DIAGNOSIS AND THERAPY OF SUBCLINICALLY INFECTED PROSTHESES

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We believe 5 to 7 percent of prosthetic devices are "subclinically" infected by *Staphylococcus epidermidis*. These infections are manifested by chronic pain, migration and late extrusion of the devices. To examine this problem, we cultured penile and mammary prostheses. For the experimental arm, we cultured painful penile and mammary prostheses that were being removed because of symptoms (pain). For patients in a control group, we cultured penile prostheses being replaced because of mechanical failure (no pain) and mammary tissue expanders that were temporarily installed. Actual parts of the device were cultured in Trypticase Soy Broth. There were 14 and 12 painful penile and mammary prostheses, 13 and ten, respectively, were cultured positive, for an infection rate of 88 percent. The primary organism identified was *S. epidermidis*. The nonpainful penile prostheses (zero of five and three of 22 mammary prostheses) grew S. epidermidis. The differences were highly significant ($p<0.001$), suggesting that the painful prosthesis is infected. In an attempt to resolve the problem of the painful prosthesis, ten prosthesis were removed and exchanged for new devices. Patients received preoperative and postoperative antibiotics. All ten had positive cultures and nine of ten were successfully exchanged (no pain). *Surg. Gynecol. Obstet.*, 1993, 177: 504-506.

THERE ARE MANY MISCONCEPTIONS concerning the meaning of a chronically painful prosthesis (breast or penile). While chronic pain has been observed (1), it may not have been suspected that the prostheses were infected. Proving a bacterial cause of pain was difficult and most clinicians may accept these conditions as part of having a prosthesis in place. We believe that a painful prosthesis is infected at the time of implantation. It develops into a subclinical state of infection manifested by chronic pain that may be intermittent (1). *Staphylococcal epidermidis* is an organism that is frequently not associated with virulent infections and has a unique ability to grow on a surface with a mucin coat that is impermeable to antibiotics; this organism is responsible for most prosthetic infections (2–10). This mucin can sustain the bacterium indefinitely despite antibiotics to which it would normally be sensitive. The infection of penile prostheses is rapidly becoming the most common failure of the devices today because most mechanical problems are being overcome. By identifying the cause of chronic pain, device migration and late extrusion, we have the potential of correcting these problems and making the prosthesis perform better. To document whether or not a device is infected, one has to remove the device and culture it. Of course, there is the argument that, in the process of removing the device, one could contaminate it. To answer this problem, we cultured a control group who had both penile and mammary prostheses that were removed for either mechanical failure or to make way for the permanent device (removing breast tissue expanders). To help answer the problem of what may be done to resolve the problem of a painful device, ten patients underwent cultures of the device and immediate exchange for a new prosthesis. Successful device exchange has been previously reported (11).

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Supported, in part, by Medical Research Service of the Veterans Administration, Urological Research and Education Foundation and the National Institutes of Health, Bethesda, Maryland.

MATERIALS AND METHODS

Patients. The patients selected for this study were of three basic groups. The first group consisted of 40 females ranging from 22 to 67 years of age. Twenty-seven patients were admitted for revision of mammary prosthetics and 13 had initial implantation of tissue expanders to create a subcutaneous space and were having them removed for implantation of the permanent device.

Another group of patients were undergoing revision of penile prostheses. One group of patients were having revision for a painful prosthesis (presumed infected) and the second group were having revision of a malfunctioning device in the absence of pain.

TABLE I.—INFECTION RATES OF REMOVED PROSTHESES

	Pain	*No pain*
Penile prosthesis	13/14	0/5
Breast prosthesis	10/11	4/16
Tissue expanders	3/3	0/10
Totals	26/28 (93)*	4/31 (13)

*P<0.001.
Pain versus no pain; positive cultures.
Numbers in parentheses are percentages.

Surgical procedures. In all instances, when the device was removed, meticulous care was taken not to touch the implant device with instruments that had come into contact with the skin. As soon as the device was exposed, a portion of it was excised free and prepared for culture.

Specimens. Two 1 centimeter segments of the mammary or penile prosthesis were harvested and placed into normal saline solution for transport to the laboratory. In the laboratory, they were divided into 4 to 5 milliliter segments and placed into Brain Heart and Trypticase Soy Broth and incubated for 72 hours at 37 degrees C. During that time, they were shaken continuously by an Adams Nutator™. Any specimen demonstrating positive growth was subcultured and submitted to the hospital microbiologic laboratory for identification procedures. It was important to prevent sample desiccation upon removal from the patient and shipment to the laboratory.

Statistical analysis. Differences in the distribution between groups were tested with the chi-square test. The p values were reported.

Device exchange. Ten penile prostheses that were painful were removed and exchanged for a new device. All patients were prepared with 14 days of preoperative antibiotics initially with an 500 milligrams of cephalosporin given orally four times a day. The last four patients received 500 milligrams of ciprofloxin orally twice a day for two weeks. Patients were then brought into the hospital the same day of surgical treatment, begun on a course of gentamicin (5 milligrams per kilogram per day) and 500 milligrams of vancomycin every 12 hours. The device was removed, cultured and a new prosthesis inserted. No postoperative irrigation or surgical drains were used. All incisions were closed primarily. At the time of operation, the space in the corpora cavernosa was irrigated with a cefazolin solution (1,000 grams in 500 milliliters of normal saline solution). Patients were maintained in the hospital for a period of 48 to 72 hours on systemic antibiotic therapy and discharged on the same oral preparation that they received initially.

TABLE II.—INFECTION IN DEVICES REMOVED WITHOUT PAIN

	Mechanical exchange	*Symptoms, pain*
Penile prosthesis	0/5	13/14
Tissue expanders	3/13	
Breast prosthesis*		14/27†
Total	3/18 (17)*	27/41 (66)

*P<0.01.
†Capsule contraction or painful prosthesis were the symptoms.
Positive cultures in devices removed for mechanical reasons only versus symptoms and device revision.
Numbers in parentheses are percentages.

RESULTS

Prosthetic cultures. Painful devices had positive cultures primarily for *S. epidermidis* (93 percent), while devices with no associated pain had negative cultures (17 percent) and the differences were highly significant ($p<0.01$).

Prosthetic exchange. Nine of ten patients were successfully exchanged in terms of control of patients and clinical symptoms of pain. The tenth patient maintained chronic pain six weeks past exchange of the device. The two patients who had diabetes and were exchanged had no subsequent problems with the device. Patients have had follow-up evaluation a minimum of 12 months postoperatively. Nine of ten patients never exhibited any recurrence of pain.

DISCUSSION

A limiting factor for prosthetics is rapidly approaching problems with infection as the mechanical aspects of the prosthetics improve. It has been observed in a number of studies that a certain percentage of patients will experience chronic pain, device migration and late extrusion (1). There are a number of theories promulgated for these processes, for example, the device is too long or dental therapy caused infection (12), but we believe that chronic subclinically infected devices by *S. epidermidis* are responsible for most of these complications.

S. epidermidis has several unique characteristics that would enable it to successfully infect foreign

TABLE III.—PROSTHETIC CULTURES

	Devices culturing positive with one organism	*Devices culturing positive with two organisms*
Staphylococcus epidermidis	17	5
Corynebacterium species	1	1
Propionibacterium	1	—
Bacillus species	1	1
E. coli	1	—
Klebsiella species	1	—

In two instances, more than one isolate was cultured.
E. coli, Escherichia coli.

material implanted into humans. First, it is not an organism of strong virulence that leads to marked tissue infection and destruction. Second, it has the ability to form a mucus or mucin layer surrounding microcolonies of the organism, which are impermeable to routine antibiotics. We believe that, in this type of "spore" state, the organism can survive indefinitely despite serum levels of antibiotics to which the organism is susceptible. Once the microcolonies are established on the surface of the device, it is possible that they can exist in this low-growth state indefinitely. Should they increase their metabolic rate, they are likely to produce byproducts, soliciting an inflammatory response and resulting in pain. If the infection should escalate further, it could lead to clinical infection or device migration and extrusion, or both. The organisms could also de-escalate their growth and diminish pain, accounting for the intermittent nature of the pain (13).

The current study was conducted to determine whether or not the painful prosthetic is indeed infected. Several groups were evaluated to provide adequate controls. Painful mammary and penile implants and similar prosthetic devices that were asymptomatic (removed for mechanical or failures) were cultured to detect the presence of bacteria. An additional control was provided by mammary tissue expanders that were implanted to increase the subcutaneous pouch to ultimately place a large prosthesis. Removal of these devices was done not for symptoms (pain) and provided controls to help answer the question concerning possible device contamination by the surgeon at the time the device was removed and cultured.

As the results indicate, patients with painful prostheses had a device infection rate of more than 95 percent, whereas those patients without pain had an infection rate of 13 percent. Devices being removed for mechanical failure or implantation of a tissue expander had an infection rate of 16 percent compared with 66 percent of devices removed for any symptoms. All the differences were highly significant.

An additional aspect of this study was to remove infected prostheses by a method of preoperative infection suppression with antibiotics, device removal and postoperative antibiotic therapy. Nine of ten painful devices removed (culture positive) and replaced with a new device were successful at resolving the clinical symptoms. It would seem that painful devices are infected and can be exchanged for new ones, as previously reported (11). It is worth risking a second device at this time. If a second device is infected, it can always be subsequently removed. However, much is to be lost if the device is removed. Subsequent reimplantation may not be possible and when successful, usually results in a shorter penile length and less patient satisfaction (12).

SUMMARY

The hallmark of a subclinically infected prosthesis is chronic pain. In devices removed that were painful, more than 90 percent of those cultured were *S. epidermidis*. Devices removed for mechanical reasons had only a small percent culture positive for this bacterium. Clinically infected devices can be treated successfully with antibiotic therapy and exchanged for a new uninfected device.

REFERENCES

1. Kaufman, J. J., Linder, A., and Raz, S. Complications of penile prosthesis surgery for impotence. J. Urol., 1982, 128: 1192-1194.
2. Dickinson, G. M., and Bisno, A. L. Infections associated with indwelling devices. Concepts of pathogenesis. Antimicrob. Agents Chemother., 1989, 33: 602-607.
3. Schmitt, D. D., Bandyk, D. F., Pequet, A. J., and others. Mucin production by *Staphylococcus epidermidis*: a virulence factor promoting adherence to vascular grafts. Arch. Surg., 1986, 121: 89-95.
4. Slaughter, L., Morris, J. E., and Starr, A. Prosthetic valvular endocarditis. Circulation, 1973, 47: 1319-1326.
5. Bayston, R., and Penny, S. R. Excessive production of mucoid substance in staphylococcus SIIA. Dev. Med. Child Neurol., Suppl., 1972, 27: 25-28.
6. Bandyk, D. F., Berni, G. A., Thiele, B. L., and Towne, J. B. Aortofemoral graft infection due to *Staphylococcus epidermidis*. Arch. Surg., 1984, 119: 102-108.
7. Marrie, T. J., Nelligan, J., and Costerton, J. W. A scanning and transmission electron microscopic study of an infected endocordial pacemaker lead. Circulation, 1982, 66: 1339-1341.
8. Franson, T. R., Sheth, N. K., Rose, H. D., and Sohnle, P. G. Scanning electron microscopy of bacteria adherent to intravascular catheters. J. Clin. Microbiol., 1984, 20: 500-505.
9. Christensen, G. D., Simpson, W. A., Bisno, A. L., and Beachey, E. H. Adherence of slime-producing strains of *Staphylococcus epidermidis* to smooth surfaces. Infect. Immun., 1982, 37: 318-326.
10. Nickel, J. C., Heaton, J., Morales, A., and Costerton, J. W. Bacterial biofilm in persistent penile prosthesis-associated infection. J. Urol., 1986, 135: 586-588.
11. Furlow, W. L., and Goldwasser, B. Salvage of the eroded inflatable penile prosthesis. J. Urol., 1987, 138: 312-314.
12. Kabalin, J. N., and Kessler, R. Infectious complications of penile prosthesis surgery. J. Urol., 1988, 139: 953-955.
13. Virden, C. P., Dobke, M. K., Stein, P., and others. Subclinical infection of the silicone breast implant surface as a possible cause of capsular contracture. Aesthetic Plast. Surg., 1992, 16: 173-179.