

# Coated Implants and “No Touch” Surgical Technique Decreases Risk of Infection in Inflatable Penile Prosthesis Implantation to 0.46%

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<b>OBJECTIVE</b>	To explore whether a “no touch” enhancement to the surgical technique of inflatable penile prosthesis (IPPs) implantation will further decrease infection rates.
<b>MATERIALS AND METHODS</b>	A single surgeon performed 2347 IPPs between January 2002 and June 2011. Patients receiving each manufacturer’s implants were stratified for age and diabetes. Since 2003, infection retardant-coated IPPs were implanted through the standardized penoscrotal approach. Since 2006, the “no touch” enhancement was added to the surgical procedure. Infection rates in the noncoated IPP, coated IPP with standard technique, and coated IPP implanted with “no touch” enhancement were calculated and subjected to statistical analysis. The two company’s implants were scrutinized for their individual infection rates in each group.
<b>RESULTS</b>	Patients in all the groups were similar for age and diabetes. 132 noncoated implants had an infection rate of 5.3%. In the years 2003-2005, 704 coated devices had a statistically significant improvement in incidence of infection to 2%. In the years 2006-2010, the “no touch” technique enhanced the standard surgical procedure in 1511 patients. Only 7 infections were seen yielding an infection incidence of 0.46%. There was no difference in the two manufacturer’s infection rates. Differentiation between virgin and revision operation displayed no bias in the infection rate.
<b>CONCLUSION</b>	Infection-retardant coatings lower the risk of infection from 5.3% to 2%. The “no touch” enhancement to the surgical procedure further decreases the rate of infection to 0.46%. Neither manufacturer showed statistical superiority in survival from revision for infection. UROLOGY xx: xxx, xxxx. © 2012 Elsevier Inc.

After 38 years, implantation of an inflatable penile prosthesis (IPP) remains a treatment for men with erectile dysfunction. Postoperative infection remains the most dreaded complication of this procedure. Infection-retardant coatings of the implant have reduced the incidence of infection from 3-5%<sup>1</sup> to 1-2%<sup>2</sup> in patients without risk factors and from 8-10% to 2-3% in patients who are diabetic or undergo revision operations.<sup>3,4</sup> Organisms that reside on skin—most commonly coagulase-negative staphylococci (CoNS)—have historically caused 75% of infections.<sup>5</sup> Recently, it has become evident that the infection-retardant coatings substantially reduce these relatively mildly symptomatic, late-appearing infections.<sup>6</sup> We believe the antibiotics eluting off the devices and/or the lubricious surfaces of

the implant create an unfriendly milieu for bacterial proliferation and attachment, reducing clinical infections. Although the total number of device infections has decreased significantly, aggressive early infections with organisms, such as *Enterococcus*, *Escherichia coli*, and *Pseudomonas aeruginosa* now seem to cause an increasing number of infections occurring in patients implanted with coated devices.<sup>6-9</sup>

If we believe that the infection-retardant coatings of the implants are markedly reducing infection from CoNS, we must then focus on eliminating potential breaks in surgical technique that allow contamination with the more virulent organisms. This paper describes our results with a surgical technique enhancement that features IPP implantation without the surgeon, the instruments, or the device having contact with the patient’s skin. We call this the “no touch” technique. We evaluate the impact of infection-retardant coatings on the survival from infection in both virgin and revision patients and if the “no touch” further reduced the risk of infection. Finally, we compare both manufacturers’ IPP infection avoidance rates.

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## MATERIAL AND METHODS

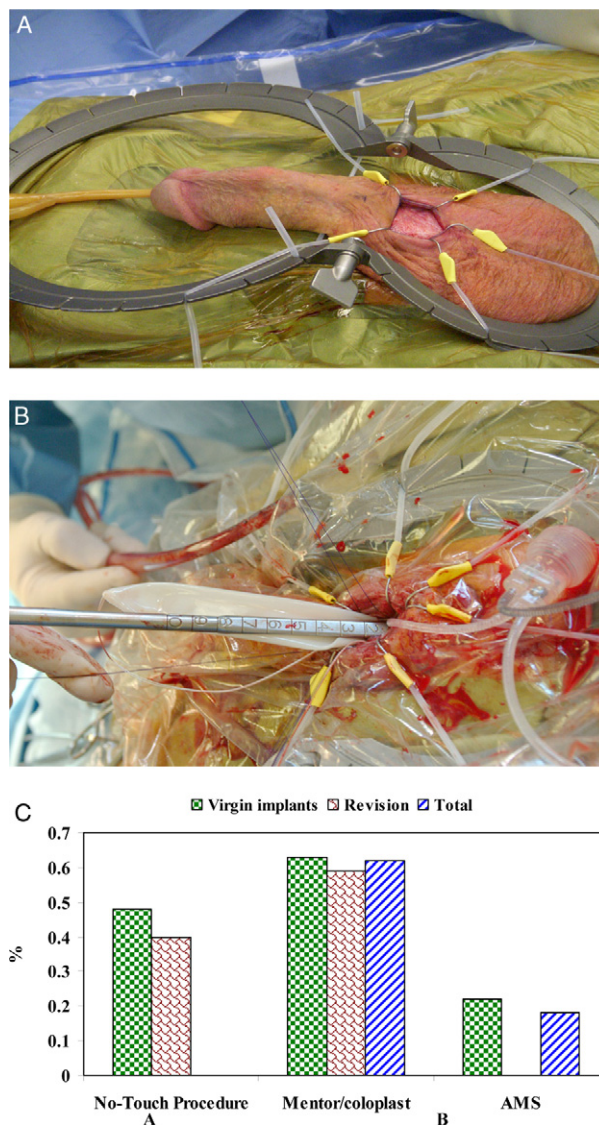
After obtaining approval from our institutional review board, we reviewed infection-free survival for all patients who had undergone IPP by a single surgeon during the previous 10 years. Both first-time implant (virgin) and revision replacement for mechanical or medical problems (revision) surgery were included. Each patient's age and diabetic status were catalogued.

Between January 2002 and June 2011, 2347 patients underwent virgin (1974) or revision (373-15.9%) IPPs: 1476 patients received Mentor/Coloplast (Minneapolis, MN) and 871 patients received American Medical Systems (Minnetonka, MN) IPPs. All implants were coated with infection-retardant coatings except the 132 devices implanted in 2002. From 2003 onward, the implants routinely included antiinfective technological approaches. American Medical Systems IPP has a factory-applied coating of antibiotics titled InhibiZone consisting of rifampin and minocycline that elute off the implant surfaces after implantation. Coloplast (then Mentor) IPP components have a factory-applied hydrophilic coating that, if dipped in an aqueous solution immediately before implantation, makes the surface lubricious, potentially inhibiting bacterial attachment. This coating also absorbs antibiotics or other drugs for subsequent elution, if antibacterial medications are added to the aqueous dip solution. In this series, the Coloplast implant was only dipped in injectable saline devoid of antibiotics because of a particular hospital's regulations. Similarly, intraoperative irrigations were limited to saline because of hospital rules. The patients were randomized to a particular manufacturer's model by our habitual practice of doing only one manufacturer's implants at a particular surgical session.

In 2002, 132 implants without infection-retardant coatings were placed. Between 2003 and 2005, 704 patients received a coated IPP. The patients underwent the following protocol intended to reduce the incidence of postoperative infection. The patient washed with chlorhexidine soap for 3 days before the surgery. An oral fluoroquinolone was given the day before. Intravenous vancomycin and gentamycin were given perioperatively. Shaving in the operating room and a 5-minute scrub of the surgical field with povidone soap preceded painting of the skin with povidone preparation and 70% alcohol. Finally, an iodophor drape was used over the exposed skin and genitalia. A small fenestration in the drape allowed the penis and scrotum to be delivered and a midline upper scrotal incision was used. A Scott retractor with blunt hooks was used to maintain exposure (Fig. 1A). The wound was irrigated frequently with saline during the operation.

The next 1511 surgical procedures performed after June 2006 incorporated all the above steps, but the actual implantation was conducted with the "no touch" surgical enhancement. As in the unenhanced surgical technique, the penis and scrotum are delivered through a small hole in the iodophor drape. An incision is made in the penoscrotal raphe and the dissection is carried down through the subcutaneous tissue and dartos to the level of Buck's fascia (Fig. 1A).

The procedure is halted and all the surgical instruments used thus far, including the electrocautery pencil, are discarded and considered contaminated. All surgical gloves are changed. The 3M 1012 drape (3M, St. Paul, MN) is used to loosely drape the operative field and completely cover the Scott retractor. A small fenestration is made in the drape and 4 additional blunt hooks are used to secure the opening in the 3M 1012 to the edges of the scrotal incision. This retracts the cut edges of the



**Figure 1.** (A) Dissection is carried down to Buck's fascia with aid of the Scott retractor and blunt hooks. At this point, gloves and instruments that have touched the patient are discarded and "no touch" enhancement instituted. (B) "No touch" drape is deployed and cylinder implantation occurs with "no touch" enhancement. Note that the pump is isolated from the scrotal skin. (C) Infection rates of IPPs implanted using the "no touch" surgical procedure and stratified by manufacturer. *P* value between virgin and revisions implants = 1.00. *P* value between Coloplast and AMS for virgin, revisions, and total implants = .4227, 1.00, and .4329, respectively.

skin and drape by securing the hooks on the retractor frame. Implantation of the device is then conducted through the drape's fenestration (Figure 1B). Once the components are implanted, a layer of Buck's fascia or dartos is closed entirely, covering all components. Then the drape is removed and the subcutaneous tissue and skin are closed.

Fisher's exact test was used to compare infection rates between implant groups, between manufacturers, and between virgin and revision patients. A *P* value <.05 was considered significant. Data analysis was conducted using Stata Statistical Package version 11.2 (StataCorp, College Station, TX.)

## RESULTS

In 2002, 132 patients had an IPP without infection-retardant coatings and the infection rate was 5.3%. Most cultures of the infected patients grew coagulase-negative *Staphylococcus* or had no growth. These patients were diagnosed with infection as much as 2 years later. Two infections presented acutely (29%) with *Enterococcus* and *Pseudomonas*. In the group of patients operated between 2003 and 2005 with infection retardant-coated IPP, but without the “no touch” surgical enhancement, postoperative infection was reduced to 2%. In the 1511 “no touch” patients, infection developed in only 7 (0.46%) patients (Table 1).

The patients in the noncoated, coated, and coated with “no touch” were similar in age distribution (61.3, 61.8, and 64.8 years, respectively) and risk factor for diabetes. It is notable that diabetes is prevalent in our population with 39%, 37.9%, and 43%, respectively, having the disease. When we analyzed virgin and revision infection incidence, there was no difference in the rate of infection (Table 1).

Half of the patients with infections in the noncoated implant group cultured CoNS, presented late, and were mildly symptomatic. Most of the 13 infections in the coated implant population without “no touch” enhancement were diagnosed by their acute appearance. Most infections generated a host response that could be diagnosed as device infection within 2-6 weeks of implantation. The organisms that could be cultured (only 6 positive cultures) were usually found to be aggressive bacteria of *Staphylococcus aureus*, *Enterococcus*, and *Pseudomonas*. The very rare infection seen in the “no touch” cohort was also diagnosed very quickly with one exception. Five of 6 infections appeared at 15, 16, 29, 30, and 32 days. In 4 of the infected implants, there was no growth and two grew aggressive organisms of *Enterococcus* (16 days) and *Pseudomonas* (32 days). The remaining “no touch” infection appeared at 132 days and grew CoNS (Table 2).

When the implants were stratified by manufacturer, there was a statistically significant infection reduction for both AMS and Coloplast comparing noncoated with coated implants and from using the “no touch” technique. There was no statistical difference in the infection rate of the manufacturer either in the noncoated or coated groups (Table 3).

Analysis of the 1511 “no touch” patients showed only 7 infections (Fig. 1C). Six infections were within the 964 patients receiving the Coloplast device (0.62%) and 1 infection in the 547 AMS patients (0.18%) ( $P = .4329$ ). The difference between the infection rate of virgins and revisions was also not significant (Fig. 1C).

## COMMENT

The AMS InhibiZone coating of rifampin and minocycline was formulated for common infecting organisms and its zone of inhibition was tested against the most

**Table 1.** Infection rates of virgin and revised implants by IPP type and surgical procedure

IPP Type	“No touch” Procedure	Virgin Implants			Revised Implant			Total		
		Number Implanted	Number Infected, n (%)	P Value*	Number Implanted	Number Infected, n (%)	P Value*	Number Implanted	Number Infected, n (%)	P Value*
Without infection retardant	No	116	6 (5.17%)		16	1 (6.25%)		132	7 (5.30%)	
With infection retardant	No	600	10 (1.67%)	.0317 <sup>†</sup>	104	4 (3.85%)	.5175 <sup>†</sup>	704	14 (1.99%)	.0350 <sup>†</sup>
With infection retardant	Yes	1258	6 (0.48%)	.0001 <sup>†</sup>	253	1 (0.40%)	.1156 <sup>†</sup>	1511	7 (0.46%)	<.0001 <sup>†</sup>
				.0096 <sup>‡</sup>			.0267 <sup>‡</sup>			.0013 <sup>‡</sup>

\* Fisher’s exact test.

<sup>†</sup> Compared with IPPs without infection retardant.

<sup>‡</sup> Compared with IPPs with infection retardant and no “no-touch” procedure.



**Table 2.** Organism present in infected IPPs by type and surgical procedure

IPP Type	“No touch” Procedure	Implanted	Infected	Organism	n
Without infection retardant	No	152	7 (5.3%)	Coagulase-negative <i>Staphylococcus</i>	3 (42.9%)
				<i>Enterococcus faecalis</i>	1 (14.3%)
				No growth	3 (42.9%)
				Coagulase-negative <i>Staphylococcus</i>	3 (21.4%)
With infection retardant	No	704	14 (1.99%)	<i>Staphylococcus aureus</i>	1 (7.1%)
				No growth	10 (71.4%)
				Coagulase-negative <i>Staphylococcus</i>	1 (14.3%)
With infection retardant	Yes	1511	7 (0.45%)	<i>Enterococcus faecalis</i>	1 (14.3%)
				<i>Pseudomonas aeruginosa</i>	1 (14.3%)
				No growth	4 (57.1%)
				Coagulase-negative <i>Staphylococcus</i>	1 (14.3%)
				No growth	4 (57.1%)

**Table 3.** Infection rates by IPP type and surgical procedure stratified by manufacturer

IPP Type	“No touch” Procedure	Mentor/Coloplast			AMS		
		Number Implanted	Number Infected, n (%)	P Value*	Number Implanted	Number Infected, n (%)	P Value*
Without infection retardant	No	57	4 (7.0%)		75	3 (4.0%)	
With infection retardant	No	454	10 (2.20%)	.0049 <sup>a</sup>	250	4 (1.60%)	1.0000 <sup>†</sup>
With infection retardant	Yes	964	6 (0.62%)	>.0001 <sup>†</sup> .0134 <sup>‡</sup>	547	1 (0.18%)	.2268 <sup>†</sup> .0358 <sup>‡</sup>

\* Fisher’s exact test.

<sup>†</sup> Compared with IPPs without infection retardant.

<sup>‡</sup> Compared with IPPs with infection retardant and no “no-touch” procedure.

commonly infecting organism—*Staphylococcus epidermidis*. Dhabuwala reported a recent laboratory study with the Coloplast implant dipped in rifampin and gentamicin testing the zones of inhibition (ZOI) created against *S. epidermidis* and *E. coli*. This study showed ZOI to be equal to or better than those created with InhibiZone.<sup>10</sup> Wilson et al tested ZOI with similar Coloplast Titan strips dipped in several different antimicrobial combinations. The best dip results showed that trimethoprim sulfamethoxazole provided a significant ZOI. ZOI for the Titan strips tested against the 5 different bacteria were better than InhibiZone strips tested against the same bacteria.<sup>11</sup>

In this study, the hospital where the surgery was conducted had regulations that prohibited adding antibacterial drugs to the dip or to surgical irrigation conducted during operations. We were allowed to dip the components in saline to engage its slippery hydrophilic surface to discourage bacterial attachment. Despite the absence of antibiotics in the Coloplast dip, the two manufacturer’s implants had similar progressively low rates of infection with the enhancements of coating and “no touch” technique. Although the difference in the 2 manufacturer’s infection rates was not significant, it is notable that 6 of the 7 infections sustained with a combination of coated implant and “no touch” were Coloplast implants. It is uncertain whether inclusion of antibacterial medications in the aqueous solution for dipping the device and/or in the irrigations accompanying surgery would have impacted these clinical infections. Selph and Car-

son in a recent review article predicted that future directions for further implant infection reduction included novel agents targeting biofilm and guidelines for intraoperative antibiotic irrigation.<sup>12</sup>

A mild CoNS implant infection diagnosis typically takes more than 2 months (and frequently several months or even years) from the surgery to become clinically evident. Before the availability of infection-retardant coatings, these infections were responsible for 75% of IPP infections.<sup>13</sup>

After 2003, coated implants were widely available in the United States, and infections that occurred seemed less likely to be the typical skin organism infections experienced with noncoated models. These coated implant–infected patients presented acutely in an aggressive fashion. When cultures were successful, the organisms were not usually the typical CoNS from the skin. Many times cultures failed to indicate the infecting bacteria, as is apparent from our multiple “no growth” infections diagnosed early in the clinical course. If cultures were successful, aggressive bacteria like *Enterococcus*, *S. aureus*, *E. coli*, and *Pseudomonas* were cultured (Table 2).

Unfortunately, many times cultures yield “no growth” because free-floating or planktonic bacteria forms were not present in the implant spaces. Antibiotics or the body’s defense mechanisms had eliminated the free-floating bacteria and the bacteria causing the infection were protected by a biofilm. Bruner et al reported aggressive organism growth when they sonicated infection retardant–coated IPP and AUS components that had to be removed for clinical infection. Although coagulase-neg-

ative *Staphylococcus* could be grown from a tissue swab, much more aggressive organisms were cultured from the biofilm broken up by the sonification.<sup>8</sup> Other recent studies by Kava et al<sup>7</sup> and Henry et al<sup>9</sup> support similar changing bacteriology of infection in the coated implant era.

In examining our 6 coated implants with “no touch,” enhanced-technique device infections, we found that 5 of the patients had a second operation for aggressive infection within 32 days (average 24 days). One of these cultured *Enterococcus faecalis* (15 days), 1 *Pseudomonas aeruginosa* (32 days), and the remainder had “no growth,” demonstrating the well-known difficulty of obtaining reliable cultures from biofilm with current culture methods.<sup>14</sup> Only one of our coated “no touch” patients had a CoNS cultured and this patient had a typical subclinical infection course and underwent device removal at 132 days. Similar quick acute “no growth” infections occurred in the coated implants implanted from 2003-2006 without “no touch” (Table 2).

The typical tissue swab taken at surgery for microbiological culture and sensitivity testing are extrapolated from planktonic free-floating bacteria, which may be very different from bacteria in the biofilm mode of growth.<sup>8-10</sup>

The bacteria deep in the layers of biofilm that have actually caused the immune response of the host, which clinicians recognize as device infection, are metabolically inactive and resistant to both antibacterial drugs and culture media. To date, no standardized methods to retrieve biofilm-protected organisms and no antimicrobial sensitivity tests are available to evaluate drug activity against these adherent, protected bacteria.<sup>15</sup>

A statistically significant reduction in infection using coated implants occurred in this study from enhancing the standard surgical procedure with the addition of the “no touch” technique. It stands to reason that the coating on the implants reduced the skin organism contamination and the “no touch” enhancements reduced the toxic organism contamination, making an already low rate of infection even lower. It is obvious that if the aggressive organism infection rate is diminished by use of a barrier plastic drape designed to minimize contact with the patient’s skin, these toxic organisms must also be present on some patients’ skin.

The use of plastic drapes as a barrier to prevent post-operative wound infection has been explored with small trials in other surgical fields but the results have not been compelling.<sup>16</sup> Nevertheless, none of these studies involved placement of foreign bodies (prostheses). Although the iodophor-impregnated drape has been shown to be effective<sup>17</sup> and is used in our technique, it is not used as a barrier. Because the iodophor-impregnated drape is an adhesive vehicle, it restricts manipulation of the penis and scrotum, making placement of the components cumbersome without violating the drape. In our enhanced technique, the iodophor drape is violated and the penis and scrotum delivered through an incised win-

dow. Then the incision is made, all the instruments and gloves exchanged, and the barrier placed and secured with hooks. With the loose surgical drape used in the “no touch” enhancement, the barrier function is preserved, with the advantage of allowing mobility of the penis and scrotum. Because the tissue spaces for the components are created without contact with the patient’s skin, contamination of these spaces is thought to be minimal. Because the components are prepared and implanted by gloved hands that have never touched the patient’s skin, the contamination of the implant with organisms from the patient is thought to be negligible.

One limitation to this study is that the “no touch” enhancement increases the cost of the operation to a mild degree by requiring duplication of some supplies, and increases the operative time by approximately 15 minutes. When compared with the substantial cost of an infection in both real money and emotional impact on the patient, these increases appear to be trivial.

## CONCLUSIONS

This single-surgeon study of 2347 IPPs shows that using coated implants reduces device infection from 5.3% to 2% for both manufacturers’ implants. Further significant reduction in prosthesis infection occurs by the addition of the “no touch” enhancement to penoscrotal IPP implantation. A combination of coated implants and the “no touch” technique achieved an infection incidence of only 0.46% in a population of 43% diabetics regardless of specific manufacturer or whether the operation was a first time or a revision procedure.

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## EDITORIAL COMMENT

Infection is the bane of penile prosthesis implantation surgery. To eliminate the infection, removal of all of the prosthetic material is necessary. Implantation of a second device at a later date is complicated not so much by placement of the pump or fluid reservoir as it is by cylinder implantation. Infection causes varying degrees of corporeal smooth muscle death, with subsequent fibrosis. This scarring makes the penis smaller and makes cylinder implantation difficult. In some cases, the fibrosis is so pronounced that removal of corporeal fibrotic material (corporeal excision) is necessary.<sup>1</sup>

Various attempts have been made to prevent infection. At one time, the use of a laminar air flow tent, the Surgical Isolation Bubble System, was en vogue.<sup>2</sup> However, because of lack of evidence that this device reduced infection rates, this system is no longer used. Brant et al in 1996 introduced the concept of salvage surgery for infected penile implants.<sup>3</sup> Salvage surgery is not recommended for all infected penile prosthesis cases, and even when it can be performed, the infection rate is still high (18%), as shown in an update in Mulcahy's series.<sup>4</sup>

Clearly, avoiding infection in the first place should be the goal. At one time, the infection rates for revision penile prosthetic surgery were significantly higher than they were for first-time penile prosthesis implantation. This was in the early days of penile prosthesis surgery when early mechanical failure was common.<sup>5</sup> For revision surgery, replacement of only the failed component was the rule. With improvements in penile prosthesis design, mechanical failures became less common and were seldom seen until at least 5 years after implantation. Because of this, revision surgery for mechanical failure changed to removal of all of the old components, copious antibiotic fluid irrigation, and implantation of all new prosthetic material. This led to a reduction in the revision infection rate so that it paralleled the infection rate of first-time implant surgery.<sup>6</sup>

The next and most recent advances in the efforts to reduce penile prosthesis infections were the introduction of antibiotic-coated and hydrophilic-coated inflatable penile prostheses. These coated devices reduced infection rates by approximately half.<sup>7,8</sup>

In this paper, Eid et al introduce a new concept, the "no touch" technique, for reduction in penile prosthesis infection rates. Using this implantation technique in a large single-surgeon series and implanting antibiotic or hydrophilic coated devices, they demonstrate an unparalleled low infection rate of only 0.46%. There were no significant differences in infection between first time and revision surgeries. Because the literature shows divided evidence as to whether diabetics are at greater risk for this type of infection compared with nondiabetics, it would have been nice if the authors could have provided information regarding the infection rates in the diabetic and nondiabetic cohorts in their series.

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## REPLY

Diabetes was prevalent in our patient population, with 39% of noncoated implant patients, 37.9% of the standard technique patients, and 43% of the patients implanted with "no touch" having the disease. In our series, we had 28 infections total. Six patients (21%) had diabetes, 4 (14%) had erectile dysfunction (ED) after radical prostatectomy, 7 (25%) had hypertension as an associated condition, and 11 (39%) had other conditions. However, because the total number of infections was small, these figures lack statistical significance.

The issue of penile prosthesis infection in the diabetic patient population is an interesting one because of many different reasons. The first and foremost fact that we need to keep in mind is that infections do not occur in the absence of an organism. However, if a surgical field is inoculated with bacteria at the time of implantation, then the more appropriate questions are: Is a patient who has diabetes more likely to develop an infection? Is there a critical volume of bacteria, which is necessary to cause an infection, and is this volume lower in patients with diabetes? Are there other factors such as bleeding and or formation of fluid collection around a component of the

device such as the scrotal pump, which promotes bacterial growth and infection?

Clinical trial data from the pharmaceutical industry reveals that patients with diabetes and ED are less likely to respond (50%) to a phosphodiesterase inhibitor than the general population of men with ED (67%) and are therefore more likely to need a penile implant than patients who have ED related to other causes. This lack of response to oral medication could possibly be attributed to a marked reduction of blood flow to the penis, leading to deterioration and atrophy of healthy cavernosal tissue. The diabetics in my experience bleed less from the corporotomy at the time of implantation and are therefore less likely to form a scrotal

hematoma. This could possibly explain the lower incidence of diabetes (21%) observed in our series of 28 patients who developed an infection after penile prosthesis implantation than the incidence of diabetes (37.9-43%) in our total patient population.

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