures. We do not have a good reason for this finding. Future research could involve an even larger series of patients, evaluating the best solution or amount of fluid to use for revision washout/salvage rescue lavage for an optimal decrease in bacteria, and determine whether an antibiotic coating on the IPP decreases the positive bacterial swab and/or the tissue capsule culture rate.

CONCLUSIONS

Positive cultures and visible bacterial biofilm were present on clinically uninfected IPPs at revision surgery in most patients in a larger series than previously reported. Revision washout appears to decrease the bacterial presence on implant capsule tissue at revision surgery of IPPs for noninfectious reasons.

Abbreviations and Acronyms

IPP = inflatable penile prosthesis

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EDITORIAL COMMENT

This study shows a 25% positive culture rate at reoperation in the capsular tissue surrounding the pump after vigorous antibiotic and antiseptic washing of the tissues following removal of the penile implant. In some cases bacteria become imbedded in the capsular tissues. Removing this capsule entirely would be difficult and unwise, especially the capsule surrounding the cylinders. This would lead to additional postoperative scarring and likely shortening of the erection.

It has been our policy to give a month of oral quinolone antibiotics following a true salvage procedure and this study supports that routine. Quinolones have good tissue penetration and they are effective against many of the pathogens found in wounds, including most staphylococcal species. Adding a second antibiotic such as amoxicillin/clavulanate would provide a broader spectrum of coverage. The tissue penetration of these antibiotics may help decrease bacterial levels in the capsule even further. Using copious amounts of irrigation during the initial implant procedure is certainly the best way to decrease the bacterial growth surrounding a significant number of implants at reoperation.

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REPLY BY AUTHORS

We routinely give a 5 to 7 day course of an oral quinolone and a second antibiotic similar to amoxicillin/clavulanate for broader spectrum of coverage, even for routine revision cases. Giving an oral quinolone for 1 month after salvage procedures, as suggested in the comment, is an excellent idea which I will implement. The 25% positive culture rate for capsular tissue surrounding the pump despite antibiotic and antiseptic lavage after implant removal warrants a more aggressive approach during revision washout. During the initial (virgin) implant procedure we typically only irrigate the corpora to check for distal perforation and to "wash off" any parts of the implant that touched the skin, especially the pump, before placing it in the body. For the infrequent implanter ensuring proper alcohol based skin preparation (not iodine), preoperative antibiotics and reduced operative time, and limiting the implant from touching the skin are probably the best ways to reduce the bacterial contamination surrounding significant numbers of implants at reoperation.