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# PENILE PROSTHESIS CULTURES DURING REVISION SURGERY: A MULTICENTER STUDY

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## ABSTRACT

Purpose: Initial implantation of inflatable penile prosthesis has a 3% risk of infection. Reoperation of penile implants has a higher rate of infection, estimated between 10% and 18%. To explain the higher risk in revision surgery in this prospective study we cultured clinically uninfected prostheses requiring revision. Prosthesis pain was also investigated as a predictor of positive culture.

Materials and Methods: At 3 institutions cultures were prospectively obtained from 77 clinically uninfected penile prostheses at revision surgery. Immediately upon surgical exposure of the pump cultures were obtained. If a bacterial biofilm was noted on any component it was additionally cultured. All culture isolates positive for a staphylococcus species were tested for sensitivity to rifampin and tetracycline (minocycline). An implant is now available that is coated with these antibiotics. Patient history of chronic prosthesis pain was ascertained.

Results: Culture positive bacteria were found in 54 of 77 (70%) patients with clinically uninfected penile prostheses. In some patients more than 1 organism grew and, occasionally, the pump culture was negative but the biofilm was positive. Of 54 patients 49 had positive (90%) culture for staphylococcus genus with 10 different species. All staphylococcal species were sensitive to rifampin and/or tetracycline. We did not find a significant association between prosthesis related pain and culture laboratory results.

Conclusions: The majority of clinically uninfected penile prostheses have organisms growing in the implant spaces at reoperation. Most of these organisms are staphylococcal species that are sensitive to rifampin/minocycline.

KEY WORDS: 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 genitourinary prosthetic surgery. While the incidence of infection during the initial implant is only 1% to 3%, revision surgery has a 10% to 18% risk.[1–3] It is believed that in most cases of infection bacteria are introduced at surgery.

Previous articles in the literature have shown Staphylococcus epidermidis to be the most common bacterium cultured from infected penile prostheses and urinary sphincters. It typically takes more than 6 weeks for a patient to present with clinical infection. Chronic prosthesis pain has been labeled a predictor of which patients will eventually present with subclinical infection due to staphylococci species.[4] Licht et al reported in 1995 that 43% of penile prostheses and 36% of artificial urinary sphincters cultured organisms from clinically uninfected devices during revisions.[5] To our knowledge no studies have evaluated the sensitivities of cultured organisms.

We prospectively obtained intraoperative cultures of genitourinary prostheses in patients undergoing reoperation for reasons other than infection. All were clinically uninfected. For cultures positive for any staphylococcus species we evaluated sensitivities to rifampin and tetracycline (minocycline), the new antibiotic coating (InhibiZone) of the American Medical Systems (AMS) 700 penile prosthesis (AMS, Minnetonka, Minnesota). Finally, we evaluated the complaint of chronic prosthesis pain to correlate it with positive implant cultures at revision surgery.

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## MATERIALS AND METHODS

A total of 77 patients who underwent reoperation of a penile prosthesis at 3 centers between January 2002 and February 2003 were entered in the study. There was no clinical evidence of infection in any of the patients. Patients underwent either revision or explantation/replacement of the prosthesis for mechanical failure, patient dissatisfaction or poor functional outcome. The indications for reoperation are listed in table 1. The majority of the patients underwent reoperation because of mechanical breakdown of the prosthesis (68%), primarily tubing fractures. History of chronic prosthesis pain was determined before reoperation. Of the patients 51 had a Mentor Alpha (Mentor Corporation, Santa Barbara, California), 19 had an AMS 700, 2 had a Dynaflex, 2 had an Ambicor, 1 had a Hydroflex and 2 had malleable rods. Average patient age was 64 years (range 45 to 91). Mean interval to reoperation for the group was 53 months (range 2 to 190).

All patients received perioperative intravenous antibiotics and underwent a 10-minute skin preparation with a povidone-iodine scrub. For penile prosthesis revisions, aero-

TABLE 1. *Indications for reoperation*

| Indication | No. Pts (%) |
|---|---|
| Mechanical (tubing fracture, loss of fluid) | 52 (67.5) |
| Patient dissatisfaction | 4 (5.2) |
| Chronic prosthesis pain | 4 (5.2) |
| Impending cylinder erosion | 4 (5.2) |
| Tissue expansion | 5 (6.5) |
| Other (reservoir hernia, proximal migration, cylinder aneurysm, deformity, hematoma, pump induration) | 8 (10.4) |

TABLE 2. *Isolates cultured from clinically uninfected penile prostheses*

| Organism Cultured | No. (% total isolates) |
|---|---|
| S. epidermidis | 25 (39) |
| S. lugdunensis | 14 (22) |
| S. capitis | 3 (5) |
| S. haemolyticus | 3 (5) |
| Streptococcus mitis | 3 (5) |
| Methicillin resistant S. aureus | 2 (3) |
| S. auricularis | 2 (3) |
| Propionibacterium | 3 (5) |
| Others (S. warneri, S. ureolyticus, S. simulans, Escherichia coli, Pseudomonas aeruginosa, yeast [2], corynebacterium [2]) | 9 (14) |

bic and anaerobic culture swabs were taken of the pump and capsule/fluid surrounding the pump upon entering the pump space. If the surgeon saw a suspicious area of biofilm on any component an additional culture swab was taken of that area (fig. 1). The cultures were taken immediately upon surgical exposure of the pump with the implant still essentially in vivo. If the culture was positive for a staphylococcus species sensitivities to rifampin and tetracycline were determined.

The association between penile implant infection and implant related pain was tested using Fisher's exact test.[6] Nonparametric revision-free duration curves were computed using the Kaplan-Meier product limit method. The patients were separated into 2 groups for analysis, those requiring revision for mechanical reasons and for nonmechanical reasons. Separate curves were estimated for patients with and without positive growth cultures, and the 2 curves were compared using the log rank test.[7] Because the entire patient cohort underwent implant revision (ie failed) the mean revision-free time was estimated without bias by computing the area under the Kaplan-Meier curve.[8,9] Data management and analysis were performed using the Stata statistical package version 8.0 (StataCorp LP, College Station, Texas).

## RESULTS

Culture positive bacteria were found in 54 of 77 (70%) patients with clinically uninfected penile prostheses at reoperation. Of the 54 patients with culture positive bacteria more than 1 isolate grew in 3. Of the 54 patients 49 had positive (90%) culture for staphylococcus genus with 10 different species. S. epidermidis was the most prevalent, evident in 46%, followed by S. lugdunensis (26%). Isolates cultured from clinically uninfected penile prostheses at reoperation are shown in table 2. Only 2 of the 52 staphylococcal isolates were resistant to rifampin, however both were sensitive to tetracycline. Therefore, all the staphylococcal species were sensitive to rifampin and/or tetracycline.

Preoperative chronic prosthetic pain was present in 4 of the 77 patients. Of the 4 patients 3 (75%) with chronic pain had positive culture whereas 51 of 73 (70%) patients without prosthetic pain had positive culture. S. epidermidis grew in all 3 of the patients with chronic pain and positive cultures. No statistically significant association was found between the occurrence of penile implant bacterial growth and implant related pain (Fisher's exact test $p = 0.655$). Approximately 70% of patients not reporting penile implant associated pain had a positive growth culture compared to 75% of patients reporting pain (table 3).

In this series 48 patients had time to revision data culture results and underwent revision due to mechanical failure. Kaplan-Meier product limit estimated revision-free duration curves by culture growth outcome for implants revised for mechanical failure are plotted in figure 2. Patients with positive growth cultures had significantly shorter revision-free times than patients with negative growth cultures (log rank test $p = 0.0198$). The mean revision-free time for patients with positive cultures was 6.3 years (95% CI 5.0, 7.6) compared to 8.9 years (95% CI 6.8, 10.9) for patients with negative cultures ($p = 0.039$). Only 2 of the patients who underwent revision for nonmechanical reasons had negative cultures, thus accurate survival probabilities could not be estimated for this group.

## DISCUSSION

Inflatable penile prostheses are a well established treatment for erectile dysfunction. Multiple product enhancements during the last 25 years have resulted in markedly decreased mechanical failure rates. In fact most authorities now believe the devices are more often revised for human factors such as infection and medical problems than mechanical reasons.[1–3] Despite these mechanical improvements infection has remained a significant complication in prosthetic surgery.

Multiple studies in the medical literature have indicated an increased risk of infection when reoperations (revisions) are performed on genitourinary prostheses.[1–3,5,10] This increased incidence of infection associated with reoperation has been postulated to be due to decreased host resistance factors, impaired antibiotic penetration of the area because of the capsule surrounding the components and decreased wound healing related to scar formation. The organism most often found responsible for the infection in reoperation is S. epidermidis.[5] This bacterium is also the most common cause of infection during the original implantation, accounting for 35% to 80% of all positive cultures.[10]

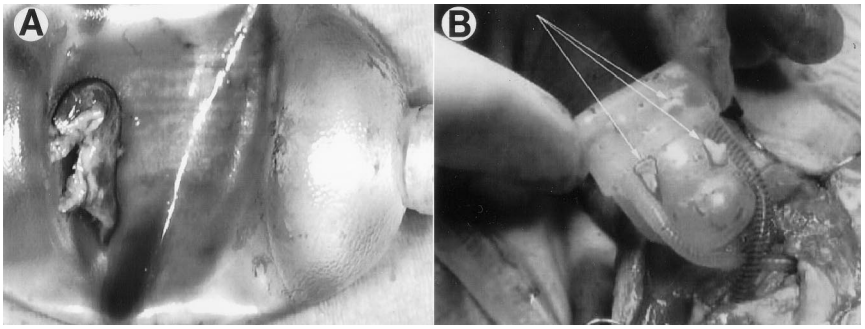


FIG. 1. Example of gross biofilm production on reservoir (*A*) and on pump (*B*). (Arrows indicate biofilm)

TABLE 3. *Association between penile implant infection and penile implant related pain*

| | No. Infection (%) | | Totals |
|---|---|---|---|
| | No | Yes | |
| Pain: | | | |
| No | 22 (30.1) | 51 (69.9) | 73 |
| Yes | 1 (25.0) | 3 (75.0) | 4 |
| Totals | 23 | 54 | 77 |

Fisher's exact test p = 0.655.

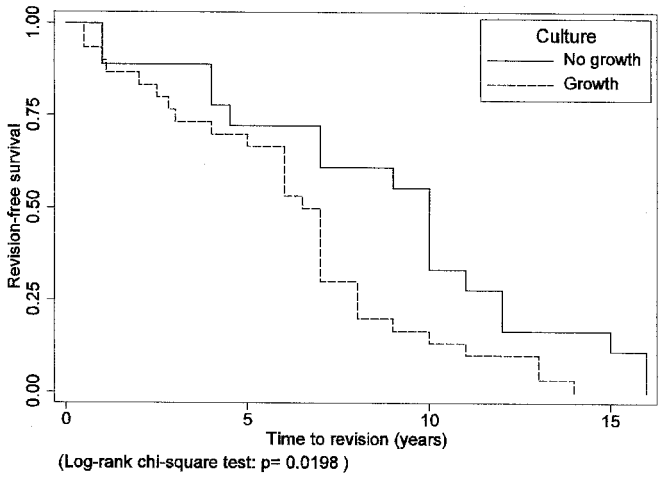


FIG. 2. Kaplan-Meier product limit estimated revision-free duration by culture growth outcome in implants revised for mechanical failure.

Most authorities believe genitourinary prosthetic infection is caused by contamination of the implant space at surgery. Studies suggest that preoperative nasal swab cultures of certain staphylococcus species are significantly correlated with postoperative surgical site wound infections.[11] Hematogenous late infections do occur, but rarely.[12] After adherence to the implant many staphylococcus species produce a protective mucin coat or biofilm.[13] Bacteria present within the biofilm may survive at a decreased metabolic rate chronically and without the patient realizing bacteria are present in the implant spaces. Occasionally bacteria are released from the biofilm in a "planktonic" fashion and may cause symptoms.[13] Antibiotics or the body's defense mechanisms can kill these planktonic bacteria. Those organisms present within the biofilm are protected, and cannot be eradicated except by removal of the implant and lavage of the implant spaces.

In 1996 Brant et al reported salvage success with clinical infections.[14] Their method, since successfully repeated by others, involves removing the infected device, using sequential lavage with antiseptic solutions to sterilize the implant space and immediately reimplanting a sterile replacement device. Only after the complete implant has been removed and the entire capsular space has been thoroughly irrigated is the new implant placed. We believe the success of this technique in eradicating infection is predicated on removal of the bacteria and the biofilm. Perhaps the increased infection rate seen in revision prosthetic surgeries is due to activation of preexisting biofilm. Therefore, we have adopted a policy of removing all components of an implant together with foreign material such as polytetrafluoroethylene at prosthesis revision. All components are removed and a formal revision washout is performed. If all components are not removed, biofilm would be left behind which might explain the high rate of infection in revisions. This hypothesis will be tested in a study that is under way by comparing a series of revision cases in which there was no antiseptic wash with our new technique.

S. epidermidis has been shown to be the most common organism found at removal of a penile prosthesis for infection.[15,16] Moreover, Licht et al found that 40% of uninfected penile prostheses and 36% of artificial urinary sphincters had low colony counts of S. epidermidis.[5] Of the patients with positive culture 3 later became infected and higher colony counts of the organism were found at explantation. A subsequent prosthetic infection did not develop in any patients with penile prosthesis with a negative culture at reoperation. Therefore, ensuring that the replacement implant has a sterile environment in which to be placed at revision/replacement may decrease the rate of prostheses reoperation infection. Even better, using the salvage protocol of irrigation with antiseptic solutions at replacement combined with inserting an antibiotic coated prosthesis could help ensure a sterile environment for the new implant while the antibiotic elution could address bacterial contamination in the subsequent surgery.

The advent of antibiotic coating on the surface of the penile prosthesis may signify a new era in genitourinary prostheses. Early results in clinical studies are encouraging.[17,18] To our knowledge no reports of the sensitivities of culture positive isolates found on reoperation have been published. This report indicates all the staphylococcus species isolates were sensitive to rifampin and/or tetracycline. Only 2 of the isolates of staphylococcus showed resistance to rifampin and both of those isolates are sensitive to tetracycline. These sensitivity results are almost identical to those found on colonization of catheters with staphylococcus strains.[19] Another study suggested that coating silicone strips "with antibiotics, particularly rifampin/minocycline, can reduce the incidence of graft colonization in contaminated wounds in rats, even in the absence of systemic antibiotics."[20] The presence of rifampin/minocycline eluting into the implant space might have prevented these isolates from colonizing on or near the prostheses. Since the majority of implant infections reported are due to staphylococcus species, any effort to decrease staphylococcal adherence to the prosthesis could result in fewer infections.

In 1993 Parsons et al found that patients with painful prostheses had a device infection rate of more than 95%, whereas asymptomatic patients with a penile prosthesis had a low device infection rate.[4] The authors concluded that patients with pain had indolent S. epidermidis infection that was clinically unrecognized because of the lack of other symptoms. S. epidermidis was the organism responsible for most cases of chronic prosthetic pain. Chronic pain was not a major cause of reoperation in our study. Only 4 of our 77 patients had chronic prosthetic pain at reoperation. Of the 4 patients 3 had organisms on culture and all 3 were positive for Staphylococcus epidermis. Parsons et al showed a 93% device culture positive rate for patients presenting with a painful prosthesis, whereas those patients without pain had an infection rate of 13% with the difference being highly significant.[4] In contrast 70% of our patients without prosthesis pain had culture positive organisms and the difference was not significant compared to those with prosthesis pain. Our findings indicate that nonpainful penile prostheses can be subclinically infected with a variety of organisms.

Our results were unexpected. Those revisions due to mechanical failure with positive cultures had significantly worse revision-free duration than those with negative cultures (log rank test p = 0.0198). We have no explanation for this finding. A larger series should be evaluated to further examine this phenomenon.

## CONCLUSIONS

The majority of clinically uninfected genitourinary prostheses have organisms growing in the implant space at reop-

eration. Most of these organisms are sensitive to the combination of rifampin and minocycline, which is now available as a coating on penile prostheses. Chronic prosthesis pain did not significantly determine if the prosthesis was subclinically infected. However, due to the small number of patients with prosthesis pain in our sample these results need to be confirmed with a larger cohort of patients.

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